UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Memorandum

November 16, 2023

SUBJECT: Transmittal of Meeting Minutes and Final Report for the Science Advisory Committee on Chemicals Public Virtual Meeting "**2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation**" held on September 12-14, 2023

TO: Denise Keehner
Director,
Office of Pollution Prevention and Toxics

FROM: Alaa Kamel, PhD
Designated Federal Official
Science Advisory Committee on Chemicals
Peer Review and Ethics Branch
Mission Support Division
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THRU: Tamue Gibson, MS
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And

Hayley Hughes, DrPH, MPH, CSP
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Attached, please find the meeting minutes and final report for the Science Advisory Committee on Chemicals public virtual meeting held via Zoom on September 12-14, 2023. This report addresses a set of scientific issues being considered by the Environmental Protection Agency regarding EPA's "**2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation**."

Attachment

cc:
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OPPT Docket

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Science Advisory Committee on Chemicals

Meeting Minutes and Final Report

No. 2023-02

Docket ID: EPA–HQ–OPPT–2022–0905

A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding:

2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation

September 12-14, 2023

Virtual Meeting via Webcast

NOTICE

The Science Advisory Committee on Chemicals (SACC) is a Federal advisory committee operating in accordance with the Federal Advisory Committee Act (FACA) and established under the provisions of the Toxic Substances Control Act (TSCA) as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act of 2016. The SACC provides advice, information, and recommendations to the US Environmental Protection Agency's ("EPA" or "Agency") Administrator on chemicals and chemical-related issues regarding the impact of regulatory actions on health and the environment. The SACC serves as a primary scientific peer review mechanism of the EPA, Office of Pollution Prevention and Toxics (OPPT), and is structured to provide balanced expert assessment of chemicals and chemical-related matters facing the Agency. Additional peer reviewers are considered and employed on an *ad hoc* basis to assist in reviews conducted by the SACC. The meeting minutes and final report are provided as part of the activities of the SACC.

Minutes represent the views and recommendations of the SACC and do not necessarily represent the views and policies of the Agency, nor of other agencies in the Executive Branch of the Federal government. Mention of trade names or commercial products does not constitute an endorsement or recommendation for use. The meeting minutes and final report do not create or confer legal rights or impose any legally binding requirements on the Agency or any party.

The meeting minutes and final report of the September 12-14, 2023, SACC meeting represent the SACC's consideration and review of scientific issues associated with the "2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation" (US EPA 2023). The SACC carefully considered all information provided and presented by the Agency, as well as information presented by the public.

The Peer Review and Ethics Branch of EPA's Office of Program Support conducted the quality assurance and quality control of the minutes and final report. The SACC Chair, Dr. George Cobb, and SACC Designated Federal Official (DFO), Dr. Alaa Kamel, compiled and certified the minutes and final report, which is publicly available through the SACC website (2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation), and in the public e-docket, Docket No.EPA-HQ-OPPT-2022-0905, accessible through the docket portal at Regulations.gov. Further information about SACC reports and activities can be obtained from its website at TSCA Scientific Peer Review Committees. Interested persons are invited to contact Dr. Alaa Kamel, SACC DFO, via e-mail at kamel.alaa@epa.gov.

Table of Contents

CERTIFICATION

We, the undersigned, certify that the minutes in this report are an accurate and complete summary of the SACC's September 12-14, 2023, discussions of EPA's "2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation" under the Toxic Substances Control Act

George Cobb, PhD
Chair,
Science Advisory Committee on Chemicals

Signature:

George Cobb

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Date: 2023.11.16 10:41:33 -06'00'

Date: 11/16/2023

Alaa Kamel, PhD
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Science Advisory Committee on Chemicals

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LIST OF ACRONYMS AND ABBREVIATIONS

ACC	American Chemistry Council
ACI	American Cleaning Institute
AERMOD	American Meteorological Society/Environmental Protection Agency Regulatory Model
AI	Artificial Intelligence
API	American Petroleum Institute
AWQR	Annual Water Quality Report
BDL	Below Detection Limit
BMP	Best Management Practices
ChemSTEER	Chemical Screening Tool for Exposures and Environmental Releases
COU	Conditions of Use
CQ	Charge Question
CSO	Combined Sewer Overflow
CT	Central Tendency
DEC	Department of Environmental Conservation
DFO	Designated Federal Official
DL	Detection Limit
DMR	Discharge Monitoring Report
DRAS	Delisting Risk Assessment Software
DRINCs	Defacto Reuse In our Nation's Consumable Supply
DTD	Down The Drain
DWEL	Drinking Water Equivalent Level
DWI	Drinking Water Intake
ECHO	Enforcement and Compliance History Online
ECRAD	Existing Chemical Risk Assessment Division
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-know Act
ESD	Emission Scenario Document
ETAD	Ecological and Toxicological Association of Dyes
EWISRD	Estimating Water Industrial Surface Release and Down the Drain
EWISRD-XL	Estimating Water Industrial Surface Release and Down the Drain in Excel
EWISRD-XL-R	Estimating Water Industrial Surface Release and Down the Drain in Excel and R
FHWA	Federal Highway Administration
GAO	Government Accountability Office
GIS	Geographic Information System
GS/ESDs	Generic Scenario and Emission Scenario Documents
GS	Generic Scenario
HCPA	Household and Commercial Products Association

HE	High-End
HERO	Health & Environmental Research Online Glossary
HF	Hydraulic Fracturing
HR	High Resolution
IBC	Intermediate Bulk Container
IUR	Inhalation Unit Risk
km	Kilometer
LL	from Line X to Line Y
LOD	Limit of Detection
LOQ	Limit of Quantitation
LP	Liquified Petroleum
MCL	Maximum Contamination Level
MOE	Margin of Exposure
MSHA	Mine Safety and Health Administration
NAICS	North American Industry Classification System
NESHAPS	National Emission Standards for Hazardous Air Pollutants
NF/FF	Near-Field/Far-Field
NGO	Non-Government Organization
NHD	National Hydrography Dataset
NHDPlus	National Hydrography Dataset Plus
NIEHS	National Institute of Environmental Health Sciences
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NRC	National Research Council
NYSDEC	New York State Department of Environmental Conservation
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
OES	Occupational Exposure Scenario
OPL	On-Premises Laundries
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
PESS	Potentially Exposed or Susceptible Sub-populations
PET	Polyethylene Terephthalate
PFAS	Per and Polyfluoroalkyl Substances
PMN	Pre-Manufacture Notice
POD	Point of Departure
POTW	Publicly Owned Treatment Works
PV	Production Volume
PWS	Public Water Supply
RA	Risk Assessment
RCRA	Resource Conservation and Recovery Act

RE	Risk Evaluation
RRC	Railroad Commission of Texas
SACC	Science Advisory Committee on Chemicals
SHEDS	Stochastic Human Exposure and Dose Simulation
SHEDS-HT	Stochastic Human Exposure and Dose Simulation-High Throughput
SHOWER	Shower and Household Water-use Exposure
SRP	Superfund Research Program
TCEQ	Texas Commission on Environmental Quality
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
UCMR 3	The Third Unregulated Contaminant Monitoring Rule
UF	Uncertainty Factor
UI	Unemployment Insurance
UIC	Underground Injection Control
USGS	United States Geological Survey
VOC	Volatile Organic Compound
WHO	World Health Organization
WOE	Weight of Evidence
WPEM	Wall Paint Exposure Model
WQP	Water Quality Portal
WWT	Wastewater Treatment

SCIENCE ADVISORY COMMITTEE ON CHEMICALS MEETING

2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation
September 12-14, 2023

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INTRODUCTION

The Science Advisory Committee on Chemicals ("SACC" or "Committee"), established pursuant to the Toxic Substances Control Act (TSCA) of 1976, as amended by The Frank R. Lautenberg Chemical Safety for the 21st Century Act in 2016, completed its review of the set of scientific issues being considered by the United States Environmental Protection Agency (US EPA) regarding the review of the "2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation" under the Toxic Substances Control Act.

Advance notice of the meeting and request for nominations of *ad hoc* experts was published in the Federal Register on March 23, 2023, followed by a notice of meeting and request for comments on the supplement and related documents on July 10, 2023. The review was conducted in an open meeting held virtually via Zoom and streamed live on YouTube (see Meeting Viewing Information) from September 12 to September 14, 2023. The White Paper, supplemental files, and related documents supporting the SACC meeting are posted in the public e-docket at Regulations.gov, Docket No. EPA-HQ-OPPT- 2022-0905. Dr. George Cobb chaired the meeting and Dr. Alaa Kamel served as the Designated Federal Official (DFO).

In preparing these meeting minutes and final report, the Committee carefully considered all information provided and presented by the Agency presenters, and information presented by public commenters. These meeting minutes and final report address the information provided and presented at the meeting, especially the Committee's response to the Agency's charge.

During the SACC meeting, the DFO, SACC Chair and US EPA personnel provided the following presentations in the order listed below:

Opening of Meeting – Alaa Kamel, PhD, Designated Federal Official, Office of Program Support (OPS), Office of Chemical Safety and Pollution Prevention (OCSPP), EPA

Introduction and Identification of Panel Members – George Cobb, PhD, Chair, Science Advisory Committee on Chemicals (SACC)

Introduction and Welcome – Jeff Morris, Director, Existing Chemicals Risk Assessment Division (ECRAD), Office of Pollution Prevention and Toxics (OPPT), OCSPP, EPA

TSCA Existing Chemicals Overview and 1,4-Dioxane Assessment History and Current Status – Rochelle Bohaty, PhD, Chief, Risk Assessment Branch 1 (RAB1), ECRAD, OPPT, OCSPP, EPA

Overview of Assessment of Occupational Exposures and Environmental Releases – Franklyn Hall, MS, Chemical Engineer, RAB1, ECRAD, OPPT, OCSPP, EPA

Overview of General Population Exposures Resulting from Environmental Releases to Surface Water – Jason Todd, PhD, Science Advisor, OCSPP

General Population Exposures via Surface Water Sourced Drinking Water – Bryan Groza, MS, Physical Scientist, RAB1, ECRAD, OPPT, OCSPP, EPA

Groundwater Exposure Assessment – Shawn Shifflett, PhD, Physical Scientist, RAB1, ECRAD, OPPT, OCSPP, EPA

Aggregate Exposure and Risk Assessment – Kevin Vuilleumier, MS, Environmental Engineer, RAB1, ECRAD, OPPT, OCSPP, EPA

Method Application in 2023 Draft Supplement to the Risk Evaluation for 1,4-Dioxane – Susanna Wegner, PhD, Toxicologist, RAB1, ECRAD, OPPT, OCSPP, EPA

Questions from the SACC on EPA presentations

PUBLIC COMMENTERS

Oral statements were presented during the SACC meeting as follows:

	Name	Organization	Location	Written version of presentation
1	Paul De Leo	American Chemistry Council	Washington, District of Columbia	EPA-HQ-OPPT-2022-0905-0075
2	Jonathan Kalmuss-Katz	Earth Justice	Brooklyn, New York	Not submitted
3	James Kim	American Cleaning Institute	Washington, District of Columbia	EPA-HQ-OPPT-2022-0905-0073
4	Roopa Krithivasan	Defend Our Health	Portland, Maine	EPA-HQ-OPPT-2022-0905-0076
5	Swati Rayasam	University of California- San Francisco	Berkeley, California	EPA-HQ-OPPT-2022-0905-0072
6	Steve Risotto	American Chemistry Council	Washington, District of Columbia	EPA-HQ-OPPT-2022-0905-0071
7	Paige Warner	Environmental Defense Fund	Durham, North Carolina	EPA-HQ-OPPT-2022-0905-0074

Written comments submitted in response to the SACC meeting on: "2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation" under the Toxic Substances Control Act (US EPA 2023):

	Name / Signed by	Organization	Location	Docket number
1	Martin Durbin	U.S. Chamber of Commerce	Washington, District of Columbia	EPA-HQ-OPPT-2022-0905-0068
2	No signature	American Coatings Association	Not submitted	EPA-HQ-OPPT-2022-0905-0065
3	James Kim	American Cleaning Institute	Washington, District of Columbia	EPA-HQ-OPPT-2022-0905-0066
4	Stephen Risotto	American Chemistry Council	Washington, District of Columbia	EPA-HQ-OPPT-2022-0905-0067
5	Uni Blake	American Petroleum Institute	Washington, District of Columbia	EPA-HQ-OPPT-2022-0905-0063
6	Daniel Axelrad et al.	Independent Consultant/University of California	San Fransisco, California	EPA-HQ-OPPT-2022-0905-0058
7	No signature	Defend Our Health	Not submitted	EPA-HQ-OPPT-2022-0905-0062
8	Julie Froelicher	The Procter and Gamble Company	Cincinnati, Ohio	EPA-HQ-OPPT-2022-0905-0053
9	Dianne Barton	National Tribal Toxics Council	Anchorage, Alaska	EPA-HQ-OPPT-2022-0905-0056
10	John Hoke	Missouri Department of Natural Resources	Jefferson City, Missouri	EPA-HQ-OPPT-2022-0905-0061
11	NA	The Dow Chemical Company	NA	EPA-HQ-OPPT-2022-0905-0059 (Copyrighted)
12	No Signature	EarthWorks	Washington, District of Columbia	EPA-HQ-OPPT-2022-0905-0060
13	Letitia James et al.	The Attorneys General of New York et al.	Multiple States	EPA-HQ-OPPT-2022-0905-0054
14	Carrie Brown	Household & Commercial Products Association	Washington, District of Columbia	EPA-HQ-OPPT-2022-0905-0051
15	Marie Gargas	Plastics Industry Association	Washington, District of Columbia	EPA-HQ-OPPT-2022-0905-0064
16	Black Women for Wellness et al.	Environmental Defense Fund et al.	Multiple organizations	EPA-HQ-OPPT-2022-0905-0055
17	Paul DeLeo	American Chemistry Council	Washington, District of Columbia	EPA-HQ-OPPT-2022-0905-0052
18	Jason Miller	Union Carbide Corporation	Seadrift, Texas	EPA-HQ-OPPT-2022-0905-0057
19	Tracy Menan, III et al.	American Water Works Association et al.	Multiple Organizations	EPA-HQ-OPPT-2022-0905-0050
20	Jan Buberi	Huntsman International LLC	Not submitted	EPA-HQ-OPPT-2022-0905-0046
21	David Vitale	New York State Department of Environmental Conservation	Albany, New York	EPA-HQ-OPPT-2022-0905-0047
22	Penny Mahoney	DAK Americas LLC/Alpek Polyester	Charlotte, North Carolina	EPA-HQ-OPPT-2022-0905-0044

23	Michael Kennedy	American Petroleum Institute	Washington, District of Columbia	EPA-HQ-OPPT-2022-0905-0041
24	Stephen Risotto	American Chemistry Council	Washington, District of Columbia	EPA-HQ-OPPT-2022-0905-0034
25	Darius Stanton	American Cleaning Institute	Washington, District of Columbia	EPA-HQ-OPPT-2022-0905-0033

NA = Not available

EXECUTIVE SUMMARY

The Science Advisory Committee for Chemicals ("SACC" or "Committee") was asked to review EPA's 2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation under the Toxic Substances Control Act and to comment on several charge questions from the Agency. The charge questions explored various aspects of Monte Carlo analysis, watershed evaluation tools, uncertainties in data sets, down the drain (DT
D) case studies, modeled versus measured 1,4-dioxane concentrations in surface water, downstream dilution factors, estimation of 1,4-dioxane concentrations in groundwater, approaches to data aggregation for exposure assessment, and exposure scenarios for potentially exposed or susceptible subpopulations (PESS). The Committee reviewed these questions and discussed them in a forum that was open to the public. This document contains the Committee's comments and recommendations to the US EPA.

The Committee commends the US EPA for performing the assessments provided in the Draft Supplement to the Risk Evaluation for 1,4-Dioxane. That document represents a significant and important scientific endeavor. The initial 1,4-Dioxane Risk Evaluation (RE) from 2019 (finalized late in 2020) excluded essential air and water exposure pathways for US residents without scientific justification. As noted on pp 25 of the 2019 Draft Supplement to the Risk Evaluation for 1,4-Dioxane, the SACC commented that omission of these exposure routes, for 1,4-dioxane and for other REs being conducted from 2017-2020, did not represent the best available science. The Committee recognized the efforts of the US EPA for adding these routes of exposure and augmenting the data analysis approaches with Monte Carlo and other techniques to address variability and uncertainty associated with inputs to the risk assessment.

The Committee recommended changes to the description of Monte Carlo methodology. This is intended to clarify concepts and approaches that would improve the general discussion of Monte Carlo methodology in future documents. New text is needed to clarify whether the distributions assigned to input parameters address value uncertainty or address how an individual parameter varies spatially or temporally in its attempt to cover the population (facilities, workers, people, or processes) of interest and for facilities, whether within-site as well as between-site variability has been addressed. More discussion is needed on how model outputs are identified and on how Monte Carlo simulation results are assessed for intermediate and output parameters. Additional considerations and analyses in this supplement do cover areas that had received less attention in the previous risk assessment and are important to gain a thorough understanding of the potential risks and insights into thresholds for potential adverse effects.

The Committee discussion on the strengths of the Monte Carlo method emphasized how its use can increase confidence in exposure and risk estimates. The discussion of uncertainties highlighted difficulties knowing distributional shapes when assigning probability distributions to variable input parameters and how model results might be sensitive to distributional shape. While Monte Carlo methods are good at integrating variability and parameter uncertainty into exposure and risk estimation, this methodology typically does not do a good job of capturing variability in situations where good measurement data or associated statistics are not available for most model inputs/parameters. The Committee had difficulty interpreting EPA's approach for deriving the

Data Quality Ratings for the Modeling components and encouraged EPA to better describe this process.

The Committee recognized the Agency's effort in data gathering and model development to produce the Supplement including all the distribution decisions built into the exposure and release models. Overall, available data were quite limited. Only a few parameters were assigned a distribution informed by data. Default distribution assumptions were frequently used, including triangular, uniform, and discrete. The Committee addressed ways to better evaluate these distributions.

The Committee did not identify additional parameters for model equations.

The Committee recommended ways to improve the report in particular areas needing additional discussion and references; better identification of data sources; alternative distributional assignment choices; and data analyses, including approaches for datasets with many non-detected values. Particular attention was given to ways the Textile Dye Modeling, Laundry Detergent Modeling and Hydraulic Fracturing Modeling could be improved.

The Committee discussed current, historical, and future sources of data to help refine the distributions used in Monte Carlo models and assessments. A fundamental concern of the Committee was the use of distributions that are based on 'old' data or in some cases no data. Instead, some input data are based on questionable expert advice or questionable assumptions. Emerging technical capabilities, One Health, Exposome, or other frameworks can help inform potential adverse outcomes and consolidate data available for models. It is a challenge to balance safety and health with the use of models. The power of models within the 1,4-Dioxane Supplement may be viewed as diminished by the lack of sufficient monitoring data and reports to diminish uncertainty; however, models are important to gain insights and provide a platform for initial assessment despite data gaps. The overall recommendation was to continue utilizing Monte Carlo methods and develop models using available data.

The Committee commended EPA for applying the Monte Carlo approach to capture general population exposure and risks. Committee members were concerned that the EPA's approach for estimating general risk was insufficient for quantifying risk in sentinel and PESS because of lack of understanding of the data distributions underlying the Monte Carlo calculations. The Committee recommended that EPA more fully define the purpose of each random variable distribution used in its analysis. For example, whether the associated model input parameter is uncertain at a given emission source or has a distribution across national use cases. The Committee compiled several recommendations for the hydraulic fracturing analysis, including new data sources.

The Committee noted that near-field exposures in both occupational and nonoccupational settings should receive more prominent consideration and analysis using a first-principle, Monte Carlo modeling approach. The Monte Carlo methodology should be expanded to define terms and list advantages of Monte Carlo versus deterministic analyses.

The Committee discussed the various difficulties in monitoring and characterizing 1,4-dioxane releases and occupational exposures. The problem of characterizing releases and occupational

assessment is complex. Significant factors to consider include the heterogeneity, uncertainty and limitation of monitoring and exposure data. The large number of sources, physical and chemical processes can transform chemicals into unwanted byproducts and/or can add complexity in assessing their release in water, land, and air. Finally, chemical life cycles in the environment, and the different routes of exposure pathways make occupational assessment an arduous task. While this document addresses only 1,4-dioxane, the Committee was cognizant that the same type of considerations should be included for any other chemical under TSCA evaluation.

Monte Carlo methods provide a scientifically and statistically defensible way to address all the issues mentioned in the preceding paragraph, including the limited amount of definitive data on release and exposure. The Committee listed various benefits in using Monte Carlo approaches for the goal of release and occupational assessment. Some primary benefits are incorporation of uncertainty and heterogeneity in model input parameters, increasing flexibility, and allowing a greater degree of complexity in release and occupational exposure models than is often possible in traditional deterministic calculations. Several examples of factors to be considered are discussed in the response.

There is a substantial literature, dating back to the early 90s, developed within the EPA that presents, discusses, and summarizes (policies for) the use of Monte Carlo approaches in risk assessment (US EPA (1994b); US EPA (1997a); US EPA (1997b); US EPA (1997c); US EPA (2022)). This literature constitutes an invaluable resource that the Agency can leverage in delineating how to employ Monte Carlo methods for future TSCA evaluations, particularly when exposure assessment is linked to the notion of risk in a probabilistic manner.

The Committee agreed that the approach(s) taken by EPA to address Down the Drain (DTD) releases are generally appropriate, although several concerns were raised, and recommendations were provided to strengthen the approach and subsequent risk estimates to DTD exposure to 1,4-dioxane. The Committee identified several concerns and uncertainties with regard to the assumptions used in the modeling approaches. Primary among these concerns were: assumptions about exposed populations, uncertainties within the Stochastic Human Exposure and Dose Simulation- High Throughput (SHEDS-HT), and the DTD case study (Liverpool, Ohio) that was for evaluating modeling output for Publicly Owned Treatment Works (POTW) outfalls.

The Estimating Water Industrial Surface Release and Down the drain-Excel (EWISRD-XL) model aims to provide a nationally representative distribution of estimated surface water concentrations of 1,4-dioxane. The assumptions made, based on physical chemistry properties (e.g., water solubility, Henry's law constant) and fate characteristics (e.g., biodegradability) of 1,4-dioxane, are valid and appear to represent its chemical behavior accurately. Overall, the model framework presented in the draft report for estimating 1,4-dioxane concentrations in surface water appears to be well designed and comprehensive. However, the Committee identified some components which appear to include a good deal of uncertainty with respect to DTD contributions, validation modeling runs, aggregate exposures, flow variability, and data gaps.

The goal of developing a national scale model is appreciated as worthwhile, and including this approach is an important step toward deploying national scale evaluations. Several current issues limit the usefulness of national scale models. Prominent among these considerations are that

available data are variable, limited in scope, and available only for locations of uncertain national relevance. The Committee agreed that new data, just becoming available, will be critical to support refinement of models, so flexibility should be “built-in” in the model framework to incorporate new data streams. The Committee recognized significant strengths of having an ideal aggregate probabilistic model and its potential to counteract biases from locality differences, effectively pinpointing "hot spots" or areas with high contaminant concentrations. However, there remains room for improvement and reduction of uncertainties with available refinements. As detailed in the body of the Committee report, available refinements include performing a sensitivity analysis to estimate the value of various data streams, and training these models with the broadest spectrum of exposure events to ensure that the computed risks incorporate the highest levels of variability and uncertainty. The EPA should examine these refinements.

The Committee offered suggestions on the inputs and data sources that the Agency used for reported discharges and probabilistic models. The Committee expressed confidence in the measured release data to surface water encompassing multiple years, but indicated uncertainty in modeled data and whether localized models were consistent with national distributions.

The Committee suggested several modifications to the national scale model approach to lower the uncertainty. One suggestion was to incorporate population growth into the model. The EPA should also identify geographical regions having better data and for which confidence in modeled results would be highest from regions having little or no data and for which confidence in finding would be lower. Finally, the Committee suggested that EPA consider including state-based monitoring databases.

The Committee noted some strengths and several weaknesses in site-specific case studies that were used to compare modeled concentrations to available co-located monitoring concentrations. This approach has promise, and it can be improved by ensuring that sampling locations actually represent modeled reaches; all significant sources of 1,4-dioxane are accounted in the systems; detection limits are managed to provide meaningful calculations, as well as several other considerations.

The Committee agreed that evaluating drinking water exposures to assess cancer and non-cancer risks from drinking water consumption is necessary to quantify 1,4-dioxane health risks to the general population. The EPA evaluated settings where either surface or groundwater was used as a water source. The draft risk assessment does indicate that water sources may be combined in some cases; however, the degree to which this is practiced was not examined in detail.

The downstream tracing analysis, using the NHDPlus V2.1 flow network, identified 125 facilities as potential 1,4-dioxane point sources within 1000 km upstream of drinking water intakes (DWIs) Thirty-one percent of these facilities are situated within 250 km upstream of drinking water intakes and were determined to have releases that would produce adult lifetime cancer risks exceeding 1 in 1 million. Many of the uncertainties inherent in the model used to predict downstream concentrations of 1,4-dioxane are well-discussed by EPA, but the Committee identified several key uncertainties that may require additional discussion and potentially a more focused analysis in a national assessment.

The Committee suggested additional descriptive language about the Hazardous Waste Delisting Risk Assessment Software (DRAS) be added to the Supplement. Several Committee members found it difficult to tell from the information presented if this model was appropriate for this type of assessment and found more uncertainties than strengths in the use of the DRAS model. The Committee recommended that the uncertainties and data gaps in the groundwater scenarios should be discussed more thoroughly in the Supplement.

The Committee noted significant surface water and groundwater exposure scenarios, absent in EPA's assessment. These omissions call into question the use of only ingestion of groundwater sources as the representative marker of exposure. This consideration is especially critical for PESS and certainly for most of the Arctic population where surface water is the more likely source and one that is highly vulnerable to contamination. A key omission in the assessment is consideration of exposures and risks from steam (including 1,4-dioxane) that is used in closed spaces for hygiene and health/relaxation practices (common in the general and tribal populations). A subset of the committee noted that indoor pools and spas as well as laundries could be important. Consideration of volatilization during household use should be addressed as well. Another key omission is the assessment of major potential sources of contamination associated with hydraulic fracturing, including injection of produced water into Underground Injection Control (UIC) Class II disposal wells, spills of produced water and hydraulic fracturing fluids on oil and gas well sites, and casing failures on oil and gas wells.

The Committee posited that contaminant concentrations calculated by EPA for scenarios of leachate into groundwater associated with a 1×10^{-6} cancer risk should be called "levels (or concentrations) of concern" and, while useful to inform monitoring, they should not be considered sentinel. The Committee recommended that EPA determine the potential for contamination, based on different types of landfills as useful information for communities and for more relevant risk assessment.

The Committee agreed that, as noted by several public commentators, assumptions used in the assessments serve to underestimate exposure potential, especially when focusing on populations experiencing high exposures. In particular, it is not clear how bounding the upper tail of model input distributions may limit the maximum model-estimated exposures. The assumption of a 33-year exposure profile was most obvious as potentially insufficient to describe the potential for lifetime exposure in some populations, but upper bounds of other distributions may underrepresent lifetime exposures for PESS populations.

The Committee emphasized the need for meaningful inclusion of non-chemical stressors (such as psychosocial and environmental stress, diet, housing and resource availability, or pre-existing disease) in the quantitative risk assessment, offering both a short-term approach for use now and a longer-term campaign toward quantitative accommodation of these factors in the risk assessment, especially for PESS.

The Committee concluded that in general, the methodologies and assumptions for drinking and groundwater seem appropriate for the analysis and level of certainty. The Committee recommended that EPA include the justification for these default loading rates and exposure

assumptions that were used in the Supplement. The Committee noted it was appropriate to consider groundwater well risk estimates as potential maximum exposure through the groundwater pathway, and as such use them as potential sentinels. The Committee noted that the EPA statement, "Recent changes in industrial activities and disposal may have largely reduced groundwater contamination with 1,4-dioxane" adds uncertainty to the assumptions underlying the groundwater exposure scenario.

In addressing the many facets of CQ 4, Committee members agreed that considering calculations for both grouped and individual facilities represents a strength of the aggregate analysis, as is consideration of risks to be greater in areas where there are grouped facilities. Committee members also identified additional uncertainties, data needs, and areas needing further clarifications for EPA to consider in future iterations of this and other reports.

The Committee evaluated EPA's quantification of multiple sources of 1,4-dioxane releasing to surface water, and the exposure and risk associated with those releases. The Committee's key findings are that the overall approach was a strength. However, the Committee identified several uncertainties. In particular, the Committee indicated that the aggregating approach, the validation of the exposure model, the drinking water intake estimates, and the Margin of Exposure (MOE) approach were sources of uncertainty.

EPA performed qualitative risk assessment instead of quantitative risk assessment for aggregate exposures across routes and pathways because of lack of actual data and significant uncertainties. Whereas this is justified at some level, the majority of the Committee agreed that, in several instances, there are enough data that quantitative risk assessment can be attempted. Some of the Committee recommended that oral and inhalation exposure routes, as well as population and occupational exposures be quantitatively aggregated; and that, at a minimum, EPA perform several different quantitative analyses of aggregate risks for the same populations, using different assumptions or methods to address uncertainties. Other Committee members recommended that EPA provide additional language to support the decision to perform only a qualitative evaluation of aggregated risk.

DETAILED COMMITTEE DISCUSSION AND RECOMMENDATIONS

1. ENVIRONMENTAL RELEASES AND OCCUPATIONAL EXPOSURES ASSESSMENT

The development and incorporation of Monte Carlo methods into an assessment model equation comprises multiple steps as described in **Appendix E. 10** (US EPA/ECRAD Developing Release Models that Use Monte Carlo Methods) of the 2023 draft supplement.

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.

The Committee recommended changes to statements used to present the Monte Carlo methodology that clarify concepts and approaches. These changes will improve the general discussion of Monte Carlo methodology in future documents. Some changes are minor word changes which better describe what should be done. Other changes address definitions which may be unclear in the draft document.

The goal of Appendix E.10, Developing Models that Use Monte Carlo Methods, is to "describe the process" of developing the parts of a Monte Carlo simulation. The Committee wondered why EPA in this appendix makes no reference to key EPA documents where Monte Carlo methods are better described. Namely these include EPA (1997), EPA (2014), and NRC (2009).

The definition of a stochastic process given in lines 7692-7702, needs to be improved.

Recommendation 1: Replace lines 7692-7702 with text that better describes how the stochastic inputs are applied to deterministic risk models.

The Committee suggested the following replacement for lines 7692-7702.

A stochastic (or probability) process has one or more inputs (or parameters) that can take values generated at random from a prespecified probability distribution. The model outputs from randomly generated inputs are also random. The output from multiple runs of a stochastic model produces a distribution of values.

Monte Carlo methods are a technique for propagating uncertainty through a deterministic model. Essentially, Monte Carlo methods as applied here incorporate stochastic inputs in deterministic risk models. The deterministic risk model is run multiple times, each run based on input values that are drawn from a set of prespecified univariate and/or multivariate probability distributions. Random values for each run are generated independently of those of previous runs. Model outputs are collected, and the resulting distribution of output values is used to describe the probability or likelihood of that outcome value occurring.

Line 7714: Figure Appendix E-1 is not clear due to the "black box" aspect on the "Monte Carlo

Add-In Tool" box. Actually, most of the modeling steps are performed inside the "Monte Carlo Add-In Tool," so the graph is not a proper description of the approach. In addition, it is noted in Tables Appendix E-4, Appendix E-6, and Appendix E-8, Summary of Weight of Evidence (WOE) of the Scientific Evidence Conclusions for air, land, and water releases, that while Monte Carlo modeling is used in tandem with the Generic Scenario and Emission Scenario Documents (GS/ESDs), not all GS/ESDs for the Occupational Exposure Scenarios (OESs) get a Monte Carlo assessment. It is not clear what criteria are used and/or how WOE is factored in to support this decision. Figure Appendix E-1 should include a decision box noting this opt-in/opt-out step in the process and discussion on this decision step included in or before Section 10.2.

Recommendation 2: Remove Figure Appendix E-2 or replace it with a figure that more accurately describes the steps in a Monte Carlo assessment.

Replication is an essential component of good science. Use of freeware products is recommended in many Monte Carlo analysis situations since it allows others not directly tied to the development of the model to replicate the Monte Carlo analysis and to examine the implementation for mistakes.

Section E.10.3 should point out that when the deterministic model is fairly simple, the model can be described in a spreadsheet program, such as Microsoft's ©Excel and that there are a number of software (add-in) products, such as Palisade's @Risk and Oracle's ©Crystal Ball that simplify implementing the Monte Carlo process in an Excel worksheet. When the model is complex, which is often the case with pharmacokinetic and pharmacodynamic models (where the integration of a set of differential equations is required), a programming language with a set of built-in random number generators for a suite of probability distributions might be a better, more efficient choice for Monte Carlo implementation. Freeware tools such as R (R Core Team, 2021), and Python (Van Rossum and Drake, 2009) have been successfully used in this case. Other popular Monte Carlo tools, though not free are readily available such as MATHAB (©The MathWorks, Inc.), GAUSS (© Aptech Systems Inc.), and others, have also been used successfully.

More discussion is needed to describe what is included in the label "deterministic model." For 1,4-dioxane, this risk assessment seems primarily concerned with modeling releases of chemical to air, water, and soil. But there are also models that are used in other risk contexts that describe how the chemical of concern once deposited on skin, inhaled, or ingested in food or water, gets translated into an exposure dose.

A general, discussion is needed of the components of a deterministic release model. Gleaning from sections E.11 and E.12, we find that these include a number of parameters, some of which, but not all, that are potentially variable.

daily rates – product used, product manufactured, treated commercial goods,
mass fractions – amount of target chemical in product, residual left in containers, etc.,
facility operating parameters – operating days, container sizes, batch sizes, etc.

The text can emphasize that most exposure and release deterministic models are "accounting models." That is, these models describe how and how much of the target chemical (in this case 1-4 dioxane) enters a "facility" (manufacturing plant, sewage treatment facility, land fill, etc.), how much is transformed within the "facility" and then how much and in what form the chemical exits as a release in product and as waste. Typically, there is only one point of entry at a facility, but

there may be multiple places (points) in the system where releases can occur.

Recommendation 3: Revise Section E.10.2 to be less specific to the @Risk Add In tool and to focus more on the general components of deterministic release models and on the use of available software to apply the Monte Carlo approach to these models.

The draft document does not always clearly describe why one model component (input parameter) is assigned to be a "random variable," and another is assigned a "constant" value. It may be obvious why one parameter is a constant, but in other cases, it is not so obvious. If a parameter that is obviously random (varies over space or time) is assumed to be constant, the reason for that assumption should be clearly stated and justified.

When a parameter is assumed to be random, the assigned distribution needs to be identified as to whether it describes:

1. uncertainty in our knowledge of the true value of a constant for a facility,
2. variability in parameter values over time for one facility (temporal variability), or
3. variability in parameter values across the population of facilities (spatial variability).

This is critical in understanding the results of the Monte Carlo analysis.

There are a couple of places where word changes are needed to properly describe the process.

Section E.10.3.2 uses the word "Define" in describing how probability distributions are assigned to input parameters. The word "Define" should be replaced with the word "Assign" when thinking about the process of linking a probability distribution to an input parameter. This may seem like a minor thing, but the word "define" implies that there is one true distribution whereas "assign" more correctly describes how one chooses among a set of candidate distributions the one to be used for this assessment. It also reinforces the need to justify the distribution assigned.

Recommendation 4: Modify Section E.10.3.2 to better describe how model inputs are identified as constants or random and for random inputs. Additionally, identify whether uncertainty or temporal or spatial variability are being addressed by the associated probability distribution.

In Step 1 (beginning line 7737) *the text reads: Step 1 Select the model input parameters for which probability distributions will be developed.*

The process is really one of identification rather than selection. Selection suggests a more subjective process than it really should be. The reasons behind the choice of a parameter for inclusion in the model should be clearly stated. The discussion following line 7737 is a start, but the discussion should include more detail, and include discussion of all model parameters.

Recommendation 5: Relabel Step 1 as "Identify which model parameters will be treated as random and which as constants."

The availability of data to inform a distribution: Availability of data should not be the key decider of which parameters are considered random. Some model values are clearly random. They vary temporally, spatially, or by emission source. Some model parameters will be clearly constant because of engineering constraints, regulatory constraints, etc.

Model parameters that are clearly random, but for which measurement data are not available, may be treated as a constant or be assigned a probability distribution that is not "data informed" but is rather informed by querying experts, for example via some sort of Delphi Method (see for example Dalcanale et al., 2011) or in a Bayesian inference prior elicitation process (Stefan et al., 2022).

The discussion starting at line 7743 is good as far as it goes, but it needs to include much of what has been mentioned previously in the Committee response to this charge. A discussion of potential bias in the distribution provided by available data/information would be helpful here. If data are from one site, one type of process, or one location, it may not be truly representative of the full range of potential values for the model parameter. It makes a difference whether the published distributional parameters are obtained from a study with few observations or from a study with many observations, even if the underlying observations are no longer available for use.

The concept of within-site and between-site variability should also be discussed when discussing random variables. If the parameter's statistical distribution is meant to describe a "typical" site, then the distribution may require a compound distribution created by parameterizing the within site distribution and then assuming that within site distributional parameters themselves vary among sites and according to a different statistical distribution.

For example, in the Textile Release Model, one might assume for a given site that the mean number of operating days is 155 days, whereas, for another site the mean number of operating days might be 160 days. Hence, the means themselves would be assumed to vary across the 783 sites and a distribution would be assigned to describe this spatial variability. Similarly, the upper and lower bounds might vary from site to site and hence a distribution might be assigned to describe how the lower bound varies geographically as well as how the upper bound varies geographically.

Recommendation 6: Include a discussion of the concept of within-site and between-site variability in identifying the distribution for an input parameter.

The dependency of the input parameters on one another (line 7741): This statement covers two differing situations.

One situation involves a situation where one quantity is "derived" from another. If a model parameter is derived from other input parameters which themselves are random, then the derived parameter is also random. Typically, a probability distribution is only assigned to the base parameter (on the right side of the equation) and not to the derived parameter. But when the derived parameter is a function of multiple random parameters it is important to check whether use of the implied distribution of the derived parameter generates reasonable values.

The second situation occurs when two or more random variable input parameters co-vary (correlation is not zero) but their relationship is not exact (correlation between the two is not

equal to 1 or -1). In this case, one might have to assign a multivariate distribution to the set of random variables. Typically, this is done only if sufficiently robust data are available to inform the distribution.

Note that creating multivariate distributions that are not Normal (Gaussian), but which have a correlation is quite difficult. A short cut often used is to move one of the variables from being random to being derived and then adding a little variability around the derived value. Essentially, the model regresses one variable on the other and uses the regression line with uncertainty to describe the two correlated variables. Transformation and back transformation of variables may be needed to get the needed distributions. The regression does not need to be linear. This is not often discussed in the Monte Carlo methodology but is quite effective for accommodating correlation in situations where random variables follow distributions that are not Normal (e.g., when the distribution is unimodal and symmetric).

For the example described starting on Line 7756, it is not clear whether the EPA is describing a set of jointly derived variables or a set of co-varying random variables.

Recommendation 7: Broaden the Step 1 discussion on input parameter dependency and the identification and assignment of a multivariate distribution to sets of covarying input parameters.

The sensitivity of the model results reflects input parameter values and distributional assumptions: Again, the EPA 1,4-Dioxane Supplement emphasizes what the @Risk software can do. But all the other software tools mentioned above can do this same type of analysis. It would be better to use the @Risk text as an example rather than suggest this is the only way to do it.

It is important that the assessment of parameter sensitivity be divorced from Monte Carlo analyses of parameter variability. Uncertainty characterization is appropriate in a higher-tiered assessment; that is, it is typically done once parameter variability is properly incorporated into the model and results are analyzed. The sensitivity analysis needs to proceed according to a plan, with the goal being to estimate the potential consequences on the final findings of the Monte Carlo analysis.

Recommendation 8: Discuss the need to develop a sensitivity analysis plan as part of Step 1 tasks.

Step 2 Determine a Probability Distribution

The goal of step 2 (beginning line 7784) uses the word "Determine." The process is really one of "assigning" rather than determining. Determining suggests that there is one real distribution, and our task is to "determine what it is". Rather, as is mentioned on lines 7807-7809, the process is one of choosing from among a set of potential candidate distributions the one that best matches with what we know from the data and/or can infer from expert knowledge.

Recommendation 9: Relabel Step 2 as "Assign Probability Distributions to random input parameters."

The standard statistical distributions, Uniform, Triangular, Normal, and Lognormal, are nice in that they have mathematical forms and that random values can be fairly easily generated. But in

the situation where we have a lot of available data, it is possible to let the data define the distribution, and there are tools/functions/modules in the risk simulation packages and programming languages that facilitate sampling from such data defined distributions, including sampling directly from the data using bootstrapping or jackknife techniques (Efron,1982).

As mentioned before, a mixture distribution may be required to describe the situation. This may be the case where we know the underlying distribution is truly multi-modal, or where there are many below-detect values that need to be accounted for. For example, during the 160 days a facility may be processing product, and a large fraction of days may involve no production that involves the chemical of concern. Hence the distribution of the parameter "fraction of the chemical of concern" may have a value of 0 for 20% of the days, and then for the other 80% of days, a value would be selected from a probability distribution having a non-zero minimum value.

Step 3 Check for and Define Statistical Correlations.

The text in Step 3 (beginning on line 7838) discusses how EPA "evaluates" possible correlations among parameters. The Committee prefers the use of the term "evaluate" to the less descriptive," check for" phrase in step label.

Recommendation 10: Relabel Step 3 as "Evaluate and incorporate correlations among parameters where justified."

In line 7839 replace "setting" with "assigning" statistical distributions.

In line 7841, "each parameter is assumed to be independent of all other parameters." The text needs to emphasize that this assumption needs to be justified and, if found to be invalid, the sampling methodology needs to accommodate sampling with correlation. Not accommodating correlations among model parameters can result in sets of parameters that are unlikely, that is, have low or no probability of occurring in practice. (i.e., not logical for the scenario as mentioned in the document).

The example starting at the middle of line 7842 that discusses the correlation among annual Production Volume (PV), daily PV, and operating days is well done.

Line 7872. The text tells us that @Risk only uses Spearman's correlation coefficients but does not describe how it uses this coefficient to generate correlated random values. The committee suspects this is some sort of conditional sampling methodology. Does it work for non-Normal distributed data? For bounded distributions? The Committee could not determine an answer to these questions. The text should describe generation of random correlated values here if in fact this is how EPA wants it done.

Section E.10.3.3 Select Model Outputs for Aggregation of Simulation Results

The draft supplement offers discussion of each input to the Monte Carlo models, and in a few cases justifies the distributions assigned to random parameters and values assigned to constants. But there is no discussion on the key outputs from the Monte Carlo assessment. This section should discuss how key assessment outputs are "identified."

The key model outputs are typically statistics computed from select output parameters whose distributions result from running the deterministic model multiple times with varying inputs. In the three examples discussed in this report, it is implied that key output parameters are "releases per day from the pre-identified release points." What are discussed are statistics of interest, such as mean daily release, the upper 95th percentile of daily release, the maximum daily release. But, in some assessments, the output of a Monte Carlo run is a sequence of daily releases. Hence a statistic such as the "number of days above a specified threshold release value" might be a key statistic of interest whose distribution across runs would be of interest. If a Monte Carlo run generated a spatial distribution of releases, then "total contiguous area having release concentration above a prespecified threshold" might be the key statistic of interest. The key statistic of interest needs to be linked to exposures identified as impacting human health or environmental quality.

Recommendation 11: Include in Section E.10.3.3 a short paragraph on each key model output, including discussion of which input parameters would be expected to strongly influence the shape, location and spread of the distribution of the key model output.

Also, those performing the Monte Carlo analyses should remember that intermediate results typically need to be assessed as well. Consider, for example in the textile dying example, the number of containers unloaded per site per year which is a function of operating days (a random variable), the daily use rate of 1,4-dioxane per site per day (a random variable), fraction of dioxane in the dye (a constant), container size (a random variable) and dye density (a constant). It is important to examine the distribution of the number of containers unloaded per site per year to ensure that unreasonably high or low values are not being generated.

Recommendation 12: Include in Section E.10.3.3 a discussion on the need to identify key intermediate variables and assess the quality of their derived distributions.

Section E.10.3.4 Select Simulation Settings and Run Model

This discussion needs to be divorced from what @Risk does. Discuss the generic operative tasks, not how it is done in @Risk.

Recommendation 13: Generalize the discussion on simulation setting in Section E.10.3.4 to the generic tasks and away from what might be done in a specific Monte Carlo modeling tool.

Number of Iterations: Computational time is cheap. As was mentioned in the EPA presentation before the Committee, 100,000 iterations are used since they produce "stable mean estimates". But what happens if the key output parameter is not a mean? Often the goal of the Monte Carlo exercise is to understand the distribution of key model outputs (e.g., release amounts) not just the average. In theory, one can get a decent but maybe unstable estimate of the upper 99-th percentile with 100 iterations and a very good estimate with 10,000 iterations and likely a very stable estimate with 100,000. If examination of a sorted list of the output values shows a large number of repeated values, it is likely that too many iterations are being used, and one can cut back on iterations in subsequent runs. A search of the statistical literature may provide a procedure for estimating the number of iterations needed to estimate an upper percentile to a given level of precision. (An algorithm to do this can be found in Royet al., 2016).

Sampling Method: Latin Hypercube is a type of stratified random sampling within a multi-dimensional space whereas "Monte Carlo" is just simple random sampling. Many on the Committee agreed that Latin hypercube sampling is often the preferred method for the reasons mentioned elsewhere in the draft document.

Random Number Generator: All computational tools use methods that produce pseudo random numbers. It is impossible to get "perfect" random numbers. The Committee is not sure if the EPA needs to mention what @Risk prefers unless EPA recommends this method. Note that the Mersenne Twister method is the method used by default in the professional programming tools typically used in Monte Carlo risk assessments such as GAUSS, MATLAB, R, Python, and Maple™ (Waterloo Maple Inc., Waterloo, Ontario).

Section E.10.3.5 Aggregate the Simulation Results and Produce Output Statistics

Sometime earlier in the Monte Carlo process, the target percentiles of interest should have been specified. Here we learn that "EPA typically uses the 50th percentile and 95th percentile of the output as the central tendency and high-end estimates, respectively." The justification of the target percentile should be specified in Step 2. Aggregating the results of Monte Carlo runs and producing statistics of interest is the final operational action in the process.

Recommendation 14: In Section E.10.3.3 discuss how target percentile of interest is selected.

Comments on Strengths

The Monte Carlo approach allows:

- integration of information from multiple sources as well as integration of summarized, incomplete, or even biased information into one logical framework,
- propagation of uncertainty of model parameter values through a deterministic model to quantify the resulting uncertainty in the preidentified critical end points/statistics,
- use of monitoring data to validate modeling assumptions and to support the utility of findings, and,
- simulation of a large number of scenarios which provide increased confidence in risk assessment findings.

Comments on Uncertainties

The Committee limited itself to general comments on uncertainties related to the use of Monte Carlo modeling, providing detailed comments in response to CQ 1.b.

Assignment of model component (input parameter) distributions for a Monte Carlo assessment is dependent on: 1) having published values; 2) analyses of data the EPA has been able to accumulate; or, 3) estimates derived from expert elicitation. None of these information sources guarantee accurate and unbiased distributions that reflect model component values across the target population. More discussion of issues with the assignment of model component distributions is found in the Committee response to CQ 1.b.

If the population of interest is vaguely defined, the parameter distributions are likely to reflect this uncertainty. Knowing select statistics (such as location, variability, min, mode, max) for the distribution assumed for a key input parameter typically will not inform the shape of the distribution. Identification of shape, defined by descriptors such as unimodal, skewed, bounded, etc., requires more than two or three parameters. Some would argue that even having extensive measurement data for a parameter does not guarantee that we know the true shape of the underlying distribution, because observations often have limitations imposed by the measurement processes. Having a large fraction of below detection limit observations is a common limitation. Sampling from available data, for example using bootstrap or jackknife resampling, typically require more observations than are available. The uncertainty in shape propagates into uncertainty in Monte Carlo assessment results.

Published distributional parameters, such as the lower bound, upper bound, and mode specified in Table Appendix E-12, often come without any measure of the uncertainty in those estimates (that is, without standard error estimates). Depending on the shape of the distribution assumed for a model component, if the model is sensitive to values of that component, a small change in the distributional parameter value can produce big changes in the distribution of one or more key outputs.

Comments on Incorporation of Variability

The goal of Monte Carlo modeling is to propagate variability in model inputs through the deterministic model to outputs (estimated release amounts) and the computation of statistics on the simulated outputs. The extent to which the exercise is successful depends on getting all the previously mentioned steps correct.

Monte Carlo modeling, as typically applied, does not do a good job of capturing variability associated with model parameters in situations where no information or acknowledged poor information is available for some model parameters. While the Delphi-based method previously mentioned provided a reasonable short-term solution for generating values for uninformed parameters, several Committee members suggested that a full Bayesian approach should be attempted as a better long-term solution. A Bayesian approach would allow all sources of uncertainty to be handled in a coherent fashion. Undertaking a Bayesian assessment would require educating more EPA staff on how to implement Bayesian estimation methodology and Bayesian modeling approaches.

Comments on Assessing Confidence in Monte Carlo results.

In the draft document, the quality of the risk estimates is assumed to be dependent on the quality of the underlying information and data used. How the quality of this underlying information and data is assessed is discussed in Section C.4.2.2 and in Section E.8. In Section C.4.2.2, specific descriptors are provided for each quality level (“High”, “Medium”, “Low”, “Critically Deficient”, etc.) for various metrics (“Sampling methodology”, “Analytical methodology”, etc). This scoring is then integrated into a weight of evidence (WOE) assessment. Table Appendix E-10 provides a summary of the overall WOE for releases based on OES. The Committee was not clear on how the Data Quality Ratings for the Modeling components are derived. The monitoring and modeling quality assessments in the draft document seem to be based primarily on the quality of the data

rather than on some wholistic assessment of the Monte Carlo process. For example, how does the tightness of the distribution of the key output parameters factor into the final rating.

A couple of Committee members wondered if a more formal quality assessment process might be created and applied to the Monte Carlo modeling exercise. They suggested it might be possible to derive the quality label assigned to the Monte Carlo modeling results through applying quality values to predefined model metrics.

One Committee member referred to the following statement in the draft document: that the "Sampling method specifies preference towards the use of Latin Hypercube rather than Monte Carlo with the rationale for efficiency and potential for clustering and under-representing low probability events." Please add more information here (lines 7893-7900) and specify in the draft document where each is used.

One Committee member noted that quality characterization needs to be performed on each dataset so that the highest quality data are being used to form the final dataset from which input parameter distributions are formed. Some datasets have a large number of observations, others are quite small. Some datasets will be accompanied by detailed metainformation, others with no metainformation at all. Some data may have been generated with recent high-precision analytic techniques or careful sampling, others with less precise methodologies. These factors need to be carefully examined before data are considered fit for purpose. This ensures that the input parameter distributions used actually reflect the population of interest and are not an artifact of some characteristics of how the data were collected. For example, data that are generated using a low-precision measurement methodology often display clustering of values and this clustering can strongly influence statistics that identify the center, spread, and/or shape of the derived distribution. The problem can be magnified in situations where data from different sources and of different quality are combined to identify a distribution that has broader population relevance.

Finally, analysts should be aware that there may be specific (influential) observations within the dataset that when excluded produce very different estimates of center, spread or shape and hence yield different distributions.

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.

GENERAL COMMENTS ON THE APPROACH TO THE PROBABILISTIC ANALYSES

Recommendation 1: Expand the background explanatory text about the value and utility of Monte Carlo methods and include references to Agency documents and guidance and scientific literature in those background sections. Some documents to include are noted above in the response to CQ 1a.

The agency approach meets the standards of fit for purpose using available literature and standard probability distribution assumptions. With that said, it is notable that uncertainty estimates are not featured in results. A limited sensitivity analysis in some cases may provide useful insights. Wu et al (2019) provide a useful overview of methods to account for uncertainties in exposure assessments. Commonly used statistical approaches that are described may guide assessment of uncertainties in dioxane exposure assessments.

Recommendation 2: Discuss/explain the reasons for not performing a quantitative uncertainty analysis.

ADDITIONAL DATA OR UNDERSTANDING OF PROCESSES WOULD INDICATE A DIFFERENT DISTRIBUTION

Annual Use Rate of Fracturing Fluids Containing 1,4-Dioxane and Mass Fraction of 1,4-Dioxane in Hydraulic Fracturing Additive/Fluid – these were modeled as discrete. 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; many of these wells are small but about 20% (180,000 wells) produce >100 barrels/day) and the industry is projected to grow (US Energy Information Administration 2022 and 2023). A triangular distribution informed by the discrete values may better reflect the variability of this large industry. (E.13.12 and E.13.13 Pg 355, lines 8887-8907)

Recommendation 3: Revise the distribution assignments for the annual rate of fracturing fluids and mass fraction of 1,4-dioxane in hydraulic fracturing additive fluid to better represent current and future industry directions.

The Consumer Use Rate of Antifreeze section of the supplement notes that commercial use rate data were not found. It appears that only a "top-up" amount is modeled. The Committee recommended revising this input to include both the 'top-up' amount and potential for full replacement of antifreeze. An online data source suggests a full replacement amount of ~2 liters (2 kg/job) (Hawley 2023). (F.7.9 pg 417, lines 10462-10468)

LACK OF CLARITY OR NEED FOR ADDITIONAL INFORMATION TO ASSIGN A DISTRIBUTION

Daily use rate of detergent: The statistics provided for this parameter's distribution does not really provide enough information for the reader to fully understand the distribution used. OECD, 2011 provides tables of statistics that describe annual use rates but also lacks sufficient information describing how daily use rates are modeled. The report needs more detail here to support the distribution assignment.

Container residual fraction of totes, drums, and pails: The residual fraction distributions are assumed to be Triangular based on lower, mode, and upper bound estimates obtained from the ChemSTEER User Guide (US EPA, 2015a). Four models are mentioned in OECD, 2011 as useful for estimating container residue releases separately from large containers (EPA/OPPT Bulk Transport Residual Model), drums (EPA/OPPT Drum Residual Model), small containers

(EPA/OPPT Small Container Residual Model), and solid transport containers (bags, fiber barrels) (EPA/OPPT Solid Residuals in Transport Containers Model). All of these seem to be based on a 1988 study (US EPA, 1988). The Committee recommended reviewing this study and the data therein: they may indicate another choice of distributional form rather than the default triangular. This comment also addresses issues that arose in the discussion for CQ 1.c.

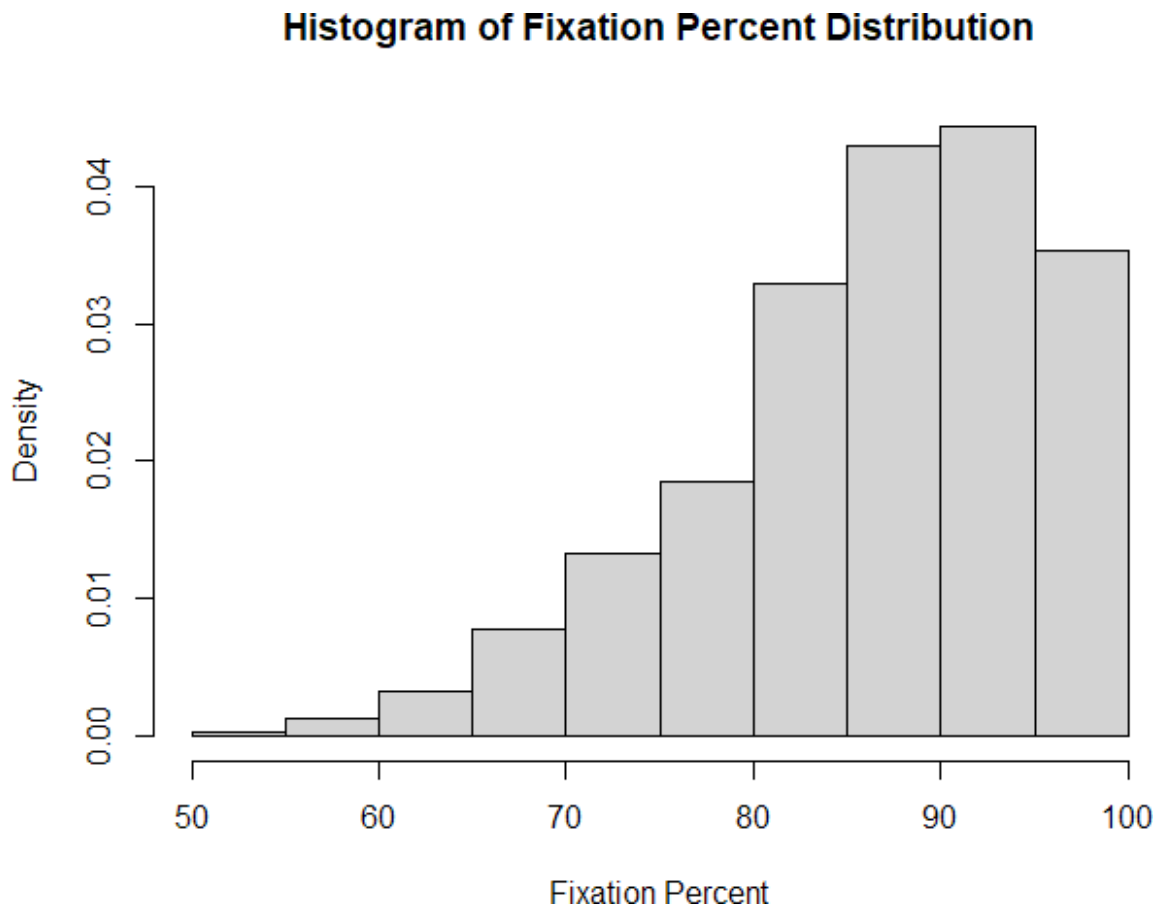
Textile Production Rate: Parameters for the associated triangular distribution come from the 1994 EPA Scenario document (US EPA (1994) US EPA. HERO ID: 4286532) and are based on one 1993-94 analysis of data provided in fabric finishing Pre-Manufacture Notices (PMNs). This assessment has no citation but seems to be a personal communication with Bercen resin sales staff, Sept 16, 1994. More recent data, perhaps obtained through outreach to industry representatives or sales people, would be useful here. This comment also addresses issues that arose in the discussion for CQ 1.c.

Mass Fraction of the Dye Formulation in the Dyebath: OECD, 2017 references ETAD (Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers) as the source for these data. Objective data, perhaps a targeted sampling effort, would be useful here.

The Committee has concerns with the accuracy of data on container size for dye formulation: the OECD (2017) states on page 36: “Dyes can be transported in containers ranging from 25 kg through 1,000 kg (ETAD, 2011), but according (to) correspondence with Dr. Warren Jasper (North Carolina State University College of Textiles), most are shipped in 35- gallon drums (Jasper, 2011).” However, an internet search could not find any company in the US or Europe selling 35-gallon (132.5 Liter) drums. Typical are 30-gallon, 32-gallon and 55-gallon drums or 113-liter, 120-liter or 210-liter drums. Tote sizes are typically 135-gallon, 275-gallon or 330-gallon. Dry power might be shipped in 72-gallon fiber drums. The smallest plastic drum found was 8-gallons or 5-gallons for a metal drum. (Dalcanal, 2022).

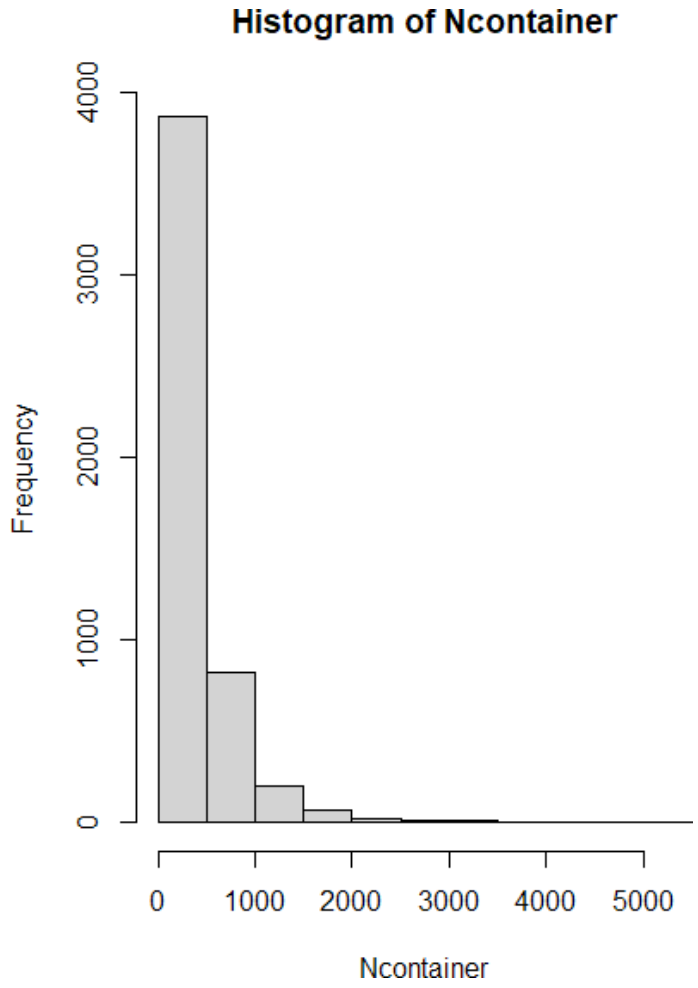
Fraction of dye product affixed to textile during dyeing process substrate: Different triangular distributions are used depending on the dye type (Table E-13). Simple simulation shows that the form of this distribution is sensitive to the assumption of equal probability of Dye Class choice. What is reported as the modal value in Table Appendix E-13 is actually the average fixation percentage (default value) in Table 1-2 of OECD, 2017. When Dye Class is chosen with equal probability and values simulated using the Dye Class specified triangular distribution, the final fixation percent distribution (Figure 1) does not look like a triangular distribution, illustrating the point made earlier in the Committee response to QC 1.a about checking the validity of the distributional form for derived or intermediate parameters.

Figure 1 Histogram of fixation percent distribution



Eq. Appendix E3: The Committee noted that because the mass fraction of 1,4-dioxane in dye formulation (Fdioxane_dye), container size (Vcontainer), and dye density (RHOform) are in the denominator of equation Appendix E-3, it is very likely that the final results could be greatly sensitive to minor changes in these values. The distribution of the number of containers unloaded per site per year (Ncontainer_unload_site_yr) is a random variable since it depends on the random variables "container size" and, through the "daily use rate of dioxane per site day", on the random variable "textile production rate" (Vfabric). Essentially this intermediate parameter has a distribution formed as the ratio of two triangle distributed random variables. A simulation using these equations and assumed distributions shows that Ncontainer_unload_site_yr has a skewed distribution. Further simulation suggests that the shape of this distribution does not seem to be particularly sensitive to any of the fixed parameters (see Figure 2 Histogram of Ncontainer).

Figure 2. Histogram of Ncontainer



Recommendation 4: Retrieve data from the Organisation for Economic Co-operation and Development **(OECD), ascertain validity/uncertainty of data, and consider other sources to verify information, such as recent sales staff to refine estimates.**

Notes on Appendix E.13 Hydraulic Fracturing Modeling Approach and Parameters for Estimating Environmental Releases

Section E.13.12 Mass Fraction of 1,4-Dioxane in Hydraulic Fracturing Additive/Fluid: What is the difference between $FF_{ddddddddddddd\_ffffdfffffffffdddfff\_ffffffddd}$ (Mass fraction of 1,4-dioxane in hydraulic fracturing fluid [kg/kg] and $F_{dioxane\_additive}$ (Mass fraction of 1,4-dioxane in hydraulic fracturing additive [kg/kg])? The assigned distributional parameters are discussed (but we can get these from Table Appendix E15) but the differences between these parameters are not. So, is "additive" actually another chemical combined with the drilling fluid (water + lubricants + bulking agents) that produces the final hydraulic fracturing fluid (water + lubricants + bulking agents + additive)? The

potential correlation between these two key parameters is discussed in the Draft Document but not why that correlation might be expected to exist. From the text it sounds like the FracFocus 3.0 submissions dataset (GWPC and IOGCC, 2022) contains data from which a data-informed joint distribution might be obtained. It is not clear whether in the actual Monte Carlo study correlated values were used. Also, a Discrete distribution typically is used for a random variable that has discrete set of possible values. With $FF_{ddddddddddddd\_ffffdffffffffddddff\_fffffddd}$ and $F_{dioxane\_additive}$ both assigned Discrete distribution types, the reader needs to see the potential discrete values. Are only the lower bound, mode and upper bound values used and with equal (1/3) probability?

Section E.13.5 Container Size: Typical drum sizes for liquids start at 30 gallons. Does the 20-gallon lower bound represent the situation where a partial container is used? Is $N_{cont\_unload\_yr}$ (line 8681) an integer or can it contain a fraction suggesting that partial containers are used. What is assumed about the unused fraction of a container? Is it assumed it is saved for the next project or discarded in the wastewater?

E.13.6 Diameter of Container Opening: While most barrels have a standard 5.08 cm (2") opening, is this also true for totes? A quick internet search shows that a 275 to 550-gallon Intermediate Bulk Container (IBC) tote tank for chemical transport has a 6"-6.25" (15.24 – 15.875 cm) threaded fill port and a 2" (5.08 cm) drain ball valve and 2" (5.08 cm) male quick-connect camlock. Wouldn't the 15.24 cm (47.9 square cm) fill port be used for container cleaning offering more opportunity for air release than the 5.08 cm (15.95 square cm) opening?

E.13.10 Container Fill Rate: For a 55-gallon drum with a 5.08 cm fill opening to be filled in 3 minutes (20 containers per hour) requires an input rate of 18 gallons per minute through a fill opening of 15.95 square cm (1.2 gallons/square cm). For a 275-gallon IBC tote tank with a 15.24 cm fill port to be filled in 3 minutes requires an input rate of 91 gallons per minute through a fill opening that is 47.9 square cm (1.9 gallons per square cm). This assumption seems reasonable.

Recommendation 5: Additional description and justification should be provided in Section E 13 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, operating days.

IN SOME CASES THERE ARE DATASETS MENTIONED THAT COULD SUPPORT AN EMPIRICAL MODELING APPROACH

E.11 Textile Dye Modeling - Operating Days – assumed Triangular Distribution: From the OECD, 2017 document we find the statement "A search of 31 past PMN submissions from 2006 through 2014 revealed an approximate average of 157 operating days per year, over a range of 31 (5th percentile) to 295 (95th percentile) days per year" and references (EPA, 2015) but the 2017 OECD document does not provide the full document citation. This suggests that there were at least 31 values for operating days that could be used to determine the form of the underlying statistical distribution if the EPA, 2015 document could be identified. This is more than enough to allow determination of whether the triangular distribution is more relevant than say the Uniform. Simple Quantile-Data plots would be adequate to justify the underlying distribution.

Recommendation 6: Additional description and justification should be provided in Section E 11 for not using original data to define the distribution for operating days.

E.12 Detergent Modeling - Operating days: EPA assumed triangular distribution but from OECD, 2011 (discussion just before Table 0-2, page 32), there were 600 industrial laundries which provided data on operating days for the years 1994 to 2002. An analysis of these data may suggest a different distributional form. With a relatively large dataset a Normal or Lognormal form is likely. This point also addresses aspects of CQ1c.

Recommendation 7: Analyze the available data to inform the distribution assignment. If that is not possible for some reason, an explanation and justification should be provided in Section E 12 for why the data were not used.

SENSITIVITY ANALYSES RECOMMENDED

For the Discharge Monitoring Report (DMR) Release Data (described on Line 7519), the EZ Search Load Module uses a combination of setting non-detects equal to zero and as one half the detection limit to calculate the annual pollutant loadings. – What is the impact of using other assignment values, e.g., half of the detection limit (½DL) and DL instead of 0 and ½ DL?

One major point of concern is the way surface and drinking water monitoring data were evaluated. Assessments focused on detected values. This represented a small fraction (<10%) of results. A more robust analysis should include the values where results were below the limits of detection. Shoari and Dube (2018) summarize implications for uncertainty analysis in exposure assessments.

There are three TRI range codes: 1 to 10; 11 to 499; and 500 to 999 lb (see line 7549). TRI data tools display the approximate midpoint of the range (i.e., 5, 250, or 750 lb.) – What is the impact of assigning a uniform distribution to this variable instead of using the midpoint of the range?

Where facilities reported to TRI with a Form A, EPA used the Form A threshold for total releases of 500 lb./year for each release media (e.g., fugitive air, stack air, surface water, POTW, non-POTW waste water treatment (WWT), Resource Conservation and Recovery Act (RCRA) landfill, other landfill) (see line 7571). EPA used the entire 500 lb./year for each release media; however, if this threshold is for total site releases, these 500 lb./year refer to only one of these media at a time (since assessing 500 lb./year for all media at once would double count the releases and exceed the total release threshold for Form A). What is the appropriateness and impact of randomly distributing the total release as fractions to the different release media?

The EPA used reported annual release data to create daily time series (line 7621). Pollutant Load values of "0" in the Enforcement and Compliance History Online (ECHO) Pollutant Loading Tool Advanced Search output file are by default reported as below the detection limit in the monitoring reports used by the Loading Calculator Module. How are daily below detection limit (BDL) values handled in creating a daily air and water release time series? If they are set as 0, what happens if they are modeled as DL or ½ DL?

Recommendation 8: Consider alternative statistical approaches and sensitivity analysis for assessing how non-detected values are incorporated and how TRI Form A total release values are assigned to media impact estimated releases to surface and drinking water.

SITUATIONS THAT MAY RESULT IN UNDERESTIMATION

Line 7528: The Emergency Planning and Community Right-to-know Act (EPCRA) section 313 states that facilities may estimate their release quantities using "readily available data," including monitoring data, collected for other purposes. When data are not readily available, EPCRA section 313 states that "reasonable estimates" may be used. Additional discussion about whether "reasonable estimates" correspond to "monitored levels" of similar sized sites would be helpful.

Recommendation 9: Provide additional discussion as to what constitutes "reasonable estimates" and how these are related to "monitored levels" at similar sites (Line 7528).

Temperature is modeled as a single value (298 K or 25 C). In the Laundry Detergent Exposure Modeling (and potentially other scenarios) it could very well get warmer in laundries given use of hot water and driers. The Occupational Safety and Health Administration recognizes that laundries can be hot working environments (OSHA 2023). The Committee expects that using a single value of 25 C underestimates potential exposure. (Appendix TableF-35, Pg 423, line 10682)

Recommendation 10: Discuss the impact on the exposure estimate of choosing a higher working environment temperature than 25 C in the Laundry Detergent Exposure Model.

OTHER – TEXT EDITS, TYPOS, ETC.

Line 8129: Add two lines to differentiate industrial laundry from institutional laundry. Alternate text recommendation: "Industrial laundries are off-premise laundries that wash soiled linen (52%), including table and bed linens, towels, diapers, uniforms, gowns, and coats of the type used by doctors, nurses, barbers, beauticians, and waitresses, and industrial coverings (48%), including work uniforms and related work clothing, such as protective apparel (flame and heat resistant) and clean room apparel; dust control items, such as treated mops, rugs, mats, dust tool covers, cloths, and shop or wiping towels. Institutional laundries are commonly referred to as on-premises laundries (OPL) and the items laundered will vary by facility, primarily hospitals (73%), nursing homes (13.6%), and hotels (13.4%) (OECD, 2011, Table 0-2)."

Line 8528: The lower bound on container residual fraction for totes should be 0.0002 kg/kg.

Line 10682, Appendix Table_F-35. Respirable particulate concentration – data here for institutional laundries does not match the descriptive text on page 424, lines 10715-10728. Also correct the spelling of the word "Rationale" in the last column".

Lines 11609 and 11677: Correct dilatation to dilution in Dilution attenuation factor."

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.

Recommendations and Comments:

The Committee recommended that EPA consider additional sources of data to better inform the distributions assigned to parameters. Monte Carlo simulations utilize parameters, generally with known information availability (see F.8.2 lines 10678-10681 for an example). When data are not available, the use of a triangular distribution could be a limitation for the assessment. A more conservative distribution that reduces underestimation is preferable where possible and based on existing data. A wide range of data sources are already considered, with the following caveats:

- Addition of aging and life stage as variables, where possible, using available data.
- Consider if there are potential synergistic effects from coincident exposure to a mixture of environmental chemicals if these data could be integrated into the models.
- Are non-linear effects considered in the distributions used in the Monte Carlo models?
- There are many contributing factors that are recognized, which may have differential effects on any outcomes, adverse or negligible (Ottinger and Geiselman, 2023).
- The shape of the distribution curve and variability of parameter(s) could provide additional insight into its true distribution (see specific recommendations).
- Are there additional datasets available for air and water release from "unconventional oil and gas development" including practices of fracturing (see specific recommendations)?
- Data for inhalation exposures could be considered and may be available from manufacturers (see specific recommendations and public and written comments from the American Chemistry Council (ACC), the American Cleaning Institute (ACI), and the American Petroleum Institute (API)).
- Frameworks such as One Health and the Exposome can help in identifying and projecting potential adverse outcomes and consolidating the data available for models (Ottinger and Geiselman, 2023).

Recommendation 1: Consider additional sources of data that optimize existing information on pertinent influencing factors:

An approach that the Environmental Protection Agency (EPA) could use would be to construct distribution for parameters, where here distribution is intended to capture the heterogeneity in the value of a variable. Specifically, in the Draft Supplement to the Risk Evaluation (RE) for 1,4-Dioxane, Appendix E7, the Agency discusses different instances and provides reasons as for why the values reported in the Toxics Release Inventory (TRI) or DMR database can be interpreted as underestimating or overestimating the actual variable. This information could be used to create a distribution that puts more mass on the lower end, or higher end of the distribution respectively, depending on whether the monitoring data is assumed to be overestimating or underestimating the key input parameter.

Recommendation 2: Modify parameter distribution to accommodate predicted under- or over-estimation in specific variables:

Within the Bayesian statistical framework, there is a rich literature on elicitation of prior distributions based on expert opinion leveraging limited, historical data. Even though the Agency is not using a full Bayesian modeling strategy to characterize environmental release of dioxane or to characterize exposure to dioxane, the methods for prior elicitation could be used in this context to elicit and specify distribution for some of the input parameters leveraging the limited data available in the TRI and DMR databases as well as the scientific knowledge of members of the Agency involved in this effort. See discussion following Recommendation 5 in response to CQ 1a with reference to Bayesian inference prior elicitation process. Additionally, the following references could be of use (Gathwaite et al. (2005); O'Hagan et al. (2006)).

EPA should do more to formalize this kind of information gathering, especially for Tier I assessments and especially for model parameters that are logically constants that need to be updated. Can a process be developed that would allow query of multiple industry "experts" in a formal way, in a similar fashion as literature is formally examined in the systematic review. Expert determination seems to be a quick and easy method of filling some critical data needs to better inform the model as well as insights that could add to the validation of model intermediate results, such as the number of barrels used per facility per year. A quick review of the research literature suggests that there are methods available to combine expert judgements into information that informs values and potentially informs distributions (see CQ 1a; Wilk and Gnanadesikan, 1968).

Recommendation 3: Utilize the available literature on Bayesian statistical framework for methods that may help specify distribution for some input parameters.

The power of models may be viewed as being limited by the lack of sufficient monitoring data and reports to diminish uncertainty; however, models are extremely useful in achieving insights and provide a platform for initial assessment despite data gaps. Both models and monitoring data are essential, with relevant caveats and contextual considerations.

In response to identifying additional sources of data to refine the input data and reduce uncertainty, written comments by commercial stakeholders indicate that they may provide data to achieve a more confident RE (see below for more detail). Lacking more complete information, the Agency is compelled to trade conservatism for data that will appropriately overestimate exposure and risk in the initial release of the RE. Monitoring data, with or without contextual information on model determinants, would contribute insight for evaluation and refinement.

Recommendation 4: Utilize monitoring data in tandem with models; respecting the contributions of both to obtaining assessments that diminish uncertainty to the extent possible

The EPA document is replete with statements about the limited availability of data and inability to gather critical information to even take a guess at the values for model parameters. When data are available, they may well not be representative of the local, regional, or national situation. In many cases, we have no idea if the available data reflect the past only or can be predictive of the future.

While a rich data base is an obvious advantage for assessment, EPA is likely working with a very different reality. With that perspective, it is important that EPA employ modeling techniques not only to compute normative values and high-end values, but also to use the modeling to suggest bimodal distributions or indications where data sets should not be mingled, or evidence of PESS, etc. In other words, a well-designed model can help to identify and utilize the most appropriate information from the available information. The documents should include discussion of these issues as in justifying the assignment of the selected distributions to parameters, using combinations of data to inform parameter distributions, and incorporating data with unusual, atypical or "rare" values, etc.

One Committee member recommended a reversal of the current Agency paradigm that considers monitoring as superior and preferable to modeling, particularly for Occupational Exposure Scenarios. It was recommended that modeling should be used first and foremost to analyze and develop in detail the OES using available monitoring data to support and verify the model. Because monitoring data may not have contextual information about the primary determinants that caused the exposure, the assessor is blind to what factors produce the exposure. Models, on the other hand, literally represent the hypotheses for the various exposure scenarios, e.g., properly constructed, they can provide the explicit, open, and detailed elements of Occupational Exposure Scenario (OES). Properly formulated, a model can provide a technical representation of the many explicit elements that drive exposure.

Recommendation 5: Emphasize the value of utilizing both modeling and observations in assessments.

This recommendation addresses a slightly different release scenario than those considered for the metrics in the modeling. In addition to the statistical considerations, an additional scenario exists which could influence the variability imposed from real life disposal practices for hydraulic fracturing produced water. Some states permit fracking waste to be spread onto roads to melt ice or suppress dust. That scenario does not seem to be represented in EPA's calculations, as it is quite different than represented by the surface impoundment analysis using Delisting Risk Assessment Software (DRAS; lines 11651 - 11687). This scenario plausibly could contribute to variability as well as introduce areas of pooled contamination in communities where the practice is common. States that permit spreading on roads for ice and dust control with or without regulations related to contaminants are: New York, Massachusetts, Ohio, Pennsylvania, Vermont, Kansas, Texas (from conventional drilling operations as well). Although some testing is required, 1,4-dioxane does not seem to be on lists of required testing moieties (Harrington, 2015). Not only fracking waste but produced water from conventional drilling could be involved.

In addition, the Yale's School of Public Health has been working with the National Cancer Institute of the National Institutes of Health measuring toxicants purportedly released into air and water as a function of "unconventional oil and gas development" including practices of fracturing. The publication (Elliott et al., 2017) has results for 1,4-dioxane. These investigators may have additional data as well as related information about scenarios of these processes that could contribute to 1,4-dioxane contamination. If there is evidence here that 1,4-dioxane contamination is consequential to drilling processes other than fracturing, those release scenarios should be considered, with the geospatial areas of concern identified for those situations. It is suggested that experts on drilling practices/fracturing consider this scenario and its importance for estimating

contamination (and ultimately exposure) levels under varying realities and relevant to a range of drilling waste, not just fracturing, which could affect the statistical views on the estimates.

Recommendation 6: Incorporate additional release scenarios for which data exist, including data associated with fracking and its waste into assessment.

It is noted that air release estimates (2.1.1.4) are focused on fence line exposures, with no mention of any other releases during commercial or consumer use of products. Near-field indoors sources could provide the majority of exposure potential, with later mention of limited monitoring data. The EPA has been a pioneer in modeling inhalation exposure from paint over the last 30+ years (e.g., Wall Paint Exposure Model – WPEM (US EPA 2023b)). Monte Carlo modeling using our best "aimed" parameter estimates and associated uncertainty distributions for the reasonable worst case for 1,4-dioxane release in an indoor scenario would have provided for a much richer assessment that acknowledges and quantifies our uncertainty around this potential exposure and health risk. Defaulting to weak, incomplete monitoring data could lead one to falsely conclude the existence of significantly lower levels of exposure than may actually be extant. Using the above modeling approach admits to the relative lack of data and knowledge around this exposure potential. This approach appropriately trades conservatism for data, which has become or should be a strong touchstone of the RA Process. The EPA could also challenge interested and invested stakeholders to provide data to refine the resulting broad exposure distribution to render a more confident and potentially lower estimate.

Assessments of 1,4-dioxane releases that may influence drinking water in municipal, tribal or private supplies would be much more robust if monitoring data requirements were triggered when EPA initiates a TSCA risk determinations for a chemical or class of chemicals. This would allow sufficient time for producers of chemicals being reviewed to generate the data needed to inform risk determinations.

Recommendation 7: Expand the air release estimates beyond fence line exposures to include near-field indoor sources associated with releases during commercial or consumer use of products.

The quintessential task of the EPA is to rationally regulate human and environmental exposure to chemicals. Under-regulation results in damage to people and the environment, while over-regulation harms the economy. Both harm the national interest. Therefore, the EPA needs more - high-quality input data to inform these decisions.

Public comments were sharply divided in their opinions that the 2020 and supplemental 2023 RE either over- or underestimated exposure and risk from this chemical. A significant portion of this disagreement comes from their perspective and viewpoint relative to the uncertainty posed by the RE. Uncertainty borne of a lack of knowledge typically dominates the uncertainty of most REs. Enhancing the scientific process to decrease uncertainty will benefit the assessment outcome.

Refined data could come directly or indirectly from the manufacturers who, if faced with these potentially high estimates born of high uncertainty, could provide more information on residential 1,4-dioxane as an incidental contaminant. They may even have, or could implement, a production

specification setting a maximum level of this compound or total Volatile Organic Compound (VOC), that they could certify from their data and management of their process (please see the public comments by the ACC, ACI, and API as they appear willing and able to provide Occupational Exposure Scenario (OES) info in collaboration with EPA assessors). This could allow a generalized modeling approach by the Agency that would give the manufacturing/selling stakeholders an opportunity to provide confident and reasonably certified OES data.

Recommendation 8: The EPA request information from manufacturers as an additional source of refined data.

See LL1609-1612. Manufacturers of dyes, soaps, and detergents can provide 1,4-dioxane content of their products. This would allow estimation of air emissions from these sources.

Given a reasonable appeal process, the manufacturing stakeholders could identify the sources of uncertainty in the initial assessment models and conduct the work that will provide scientifically certified, less uncertain, and more confident inputs. This will invariably lower putative risk. Manufacturers can also mandate risk management options such as product specifications for the maximum amount of chemical allowable in products that they sell. The end result could be a more rational RE process that does not dramatically overestimate exposure and risk while providing confident knowledge of the actions needed to protect people and the environment.

Recommendation 9: Obtain product information on 1,4-dioxane content from manufacturers.

An important issue is proper interpretation of the existing data, separate from including additional data sets. One Committee member had more specific comments regarding the assessment of occupational exposure data, in that it may misrepresent actual exposure, which can cause overestimates or underestimates. For example, a plant manager may have asked a technician to determine the worst-case exposures to select adequate controls. Alternately, he or she may minimize exposure in reports to higher management, the union, workers compensation carriers or regulatory agencies, without directly falsifying the results. Production can be cut back; ventilation can be increased; workers wearing personal monitoring equipment can be kept in low-exposure areas; leaky vessels can be run at lower pressures, or even opening all the windows. This can even be done when the monitoring is performed by regulatory agencies, and it can influence environmental monitoring as well (classic example being increased production at night, when opacity monitoring is impossible). Sometimes the highest exposures are completely missed by routine workplace monitoring. Maintenance workers often have the highest short-term exposures, but are monitored less frequently than production workers, and sometimes not at all. The gap between production and maintenance exposure is especially large in the chemical industry, where production often takes place in closed, sealed reactor vessels. When something fails, maintenance workers are required to open and sometimes enter that equipment. Monitoring those tasks is infrequent as are OCSPP defined maintenance workers ("workers" or "occupational non-users").

Some examples:

- A Canadian gold mine had a surface plant recovering arsenic trioxide from arsenical mine-tailings. The system was fully enclosed and used cold, wet electrochemical methods. Personal and area monitoring under routine conditions showed very low exposure. Yet their urinary arsenic concentrations were extraordinarily high. It turned out that the plant

was frequently down for maintenance, at which time workers – who did both production and maintenance – had to enter the reactor and storage vessels with inadequate protective equipment.

- In 1992, EPA sponsored a regulatory negotiation to write a new National Emission Standards for Hazardous Air Pollutants (NESHAPS) (hazardous pollutant air standard) for coke oven emissions. One coke plant stood out with recorded emissions that were a fraction of the industry average. However, the monitoring was done by a local air pollution control agency whose practice was to give the enterprise advance notice. Coke ovens operate under positive pressure for production and to avoid damage, but the pressure can be curtailed for several hours without much impact, and that was done whenever the inspector showed up, greatly reducing leaks from coke oven doors and lids.
- Mine Safety and Health Administration (MSHA) requires mine operators to monitor coal mine dust with a direct-recording personal sampling device worn by one miner per area per shift. The chosen miner is supposed to be the highest exposed, but it is well-known that some mine operators move that miner to a low exposure area or tasks on the day they wear the equipment. This can happen even when MSHA does the monitoring, since one mine inspector cannot watch all the miners with dust monitors. (Even so, monitoring by agency personnel is generally more reliable than monitoring done by employers under a regulatory mandate.)
- A member of the Committee was involved in a major epidemiological study along with several industry counterparts. It was the Committee's member job to characterize exposures and to explore a possible dose-response relationship. It proved impossible. Recorded exposures varied wildly between plants, and the Committee member and colleagues concluded that without knowing the circumstances under which the monitoring was done, they had no way of knowing whether any particular data set was representative.

While underestimates are more likely than overestimates, both can certainly occur. This is not a criticism of EPA or any regulatory agency, nor of the majority of employers, who are genuinely interested in accurate data. The point is that data sets should not automatically be taken at face value, and knowing the circumstances under which data were collected can be helpful in reaching the correct interpretation.

Recommendation 10: Consider potential human and environmental sources of uncertainty in interpreting outcomes from existing data.

See CQs 1a and 1b for comments on Tables: Appendices E.11, E.12 and E.14.

What constitutes "reasonably available information" and what constitutes "reasonably representative information?" In the draft document, it seems that reasonable available information is limited to characteristics of previously available data, such as min, max and mode or mean and upper and lower bound, readily abstracted from previously published reports. Some pertinent examples follow.

What about greater use of experts? EPA, in certain situations, uses experts to establish values for certain input parameters, specifically when the value needed would be considered a constant. Two situations for the textile dye modeling in the draft document were noted:

1. Personal communication with Bercen resin sales staff, Sept 16, 1994, were used to establish the Textile Production Rate: (US EPA (1994) US EPA. HERO ID: 4286532).

   The Textile Production Rate from the 1994 EPA Scenario document (US EPA (1994) US EPA HERO ID: 4286532) is itself based on one 1993-94 analysis of data provided in fabric finishing PMNs. This assessment has no citation but seems to be a personal communication with Bercen resin sales staff, Sept 16, 1994. Is this really the best estimate or could recent sales staff provide more accurate information?

2. Correspondence with Dr. Warren Jasper (North Carolina State University College of Textiles) to establish Container Size for dye formulation: (OECD, 2017 which references ETAD, 2011 and Jasper, 2011). Container residual fraction of totes, drums, and pails—the residual fraction distributions are assumed Triangular based on lower, mode and upper bound estimates obtained from the ChemSTEER User Guide (US EPA, 2015a). Four models are mentioned in OECD, 2011 for estimating container residue releases separately from large containers (EPA/OPPT Bulk Transport Residual Model), drums (EPA/OPPT Drum Residual Model), small containers (EPA/OPPT Small Container Residual Model), and solid transport containers (bags, fiber barrels) (EPA/OPPT Solid Residuals in Transport Containers Model). All of these seem to be based on a 1988 study (US EPA 1988, Releases during cleaning of equipment, US EPA Health & Environmental Research Online (HERO) Glossary ID: 8731013). If this study could be found, could these data suggest a better choice of distributional form than the default triangular?

3. Operating Days have an assumed Triangular Distribution: From the OECD, 2017 document we find the statement "A search of 31 past PMN submissions from 2006 through 2014 revealed an approximate average of 157 operating days per year, over a range of 31 (5th percentile) to 295 (95th percentile) days per year (EPA, 2015 – OECD document. This suggests that there were at least 31 values for operating days that could be used to determine the form of the underlying statistical distribution. This is more than enough to allow determination of whether the triangular distribution is more relevant than say the Uniform. Simple Quantile-Data plots (see Wilk and Gnanadesikan, 1968) would be adequate to justify the underlying distribution. In addition, operating days are assumed to have a triangular distribution, but from OECD, 2011 (discussion just before Table 0-2, page 32), there were 600 industrial laundries which provided data on operating days for the years 1994 to 2002. The EPA should determine whether these data suggest a distributional form significantly different from the Triangular.

Recommendation 11: Utilize specific pharmacokinetic and pharmacodynamic models that would provide additional information that could make the distribution more accurate and verify information, where possible to refine estimates.

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.

Specific Comments

The Committee noted several strengths 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. The strengths identified are that:

- The Monte Carlo approach allows an estimation of uncertainty in site-specific emissions, or generic facility emissions.
- The approach increases certainty that the actual modeled release and resulting risk is captured in the output distribution.
- The approach integrates substantial disparate information into a logical assessment allowing EPA to understand the magnitude of exposures to specific populations and to assess who might be at risk.
- EPA can gain additional insights from the sensitivities of the Monte Carlo model to various input assumptions for future applications.

The Committee additionally noted weaknesses and raised general questions related to 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:

- Monte Carlo simulations increase the likelihood that inputs to the model reflect reality to a greater extent than do single value inputs, but at the end of the process the derived distributions for release and associated summary statistics (e.g., median and upper percentiles) remain uncertain.
- The use of Monte Carlo modeled releases alone without some form of "ground truth," makes understanding the uncertainty structure of the final exposure or risk estimates difficult to interpret.
- Monte Carlo assessments require a lot of assumptions to be made. Many will take issue with some assumptions wishing to insert their own (often less justified) assumptions.
- In the current RE, only the tails of distributions are evaluated. Monte Carlo approaches can provide much more than some value at the mean or upper end of the distribution. It can help in understanding the conditions which contribute to a given set of modeled output and the sensitivity of modeled output to input parameter distributions.
- Monte Carlo simulation results may be very sensitive to how outliers in associated data are handled. Outliers are sometimes discarded from data sets as non-representative, but of course they may represent real exposures, for example from process upsets and spills. There is interest from the Committee to learn 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.

- The Committee highlighted points raised in CQ 1a about recommending that EPA define more clearly whether the variable distributions used in the Monte Carlo modeling are designed to capture variability at individual sites or variability across a nationally representative set of sites.

- When using a censored dataset where a significant percentage of the data show less than the limit of quantitation (<LOQ) or less than the limit of detection (<LOD) values, EPA may need to follow other conventions when using such data. It can be problematic to use only the >LOQ values to construct the distribution from which an upper bound value is cited for conclusions. EPA's pesticide residue databases regularly present this situation and along with other authoritative references noted earlier can serve as a guide for this. Also, again such data situations should inspire EPA to ask why only 5 % of the database show these elevated values.

Incorporating variability in Monte Carlo modeling to estimate general population exposures.

The Panel discussed the challenge of how to incorporate variability in Monte Carlo modeling to produce exposure and risk estimates that are generalizable to the general population. Like most statistical tools, Monte Carlo is most useful when it is fueled with an abundance of relevant, contemporary quality data, but it may be especially applicable when there is a paucity of data and/or when the data are taken from multiple sources over disparate conditions and time. EPA is encouraged to explore the application of tools like Monte Carlo for better understanding of the data in hand (strengths, weaknesses, inferences of uniqueness, prioritizing need for additional data, etc.) and for using the data to create appropriate parametric distributions which may characterize the potential exposures and risks. The Committee outlined two ways in which Monte Carlo assessments are typically used to generate nationally generalizable exposure information.

In one approach, a set of scenarios are run, each scenario using model input parameter values/distributions that describe one type of practice (for example one method of doing hydraulic fracturing, one type of dye operation, etc.). The scenarios collectively capture the diversity of practices across the industry. Each scenario is then run and statistics (such as an upper 95th percentile) from key output parameter (e.g. release) distributions are estimated and archived. The set of estimated statistics from all runs in the archive are then used to compute a distribution, and a statistic (again, say and upper 95th percentile across all scenarios) is used in subsequent risk estimation. This requires that modelers understand in some detail the diverse practices in the industry and are capable of translating these differences into scenarios defined by different input parameter values and distributions.

In the second approach, each random input model parameter is assigned a distribution that captures both within-site and between-site variability. This produces a broader distribution than used in any of the scenarios in the previous approach. As this increased variability is propagated through the Monte Carlo assessment, the key question becomes whether the upper percentiles of the key output parameter (release) distribution from this approach is greater or similar to that computed from any of the scenarios used in the first approach. One cannot know which will

produce the greater value. It is also possible that in some situations the use of the within-and-between compound distribution may produce the larger value and in others the larger value may come from the multiple scenario approach. This suggests that both approaches should be attempted.

The Committee noted that the second approach might be more appropriate for a Tier 1 assessment whereas the first approach would provide more detail to management decision and hence would be useful in a higher Tier assessment.

Recommendation 1: For each input parameter discuss whether its associated distribution represents within scenario (within site) variability or represents both within and between scenario (site) variability.

Recommendation 2: EPA should more fully describe how outliers in datasets used to define parameter distributions affect the results and should consider how the existence of outliers in modeled Monte Carlo emissions, exposure, and risk distributions affect the reported risk percentiles.

Representativeness of the exposure and risk estimates for the general population and PESS

The Committee raised questions about the "representativeness" of the values utilized for the modeling and probable impact on utilizing the generated distribution for assignment of "sentinel" and potentially exposed or susceptible subpopulations representation at the upper 95th percentile.

A relevant issue is a definition of the objective of the assessment. EPA has stated that the objective is a nationally relevant assessment for the General Population. Again, this disregards the objective of defining PESS circumstances. It cannot be assumed that somewhere in the tail, or elsewhere, the distribution for General Population contains all population subgroups. The Committee noted that EPA utilizes EPA Exposure Factors Handbook values which are clearly not representative of tribes, diverse socioeconomic communities and other unique situations. The homeowner mobility value (33 years) exemplifies this and 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. *(fracking example).*

Combining quality data with poor data hides data peculiarities, and the poor data may distort the exposure picture through creating "unrealistic" distributions (for example multimodal when it should really be unimodal) for some input parameters. Examination of the distributions appropriate to each grouping of data may reveal significant differences which suggest that some element of the data set is unique, and that brings into question whether or not it should be combined with the other data or is indeed representative of the "nation" or "general population". It may represent some narrower scenario. Why are these data different than other groups of data? Combining all the data into one pile mixes the good and the "quality challenged" and as a result the quality challenged data get lost, and the quality challenges become invisible in future reviews. What contributes to the upper bounds or where the distribution gets unstable? EPA stabilizes at the mean. If the mean is "late to stabilize", should you suspect that the data are segregated and dissimilar? It might be bimodal. Or another choice of distribution type may be appropriate.

Recommendation 3: More clearly define the purpose of the Monte Carlo assessment and ensure the methodology and data supports risk calculations in sentinel and PESS populations.

Monte Carlo modeling to estimate general population exposures to hydraulic fracturing operations.

Hydraulic fracturing involves a diversity of practices. Some Committee members mentioned that some of the differences in practice are a function of state regulations while others simply reflect local practice. The Committee could not determine the extent to which this diversity of practices is captured in the Monte Carlo model runs summarized in the draft document. From Line 3166 of the draft document, EPA informs that "A total of 125 release scenarios were evaluated based on water concentrations estimated for annual releases that occur over a single day (a peak exposure scenario), over 30 days of release, or over 250 to 365 days of release." Committee members were unable to find the details of these runs and so were unable to assess how representative these are related to coverage of national situations.

The Committee noted that getting access to details on hydraulic fracturing operations is difficult and this offers support to the initial assignment of distributions to parameters that represent both within-site and between-site variability when attempting to generate nationally generalizable exposures. This seems to be what EPA has attempted in the current draft document.

The Committee raised several specific points related to the hydraulic fracturing discussion in the draft 1,4-Dioxane Supplement:

- Emissions from hydraulic fracturing are highly episodic and process dependent. The Committee recommended the discussion on this issue provided in Allen et al. (2023). While that paper's discussion is specific to methane, some of the same processes (including application of hydraulic fracturing methods) are related to 1,4-dioxane emissions.

- E.13.3: 411 sites reported 1,4-dioxane emissions. What fraction of all hydraulic fracturing operations is this, and how complete of a dataset is this? (Section 2.3.2.4.2 notes that the FracFocus database contains thousands of wells in the US). The Committee expressed concern that, because this is a self-reported database, sources may have been omitted from this database. EPA may consider calculating the fraction of wells reporting 1,4-Dioxane in hydraulic fracturing waters and expanding that to all wells in the United States.

- The Committee noted in general the difficulty in characterizing heterogeneity in fracking well operations due to between-site differences in regulation; the phase of development; number of wells per size; variability in controls; variability in how produced water is handled. Some Committee members argue for modeling specific scenarios, where possible, beyond the single drilling scenario assessed in the report.

- For model evaluation, the Committee pointed to a recently published report from the Texas Commission on Environmental Quality (TCEQ) monitoring criteria and hazardous air pollutants at monitors around Texas

- Sensitivity analyses to input parameters is discussed in lines 7770-7783, but the discussion

is not clear on how sensitivity analyses findings were used for model development or risk determination. The Committee recommended that EPA more fully describe how the sensitivity analyses informed modeling decisions.

- The Committee noted several sources of data useful to EPA for quantifying emissions, exposure, and risk from fracking activities:
    - A recent paper on air quality in the Barnett Shale area (a fracking area in Texas): (Lange et al., 2023)
    - Texas Commission on Environmental Quality (TCEQ) air monitoring data, available online: https://www.tceq.texas.gov/airquality
    - The website for the Railroad Commission of Texas (RRC) maintains a database of oil and gas wells that may be useful for the agency. The RRC is the state agency with primary regulatory jurisdiction over the oil and natural gas industry, pipeline transporters, natural gas and hazardous liquid pipeline industry, natural gas utilities, the Liquified Petroleum (LP) gas industry, critical natural gas infrastructure, and coal and uranium surface mining operations (RRC, 2012).

Recommendation 4: Describe in more detail the 125 release scenarios evaluated in the Monte Carlo assessment of hydraulic fracturing releases, including the representativeness of the data for all wells across the United States.

One committee member noted that icons in Figure 1-2: are confusing (e.g., the pipe emitting to water labeled as "releases to air and water" (Section 1.3.1.1 1,4-Dioxane as a Byproduct). Figure Appendix E-2 needs description of labels 1, 2, 3, 4, A, B, and C in the figure caption. In Line 1287 the text reads: "proximity goes out to 10,000 m." One committee member suggested that his is awkward and suggest "proximity is defined as within 10,000 m of an air emitting source."

On Line 1013, the phrase "resulting for air concentrations" should be "resulting from air concentrations."

Edits needed.

- The Committee noted that it is somewhat unclear at various points throughout the report which year's data is used as base emissions. In particular, language in the following sections is ambiguous:
    - 7173: "years" included in this analysis
    - Note a in Table Appendix E-7 states years 2013-2019
    - Line 12018: years 2015-2020
- In lines 1651-4 and 1673, it is unclear whether these values represent total emissions by state or individual facilities.

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.

Sec 2.1.1:

EPA assessed environmental releases (air, water, and land) and occupational exposures (inhalation and dermal) to 1,4-dioxane for each of the occupational exposure scenarios (OESs) listed in Appendix Table_D-1. EPA used the environmental release estimates for each OES for subsequent environmental concentrations and general population exposure calculations.

Appendix Table_D-1 presents a precise and complete listing of all the OESs evaluated. This listing appears to be well-constructed and exhaustive. The SACC agrees that inhalation and dermal exposure comprise the majority of potential exposure to this compound to occupational workers.

Air release estimates (2.1.1.4) are mainly focused on fence-line exposures, with no mention made of any other releases during commercial or consumer use of products containing 1,4-dioxane. Indoor near-field sources that are likely to provide the majority of exposure potential are not discussed. Instead, we see later in the report that there was a dependence on limited monitoring data.

Near-field exposure occurring within the indoor environment and typically within arm's reach can, and more often does, dominate the human exposure potential to many environmental contaminants. The compound under consideration, 1,4-dioxane, almost certainly fits this profile in which exposed subpopulations (PESS) receive the majority of the exposure and, thus, the majority of any untoward consequences of exposure. The original 2020 RE and this supplement appear to be more focused on general releases to the environment and subsequent far-field exposure potential. Focusing resources on elucidating the determinants of the near-field potential can pay big dividends in identifying sentinel human exposure scenarios and exposures while streamlining the risk assessment effort. General far-field environmental contamination/exposure should be considered but not at the expense of the application of resources designed to provide a detailed analysis of the near-field exposure and risk potential posed by this compound.

Recommendation 1: Near-field exposures in both occupational and nonoccupational settings should receive more prominent consideration and analysis using a first-principle, Monte Carlo modeling approach.

Sec 3.1.1:

Using the 50th percentile as a central tendency (CT) and 90th and 99th percentile for high-end (HE) estimates is very appropriate. The Committee noted that it was difficult to "comment on the application of the Monte Carlo method taken by EPA" when the Agency did not use the Monte Carlo approach for some critical near-field human exposure scenarios such as sources to estimate occupational inhalation exposure when limited personal sample monitoring data were used for the textile dye, surface cleaner, dish soap, paint, and floor lacquer. Monitoring data were also used from polyethylene terephthalate (PET) byproduct and the Ethoxylation Process Byproduct OESs. Available monitoring data could have been put to better use if it had been combined with Monte Carlo modeling, either to inform input parameter distributions or to validate estimated releases/exposures.

The EPA did use Monte Carlo models to estimate human health exposure estimates for the antifreeze, laundry detergent, and hydraulic fracturing OES. The Monte Carlo approach in all these OES appears valid. For antifreeze, the EPA AP-42 Loading Model and the EPA Mass Balance Inhalation Model were used with variations in the input parameters. The Committee found this to be a credible approach, especially since relatively low exposure/risk can be confidently predicted from exposure 1,4-dioxane in antifreeze. On the other hand, if the results turned out to be high, The Committee suggests that the source rate from the EPA AP-42 Loading Model be used to run the near-field/fair-field (NF/FF) model with Monte Carlo from IH MOD (AIHA 2023) for comparison. Similarly, the approach for Industrial Laundries is fine in that it is credible and also renders relatively low exposure/risk estimates. The modeled results from Hydraulic Fracturing really stand out. The Monte Carlo simulations present perhaps the overall highest inhalation exposures in the Draft supplement.

Recommendation 2: A more detailed analysis of the above OESs modeling assessment from Hydraulic Fracturing should be done by a modeler with experience with the NF/FF Model (that has Monte Carlo capabilities) in the AIHA Model Suite IHMOD. The Agency should also initiate on-site visits to perform monitoring and ascertain reasonable modeling inputs.

The Monte Carlo modeling of far-field releases in the various OES appears to be appropriate.

It seems as if Monte Carlo was not formally used to estimate the central tendency (CT) or high end (HE) absorbed dermal dose; however, Monte Carlo could have been applied to variables of the absorption model used. For example, single values were assigned to the CT and HE for the model variables S, Qu, and Y_{derm}. These variables could have been described and assigned distributions along with other variables while Monte Carlo simulations are used to determine the 50^{th} and 95^{th} percentile of modeled dermal exposure.

Appendix E10: Developing Models that Use Monte Carlo Methods

This appendix was reportedly included to provide general background information related to the specific Monte Carlo models. In the section "Developing Models that Use Monte Carlo Methods

(E.10)", the description is appropriate but generic and can be strengthened. It would be helpful to see EPA's own guidance and relevant scientific literature cited in support of the approach.

Two items are missing in describing how distributions are assigned/selected: 1) an understanding of the context (the industrial activity, products, and processes) being modeled which would have been helpful in assigning distributions; and 2) when there are some data available, statistical analysis to "fit" an appropriate distribution is possible as an empirical approach to identifying distributions.

This section needs to do a better job of defining terms. For example, the word "stochastic" used in this document needs some perspective and definition. The definition in the Merriam- Webster's Collegiate Dictionary for this word: " sto·chas· tic (adjective)---etymology: Greek *stochastikos* skillful in aiming, from *stochazesthai* to **aim** at, **guess** at, from *stochos* target, **aim**, **guess**" [emphasis added]. When we have good data defining the natural variability around a variable (e.g., adult male body weight), this distribution is **not** stochastic it is a known probabilistic distribution. We are not guessing or "aiming" at what we think the answer might be. In this instance we have good data and essentially know the answer as a distributional portrayal of reality. When we have poor data and apply our best judgment to assign a variable, and perhaps only have a broad range, with or without an estimated central tendency, the distribution is more stochastic than known. All Monte Carlo distributions are probabilistic, most have a mixture of variability and lack of knowledge; when lack of knowledge is dominant, they are weakly known and strongly stochastic.

Somewhere in this section, the advantages of Monte Carlo analysis as an important tool should be put forward. (Jayjock 1997; Jayjock et al 2009) Specifically:

- By using sensitivity analysis, Monte Carlo approaches will show which variable(s) is/are driving the exposure. If the distribution is wide because of a lack of knowledge – then further investigation can pay big dividends.
- It shows the width of uncertainty in the possible exposure and, if mostly from stochastic variable, our level of confidence.
- By allowing the sharing of details of model sensitivity to input data and output uncertainties with Risk Managers as part of the overall regulatory decision-making process.

The Committee agreed with the use of Latin Hypercube sampling to ensure the full range of values is drawn from when the models are run (section E.10.3.4).

Appendix F.4

As mentioned above, the inhalation exposure assessment for Textile Dye just used monitoring data that is typically highly skewed with a few very high values and mostly much lower values. Trying to explicate this difference and actual conditions of exposure with modeling rather than

simply using these monitoring data is a lost opportunity. These OESs could represent a significant number of highly exposed, but under-sampled, individuals in this industry.

To illustrate the Committee's recommendation to default to the use of Monte Carlo modeling as the first and dominant approach with available monitoring as a support piece, the discussion below is provided for Paint and Floor Lacquer as a general case to be applied to all OES that simply rely on limited monitoring.

In the Draft supplement, monitoring data from one National Institute for Occupational Safety and Health (NIOSH) onsite study in 1989 was used to estimate exposure in the Paint and Floor Lacquer Worker Exposure OES. The tacit assumption is that the limited number of paint formulations used at that one site are representative of all sites and paints. No information is provided on the concentration of 1,4-dioxane in the coatings or products used. There was, of course, a concentration of 1,4-dioxane in these paints; however, the universe of paint formulations used in the US is potentially much broader relative to their potential bulk concentration of 1,4-dioxane. Also, there are no details on the specific exposure scenarios at this site which may be better or worse elsewhere. This situation demonstrates the need for a broadening of the analysis via Monte Carlo modeling fed with the best estimates or professional insights on reasonable or even worst-case estimates of input values or distributions.

By defaulting to relatively weak and/or incomplete monitoring data as was done in the Draft Supplement, EPA may have incorrectly concluded the existence of a significantly lower level of exposure than may actually be extant. Using a Monte Carlo modeling approach acknowledges the relative lack of data and knowledge around this exposure potential. That is, using Monte Carlo and disclosing uncertainty aids the transparency and the integrity of the process. By admitting uncertainty and choosing distributions with relatively high upper ends relative to predicted exposure, the EPA's approach appropriately trades conservatism for data. This general approach has become and is a strong touchstone of the risk assessment process. This approach will challenge interested and invested stakeholders to provide data to refine the resulting broad exposure distribution to yield more accurate estimates of input parameter distributions and ultimately increased confidence in the final risk estimates.

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 evaluation under TSCA.

As stated in the Executive summary, the paucity of data delineating both chemical release and occupational exposure is a major hurdle that hinders the ability of obtaining an improved understanding of these two outcomes. To address this major limitation, the Committee encourages the EPA to cooperate with other agencies, entities, associations and professional societies, to increase and "modernize" the amount of data available in terms of chemical release and exposure front. While more recent data might not solve completely the issue of data needs, additional information would help make more accurate assessment of release and exposure when it is difficult to estimate central tendency and high-end release.

Recommendation 1: Modernize the monitoring data available on release and occupational exposure.

The Committee recommends providing clear statements for the decisions or selections utilized, specifically:

- State clearly all the assumptions/conjectures undertaken within the Monte Carlo approach and indicate how such choices are supported by empirical data and justified by expert opinion.
- Justify and provide rationale for decisions regarding handling of model parameters within the Monte Carlo approach as either being constants, with a determined fixed value, or random variables equipped with a distribution.
- Elaborate on the distribution(s) adopted to represent uncertainty and heterogeneity. This could be achieved by indicating for example how the selected distributions: capture aspects and information available in the data; circumvent some of the limitations in the data (e.g., censoring, lack of representativeness, etc.); offer a combination between information in the data and expert opinions.

Recommendation 2: Provide explicit and clear statements for all the decisions/selections utilized when implementing a Monte Carlo approach so to ensure and enhance reproducibility.

Recommendation 3: Implement the Monte Carlo approach using a large number of simulations to ensure that the output distribution is well represented.

As important as it is to provide all the necessary information needed to enable others to reproduce the results obtained by EPA via a Monte Carlo approach, it is also important to validate the results obtained via Monte Carlo methods to guarantee that the model formulation, parameter choices, etc. lead to valid, plausible results.

Recommendation 4: Validate the results obtained via a Monte Carlo approach.

The implementation of Monte Carlo methods discussed in the draft report addresses exclusively uncertainty in the input parameters and heterogeneity in the inputs. However, also the form of deterministic models used to compute chemical release or occupational exposure are characterized by uncertainty. In future TSCA evaluations, implementation of Monte Carlo methods could be performed so to account not only for uncertainty and heterogeneity in the input parameters, but also for uncertainty in the deterministic model formulation, perhaps considering different functional forms that link the various input parameters. A Monte Carlo method that also addresses model uncertainty would require that, at each Monte Carlo iteration, not only a value for each input parameter is sampled from the corresponding distributions, but also the functional expression of the deterministic model that is used to perform these evaluations gets randomly sampled.

Recommendation 5: Address the uncertainty in the deterministic model formulation on which the Monte Carlo approach is currently being applied.

With the scientific field rapidly evolving, Artificial Intelligence is expected to play a significant role also in risk assessment. Examples already exist in the literature that employ AI in this context. For example, in Wittwehr et al., (2020) the authors showed how AI can be used for chemical risk assessment. Similarly, a recent application of machine learning by DeSimone (2023) showed how AI could be used to predict 1,4-dioxane concentration in groundwater on Long Island, New York. These two examples are insightful and illustrate the potential of AI and machine learning techniques to address this sort of problem.

Recommendation 6: Consider the use of Artificial Intelligence (AI) for future TSCA evaluations.

2. SURFACE WATER EXPOSURE ASSESSMENT

2.1 Incorporation of a Modified Flow Database Using NHDPlus V2.1 to Estimate Chemical Concentration in Surface Water

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.

NHDPlus2.1 is a highly robust modeling representation of river and stream flows and geometry across the US. A quick literature search shows that it has been used to simulate water quality in drainage or catchment areas as influenced by runoff, land uses, agricultural best management practices (BMP)s, etc. The draft approach presented in the 1,4-dioxane supplement of simulating point source discharges from industries as fixed locations within the NHDPlus2.1 modeling framework appears to be a new application, but if there are other examples these should be cited by EPA.

Overall, the NHDPlus V2.1 is a very useful hydrologic database, and the dataset is incorporated into record keeping across EPA programs providing both consistency and compatibility across

programs. Its application for the current modeling purpose is appropriate in terms of computing flow means when segments share a reach code and using the lowest non-zero flow within a condition of use (COUs) for facilities with no associated model flow rates.

NHDPlus V2.1 at a resolution of 1:100,000 and containing 2.7 million discrete flowline features is surpassed by NHDPlus High Resolution (HR) which is at a 1:24,000 scale and goes from 2.7 million flowline features to 27 million. A question for EPA to consider is whether using this more robust (HR) dataset would change the analysis.

Use of NHDPlus V2.1 data for estimating flows in facility-specific modeling involved using lowest monthly average over a 30 yr. period of data collection. This lowest monthly average was simulated as the 30Q5 which seems conservative for contaminant dilution modeling; however, these data are from 1971 to 2000 – is the current and future impact of climate change captured in these data? The harmonic mean flow was also used in facility impact modeling, which is less conservative. However, given that the main dioxane concern is chronic exposure and cancer risk, the long-term average water concentration rather than the peaks and valleys is of most import and so the harmonic mean flow as a central tendency and the lowest monthly flow for a 30 yr. period (as upper bound concentrations) are reasonable, with the caveat that climate change may influence these values.

Given data limitations it may be difficult to involve the NHDPlus2.1 framework into a more dynamic or probabilistic approach. One limitation is using monthly flow averages rather than a distribution of monthly flows. Rather than only 12 inputs per year, it would be ideal to have a range of flows for each month. This could be a distribution based on monthly averages with attention towards climate change scenarios e.g., moderate or extreme drought scenarios when the same release may be less diluted. In California, for example, 2 of 3 years are dryer than the average, so the wet years drive the means. Odds are likely then that when a discharge happens, it will be in a lower flow year in California. Including a range in scenarios would address this limitation.

Recommendation: 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.

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.

There is a substantial literature, dating back to the early 90's, developed within the EPA that

presents, discusses, and summarizes (policies for) the use of Monte Carlo approaches in risk assessment [US EPA (1994b); US EPA (1997a); US EPA (1997b); US EPA (1997c); US EPA (2022)]. This literature constitutes an invaluable resource that the Agency can leverage in delineating how to employ Monte Carlo methods for future TSCA evaluations, particularly when exposure assessment is linked to the notion of risk in a probabilistic manner. For example, through the use of Monte Carlo approaches, nuances and complexities linked to secondary metabolites, interactions of complex mixtures, effects of sunlight, etc. can be captured in a more encompassing way, allowing the possibility of gaining better understanding of the scope needed for assessing specific chemicals.

For the assumption that facilities reporting releases via Form A, the EPA assumed 500 lb/year of releases; for facilities without reach codes in National Pollutant Discharge Elimination System (NPDES) permits, EPA used the nearest National Hydrography Dataset Plus (NHDPlus) flowline within 2 km as the receiving water body. The following strengths were identified. Given the uneven nature of data on water concentrations of dioxane, using data from relatively near sources seems reasonable. Despite uncertainties with this approach, it is difficult to see how it could be done any other way given how sparce the data are. Therefore, the EPA's approximations are reasonable until such time as better data can be obtained, and the approach appears to have an appropriate level of conservatism. The computed overall release may be somewhat higher than the actual value, as is appropriate for situations where robust data sets are not available. Table 2.6 shows that using Form A does not affect that many facilities (23% of the 120 modeled, and it is a conservative assumption to use the max in that category). Also, Table 2.6 shows that 67/120 modeled facilities have a reach code and another 18 are within 2 km of a stream flowline so this does not seem like a big uncertainty.

The following limitations were identified. A core question is how did EPA chose these 120 discharging companies to simulate in the first place? What is the universe, and how did they narrow to this subset? There remain questions about industrial water release estimates from TRI and DMRs – do these estimates align? Which are more reliable? TRI are self-reports with EPA spot-checking – how reliable are these estimates? The EPA should address these questions.

The Committee recommended the following approach for addressing the assumption that Form A firms release 500 lb/year of 1,4-dioxane: A sensitivity analysis should be conducted to evaluate the magnitude of the impact of this assumption. The impact is likely to be small. The data summarized in Figures 5-1 and 5-2 reflect this. The distributions of lifetime cancer risks across all facilities that had releases versus only those with high quality release data exhibited very similar trends. Using National Hydrography Dataset Plus High Resolution (NHDPlus HR), which is 10x more granular, might suggest a different flowpath. It would also be better to simulate these concentrations on receiving bodies that have drinking water intakes.

For the assumption of when a facility assigned reach code is missing in the ECHO database, the nearest neighboring National Hydrography Dataset (NHD) flowline and associated reach code within a 2 km radius was identified using Geographic Information System (GIS) software. This analysis is needed so that 1,4-dioxane concentrations could be estimated when stream data are not available. In this case, definitive hydrologic data were used (US EPA 2023c). Uncertainties are not specified; however, it is reasonable to assume that flow data provide a realistic approximation to actual values. One identified limitation is that EPA provides limited evidence that this assumption is true. A recommendation for this assumption is to conduct a sensitivity analysis

where EPA could compare facilities that are within a 2 km radius that do have an ECHO code to prove that the assumption holds true.

Modeled flows are based on observed flows from the years 1971 to 2000. The mean annual and mean monthly modeled effluent flows (Qe) were extracted from the NHDPlus V2.1 database. A strength of this assumption is that the data comes from a well-established database. While a limitation is that the current observed flows could be different than those from the years 1971 to 2000. A recommendation is that while this timeframe may be the only data available, EPA should justify the use of this timeframe and why past flows would be expected to be the similar in current situations.

For the assumption that when multiple segments were within the same reach code were returned during this process, the mean of each flow metric was calculated and applied to the associated facility. An inherent limitation identified is that when taking an average, a very high or very low number can be hidden in the average. EPA should show examples of data to ensure reviewers, that high or low flows will not be lost in the average or EPA's plan to deal with this averaging issue.

For the assumption when the water body associated with a releasing facility was a lake or coastal water body, without a flow metric, the facility flow was used, if available. For facilities with no available hydrologic or facility flow rates (or a modeled flow rate of zero), the lowest non-zero flow within COU was used. A strength identified is that using the lowest non-zero flow within the COU is the most conservative approach.

2.2 Evaluation of Down-the-Drain Releases and Contributions to Surface Water

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.

To evaluate the anticipated ranges of DTD contributions of 1,4-dioxane to water bodies receiving POTW effluent, a range of combinations of hydrologic flows and populations served by a POTW were evaluated using the Estimating Water Industrial Surface Release and Down the Drain in Excel and R (EWISRD-XL-R) model. For this modeling exercise, only contributions from the DTD component were used to calculate resulting surface water contributions (i.e., no facility releases or existing background concentrations were included). Hypothetical combinations of hydrologic flows and populations contributing to wastewater loading derived from the national distribution of hydrologic flows and populated places were selected to represent a range of results, which were then compared with concentrations expected from industrial releases and used to

calculate ranges of human exposure and risk.

Inclusion of DTD pathways in the 1,4-dioxane assessment is important and the EPA has applied novel methods to estimate 1,4-dioxane in consumer and commercial products. Aqueous 1,4-dioxane concentrations resulting from DTD releases depend on the population size (an indicator of the number of people using products and contributing to the releases) and the stream flows of the receiving water bodies. The representative per capita DTD loading developed from modeling results from SHEDS-HT was applied to a range of population sizes (100 to 1,000,000 people) and 2147 stream flows (300 to 30,000 cfs) to develop a distribution of potential surface water concentrations for dish soap, dishwasher detergent, and laundry detergent.

The Committee agreed that the approach(s) taken by EPA are generally appropriate, although several concerns were raised and recommendations and were provided to strengthen the approach and subsequent risk estimates to DTD exposure to 1,4-dioxane.

The Committee identified several concerns and uncertainties regarding the assumptions used in the modeling approaches. Primary among these concerns were assumptions about exposed populations, uncertainties within SHEDS-HT, the DTD case study (Liverpool, Ohio) for evaluating modeling output for POTW Outfalls.

Population Assumptions

A major assumption of the model is that the national average proportion of the population in occupations resulting in commercial use of consumer products is the same regardless of geographic location. This is unlikely to be realistic as specific local industries vary and the population working in those industries is likely related to the actual local population. For example, the Federal Highway Administration (FHWA) notes that the typical commute in 2017 was <10 mi. These summary data are for any purpose; however, raw data could be used to estimate actual work commutes. (US Department of Transportation, 2023). Similarly, the United States Census Bureau notes that the typical commute time is 27.6 minutes, indicating relatively short distances (United States Census Bureau, 2021). By using the national average for commute time, facility representation in some locations might be skewed higher or lower, increasing uncertainty. However, the Committee recognizes that it may not be possible, nor even desirable (with regard to PESS) with the information available, to modify the underlying assumption about the geographic distribution for commercial use of consumer products.

Given the physicochemical characteristics of 1,4-dioxane, additional fate processes (e.g., sorption) could be included in the DTD model, but were excluded. This is appropriate for conservative modeling and reduces the uncertainty associated with higher degrees of "realism" – especially in national scale assessments.

Starting and modeled concentrations of 1,4-dioxane

The Committee has several concerns regarding the starting concentrations of 1,4-dioxane used in the EPA modeling. As stated in the text, EPA lacks knowledge of amount or concentration of 1,4-dioxane in detergent and dish soap. It appears that starting concentrations used in the models are not reflective of the current marketplace, especially for dish soap and surface cleaners.

Of importance, the Committee notes that this concern was raised in the 2020 risk evaluation (by Household and Commercial Products Association (HCPA)/ACI) and not addressed. 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 (New York State, 2023). The New York State Department of Environmental Conservation (NYSDEC) also has a waiver process for products that do not meet the 2/1 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. However, the Committee notes that these concentration limits have yet to go into effect, are not national in nature, and are not a guarantee that all products in each category currently or in the future will meet these requirements. Additional resources include those from Non-Government Organizations (NGOs) (Sprout San Francisco, 2023). By using some of these available resources, EPA might have conducted a probabilistic forward modeling of the DTD concentrations.

As stated on page 376 of the 2022 Risk Evaluation, "1,4-dioxane has been measured from 0.03 to 204 ppb in dish soap, but the source of these measurements and a description of how they were used in SHEDS-HT are unclear. Appendix Section G.2.3.4 states that: "Product weight fractions generated during the engineering phase of this risk evaluation were used as inputs to the modeling." For laundry detergent the mass fraction of 1.4 dioxane in product is the upper end of the range from the 2020 TSCA assessment (14 ppm, Table Appendix e E-14). However, the Committee points out that the mass fraction for dish soap and the documentation of 1,4-dioxane content of products of consumer or commercial nature is not presented in the 1,4-Dioxane Draft Supplement. There is no indication whether cleaning products available in supermarkets are any different in 1,4-dioxane content than industrial/commercial cleaners.

Concerns/Uncertainties about SHEDS-HT

SHEDS-HT appears appropriate to estimate per capita DTD loading and has been validated for similar uses as part of its development (Isaacs et al., 2014). However, the Committee pointed out that the model version used in this risk assessment is unavailable to the public and the prior version (0.18 released in 2019 with updates in 2021) is in beta version (Github Inc., 2023). Therefore, it is not possible for this Committee to review the specifics. And in particular, 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. Because the starting concentrations may not represent the measured concentrations, per capita DTD loadings for dish soap and surface cleaner appear to be overestimated from the SHEDS-HT modeling.

For industrial/commercial releases that lack Toxics Release Inventory (TRI) or discharge monitoring report (DMR) data, SHEDS-HT was used to estimate DTD releases. Similar to the point raised earlier, the modeling is based on the total population contributing to a POTW in a specific location and to the percent of the population doing a job task (e.g., dishwasher) leading to the DTD releases. EPA used upper bound (99th percentile) consumer DTD estimate from SHEDS HT for industrial releases. From the Appendix Table G-4 for dish soap or surface cleaner the 99th percentile is only approximately 10-fold greater than the mean consumer DTD release. This means that a professional dishwasher in a restaurant working an 8-hour shift and using a commercial dishwasher is putting 10-fold more 1,4-dioxane DTD than a typical household's daily load of dishes. This is a questionable assumption. While EPA clarified that the assumption for

commercial use is the 99th percentile (correction to Table G-2 needed) value and the consumer distribution is the 90th percentile value, there is concern by the Committee as to the source of these estimates and whether the estimates are realistic.

In this risk assessment, DTD releases do not model contribution to groundwater yet there are many homes, schools and businesses that release to septic systems with related environmental releases to groundwater. These releases may affect private wells. Justification for not including these sources is needed as this may underestimate DTD estimates modeled.

SHEDS-HT appears to predict mean and standard deviation DTD loadings for non-commercial use; however, no percentiles are shown. It is not clear why this would be the case nor how a mean could be calculated without any percentiles data.

DTD case study (Liverpool, Ohio): Case Study Modeling of POTW Outfalls

While the one DTD case study (Liverpool, Ohio) does not suggest that EPA is underestimating DTD releases, there are substantial limitations in that validation exercise (see below) which raise further questions about the strength of evidence for this release amount.

The mean DTD loading is used for non-commercial releases whereas the 90th percentile is used for commercial releases. The choice of 90th percentile appears to be made to accommodate the expected higher loadings from commercial releases as compared to non-commercial releases. However, neither the use of the median nor the use of the 90th percentile is justified – either qualitatively or via comparison to actual loading rates – in the 2022 Risk Evaluation. Although such a comparison may not be possible, "ground truthing" the results, or a subset of the results, is a necessary component and would greatly improve confidence in the estimates of DTD loadings for both commercial and non-commercial releases. Moreover, the estimated commercial loadings (Table Appendix_G-2) are many-fold greater than the non-commercial (from appx. 600× greater for laundry detergent to nearly 27,000× greater for surface cleaner) – indicating the potential for high variability in the DTD modeling results. Again, comparing estimates to measured values would improve the Committee's confidence in EPA's use of SHEDS-HT.

The Supplemental 1,4-Dioxane Risk Evaluation is limited by the fact that it does not represent POTW outfalls. Even though DTD releases are assumed to enter the modeled stream-flows via POTWs (e.g., the Ohio River in the East Liverpool example), locations of these POTWs, their population served and whether known industrial or commercial sources of 1,4-dioxane also release to these POTWs have not been presented. Without this POTW information, the case studies are likely insensitive to DTD and POTW releases.

The Committee recommends that EPA evaluate a case study more focused on POTW releases in a POTW which has robust 1,4-dioxane release data and for which PWS intake data from that stream system are available. For example, the Cape Fear River Basin and particularly the Haw River, North Carolina (NC) have been studied by the North Carolina Department of Environmental Quality. This analysis includes a database of POTW discharges of 1,4-dioxane and in stream concentration measurements that are publicly available (North Carolina State, 2023). It is noted that POTW releases at Greensboro, North Carolina into the Haw River and related public water supply intake detections of 1,4-dioxane downstream at Pittsboro have been matched in temporal sequence (Sorg, 2023). Greensboro is approximately 30 miles up-river of Pittsboro.

These and similar data from elsewhere in this river basin and elsewhere in the country may help EPA develop a POTW-based case study informed by sufficient source information, outfall data, dilution data and PWS intake data to better calibrate DTD and industrial sources than what EPA has modeled thus far in the Supplement, which is based upon very limited data in all three case studies.

The EPA has not justified why the paint COU is excluded from commercial releases. Appendix F identifies that 1,4-dioxane is present (intentionally or not) in "paints and floor lacquer… automotive refinishing coatings, architectural paints/coatings, and industrial coatings" (lines 9766-9768). However, only automotive refinishing coatings are evaluated in Appendix E and are presumed to not be disposed of DTD (i.e., the loading is set to 0 g/d-capita). It is not clear why these other COUs were not analyzed (or, if they were, why they are not presented in the 2022 Risk Evaluation).

Specific Comments

The SHEDS-HT model used "default model parameters" and "product mass ratios" (also referred to as "product weight fractions"). In Appendix G.2.3.1, it is stated that the "product mass ratios" are described in Appendix E (line 11183); however, in Appendix G.2.3.4, EPA explains that the "product weight fractions" were derived during the "engineering phase" of the evaluation and gives no other information (line 11405). Because the term "product mass ratio" appears nowhere else in the evaluation and "product weight fractions" only appears in the Executive Summary (line 878), Section 1.3.1.1 (in reference to hydraulic fracturing on line 1250), and Appendix F.4.11 Hydraulic Fracturing (line 10144), it is not clear to the reviewer what values were used in SHEDS-HT estimations. Reading Appendix E does not clarify this matter as the only references to SHEDS-HT in Appendix F, are to explain which COUs are modeled using SHEDS-HT.

The Committee cannot reconcile whether the DTD estimates in Table 2-9 contain both the consumer and industry/community releases.

In Appendix Table G-2, per capita DTD loading appears to greatly overrepresent Dish Soap and Surface Cleaner (non-Commercial Dish Soap represents 88.9% of all DTD estimates from SHEDS-HT) modeling - e.g., Commercial DTD Loading Dish Soap represents 35% and Surface Cleaner represents 63 % or combined account for 98% of DTD estimates from SHEDS-HT Modeling.

Recommendations:

Recommendation 1: US EPA should be clearer about the 1,4-dioxane concentration in product categories used in modeling, the source of these values and the variability/uncertainty in these data**.**

Recommendation 2: Data for 1,4-dioxane concentrations can be obtained from sources (provided above) that reflect the current marketplace, especially for dish soap and surface cleaners. These data should be used to increase the certainty of the DTD loadings.

Recommendation 3: EPA should justify its exclusion of the paint COU from commercial releases and exclusion of contributions of 1,4-dioxane from septic systems into groundwater.

Recommendation 4: Inputs to the SHEDS-HT model need to be documented and checked, perhaps by comparing residential vs commercial dishwasher loading, soap usage, run cycles per hr, and hrs/day used according to manufacturer specifications for the equipment.

Recommendation 5: Modeled estimates should be compared with measured values to improve the Committee's confidence in EPA's use of SHEDS-HT

Recommendation 6: Case Studies should include robust data (POTW releases, PWS intake data, Combined Sewer or Sanitary Sewer Overflow data) as North Carolina DEC has done to increase confidence in DTD predictions.

2.3 Probabilistic Modeling of Chemical Releases Including Incorporation of Multiple Years of Release Data and Aggregation of Chemical Concentrations Occurring in Proximity

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.

1. **DTD Contributions**

As stated under Step 1, Background Concentration, DTD calculations are too uncertain to populate the model with a starting background concentration and so the nearest upstream PWS monitoring data are used to simulate background. While this may be a good approach, by admitting the uncertainties in DTD modeling, it is questionable that the way DTD modeling is added into the aggregate model at any stage or particular reaches of the river provides any more confidence. DTD releases are based upon EPA's estimates of local population and SHEDS estimates of end user amounts used across such a population. The one validation exercise for DTD loadings (East Liverpool Ohio) is very limited and as pointed out in another response there are numerous uncertainties in the way DTD loadings are calculated and represented in Appendix Tables G-2 and G-4. A major point is that without knowing the specific locations of POTWs and the population served by these POTWs, it is very difficult to estimate DTD contributions to a particular river system.

2. **Validation Modeling Runs**

The North Carolina case study was meant to ground truth the overall modeling of inputs, river flow dilution, etc. However, Figure Appendix G-4 or main text Fig 2-14 shows that the modeled concentrations at the Brunswick intake hover around the mean Annual Water Quality Reports (AWQR) (N=5) but does not come close to the maximum concentrations in at least 2 of the years. Thus, this case study shows that the aggregate model using mean flows and 250d/yr industrial release is reasonable for estimating mean concentrations but not maximums. This has particular implications for shorter term exposures and acute endpoints but is of less concern for chronic exposures and cancer risk.

The East Liverpool Ohio case study simulates a PWS intake under the influence of background as measured at an upstream public water supply, an industrial facility (BASF Corp), and by the surrounding population DTD releases. For commercial DTD releases it appears that 3 of the product categories were simulated for commercial releases (dish soap, dishwasher detergent, surface cleaner) but not for laundry detergent, etc., and so it is unclear why some types of DTD releases are included in this scenario but not others. Further, according to Appendix Table E1, since the number of facilities (e.g., restaurants, buildings with janitorial services) is unknown for East Liverpool, a bounding assumption involving all the companies in this North American Industry Classification System (NAICS) code nationally were applied to the East Liverpool case study (i.e., 773,851 sites for companies that use dish soap, Table E1). This is an unrealistic modeling assumption and the fact that the aggregate model estimate for this drinking water intake is only 0.61 ppb would suggest that these types of DTD releases do not lead to large impacts on a river as large as the Ohio River. The fact that an overshoot of the sampling data was obtained is not surprising given the nature of the upper bounding assumptions used.

The quantitative inputs to the Ohio River from cleaners are unclear in App Table E.3 The EPA should make it clear if the results represent an individual releasing company or all companies in aggregate. Clarity should be provided about why results on an annual basis were divided by 250 to get the daily release rate. Regarding the validation exercise, there is no location identified for POTWs that discharge into the Ohio River upstream of the East Liverpool PWS intake and we do not know what percentage of the population or commercial DTD releases would be feeding into the river via POTW and what percentage would be on septic and not making it to the river. There are many census-designated localities along the Ohio River shown in Appendix Figure G.6, but how many have POTW releases to the river? If none or very few POTW outfalls occur within this stretch of river, then this run of the aggregate model may be insensitive to DTD inputs.

Another limitation is that there were no detections of 1,4-dioxane at the East Liverpool PWS intake across the 4 AWQR sampling result years, and so the modeled concentration (0.61 ppb) is without a quantified value for comparison. While this may be an overestimate, this case study does not prove that DTD releases via POTWs would not have made a measurable contribution had there been enough information on where the POTW releases exist and the population/businesses they served. One also does not know how well this one case study captures the range of DTD to surface water impacts that are possible across the country. EPA's own assessment of this case study (Appendix Table E-4 and E-10) is that: "EPA has concluded that the weight of the scientific evidence for this assessment is slight" with regards to the inputs from surface cleaners, dish soap and dishwashing detergent.

The reliance on a single location (East Liverpool, Ohio) to determine the usage and/or discharge for several OES categories carries a substantial amount of uncertainty with it, and it is not clear why this location was selected over any other location, or a range of locations. As EPA notes on line 1791-1792, "it is uncertain whether the release estimates generated from this case study are applicable to other areas of the country." From the 2022 RE, EPA does not appear to validate that this use is valid, or even reasonable. If EPA moves forward with the aggregate probabilistic model, it should re-evaluate this assumption and, if it cannot be validated as appropriate, adopt a range or distribution of values approach as it does with other aggregate probabilistic model parameters.

The Duck River, Tennessee case study is also very limited. Data from the Columbia, Tennesse PWS was used to compare DTD estimates for populations along the Duck River upstream of Columbia and since there are no known industrial releases to the river in this reach the 1,4-dioxane detections are assumed to be due to DTD. While App Figure E-5 shows towns along the river, whether these towns have POTW releases into the river or its tributaries is not described, nor the population that would be served by these releases. Once again, this validation exercise may be insensitive to DTD releases if there are few POTWs releasing into this stretch of river. Another limitation is that the case study is based upon only 4 measurements at the PWS intake.

3. Aggregate Exposure

It appears that the aggregate approach described in the 2022 RE does not completely aggregate all sources in a watershed. For example, the discussion in Appendix G.2.3 refers to three separate analyses:

1. Background sources + facility releases,
2. DTD (commercial and non-commercial) releases, and
3. Hydraulic fracturing.

These three analyses are not combined and, therefore, do not appear to give the whole picture of potential exposure concentrations. Therefore, it is not certain that the aggregate probabilistic model provides for fully informed decision-making.

4. Flow Variability

The monthly average flow data from NHDPlus and background concentration based on stream order of releasing facility derived from monitoring data is appropriate for many conditions although ideally, there are more flow scenarios considered to account for low flow conditions. A range of values for flow conditions is recommended to account for low flow conditions in which chemical concentrations are expected to be higher.

5. Data Gaps

Uncertainty is introduced through insufficient data of from TRI and DMR. Considering the widespread commercial use of carcinogens and endocrine disrupting chemicals that have high biological potency in exceedingly small amounts, it is scientifically justified to address this data gap by widening reporting requirements below 500 lbs.

- "Uncertainty is introduced by sites that report TRI with Form A because these sites do not report release quantities if the quantity did not exceed 500 lb for the total annual reportable release amount." (Section 2.2.1.3)
- "For supplemental releases modeled with TRI/DMR (PET Byproduct, Ethoxylation Byproduct, Disposal), the weight of the scientific evidence conclusion was moderate to robust because the reasonably available information relevant for the conditions of use of 1,4-dioxane at facilities in TRI and DMR is limited." (Section 2.2.1.3)

Uncertainties are also introduced by using non-commercial values to estimate commercial DTD loading values. Using the 90th percentile of household DTD to approximate commercial DTD

may underestimate loading. In some cases, we would expect to see zero-level values of non-commercial DTD loading (e.g., textile dye, floor lacquer, spray polyurethane, antifreeze) but high levels for commercial DTD loading.

- "The mean DTD loading value was applied in the EWISRD model to represent general non-commercial uses, while the 90th percentile DTD loading value was applied to represent commercial uses of the same products." (Appendix G.2.3)

Additional comments:

LL1872: The ordinate label should indicate "detected" concentrations.
LL1878 The ordinate label does not impart sufficient information to determine what is depicted in the figure.
LL 1958: Data in this map may be misleading. Unless water is sampled downstream of a known source there should be no detectable 1,4-dioxane. It would be more helpful to show concentrations in samples within the third unregulated contaminant monitoring rule (UCMR 3) that are within a few miles downstream of a likely 1,4-dioxane source.

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.

Key points summarizing the discussion were:

- 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.

- A significant strength of an ideal aggregate probabilistic model lies in its potential to counteract biases from locality differences, effectively pinpointing "hot spots" or areas with high concentrations of contaminants. However, there is room for improvement and reduction of uncertainties with refinements available now.

- For aims related to obtaining a nationally representative distribution of exposures, it will be essential to include extreme events in training such models so that the broader spectrum of variability can be incorporated. See, for example, the discussion below about low- and high-flow conditions in the response to CQ 2.4a.

For more detail on these summary points:

The goal of developing a national level set of risk estimates is important, and the EPA should be commended for their efforts to do this. As the Agency notes, there are data limitation issues. Available data describe specific locations that may or may not be nationally relevant, and the available data are also quite variable. Even when dioxane concentrations are known at the point of

release, estimating exposure after downstream dilution – given variable practices by local water treatment facilities, some of which remove or reduce dioxane and some of which do not – makes developing a national representative exposure model challenging.

The current availability of data suggests that developing a nationally representative model will be subject to error. The crucial question is what is the alternative? At present, there seems to be no alternative to the EPA model; therefore, it is worth trying, but this is at best an interim solution. The report should discuss what plans the Agency has for obtaining more data so the model can be refined in the future.

Recommendation: Discuss plans to obtain more measured data so that models can be refined.

Regarding the aggregate probabilistic model, the Committee recognizes the differences between the actual locations (in terms of the hydrology, industry, and commercial/non-commercial population). Although the Monte Carlo simulations can aid with diminishing the biasing effect of these locality differences and produce more "average" (or other statistically relevant) results, the biases introduced from using actual location characteristics could be important for defining "hot spots," or areas with intense (relatively) concentrations of contaminants. As the release of 1,4-dioxane is not ubiquitous across the US (e.g., see Figures 2-2, pg 46, 2-5, pg 49, and 2-8, pg 54, in the 2022 RE), identification of "hot spots" may be more informative than simply determining overall percentiles of concentrations. Therefore, including locality characteristics may be able to aid in interpretation of the results and estimating the likelihood of higher risk locations where additional analyses could be informative in fully evaluating the potential risk.

As with CQ 2.3a, the decision to use only one location's loading estimates (Liverpool, Ohio) greatly reduces confidence in the results. East Liverpool, Ohio is not identified by EPA as unique or representative of national release/usage trends, nor is it identified as a site with the greatest water releases of 1,4-dioxane (for example, see Figure 2-2, pg 46). Therefore, it is uncertain how these loadings are applicable to any other site and even less clear how they are representative of nationally representative distributions that could be used to inform a national risk evaluation.

The aggregate probabilistic model itself is robust in its estimates and uncertainties. However, there are several assumptions with the associated data. While EPA states that most of the input data was robust, it seems to be highly variable for a given area, which may contribute to uncertainties in a national estimate. We recommend providing validation of the model and assumptions when possible.

Separately, a sensitivity analysis can be conducted to examine how the removal or addition of less robust data affects the results of the probabilistic model.

Recommendation: Validate model assumptions to the extent possible and perform a sensitivity analysis to assess the influence of input data.

With regard to uncertainly, the value of the probabilistic model is that climate models accounting for extreme hydrology can be incorporated. Including extreme events in addition to monthly averages would be beneficial. This will be especially important as frequency of what were previously considered "extreme" events changes.

Modeling would be improved by capturing a fuller range of variability by including distributions of those days for which upstream concentrations could be captured.

The section on lines 3526-3534 should be viewed with caution. If the small number of measured data points downstream of a 1,4-dioxane discharge agree with modeled data, that does suggest that modeled are likely to be reasonable, but do not provide any indication of a proportion of waters that may contain 1,4-dioxane.

In Table 2-3, the Committee recommends adding a high centile column 90 or 95%, as was done in Table 2-11.

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.

Strengths:

- In the assessment of general population exposures to 1,4-dioxane via industrial releases to surface water, two approaches were used – first is based on reported 1,4-dioxane discharges and the second is a probabilistic model that considers expected ranges of background concentrations of 1,4-dioxane from down-the-drain (DTD) loading and other unreported releases. The Committee liked the inclusion of multiple years and sources of reported data, particularly given the disruptions of the pandemic. In general, there was greater confidence in measured, granular data and consistent methodology but less so for DTD and unmonitored releases.
- Committee members raised a concern that a specific year (2020) is used for the population - the EPA should determine whether population growth is stable or not.
- Modeling that incorporates the chemical and physical properties of a non-static system is challenging. The assumption that the water body is essentially a smooth body of water with no eddies, rocks, or coves and predictable releases provides predictions that require more monitoring data than are currently available for an unregulated contaminant in drinking water (with the exception of New York). The Committee suggests reporting segments (reaches) of the surface waters could be used to see the influence of physical properties and can also be useful to see the full range of predicted concentrations.
- Although there were some concerns as to whether there has been variability in industrial activity in the past 3 years, having multiple years of data gives a better sense of what has been typical. This would provide a better understanding of whether industrial activity is increasing or decreasing. It was not clear whether there are (or how) new industries

reporting and how EPA will account for the gap in timing for retrospective TRI reporting. This is important since it will influence and weaken the estimates of concentration downstream and the "background."

Uncertainties/concerns:

- The quality and accuracy of TRI reporting have improved, but there are still gaps in reporting. Past years may not represent current conditions.
- Line11171, refers to modeled distances for "most of the case studies" – does this refer to the three case studies provided? Perhaps this is the case for 2 of the 3 cases? Suggest clarification on this point.
- There is an assumption in the "background" estimates that releases from groundwater to the surface water are either insignificant or are not relevant. The groundwater is captured elsewhere in the analysis, but due to the ability of 1,4-dioxane to efficiently leach to groundwater, it is important to formally recognize the gap/uncertainty in the estimates of "background" and accidental releases from industrial facilities not captured by TRI. The Committee suggested incorporation of databases from States better address this uncertainty.
- Background concentrations infer that these are "naturally occurring" or, as written, due to DTD and unmonitored releases. Since the cases rely on monitored water data and the frequency of monitoring for an unregulated contaminant is not robust, the conclusions need to be tempered.
- Another aspect that is important here is that the size of the population matters for the DTD contribution to the amount of 1,4-dioxane in the water. If looking at multiple years, one could argue about whether the population estimates from the Census are reliable. It is unclear what proportion of surface water contamination is from DTD sources. It would be helpful to compare the modeling or monitoring sources in an overall exposure model.
- Committee members were concerned that the Conditions of Use (COU) distribution in the SHEDS modeling is based upon a national average and that the degree to which the distributions vary within the case study locations is not indicated. Some Committee members recommended that the report indicate a variance between (or degree of uncertainty) the national distributions and local conditions.

Recommendations

• **Recommendation 1**: Suggest clarifying whether TRI air release data was utilized to estimate groundwater concentrations.

• **Recommendation 2**: Please clarify 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…" *It seems this is a low-release estimate which in hazard and risk parlance is not conservative.*

- **Recommendation 3:** 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.

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.

Strengths:

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. However, overestimates are expected to result in health protective risk management actions, which is positive and appropriate. Tempering this positive aspect of the model is the fact that the measured values come from only three sites. It is unclear how representative these are of the rest of the country.

Uncertainties:

The surface water data were not specific to drinking water and may not accurately reflect such sources, but additional explanation would be helpful to understand the representativeness of the data used. Are some of the samples from drinking water or from sources similar to those used for drinking water? At present, the text only says the data "may or may not represent locations used as a source for drinking water" (pg 52, lines 1845-1846).

Surface water data are highly dependent on location, timing of sample collection, influence of precipitation, land use, temperature, etc. on concentrations – and some of the case studies are based on a relatively small numbers of samples. It would be helpful to see a description that states these uncertainties and how the model and measured values are influenced by these factors.

The range of detection limits is very broad, 0.001 to 28,000 µg/L. A small portion of the dataset had high limits of detection, and some were very high (see Figure 2-7, pg 54 "Frequency of Detection Limits for Nationwide Non-detect 1,4-Dioxane Surface Water Samples Retrieved from the Water Quality Portal, 1997–2022"). This is an important limitation of the data. A well-defined and robust way of incorporating these data into reported values is needed.

The SACC has previously pointed out that the use of the term "conservative" estimate is

problematic when there are missing data. Furthermore, there are other sources of DTD discharges that are unreported/unaccounted for. While these may (or may not) be small, they are important for many communities. These include Combined Sewer Overflows (CSOs) that are discharges and releases of raw or partially treated sewage in "approximately 860 communities with a total population of about 40 million people". CSOs collect sewage and storm runoff in the same pipes used for treatment. Thus, heavy rainfall can overwhelm system capacity, causing raw sewage to overflow into waterways. Only EPA Region 6 lacks CSOs. In 2023, the Government Accountability Office (GAO) did an analysis of a subset of municipalities with CSOs and found that there has been little to no progress on addressing these releases. Consequentially, with heavy precipitation events occurring more frequently in portions of the northeast and Midwest (which is trackable), the EPA should incorporate both low and high flow considerations into surface water modeling. During heavy rainfall and other wet weather events, combined sewer systems are designed to overflow and discharge untreated wastewater mixed with raw sewage directly into nearby water bodies. These CSO discharges occur through system-designed outflows and may impair water quality. While the EPA 1994 CSO Control Policy directs municipalities with CSOs, about 700, to develop long-term control plans to eliminate or reduce such discharges to achieve compliance with Clean Water Act requirements, this has not been achieved. Since discharge volumes are available, incorporation in the EPA model as potential additional sources of 1,4-dioxane into downstream drinking water intakes –through the direct modeling or as part of the DTD modeling is recommended (GAO, 2023).

Accidental releases or presence of releases from unregulated sources may be accounted for, but this is not clear based on the text or the Figure in Appendix G-2 "Schematic of the General Fit-for-Purpose EWISRD-XL Model."

(Line 2105) Table 2-3/Table 2-4 PET Manufacturing accounts for >92% of modeled releases, ethoxylation byproduct ~3% - how do these values compare to DTD byproducts in finished products? Recommend incorporating additional information relating to the relative contribution of different sources to surface water.

Additional concern: LL2212: In Section 2.3.2.4, the phrase "…or on reaches that are not impacted by releasing facilities…" indicates that monitoring data are not necessarily downstream of 1,4-dioxane facilities and should not be used in the assessment.

L2241: There do not appear to be sufficient data in Appendix G2.3.2 to verify the modeled data. These are simple data to obtain. More in-stream measurements are needed and should be provided to the Agency by the users. Otherwise, the regulated community should be prepared to accept high centile exposure data and additional uncertainty factors to provide protections for human health.

The Committee agreed that "concurrence" is not an appropriate term to describe agreement between measured and modeled 1,4-dioxane concentrations in surface water. It is noted that this term indicates agreement; however, it is not rigorous and there are no underlying statistical tests provided that are indicative of the extent to which measured and modeled values agree. There are numerous test statistics that are commonly used to assess agreement between measured and predicted values using models. Moriasi et al (2007) have described many of these test statistics and more importantly have provided guidance on generally acceptable ranges of values for each statistic. Whenever monitored and modeled data are compared the Agency should be encouraged

to compute appropriate test statistics and indicate whether the range of values are within generally acceptable ranges.

The Committee regards the use of the term "concordance" as inappropriate. Alternatives should be used such as "generally consistent" or "good to within orders of magnitude" between modeled and observed concentrations as reported in Table Appendix G-3.

2.4 Consideration of Public Water System (PWS) location data in the evaluation of chemical exposures to the general population via the drinking water pathway

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. (See below) 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.

The Committee agreed that evaluating drinking water exposures to assess cancer and non-cancer risks from drinking water consumption is necessary to quantify 1,4-dioxane health risks to the general population. The EPA evaluated settings where either surface or groundwater was used as a water source. The draft risk assessment does indicate that water sources may be combined in some cases; however, the degree to which this is practiced was not examined in detail.

In this section of the risk assessment, the EPA emphasized drinking water sources from surface water and lifetime cancer risk for adults defined as 33 years of consumptive water exposures as an adult. Generic assumptions were made about the degree of dilution that may occur from points of discharge from POTW, industrial facilities and other sources and uptake by Public Water Supply Treatment Facilities (PWS). In some cases, minimal dilution (<1%) was assumed. It was also assumed that there was no attenuation during transport from the points of discharge from POTW and industrial operations prior to uptake by PWS. Attenuation in this case implies all processes that may contribute to 1,4-dioxane degradation, transformation, and or retention by sorption on environmental media such as sediments. Further it was assumed that during drinking water treatment 1,4-dioxane concentrations at intakes were not reduced.

To evaluate potential drinking water exposures the agency used a combination of monitoring data when available and or concentration estimates based on models that used flow and discharge estimates to compute predicted concentrations. The Committee was supportive of this approach and agreed that monitoring data can provide direct evidence of 1,4-dioxane presence in water. This was recognized as a strength of the assessment. However, it was recognized that there are challenges in using the available monitoring data in risk assessments since datasets had a high percentage (>89%) of values that were reported to be below reporting or detection limits, skewing the data left. It was questioned whether this a function of an elevated reporting or detection limit or are these data truly reflective of low concentrations of 1,4-dioxane. It was further emphasized that the uncertainties in the monitoring data need to be better recognized – namely infrequency of monitoring, representativeness of sampling during releases since without continuous monitoring, there is no way to see the actual minimum and maximum concentrations and ranges over relevant time periods.

Related concerns were expressed about how monitoring data were analyzed noting that the EPA inserted ½ the detection limit and or the reporting limit when values were reported to be less than either of these values. It was agreed that this approach is problematic and that alternate approaches in handling the data should be explored. Committee members noted that the insertion approach is often used but it has serious flaws (see for example see Helsel, 2005) and that there is an extensive literature on more rigorous ways to analyze censored (left) datasets. Techniques like Kaplan-Meier survival analysis are often depended on. However, it was noted even these methods have problems with the very high degrees of left censoring.

Another observation was that in Figure 2-10, and Table 5-2, although 1,4-dioxane was below detection limits in 89% of the finished drinking water samples, only the top 5% would be above the $1x10^{-6}$ cancer risk. It was noted that although the charge question focused on dilution, the key figure in the discussion (figure 5-4) describes cancer risks. Some clarity may be achieved by including a companion figure that shows the distribution of concentration estimates.

As indicated, when monitoring data were not available, a model combining flow and 1,4-dioxane release estimates were used to calculate potential 1,4-dioxane concentrations. The EPA stated that there was accordance between measured and predicted concentrations when data were available. In the response to CQ 2.3d, one discussant on the current question raised concerns that no test statistics were provided that indicated the degree of "accordance" (i.e., agreement) between measured and monitored values. The Committee recommended that this flaw be addressed.

With regard to the assumption of the potential for dilution between discharge and PWS uptake, it was agreed that in some locations, minimal dilution may occur between the point of 1,4-dioxane release and drinking water intakes. Thus, the contribution to drinking water from the known releases is maximized and it appears that EPA has documented a bounding estimate. This is very important, particularly since multiple discharges (from upstream) may be contributing to each PWS intake.

A cautionary point was made that the assumption of minimal dilution between releases and location of PWS intake would tend to overestimate concentrations and likely generate high risk estimates. This would result in identification of risky COUs/OESs that would drive risk management actions. Further when minimal dilution was assumed predicted exposures and subsequent risks may be overestimated – or at least from known releases.

Support for the use of the minimal dilution assumption between POTW discharge and PWS uptake was linked to what is termed "de facto potable water reuse of sewage treatment plants discharges". This work is documented in several publications. (See Rice et al., 2013; Rice et al., 2015; Nguyen and Westerhoff, 2019). National scale assessments were made of flowing surface waters that received sewage treatment plant discharges upstream of drinking water intakes. The focus of the assessments was to determine the extent of dilution of POTW discharges prior to uptake in the downstream PWS. To do this, a model was developed titled "DeFacto Reuse in our Nation's Consumable Supply**"** (DRINCs). The model appears to use the same hydrologic data set used for the 1,4-dioxane assessments that are described in the EPA draft risk assessment. De facto wastewater reuse in drinking was found to range from 7% to 100% (Rice et al, 2013). In a further analysis using geocoded data for 14,651 POTW and 1,320 PWSs, the occurrence of treated municipal wastewater in drinking water supplies was observed to be geographically widespread,

with its magnitude depending on the flow condition and size of the source river (Rice et al., 2015; Nguyen and Westerhoff, 2019). Under average streamflow conditions, the median contribution of wastewater flow to drinking water supplies was approximately 1% and increased to as much as 100% under low-flow conditions (modeled by Q95).

Given this, it was emphasized that the DRINCs model assessment may provide support for the estimates used by EPA to identify high risk scenarios and the degree of dilution of 1,4-dioxane discharges that can be anticipated under varying scenarios. It was recommended that the agency consult this work and evaluate its potential for incorporation into the draft risk assessment. It appears that the assumption of no post-discharge dilution is appropriate to derive an upper bound 1,4-dioxane drinking water exposure estimate and that a lower bound estimate may be the 100-fold dilution (1%) estimate that the agency used (Figure 5-3).

One discussant questioned the "lower-bound" indicating that it may be too conservative. The discussant referred to Figure 5-4, where using a dilution of 1%, the median cancer risk was lowered from ~$1x10^{-6}$ to ~$1x10^{-8}$. It was observed that this seems more probable but still quite conservative. It was indicated that the 1% dilution is said to be based on available site-specific data reported to TRI and DMR, but it is still an estimate for the various bodies of water.

A contrasting view was expressed indicating that accounting for the dilution of point source releases to 1% still yielded cancer risks exceeding 1 in 1 million associated with drinking water for some areas. This is above the threshold of "acceptable" lifetime risk**.**

Some other points in discussions were that assumption of minimal dilution between releases and location of PWS intakes did not include a high-flow condition in the modeling – to reflect a more complete range of flow rates and potentially higher dilution. This could be incorporated into a sensitivity analysis where the impacts of low and high flow conditions could be evaluated.

Finally, the Committee agreed that another factor to be considered is the impact of climate change on flow regimes. Droughts in the south and west are contributing to abnormally low flows while in the northeast flood conditions are often being observed. These changes are influencing concentrations of releases, but also the potential for dilution.

This was expanded upon by one discussant noting that the flow data used in models come from a joint USGS-EPA effort and is a standard database used across EPA programs. The flow estimates in the database, however, are derived from observations dated from 1971 – 2000. There is potential that these older data may not represent contemporary conditions and the influence of increased frequency of extreme weather events. However, according to the EPA (2023) there has been a long-term trend of increased precipitation beginning even before the 1970s, "Since 1901, global precipitation has increased at an average rate of 0.04 inches per decade, while precipitation in the contiguous 48 states has increased at a rate of 0.20 inches per decade." This alleviates some concern about the nature of this older dataset.

Recommendations:

> **Recommendation 1:** Use more rigorous methods for inclusion of "non-detects" in monitoring data analysis.

Recommendation 2: Provide test statistics that describe the "accordance" between measured and predicted 1,4-dioxane concentrations.

Recommendation 3: To the best extent possible determine how climate change impacts on precipitation and stream flow will impact predicted 1,4-dioxane concentrations.

Recommendation 4: 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.

Recommendation 5: Conduct Monte-Carlo simulations that provide probabilistic estimates of 1,4-dioxane concentration at drinking water intakes.

Charge Question 2.4b

EPA estimated site-specific concentrations and risks to account for downstream dilution estimated based on 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.

Specific Comments:

1. The Committee found that the use of the NHDPlus V2.1 flow network had multiple strengths. The Committee agreed that the procedures used in the downstream tracing analysis based upon the NHDPlus V2.1 flow network seemed reasonable and useful for fine-tuning drinking water intake 1,4-dioxane concentration estimates; the assumptions about the behavior of 1,4-dioxane were well-documented and supported by the information provided in the Hazard Document; the ability to link known releases to potentially impacted systems is useful; and that the maximum potential distance between emission source and DWI (1,000 km) was conservative given the expected level of dilution, and seemed appropriate for assessing a health protective or maximum potential risk scenario. Further, as the NHDPlus V2.1 flow network contains one of the largest national hydrologic datasets with many years of data, the Committee found that its use to determine drinking water intakes downstream of facilities seemed appropriate, and the use of network flow models accommodated many of the challenges of discharge, dilution, and movement downstream.

- Several Committee members agreed that that use of a more recent version of NHDPlus would improve the 1,4-Dioxane Supplement by providing a more granular representation of flowing surface waters. The high resolution or "HR" version has approximately ten times more detail and spatial resolution. The use of this newer version could have significant impacts on the dilution modeling in this analysis.

2. The Committee identified several key uncertainties that may require additional discussion and potentially a more focused analysis in a national assessment.

- Multiple Committee members raised concerns about the lack of consideration of climate change-related impacts. With respect to climate influences, the dilution analysis depended upon NHDPlus streamflow inputs from 1971 to 2000. As mentioned in the response to charge Question 2.4a, the Committee found that these inputs were somewhat dated, and it was unclear to what extent stream-flows may have changed in the past two decades. The Committee suggests EPA consider how climate change and extreme weather events (e.g., droughts) may affect these flows and dilution factors now and into the future. For example, public water systems impacted by 1,4-dioxane where flow rates are decreased due to increasing temperatures and water withdrawals may experience higher than expected concentrations, where places with increases in precipitation events may experience lower concentrations. One Committee member suggested that National Oceanic and Atmospheric Administration data may be useful to compare current observations and make longer term forecasts for streamflow activity.

- One Committee member expressed that uncertainty has been introduced into the analysis in that it is limited to facilities that report via TRI and/or DMR. The Committee member suggested EPA consider capturing all facility releases, including smaller facilities, particularly considering the high biological potency of carcinogens and endocrine disrupting chemicals even in small amounts. It would also be beneficial to monitor near release sites for improved validation.

- With respect to the use of NHDPlus, one Committee member raised concerns over understanding how the downstream tracing analysis and accompanying dilution methodology would inform risk characterization for a nationally representative assessment, since confidence in the modeling was high only near facilities and facilities are not located everywhere in the nation.

- One Committee member noted that the inability to use actual public water system intake locations due to security issues required more effort in bounding from the EPA. Due to both the input uncertainties and location uncertainties, the "worst case" (i.e., maximum potential exposure) may not have truly represented the worst-case scenario. If not the "worst case," the Committee member suggested that EPA should not state it as such. Multiple Committee members agreed that the presented estimates may be an upper bound scenario based upon the available data, but unregulated discharges and unreported industry releases may result in higher-than-expected concentrations of 1,4-dioxane in some areas. Table 2-6 (Summary by OES of Data Sources for Releases and Receiving Water Body Flow) showed that NPDES permit only accounts for a very small number of releases (except for disposal – 22/25). One Committee member felt that the percent of Releases Estimated from the TRI (with the exception of Import and repackaging) showed lack of concordance, emphasizing the necessity to model releases.

3. Multiple Committee members identified concerns regarding the water monitoring data used in the analysis.

- One Committee member noted that the water monitoring data were not collected on a continuous basis, and as a result, the presented maximum concentrations may still have underestimated concentrations in some public water systems. While the Committee member acknowledged that this is perhaps not immediately addressable, the Committee suggested that EPA acknowledge it as a limitation.

- One Committee member felt that to inform risk characterization for a nationally representative assessment, the sample sites used in the validation study should have had nationally representative characteristics, including geographic regions, flow scenarios, and release conditions. The member suggested that, ideally, monitoring data could be collected near the selection of release sites, and a clear rationale of selection would be provided based on proximity to release sites.

4. Multiple Committee members expressed concerns about the 100-fold dilution factor applied between the point source release and the DWI.

- The major assumption underlying the exposure and risk modeling was a 100-fold dilution factor applied to the release point concentration to calculate what would be expected to reach the DWI (shown in Figure 5-4). One Committee member noted that the relevance of this 100-fold dilution is not fully explained and could be further clarified.

- Page 142 stated that the EPA is aware of cases where no dilution occurs, and this was shown in a detailed analysis of a limited number of industrial sources (Figure 5-3). Rather than applying this 100-fold dilution factor across the board, some Committee members suggested that EPA consider a probabilistic approach to dilution, which would include 100% concentration (no dilution) at the appropriate probability in Monte Carlo runs (e.g., Klaine et al., 1996).

- Multiple Committee members noted that the extent of chemical dilution is highly variable, and far downstream estimates in particular may be compromised by significant uncertainty. Any site-specific factors that influence downstream dilution may not be fully captured in a national-scale assessment.

- One Committee member expressed concern over which dilution scenario will be presented to policymakers as a main assumption for determining unreasonable risk. The Committee member suggested that EPA present both scenarios as a range for policymakers to consider, or if one scenario must be the main assumption, the “no dilution” scenario would be a more conservative approach.

3. GROUNDWATER EXPOSURE 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.

The Committee commended EPA on addressing possible exposure to 1,4-dioxane through groundwater exposure via private drinking water wells.

The Committee suggested additional descriptive language about the Hazardous Waste Delisting Risk Assessment Software (DRAS) be added to the Supplement. Several Committee members found it difficult to tell from the information presented if this model was appropriate for this type of assessment and found more uncertainties than strengths in the use of the DRAS model. The Committee noted that other than the modeling results giving concentrations "within the range" of some groundwater monitoring studies, uncertainties included using "default" assumptions rather than actual inputs; using "back of the envelope computations" to estimate concentrations; and not representing current conditions and practices of waste management. One Committee member stated overestimation and a conservative approach is fine if the "risk" was shown to be low with these models – but when risk margin of exposure (MOE) become high, the models may need refinement and use inputs that appropriately demonstrate actual conditions.

The Committee suggested EPA include information from the DRAS user guide that stated that the model could be used for landfills in a mismanagement scenario at an unlined Subtitle D landfill where releases to groundwater were not controlled. This information was not included in the Supplement. The EPA could add examples of where this model has been used in scenarios such as what is proposed in the Supplement.

The Committee noted the methodologies used and assumptions made seemed appropriate for the analysis and level of certainty. However, some additional potential sources related to hydraulic fracturing activities could be considered or acknowledged. One Committee member noted the default loading rates described in the technical documentation for DRAS seemed appropriate for the analysis.

Not all the modeling assumptions and source-specific parameters were defined in Section 2.3.2 or Appendix H and are not discussed. For example, assuming a finite source for continuous landfill and surface impoundment disposal would increase uncertainty in the groundwater concentrations predicted from the DRAS model.

The Committee recommended that the uncertainties and data gaps in the groundwater scenarios should be discussed more thoroughly. Data gaps included measurements of current groundwater concentrations in private wells nearby Subtitle D unlined municipal solid waste landfills and unlined surface impoundments used for disposing of hydraulic fracturing produced water. One Committee member stated the uncertainties and data gaps made it difficult to conclude whether this model was appropriate for the Supplement's purposes and whether these scenarios are important under current conditions.

The Committee suggested line 2461 should better clarify the modeling approach and in general, the modeling approach should be clarified. As an example, a committee member referred to this sentence, "…leachate concentrations were estimated for a range of possibilities until no risk could be identified at the lower end of those concentrations…"

Some Committee members noted that on line 2459 EPA noted that the assessment relied on the default waste loading rates for RCRA Subtitle C Landfills available in DRAS, however, the Supplement focused on Subtitle D landfills (municipal solid waste landfills). The Committee member suggested adding information on the differences between the waste loading rates between Subtitle C and Subtitle D landfills.

A Committee member noted the DRAS model assumption that unsaturated and saturated zones were uncontaminated was likely incorrect for landfill and surface impoundments, which would add to the uncertainty in the groundwater concentrations predicted from the DRAS model. While assumption of advection and dispersion as primary transport mechanisms for 1,4-dioxane was appropriate, matrix diffusion was not considered which would also add to the uncertainty in the groundwater concentrations predicted from the DRAS model.

Line 2293 discussed groundwater monitoring samples from 1997 to 2022 found in the water quality portal (WQP). However, one of the Supplement's cited papers (Adamson et al. 2014) stated that there have been changes in the accepted analytical methods for 1,4-dioxane starting in the 2000s to EPA 8270 and EPA 522 (with a lower reporting limit of 0.07 µg/L). Some WQP data were collected before 2000 and may have uncertainties related to the analytical methods that were not discussed. Other uncertainties with using these data (including depth of monitoring well, purpose of sampling, etc.) are recommended to be acknowledged and discussed.

A Committee member shared information from the state of Texas about their state law (Texas Water Code Section 26.408) that requires notification of nearby private well owners/users within 30 days of confirmed groundwater contamination by a state agency. This state law has been in place for over 20 years and there have been only a few remediation sites that required notification due to 1,4-dioxane.

Line 2321 stated, "Recent changes in industrial activities and disposal may have largely reduced groundwater contamination with 1,4-dioxane." A Committee member emphasized that this is an important statement that should be discussed upfront when introducing the scenarios.

A Committee member noted that on lines 2336 – 2339, EPA provided references to groundwater concentrations of 1,4-dioxane intending to give context to the modeled releases from the unlined Subtitle D landfill scenario. Other cited papers were describing concentrations of 1,4-dioxane from remediation sites using mainly monitoring well data and suggested adding information to these descriptions to clarify concentrations of 1,4-dioxane were measured in monitoring wells around identified remediation sites and not in private drinking water wells within a mile of unlined Subtitle D municipal solid waste landfills. A Committee member suggested clarifying on lines 2333-2341 whether there are actual declines or were areas being sampled not simply places that are not as contaminated as were those being sampled before 1999.

One Committee member suggested on lines 2394 to 2401 that EPA add statistics on the Subtitle D landfills currently with perforated liners and failures of leachate capturing systems and add references to strengthen the scenario.

One Committee member noted that on line 2449 EPA stated the objective of this assessment was to evaluate the potential for groundwater contamination in the absence of landfill controls and suggested adding statistics on how many Subtitle-D municipal solid waste landfills exist in the US without adequate liners that are not remediation sites.

Two Committee members noted that the EPA should include the back of the envelope calculation used to convert the weight-adjusted dilution adjustment factor to groundwater concentrations or clearly indicate where the calculation is described.

Hydraulic Fracturing Scenario

Several Committee members noted the limited data on 1,4-dioxane concentrations in produced water (lines 2536 and 2562) and suggest adding information on possible uncertainties (e.g., could 1,4-dioxane concentration in produced water vary by location, manufacturer, year).

Some Committee members requested that reported spills of wastewater during transport to disposal sites (e.g., Maloney et al., 2017) should be considered or acknowledged. It should also be acknowledged that smaller spills may go unreported due to reporting requirements and that such spills may also contribute to 1,4-dioxane contamination risk.

In reference to lines 11592 and 11660: The Supplement stated that DRAS used a 1988 survey of drinking water wells downgradient from waste management units. It is suggested that EPA add the type of wells as the 1988 document listed both private and public wells.

One Committee member suggested adding an estimate of the number of unlined surface impoundments in the United States to the discussion of the hydraulic fracturing scenario. One Committee member suggested adding the word, unlined, to surface impoundment when used throughout the Supplement.

One Committee member recommended, referring to line 2545, that assumptions and rationales should be referenced and discussed where they differ from other EPA programs. For example, EPA's regional screening levels consider the lifetime as 70 years (Supplement uses 78 years).

One Committee member noted that using the word, likely, on line 2554 was too strong for this scenario given the data gaps and uncertainties. In addition, one Committee member recommended clarifying Table 2-14 (Total Annual Release Summary) to add what sites make up the referenced 411 sites.

While quantitative analyses may only be conducted with reasonably available or known data, it is possible or even likely that disposals of hydraulic fracturing wastewater containing 1,4-dioxane have not been reported correctly or at all, and as such are underrepresented in the data used. Some Committee members recommended that it is prudent to acknowledge this as a potential limitation in the reported estimates (Section 2.3.2.2.2).

One Committee member noted Tables Appendix H-3 and H-4 appeared to report disposals from 2013 onward and noted that hydraulic fracturing operations began a decade before that. The Committee member noted the analysis did not capture such historic disposals, which may be equally or more important to 1,4-dioxane contamination potential if disposal wells were not subject to the same regulations as the years included in the analysis.

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.

Detailed points of discussion and recommendations:

Overall comment: The draft supplemental assessment fails to fully consider several exposure scenarios, pathways, and routes for 1,4-dioxane contaminated groundwater. The Committee recommended that both this assessment and future national assessments consider all complete, potentially complete, and incomplete exposure scenarios, pathways, and routes for contaminated groundwater and that discussion in the assessment address how exposure scenarios, pathways and routes were determined. The Committee recommended that decisions for not including exposure scenarios, pathways, and routes should be thoroughly explained. Below are specific comments.

1. As detailed in comment 5B from the Environmental Defense fund, the Draft Supplement fails to consider acute risks from drinking water drawn from contaminated groundwater supplies. EPA's assessment of groundwater contamination considered only chronic risks, while the surface water assessment included both chronic and acute risks. To fully assess the risk to the millions of people that rely on groundwater for domestic consumption, the Committee recommended that both this supplemental risk assessment and future national assessments of groundwater assess all exposure scenarios that are known to cause harm. Indeed, given the many communities who depend on surface water for their water sources, including PESS communities, all water sources should be included as potential sources for the exposure. Inclusion of surface water sources can also consider contamination scenarios not necessarily relevant to groundwater contamination, such as surface disposal of waters from fracking (dispersal on roads for deicing and dust control).

2. It appears that the Draft Supplemental Risk Assessment does not consider the vaporization of 1,4-dioxane from household use of domestic water and inhalation as a pathway and route of exposure for contaminated groundwater. This pathway and route are not shown in Figure 3.1. This is a major oversite. 1,4-Dioxane can volatize from tap water during showering, bathing, laundering, and other routine household uses of domestic water and expose people to 1,4-dioxane vapors (ATSDR Toxicological Profile for 1,4-Dioxane). EPA could use the Agency for Toxic Substances and Disease Registry (ATSDR)'s Shower and Household Water-use Exposure (SHOWER) Model v3.0 to calculate inhalation intakes based on estimated groundwater concentration of 1,4-dioxane. The Committee recommended that both this supplemental risk assessment and future national assessments of groundwater assess all exposure pathways and routes of exposure in order to fully assess the risk to the millions of people that rely on groundwater for domestic

consumption. For volatile compounds, The Committee recommended that modelling exposures from volatilization during household use of tap water be included.

The Committee recommended that the assessment include scenarios where water evaporation and water heating in a contained area provide unique opportunities for 1,4-dioxane to become available for inhalation over repetitive events for significant durations. This is particularly important as it represents exposure to the general population, youth, PESS communities and addresses EPA's intention to find the 95th percentile of exposure as sentinel. These exposure conditions will surely be relevant to such evaluations.

1,4-Dioxane is more volatile than and completely miscible with water so if it acts as an ideal solute, it will actually distill from the water when heated. Theoretically, the concentration of dioxane over the heated solution could be higher than the concentration in the water that is being evaporated. If the contaminated water is flash heated, a bolus of dioxane could be loaded into the air quickly. If conditions maintained the volatile dioxane in a confined space, human exposure could be relatively durable.

This scenario is much more prevalent than inferred in the summary table. In arctic, western (general population) and indigenous societies such activities may be frequent as they are part of hygiene practices as well as ceremonial and health/relaxation opportunities. In the "general population" the scenario can exist for indoor pools, spas, home hot tub rooms, home steam bathing (a bathroom fixture feature gaining popularity even for middle class apartments and houses). In northern tribal and Arctic communities, steam bathing facilities exist as a small room within the house, or a small enclosure built outside. The process is enjoyed communally by the family/friends over an hour or more daily. In southern regions sweat lodges are a popular form of the same concept. These lodges may also be used in hours-long ceremonial functions. In sweat lodges, steam bathing and commercial spas, water poured over hot rocks or heating elements provides flash volatilization.

Surely EPA could calculate some estimates—at least ranges—of potential human exposure using estimates of 1,4-dioxane concentrations in water (as used for other calculations of surface and groundwater risk) and reasonable estimates of exposure durations, degree of volatilization, and exposure opportunities over days/years. This type of exposure would be in addition to people's drinking water exposure in PESS communities as well as for youth and "general populations".

3. While it is encouraging the EPA has considered hydraulic fracturing in the draft supplemental assessment, the assessment is incomplete. Most important exposure scenarios for 1,4-dioxane contamination of groundwater from hydraulic fracturing activities appear to be absent from draft supplemental risk assessment. No potential human exposure pathways to 1,4-dioxane from hydraulic fracturing activities, including the

surface impoundment scenario, are indicated in Figure 3-1. The surface impoundment of produced water from hydraulic fracturing activities is the only exposure pathway considered in the assessment, even though there is ample scientific evidence of other exposure pathways (Lackey et al., 2022, Clark et al 2022, , Hill and Ma 2022, Lackey et al. 2021, Fontenot et al. 2013, Drollette et al. 2015, Llewellyn et al. 2015, McMahon et al. 2017). These include injection of produced water into UIC Class II disposal wells, spills of produced water and hydraulic fracturing on oil and gas well sites, and casing failures on oil and gas wells. Details on these important exposure pathways are included in the public comments provided by Earthworks, which are summarized in the following paragraphs.

The final risk assessment missed most pathways concerning disposal of hydraulic fracturing waste (produced water relevant to PESS. The oil and gas industry handles and disposes of waste and operational fluids in a different manner than EPA analyzed during this draft risk assessment. For instance, the RCRA Subtitle C's hazardous waste regulations (40 CFR part 261.4.8) allow oil and gas exploration and production wastes (produced water) to be disposed of in UIC Class II injection wells. In practice, far more waste (produced water) from hydraulic fracturing is injected in Class II wells rather than Class I wells. Thus, EPA's draft risk assessment misses the primary potential pathway for 1,4-dioxane exposure from hydraulic fracturing wastes via underground injection. The standards differ for Class I and Class II wells, which could meaningfully alter an assessment of risk to groundwater sources. For instance, Class I well operators that accept hazardous waste must conduct mechanical integrity tests on the well each year, whereas Class II wells require these tests only once every five years, regardless of the risks associated with E&P waste chemicals injected. In addition to reviewing Class I wells, EPA should include Class II wells that may be injecting produced water underground containing 1,4-dioxane in the supplemental assessment.

Another important source and associated pathways not considered in EPA's 1,4-dioxane risk assessment is the presence of 1,4-dioxane in fracturing additives, fluids, and produced waters that return to the surface (often referred to as flowback), which are typically stored in open pits or tanks at the well site prior to disposal. Exposure pathways associated with storage of flowback fluids in open pits or tanks include worker exposure to 1,4-dioxane from inhalation and dermal exposure; general population exposure from surface water contamination, groundwater contamination, and air exposure from fugitive emissions.

Additionally, spills of fracturing chemicals and wastes during transportation, fracturing operations and waste disposal have contaminated soil and surface waters. In 2013, for example, 41 spills impacted surface water in Colorado alone.
Earthworks concludes that communities relying on groundwater for drinking water near oil and gas sites represent the potential for sentinel exposure in a potentially exposed or susceptible subpopulation and are not adequately represented in the assessment.
Earthworks recommends that the assessment of exposure pathways and routes resulting

from 1,4-dioxane contamination of groundwater from hydraulic fracturing activities should be revised to address UIC class II wells, spills, and well casing failures in order to capture the total exposure and risk to 1,4-dioxane from this source.

Further, the Committee noted that even if the methodologies used and assumptions made in the groundwater risk assessment for the hydraulic fracturing (HF) and landfill pathways are deemed appropriate for the analysis and level of certainty, it is note-worthy that groundwater wells are not subject to Safe Drinking Water Act regulations and are tested only at the discretion of the home- or landowner. They are thought to be more vulnerable to contamination than regulated public drinking water systems. It seems appropriate to consider groundwater well risk estimates as potential maximum exposure through the groundwater pathway, and as such use them as potential sentinels.

The use of the nationwide Water Quality portal data seems appropriate, but only 2,284 measurements across more than forty years seems insufficient to draw nationwide conclusions, particularly given the temporally and spatially specific nature of water contamination from a point source. Such conclusions may carry only low to medium confidence.

Uncertainty and data gaps both lead to low confidence in the risk estimates from these exposure scenarios and low confidence in determining whether the two scenarios are likely for 1,4-dioxane exposure through a private drinking water well. The EPA characterizes the modeling methodology as “robust,” but supporting evidence is missing. The Committee was concerned about the apparent uncertainty, probable under-reporting and overall data gaps for contaminant concentrations in private drinking water wells.

One Committee member summarized historical evidence on this issue noting there is little evidence to suggest authorities would encourage testing of private drinking water wells. If a coordinated well testing effort is initiated, residents may not be aware of why testing is important, may be fearful of having their private drinking water wells tested, or lack resources to have the water tested (Flanagan et al, 2015). This limited reporting may be fueled by parents’ fears of having poisoned their children, fears of losing money should they try to sell their home and a variety of other reasons (anecdotal evidence from participation in public meetings). Research experience from one Committee member noted this was the case in a Cape Cod community with inadequate protections from historical and current landfills in place where leachate containing 1,4-dioxane impacted down gradient wells (Myers, 2014). The National Institute of Environmental Health Sciences (NIEHS) Superfund Research Program (SRP) (NIESH, 2023) funds university-based grants on basic biological, environmental, and engineering processes to practical solutions to exposures to hazardous substances in locations where private drinking water wells are contaminated with arsenic, chlorinated solvents, per and poly fluoroalkyl substances (PFAS), or 1,4-dioxane across the US (NIEHS, 2020). SRP researchers have worked to engage and empower private well consumers and owners through a variety means, identifying and

attempting to remove barriers to testing (Gray et al., 2021; Yelton et al., 2023). Each SRP is working with PESS communities to decrease exposures - this is important for 1,4-dioxane, but also relevant for the other chemicals that will be assessed under TSCA.

Additional concerns detailed by Committee members included:

- The DRAS model was designed for other purposes and evidence was not presented to show that it is appropriate to model concentrations of 1,4-dioxane leaching from an unlined subtitle D municipal solid waste landfill or from an unlined surface impoundment receiving produced water containing 1,4-dioxane (for the purposes of determining drinking water concentrations).
- No 1,4-dioxane monitoring data from unlined subtitle D municipal solid waste landfills.
- No 1,4-dioxane monitoring data from unlined surface impoundments where produced water has been disposed.
- No estimate of the number of unlined subtitle D municipal solid waste landfills with leachate containing 1,4-dioxane affecting private drinking water wells.
- No estimate of the number of unlined surface impoundments where produced water containing 1,4-dioxane has been disposed.
- Uncertainty surrounding the concentration of 1,4-dioxane in produced water.
- Uncertainty in the amount of 1,4-dioxane in materials disposed in municipal solid waste landfills and loading rates used to model the scenario.
- No discussion of whether these exposure scenarios have occurred in the US with 1,4-dioxane.

DRAS derives calculations based on a 1988 survey of drinking water wells downgradient from waste management units. This survey seems to be outdated and the uncertainty in number of wells downgradient is not discussed thoroughly.

There is some evidence of biodegradation of 1,4-dioxane in groundwater. This is not discussed as an uncertainty.

The groundwater assessment would better represent the potential for sentinel exposure for potentially exposed or susceptible subpopulations in a national assessment by addressing the following:

- Consider lactating people and people of child-bearing age as susceptible subpopulations. Both these subpopulations have higher drinking water intake rates (47 and 38.2 mL/kg-day) compared to adults 21 years (38 mL/kg-day).
- Consider susceptible subpopulation of unborn children.
- While use of per capita water ingestion rates may be appropriate for the general population, they may underestimate sentinel exposures in potentially exposed or

susceptible subpopulations exposures. People that drink water from their domestic water supply every day could be considered a susceptible subpopulation in this context.

Including Stressors in Quantitative Assessment: Application to PESS and general population risk assessment

The US is not a healthy population – rates of illnesses – including liver and kidney disease– relevant to 1,4-dioxane – rates of both liver and kidney disease are not equally distributed across the population. In addition to expanding the potential exposure conditions considered to include cultural and recreational practices, the Committee recommended expanding consideration of susceptible sub-populations to include those with pre-existing conditions, not just sensitive life-stages. Because 1,4-dioxane is hepatotoxic, some of the Committee encourages EPA to consider the 4.5 million US adults with liver disease (CDC, 2023) and the trends showing rates of liver disease-related deaths are rising (CDC, 2017).

This public health framework is useful to define communities already vulnerable to 1,4-dioxane and to consider similar pre-existing health status conditions for other risk assessments.

The Committee noted also that assumptions for PESS and the general population should reflect the facts that the US population is aging and the US working population have increasing instances of overtime. At the same time, some states are expanding labor to younger children. These occupational exposure situations will involve uniquely susceptible groups. In general, 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. Children may have a greater burden due to their physiological differences from adults. These differences include higher breathing rates and breathing more air per unit of body mass than adults, higher total body water percentage and need more fluid intake, and greater hand-to-mouth activities. (Fleming et.al, 2011, Gasana et al, 2012, Lu et al, 2023, Xue et al, 2007).

The Committee agreed that the continued use of exposure assumptions that are based on surveys conducted well over 30 years ago are problematic for assessment of health risk to PESS that have historically not been included in national estimates. Case in point is the duration of time that people live in their current place of residence (33 years). Such assumptions may be problematic when applied to the issue of being in a community's water source and is clearly not appropriate for PESS communities.

The Committee recognized it is not easy to find data useful to determine worker residence location. However, the Committee recommended two additional data sources—also with limitations as they apply only to people classified as employees. Independent contractors would not be covered, and temporary agency employees would be covered by their agency, not the employment site.

1. **Workers' compensation data for private sector employers**

These data, which should have home addresses, are state-specific, and arrangements would be required for individual state data. Gathering data for all 50 states would be a substantial

undertaking. However, several states with relatively good data (California, Ohio, Oregon, and Washington) might be willing to share with appropriate safeguards. They are only for injured workers, so they would not be a random sample.

2. **Unemployment insurance data.**

All employees should have their earnings reported to state Unemployment Insurance (UI) agencies. The employment site and the first and last names would be in these records. There would be no direct information about residence. An internet search might work, but it would be very inefficient or require sharp programming to scrape the needed data. Also, most state UI agencies are very reluctant to share their data, even with other government agencies. However, the data are also shared with the US Department of Labor, Bureau of Labor Statistics who have shared these data with researchers.

Other Chemical and Nonchemical Stressors—important issues for 1,4-dioxane and other TSCA evaluations

The Committee and several public commentors reflected on the meaning of EPA's calculated risk which does not formally include real and prevalent conditions of vulnerability in the population. In addition to the exposure profiles, the real adverse health consequences (risks) in communities are consequential to stressors from other chemical exposures and non-chemical stressors. These additional factors presently have no representation in risk algorithms, making the national scale evaluation unrepresentative for PESS and, as noted in the PESS summary [page 162] burdened with remaining sources of uncertainty. That may also be true for "the general population". The Committee recognized this is a generic problem with EPA risk assessments, as discussed on many occasions, and cannot be resolved by individual authors of the TSCA evaluations. As with other assessments, EPA sidesteps this (admittedly difficult) issue for two primary reasons: 1) chemical or nonchemical factors that specifically influence susceptibility to reviewed chemicals have yet to be identified, and 2) quantitative factors that would allow inclusion of such information into the risk algorithms are unavailable. This adds significant uncertainty to risk determinations.

Although scientific evidence piles up to identify chemical and non-chemical stressors as significant factors in adverse health effect outcomes (risk), the EPA scientists are handicapped in applying such knowledge, classically demonstrated for the array of cancers presented in rodent studies for 1,4-dioxane. The dose/effect calculations used to establish cancer hazard metrics are a tapestry of cancer incidence data treated with statistics according to decades-long policies and practices…devised long before genetic predispositions and stressors were considered. Creating this tapestry required the cumulative work of many advisory councils, public debates and still-ongoing arguments where stressors have no parameter in the quantitative algorithm. It is unrealistic to think that scientists authoring a risk assessment for a given TSCA chemical could successfully take on the challenge of modifying any part of those painfully negotiated settlements of long ago. Indeed, the science authors of this EPA document are laudably transparent on the assessment difficulties (lines 4830-4843).

The target health effect here…cancer…is one of those health effects for which the real outcome as a threat to life and wellness is highly dependent on many auxiliary factors not "measurable" in

most non-human cancer studies but are critical to the "general population" and PESS and fence-line communities.

- Genetic predispositions to the type of cancer
- Health screenings available to the person, to the community
- Other chemical co-exposures (including smoking, alcohol, other toxins)
- Medical care available to person, community
- Other factors inherent to socio-economic status of person or community
    - Including stress, heat, living challenges
    - Need to work, lack of recuperative time and options.

The 1,4-dioxane exposure scenario addresses a very broad proportion of the population via multiple sources and exposure routes. The probability is high that most people will be exposed via some combinations of environmental, occupational and consumer scenarios. People could experience some levels of exposure over long durations and across many life stages.

- Exposures via water and air from multiple sources
- Inability to avoid the sources and routes of exposure
- Presently unlikely that multiple sources of contamination will be detected/quantified, monitored or remediated.

This is not the only potential chemical carcinogen to exist in our environment as such. Many of these chemicals will appear a part of EPA's work under TSCA. The science itself is challenging for these chemicals' hazard and exposure assessments, but the added required task to consider the risk to unique communities (PESS) unavoidably involves consideration of the chemical and nonchemical stressors inherent in some communities. The very concept of PESS derives from a recognition that people in these communities experience more and/or different exposures to hazardous chemicals, and some living situations may increase those exposures and exact a greater toll (onset, progression, disability, morbidity and mortality) than imposed on the "general population" not subject to such conditions. Real life exists whether or not EPA can find the evidence for subpopulation vulnerability to a given chemical's threats, or if/how chemical and non-chemical stressors play into the calculations used for risk assessment.

Since there are many chemicals in the TSCA work flow, EPA should formally consider how to apply the amassing evidence that chemical and non-chemical "stressors" are a part of risk assessment. It is time to at least begin to bring computational approaches more in line with real life situations.

Until such time, starting with 1,4-dioxane, 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.

Defining PESS and representing a sentinel exposure: principles

The Committee noted that EPA assumes that exposures for PESS are described in the upper end of the distribution tails—no matter if data used to create the distribution represented the unique scenarios of exposure opportunity. The document has an underlying persistent perception that for all exposure scenarios under consideration, the exposure to the contaminant will be higher in PESS communities than experienced by the general population. There are many scenarios for which this is untrue. There are significant differences between unique communities and the general population on key parameters describing the opportunities for exposure and the contaminant concentrations in media presenting the contaminant to people during their activities. And that can result in more exposure for some scenarios and less exposure for other scenarios.

Also, though not stated, it seems that EPA's approach implies that if the upper end of an exposure distribution is used, somehow that value is truly "protective" and will represent PESS and compensate for missing information, missing scenarios, inappropriate assumptions, etc. Stated differently, the 95th percentile of an exposure distribution constructed with exposure metrics representing more generalized or mixed population groups would not necessarily be sentinel exposure values for those more defined subgroups (fence-line, occupational, etc.)

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.

EPA lines 3614-3643---"While the substantial uncertainty around the extent to which these exposures occur decreases overall confidence in the exposure scenario, this scenario represents a sentinel exposure. "

While the exposure value may represent the 95th percentile from this exposure distribution (using these metrics), it is unlikely that this represents a sentinel exposure because:

The important point is that the metrics utilized in constructing the distribution must be representative of the exposure scenario(s) expected for the population group under consideration and the environmental contaminant scenarios (drinking water in this case) which define the exposures these groups experience.

The Committee agreed that it is important to know what the upper-bound estimates may be given the existing information. But to declare those to be "sentinel" at this point could be confusing to the public and to regulators, as it implies the underlying principles of representation. 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 Committee recommended that EPA be transparent about the "representativeness" of input values which create the exposure distribution. If input values are not specifically representative for that group, but rather input values are more generalized for a larger population group, the utility of the resulting 95th percentile value as "sentinel" is somewhat compromised. That point needs to be articulated in the paragraph describing sentinel exposure. Also, when sentinel values

are presented, commentary should be made on the specificity of input metrics as to their representativeness uniquely to that population group.

Unfortunately, as EPA explains, there is a paucity of monitoring data (for 1,4-dioxane) from the various types of landfills. So, it is not known if the existing input data are representative of those scenarios where there is leachate to the groundwater under different geological conditions, landfill construction and condition, and other key factors that would inhibit or enhance contamination dynamics. Additionally, existing data are not identified as representing communities where groundwater sources are near landfills. Landfill design ranges from nothing more than a space where garbage is dumped to sophisticated containment areas which discourage or contain leaching chemicals. The classifications of landfills include different setbacks for wells and dwellings. As EPA makes clear, monitoring data do not provide insight into contamination potential under different landfill designs or across different groundwater zones (relative to landfill positions).

When considering leachate from landfills which may reach water sources, EPA has efficiently used the paucity of available data and have then estimated concentrations that could be of concern. They correctly described their approach as "*EPA does not have reasonably available information on actual concentrations of 1,4-dioxane in leachate for most landfills and therefore selected landfill leachate concentrations are based on potential for risk to human health."* (See lines 3623-3625 and *Excel sheet 21 and Threshold Calculations Tab within Excel sheet 20).* This accurately illustrates the need for such data, the probable great variations across different types of landfills and the probability that leaching of 1,4-dioxane could be notable. The calculation of a concentration that would yield a 1 per 10^6 risk is a "level of concern" for a reference point for communities and public health professionals. However, this is not a sentinel concentration value. In fact, a sentinel concentration cannot be proposed until better data on leachate concentrations are documented across different landfill scenarios.

Data representing the leachates in "waterlogged" communities should be sought as those communities may experience near-field high exposures from surface water. This scenario may indeed represent the principle of sentinel exposure…to communities dependent on surface water. Such communities include the swampy coastlines of the Gulf of Mexico and the boardwalk communities of Alaska. In these situations, water can (does) inundate the surrounding area, including landfills, making a direct link to homes and other community areas.

Committee Recommendations:

- **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.

- **Recommendation 3:** 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.

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.

The Committee noted that some of the exposure assumptions were the same as those used in EPA's Risk Screening Levels, but some were not. For example, the exposure duration of a resident is 30 years in the Risk Screening Levels and in the DRAS Technical Support Document, whereas it was 33 years in the Supplement. The Committee found that it was difficult to find all of the exposure assumptions (some were found in Appendix I) as the Supplement refers to tables in the Exposure Factors Handbook. The Committee recommended including tables with all the exposure assumptions in the appendix or main body of the Supplement. The assumptions should be clearly presented and transparent.

Specific Comments

- Overall, the methodologies and assumptions made seem appropriate for the analysis and level of certainty. However, it would significantly aid ease of interpretation if additional details on these default loading rates were provided in the Risk Assessment itself or in the relevant Appendix.

- Groundwater wells are not subject to Safe Drinking Water Act regulations and are tested and treated only at the discretion of the home- or landowner. They are thought to be more vulnerable to contamination than regulated public drinking water systems. It is unlikely that most well owners are routinely testing for 1,4-dioxane, and it is difficult to remove through conventional treatment. Thus, it is appropriate to assume that the predicted groundwater concentrations using the DRAS model would be like those in an exposed groundwater well. It also seemed appropriate to consider groundwater well risk estimates

as potential maximum exposure through the groundwater pathway, and as such use them as potential sentinels.

- On page 75, line 2321, EPA states, "Recent changes in industrial activities and disposal may have largely reduced groundwater contamination with 1,4-dioxane." Since few groundwater concentration data exist indicating that 1,4-dioxane has leached into groundwater from subtitle D landfills and unlined surface impoundments where produced water was disposed, it is difficult to conclude whether these scenarios and pathways are of current concern.

- The target cancer risk is listed as 1E-6 in the input table for DRAS, but it was not clear if other target risk levels within EPA's risk range were also considered since there was not a bright line of excess target risk stated in the Supplement. The DRAS model was used to model a clay-lined landfill, but that scenario was not discussed in the body of the Supplement.

- A Committee member recommended revising the overall confidence in drinking water exposure estimates resulting from disposal of produced water from hydraulic fracturing water to "slight to low."

- The underlying drinking water exposure scenario concerning pathways between the hydraulic fracturing produced water source and groundwater contamination was incomplete. Several pathways are not considered, including injection in Class 2 injection wells, surface spills, and leaking well casing (Lackey et al., 2022, Clark et al 2022, Hill and Ma 2022, Lackey et al. 2021, Fontenot et al. 2013, Drollette et al. 2015, Llewellyn et al. 2015, McMahon et al. 2017). Confidence in predicted 1,4-dioxane concentrations in untreated private drinking water wells for the subpopulation living near hydraulically fractured oil and gas sites and class 2 injection sites was slight.

- If a finite source was assumed in the DRAS model for continuing disposal of produced water to a surface water impoundment, then modeled groundwater concentrations may not have reflected average 1,4-dioxane concentrations in untreated drinking water wells over a 33-year period.

- Because the DRAS model did not address matrix diffusion, modeled groundwater concentrations may not reflect average 1,4-dioxane concentrations in untreated drinking water wells over a 33-year period.

- The model assumption that unsaturated and saturated zones were uncontaminated was likely incorrect for surface impoundments. This would have added to the uncertainty in the groundwater concentrations predicted from the DRAS model.

- Some Committee members recommended revising the overall confidence in drinking water exposure estimates resulting from landfill disposal to "low."

- If a finite source was assumed in the DRAS model for continuing disposal of produced water to a landfill, then modeled groundwater concentrations may not have reflected average 1,4-dioxane concentrations in untreated drinking water wells over a 33-year period.

- Because the DRAS model did not address matrix diffusion, modeled groundwater concentrations may not have reflected average 1,4-dioxane concentrations in untreated drinking water wells over a 33-year period.

- The model assumption that unsaturated and saturated zones were uncontaminated was likely incorrect for landfills. This would have added to the uncertainty in the groundwater concentrations predicted from the DRAS model.

- Line 4580. The consideration for significant groundwater recharge from streams or lakes may need to be considered. This is a major factor in water flows within Central Texas and perhaps other areas of the United States.

Recommendation 1: The EPA should provide additional details that describe these default loading rates in the Risk Assessment itself or in the relevant Appendix.

Recommendation 2: The EPA should ensure that matrix diffusion and 1,4-dioxane concentrations in saturated and unsaturated zones are properly included in models.

4. AGGREGATE EXPOSURE AND RISK ASSESSMENT

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.

Committee members agreed that considering calculations for both grouped and individual facilities represents a strength of the aggregate analysis, and it is a strength to consider the risks to be greater in areas where there are grouped facilities. Committee members also raised some uncertainties, needs, and clarifications for EPA to consider in future iterations. The Committee suggested that EPA not only consider a 10km buffer, but also 15km and 20km buffers, and to group facilities in these larger buffers. Committee members stressed that if larger buffers are not considered, the choice of 10km as the buffer should be justified. Committee members also raised that one pathway of exposure is considered (inhalation of air), and dermal and ingestion routes of exposure should also be considered. Committee members stressed that considering all routes of exposure is especially important so to not underestimate exposures and impacts for susceptible subpopulations, such as children.

Several Committee members noted that combined facility concentrations should be more

appropriate for any model evaluation efforts since they represent a larger share of all sources. A Committee member raised that EPA's quantitative aggregated exposures and risks from multiple sources releasing to air did not include releases to air from oil and gas well sites with hydraulic fracturing activities. This omission underestimates the exposure and risks for communities living near oil and gas well sites and other sources of 1,4-dioxane releases to air. This is particularly important given that releases to air could be large from multi-well oil and gas sites, located in suburban and urban areas in Colorado, Texas, Oklahoma, and other states. The Committee member recommended EPA include releases of 1,4-dioxane from oil and well sites with hydraulic fracturing activities in the quantitative aggregated exposures for air releases. 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.

A Committee member noted that it was difficult to determine which Ambient Air Concentrations and Exposure Methodology from Figure in Appendix J-1 was used for facilities included in the multi-facility modeling and which years of data were used and recommended clarification. A Committee member raised questions about the use of a regionally representative meteorology versus the local terrain, as the former may end up with different spatial concentration fields and summing them may propagate errors. A Committee member questioned the use of summing just the 95th percentile (mentioned in line 12130), as using 95th percentile from multiple facilities assumes conditions about correlation between emissions and pollutant transport that are not clear, which could end up with atypical downstream multicollinearity distributional effects. One Committee member was interested in hearing the justification for this approach as opposed to applying AERMOD with multiple sources in the model.

Committee members also raised some editorial comments. Committee members noted that the black lettering is hard to see against the dark background of figures in appendix J.4, and that there is an apparent typo in Figure in Appendix J-6 where it says "Is risk there risk".

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.

The Committee evaluated EPA's quantification of multiple sources of 1,4-dioxane releasing to surface water, and the exposure and risk associated with those releases. The Committee's key findings are that the overall approach was identified as a strength. However, the Committee identified several uncertainties. In particular, the Committee indicated that the aggregating approach, the validation of the exposure model, the drinking water intake estimates, and the Margin of Exposure (MOE) approach were sources of uncertainty. Specific comments regarding the strengths and uncertainties follow.

The Committee identified several strengths with the EPA's approach to aggregate surface water exposures. Specifically, incorporation of varying release periods and contribution of multiple facilities to a single exposure were appropriate. Further, the use of the expansive National

Hydrology Dataset Plus (NHDPlus) was found to be a strength of this approach. In addition, the approach of validation using case studies was found to be a strength, although some Committee members did find uncertainty with the specific case studies, the data used therein, and/or the results of individual case studies. Finally, the conservative assumption that all dioxane remained in the water column was specifically highlighted due to the finding that water treatments do not reliably remove 1,4-dioxane.

Although strengths were identified, a common uncertainty was found by the Committee – that the aggregate exposure risk analysis did not consider exposures across pathways (e.g., drinking water + swimming) or other environmental compartments (e.g., water + air). Committee members noted that without including multiple exposure routes, there is the potential for underestimation of risk to the general population, and especially susceptible subpopulations or those receiving the highest levels of exposure. In contrast, several Committee members noted that the validation performed using the Estimating Water Industrial Surface Release and Down the Drain in Excel (EWISRD-XL) model overestimated the monitoring data for two of the three case studies, which appears counterfactual to EPA statements on lines 4503-4505. Some Committee members suggested that EPA utilize more site-specific monitoring data, if available, to refine the model.

The Committee's uncertainty of the model and its results is increased by EPA's attribution of model sensitivity to different factors in different locations of the Supplement. In the main text, EPA notes that facility contributions are the most significant loading [e.g., "the loading from facilities far outweighs the contribution from background sources at the higher end" (2187 – 2188)]; however, in the analysis of the case studies EPA attributes sensitivity to down-the-drain (DTD) releases and background concentrations ["In [the Brunswick County] case study … the output was sensitive to [the] upstream concentration" (11259 – 11260) and the "results of [the East Liverpool, Ohio] case study appeared to be sensitive to the high concentrations reported for the Beaver River tributary as well as the high population estimated to be contributing to the DTD component" (11318-11320)]. The seeming incompatibility of these statements reduces certainty in modeled output and does not aid in identifying potential refinement strategies. EPA should, therefore, clarify the sensitivity of the model and identify areas of refinement prior to conducting further evaluations either for validation purposes or for aggregate risk assessment.

The Committee noted uncertainties with the drinking water intake estimates. Specifically, the use of central tendency estimates was inconsistent with EPA approaches to deriving lifetime Health Advisory Levels, Drinking Water Equivalent Levels (DWEL), and Maximum Contaminant Levels (MCL), in which the chronic assumption is the upper bound estimate of water intake rates. Although EPA states in the 2022 RE that acute risk estimates used upper bound intake rates, but chronic risks use central tendency water intake rates, actual drinking water intake rates for many individuals are chronic patterns and may be driven by the amount of exercise, outdoor and indoor temperature, and other factors. Therefore, the Committee recommends that EPA use upper bound drinking water intake rates from the Exposure Factors Handbook for both the acute and chronic scenarios involving 1,4-dioxane ingestion.

Several Committee members noted uncertainty with EPA's MOE approach for assessing non-cancer health risks. The members note that, although this approach may have been appropriate for studies with limited dose-response data or data on the rates of disease in the US human population, the MOE approach relies on a point of departure (POD) with no extrapolation to lower doses, does not estimate the proportion of the exposed population projected to experience a specified health endpoint or the number of individuals affected, and perpetuates the scientifically

unsupported situation that there exists a "safe" or "no risk" level of chemical exposure in a diverse population. There is also a practical reason to move from the MOE or POD based reference dose (RfD) to an approach that can be used for risk decision-making. EPA cannot do that using a single point to represent the toxicity/dose response for non-cancer effects and should adopt an approach that incorporates costs – including costs of treatment and cost to the health care budget.

For this purpose, the Committee members recommended that EPA utilize the approaches described in publications produced by the National Research Council (NRC, 2009), the World Health Organization (WHO) and others (Blessinger et al., 2020; Chiu et al., 2018; Council, 2009; Ginsberg, 2012; McGartland et al., 2017; Nielsen et al., 2023; Woodruff et al., 2023; WHO, 2017). These approaches expand the probabilistic assessment from the hazard and exposure assessments to the dose-response assessment. Committee members also recommended EPA review public comments submitted to the docket by the University of California, San Francisco (UCSF), Program on Reproductive Health and the Environment.

Recommendation 1: 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.

Recommendation 2: EPA should 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.

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.

In this supplemental risk assessment on 1,4-dioxane, EPA has considered aggregate risk assessment defined as the combined exposure from one chemical across multiple pathways, which includes aggregation across exposure routes (dermal + inhalation) combined air and water exposures, across multiple sources (various industries and other sources), and across scenarios. For qualitative approaches, oral + dermal +inhalation exposures were considered. Further combined air + water exposure was considered, and finally occupational and general population exposures were considered. EPA states that they were not able to quantitative conduct aggregate risk analysis due to mainly lack of reliable data and further significant uncertainties. Therefore, qualitative risk aggregation was conducted.

Comments from reviewers that recommended EPA quantify aggregate risks:

In Part 5.2.2.5 Aggregate and Sentinel Exposures, EPA states that there is uncertainty around the extent to which cancer risks across routes are additive for 1,4-dioxane and goes on to explain that liver tumors are the primary site of cancer risk from oral exposures and inhalation exposure in rats is associated with multiple tumor types, including liver. The inhalation unit risk used to calculate

inhalation cancer risk reflects combined risks from multiple tumor types. This reasoning does not preclude a quantitative assessment of aggregate exposure across the oral and inhalation exposure routes. Given that liver tumors are cancer sites for both routes, at least some additive effect is indicated. For these reasons, it is recommended that the quantitative cancer assessment include aggregate exposure across the oral and inhalation routes, with discussion of uncertainty.

Likewise, even though there is uncertainty around the degree to which nasal cavity lesions could be partially due to portal of entry effects following inhalation exposure, this reasoning does not preclude a quantitative assessment of aggregate exposure across the oral and inhalation exposure routes. Because nasal cavity lesions are likely to be primarily the result of systematic delivery (as discussed on p.192 of the 2020 RE), an additive effect from oral and inhalation exposures is indicated. For these reasons, it is recommended that the quantitative non cancer assessment include aggregate exposure across the oral and inhalation routes, with discussion of uncertainty.

EPA determined that it could be biologically appropriate to aggregate risk from dermal and oral exposures but did not aggregate risk from these routes of exposure because this draft supplement does not include COUs or pathways in which both oral and dermal exposure routes are considered. However, the general population includes consumers and as such, some Committee members recommended that aggregate exposures be quantified for the general population and consumer scenarios and routes within these scenarios. Likewise, workers (e.g., dishwashers, domestic workers) are also consumers and in the general population. Some of the Committee recommended that aggregate exposures be quantified for these scenarios and routes within these scenarios.

As EPA states, Section 2605(b)(4)(F)(ii) of TSCA requires EPA, as a part of the risk evaluation, to describe whether aggregate or sentinel exposures under the conditions of use were considered and the basis for their consideration. EPA defines sentinel exposure as “the exposure to a single chemical substance that represents the plausible upper bound of exposure relative to all other exposures within a broad category of similar or related exposures (40 CFR § 702.33). To comply with TSCA requirements for sentinel exposures, it is recommended quantitative aggregate exposures across groups be considered.

EPA has published a set of draft guidelines for cumulative risk assessment, building on several previous guidance documents and the recommendations of numerous other organizations and public health advocates. Clearly, the EPA recognizes the need to evaluate the combined impact of multiple exposures. While the guidelines primarily address cumulative risks from different chemicals or stressors, the need to assess the cumulative risk from multiple exposures to the same chemical is equally important, and the analysis seems less complicated to perform (US EPA 2023e).

Because of data gaps and uncertainty discussed during the public deliberations within all the exposure scenarios and risk estimates considered in the Supplement, the qualitative characterization of aggregate risks for 1,4-dioxane could be appropriate, but further evaluation is necessary.

At a minimum, some Committee members recommended that EPA perform several different quantitative analyses of aggregate risks to the same populations, using different assumptions or methods to resolve the uncertainties. If these result in substantially different results, and so long as the assumptions and methods are reasonable, it is recommended that the analysis most protective

of human health should be used.

As stated in lines 1356 and 1357, aggregate exposure was defined by the EPA as "combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways (40 CFR § 702.33)." While the current draft does a good job of aggregating and characterizing sources of 1,4-dioxane to a single exposure source (i.e., water and air, separately), it does not account for multiple pathways of exposures. Although aggregating across pathways (i.e., inhalation, dermal absorption, and ingestion) would have levels of uncertainty, it would be a better reflection of real-life scenarios. The general population, especially those in the susceptible subpopulations, may suffer higher risks than indicated by the potential underestimation of 1,4-dioxane risk.

An argument can be made that aggregation of exposure to estimate total body load is appropriate (given that there is no calculation for total body load), biologically revealing and in keeping with the realities of exposure. A vast number of people in the US are exposed, with differences in proportion of exposures from dermal, oral and/or dermal routes. There are both intraindividual differences across a lifetime and surely interindividual differences due to geography, occupation, life activities, and other factors discussed by EPA. The Agency should evaluate probability risks calculated for different exposure and lifestyle scenarios to evaluate ranges across these different situations.

EPA has the ability to mathematically aggregate exposures across different routes of exposure and existing computational tools can handle the task. There may be value in parsing the meaning of variability across exposure sums of these multiple routes. EPA's approach here emphasizes a biological relevance as presented by tumor incidence consequential to route-specific exposures in systemic delivery systems across different rodent species. It would be helpful if EPA reflected (in the introduction of this topic in the document) on how this approach aligns with the scientific policies and approaches of other regulatory bodies and authorities and EPA's own policies and precedent. The key issues in this analysis seem to be a need for concordance across cancer studies for organ specific effects and how the aggregation over multiple sources is to be done. EPA's logic on these key issues for this risk assessment should be presented if, indeed, they are leading TSCA on an independent course for this and future assessments.

It is recommended that population and occupational exposure should be aggregated. In addition to the qualitative analysis, it is recommended that cumulative exposure be quantified. Having a shared target organ, even if not an exactly overlapping set of target organs from different routes of exposure, does not preclude a quantitative cumulative analysis due to synergistic adverse health effects. Rather, it is a justification for quantifying an additive effect. Further, considering the geographic juxtaposition of communities with potential aggregate exposures that have high potential exposures to additional stressors (chemical and non-chemical) that may have synergistic adverse effects is critical. Additionally, consideration of lifetime exposures, life stage, and chronic versus intermittent exposures is important. Special consideration should be given in cumulative risk assessment for the fence line communities which are disproportionately affected by multiple routes of exposure. Any data on exposure to fence line communities will be useful. Further, consideration of cumulative risk for PESS communities needs to be prioritized. In Table 5-11 EPA states that it did not identify any factors that affect exposure from a quantitative standpoint but added a 10x uncertainty factor (UF) to account for life stage, genetics and pre-existing disease. It is recommended that EPA provide a rating of low, medium or high for confidence in cumulative risk

assessments to further inform the reasoning for adding this UF.

Although EPA risk estimates should err on the side of overestimating risk to ensure public health protection, by making successive overestimating assumptions EPA could generate risk estimates that are the product of compounding conservatism due to data gaps and uncertainty in the available data. In some cases, this means that the final estimated risks could be more a function of the conservative assumptions than they are of the actual chemical risks. To address this concern, it is recommended that EPA consider quantitative uncertainty analyses, if appropriate, that could provide confidence limits on their risk estimates by evaluating the impact of each assumption.

Comments regarding additional language to support the decision to perform only a qualitative evaluation of aggregated risk.

Because of data gaps and uncertainty discussed during the public deliberations within all the exposure scenarios and risk estimates considered in the Supplement, the qualitative characterization of aggregate risks for 1,4-dioxane could be appropriate but further evaluation is necessary.

It would be helpful if EPA reflected (in the introduction of this topic in the document) on how this approach aligns with the scientific policies and approaches of other regulatory bodies and authorities. The key issues seem to be TSCA's need for concordance across cancer studies for organ specific effects and how the aggregation over multiple exposure routes and scenarios is to be done. EPA's logic on these key issues could be presented if, indeed, they are leading TSCA on an independent course for this and future assessments.

EPA's rationale for qualitative assessment is discussed in Section 5.2.2.5 on page 164. It states that oral exposure primarily results in liver tumors. This finding is apparently extrapolated to dermal exposure. In contrast, inhalation exposure is associated with multiple tumor types. This seems an inadequate basis for abandoning any attempt at quantitative analysis. The failure to aggregate exposures across pathways is never really explained, except for a reference to "uncertainties." It is important to determine whether the current qualitative aggregation would affect the ultimate decisions on unreasonable risk. Thus, it is recommended additional language to support the decision to perform only a qualitative evaluation of aggregated risk.

Under different exposure scenario situations there may be good reason to offer a counterpoint to EPA's decision to not quantitatively aggregate the exposure routes. However, that effort may be less important for this case given the broad, complex exposure scenarios likely to involve a broad swath of America's residents. Also, the cancer risk calculations show variabilities in orders of magnitude which will not narrowed further by quantitatively aggregating exposure routes. It seems of little value to reopen the hazard assessment (cancer risk) discussions because of these mathematical circumstances. It is, however, important to identify groups of people who are likely to experience high exposures and/or durable exposures—by single or multiple routes. It is important to describe stressors (with some quantitative perspective) which can make such exposures more consequential to people in terms of their vulnerability or response to the cancer occurrence. That is key to meaningful risk assessments and in concert with the Lautenberg Act. EPA's delineation of PESS exposures by any routes (summarized in Table 5-11) does not meet that standard and thus exposure estimation—with or without aggregation-- does not presently address PESS risk.

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