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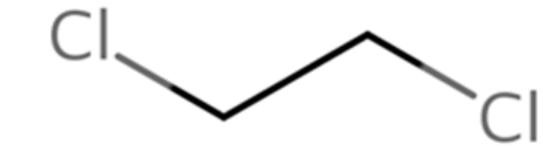
Office of Chemical Safety and
Pollution Prevention

Summary of and Response to Public Comments on the Risk Evaluation for 1,2-Dichloroethane

CASRN 107-06-2



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KEY ACRONYMS AND ABBREVIATIONS

7Q10	Lowest 7-day average flow that occurs (on average) once every 10 years
30Q5	Lowest 30-day average flow that occurs (on average) once every 5 years
ADAF	Age-dependent adjustment factors
AERMOD	American Meteorological Society/Environmental Protection Agency Regulatory Model
AIHA	American Industrial Hygiene Association
AIM	Analog Identification Methodology
AMTIC	Ambient Monitoring Technology Information Center
APF	Assigned protection factor
ATSDR	Agency for Toxic Substances and Disease Registry
BLS	Bureau of Labor Statistics (U.S.)
BMD	Benchmark dose
CAA	Clean Air Act
CBI	Confidential business information
CDR	Chemical Data Reporting
CEHD	Chemical Exposure Health Data
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	Code of Federal Regulations
ChV	Chronic value
CI	Confidence interval
COC	Concentration of concern
COU	Condition of use
CPVC	Chlorinated polyvinyl chloride

CTC	Carbon tetrachloride
CWA	Clean Water Act
DDEF	Data-derived extrapolation factors
DEVL	Dermal Exposure to Volatile Liquids (Model)
DMR	Discharge monitoring report
DOT	Department of Transportation (U.S.)
DRAS	Delisting Risk Assessment Software
ECA	Enforceable Consent Agreement
ECHO	Enforcement and Compliance History Online
EC50	Effect concentration at which 50% of test organisms exhibit an effect
EDC	Ethylene dichloride
EOGRT	Extended one-generation reproductive toxicity
EPA	Environmental Protection Agency (U.S.)
HAP	Hazardous air pollutant
HC05	Hazard concentration that is protective of 95% of the species in the SSD
HEM	Human Exposure Model
IIOAC	Integrated Indoor-Outdoor Air Calculator
ITC	Interagency Testing Committee
K_{OC}	Organic carbon:water partition coefficient
K_{OW}	Octanol:water partition coefficient
LADC	Lifetime average daily concentration
LC50	Lethal concentration at which 50% of test organisms die
LD50	Lethal dose at which 50% of test organisms die
LOD	Limit of detection
LOEL	Lowest-observed-effect level
MCL	Maximum contaminant level
MIE	Molecular initiating event
MRRE	Manufacturer-requested risk evaluations
MTD	Maximum tolerated dose
NEI	National Emissions Inventory
NIOSH	National Institute for Occupational Safety and Health
NOAEL	No-observed-adverse-effect level
NOEL	No-observed-effect level
NPDES	National Pollutant Discharge Elimination System
NRC	National Response Center
OECD	Organisation for Economic Co-operation and Development
OES	Occupational exposure scenario
OEV	Occupational exposure value
ONU	Occupational non-users
OPPT	Office of Pollution Prevention and Toxics (EPA)
OQD	Overall quality determination
OSHA	U.S. Occupational Safety and Health Administration
OW	Office of Water (EPA)
PCE	Perchloroethylene
PESS	Potentially exposed or susceptible subpopulation
POD	Point of departure
PPE	Personal protective equipment
PSC	Point Source Calculator
PTL	Priority Testing List

PVC	Polyvinyl chloride
QA/QC	Quality assurance/quality control
RQ	Risk quotients
SACC	Science Advisory Committee on Chemicals
SDS	Safety data sheet
SEG	Similar exposure group
SSD	Species sensitivity distribution
SSM	Start up, shutdown, and malfunctions
STEL	Short-term exposure limit
TCE	Trichloroethylene
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TSD	Technical support document
TWA	Time-weighted average
UF	Uncertainty factor
UF_H	Intraspecies uncertainty factor
U.S.	United States
USGS	U.S. Geological Survey
VCM	Vinyl chloride monomer
VI	Vinyl Institute
VVWM	Variable Volume Water Model
Web-ICE	Web-based Interspecies Correlation Estimation

1 INTRODUCTION

On November 19, 2025, the U.S. Environmental Protection Agency (EPA or the Agency) published the 2025 *Draft Risk Evaluation for 1,2-Dichlorethane* and accepted public comment until January 20, 2026. Materials on the Draft Risk Evaluation for 1,2-Dichloroethane are available at www.regulations.gov in docket EPA-HQ-OPPT-2018-0427.

This document summarizes all public comments that the EPA's Office of Pollution Prevention and Toxics (OPPT) received for the Draft Risk Evaluation of 1,2-Dichlorethane, including all technical support documents and supplemental files in EPA-HQ-OPPT-2018-0427. It also provides EPA/OPPT's response to the comments received from the public. EPA/OPPT appreciates the valuable input provided by the public. The input resulted in revisions to the *Draft Risk Evaluation for 1,2-Dichlorethane*. Within each theme comments that cover similar topics are presented together:

2. Overarching comments
3. Chemistry, fate, and transport of 1,2-dichlorethane
4. Releases and concentrations of 1,2-dichlorethane in the environment
5. Environmental risk assessment
6. Human health risk assessment
7. Unreasonable risk determination
8. Systematic review
9. Other comments on the draft risk evaluation
10. Comments not relevant to the draft risk evaluation

Appendix A. Summary of and response to external peer review and public comments on the human health hazard technical support document for 1,2-dichloroethane

The draft 1,2-Dichloroethane Human Health Hazard Assessment was peer reviewed by the independent Science Advisory Committee on Chemicals (SACC) with the draft 1,1-Dichloroethane Risk Evaluation September 17 to 19, 2024. The SACC report was published on November 27, 2024; EPA published the 1,1-dichloroethane risk evaluation on June 23, 2025, which included a response to public and SACC comment on the 1,1-dichloroethane risk evaluation and 1,2-dichloroethane human health hazard assessment. A summary of the charge to the SACC for the 1,2-dichloroethane human health hazard assessment, the summary of SACC and public comments, and EPA's response to the SACC and public comment for each charge question are provided in Appendix A Summary of and Response to External Peer Review and Public Comments on the Human Health Hazard Technical Support Document for 1,2-Dichloroethane. In some instances, EPA has made additional updates to the 1,2-dichloroethane human health hazard assessment, which are briefly noted in Appendix A as an "Updated EPA Response" and where those updates are relevant to specific charge questions and prior EPA responses.

Table 1-1. Index of Unique Public Comment Submissions Sorted by Submission Number[a]

Submission Number	Commenter Name	Commenter Type
EPA-HQ-OPPT-2018-0427-0051	Earthjustice et al.	Advocacy organization
EPA-HQ-OPPT-2018-0427-0052	Earthjustice	Advocacy organization
EPA-HQ-OPPT-2018-0427-0053	Earthjustice et al.	Advocacy organization
EPA-HQ-OPPT-2018-0427-0055	American Chemistry Council (ACC)	Industry trade organization
EPA-HQ-OPPT-2018-0427-0056	American Chemistry Council (ACC)	Industry trade organization

Submission Number	Commenter Name	Commenter Type
EPA-HQ-OPPT-2018-0427-0057	Washington State Departments of Ecology and Health	State government agency
EPA-HQ-OPPT-2018-0427-0060	American Chemistry Council (ACC)	Industry trade organization
EPA-HQ-OPPT-2018-0427-0061	American Chemistry Council (ACC)	Industry trade organization
EPA-HQ-OPPT-2018-0427-0064	American Chemistry Council (ACC)	Industry trade organization
EPA-HQ-OPPT-2018-0427-0144	Anonymous	Anonymous
EPA-HQ-OPPT-2018-0427-0148	Safe Piping Matters	Advocacy organization
EPA-HQ-OPPT-2018-0427-0149	Kavya Parsa	Individual commenter
EPA-HQ-OPPT-2018-0427-0150	Vinyl Institute	Industry trade organization
EPA-HQ-OPPT-2018-0427-0151	American Chemistry Council (ACC)	Industry trade organization
EPA-HQ-OPPT-2018-0427-0152	Campus Safety, Health, and Environmental Management Association (CSHEMA)	Advocacy organization
EPA-HQ-OPPT-2018-0427-0153	American Petroleum Institute (API)	Industry trade organization
EPA-HQ-OPPT-2018-0427-0154	Olin Corporation	Chemical manufacturer/importer
EPA-HQ-OPPT-2018-0427-0155	Global Organotin Stewardship Council (GOSC)	Industry trade organization
EPA-HQ-OPPT-2018-0427-0156	Plastic Pipe and Fittings Association (PPFA)	Industry trade organization
EPA-HQ-OPPT-2018-0427-0157	Alliance for Chemical Distribution (ACD)	Industry trade organization
EPA-HQ-OPPT-2018-0427-0158	Alliance for Automotive Innovation	Industry trade organization
EPA-HQ-OPPT-2018-0427-0159	Westlake Corporation	Product manufacturer/importer
EPA-HQ-OPPT-2018-0427-0160	Environmental Defense Fund (EDF)	Advocacy organization
EPA-HQ-OPPT-2018-0427-0161	American Industrial Hygiene Association (AIHA)	Professional association
EPA-HQ-OPPT-2018-0427-0162	Dow Chemical Company	Chemical manufacturer/importer
EPA-HQ-OPPT-2018-0427-0163	American Chemistry Council (ACC)	Industry trade organization
EPA-HQ-OPPT-2018-0427-0164	National Tribal Toxics Council (NTTC)	Federal government agency
EPA-HQ-OPPT-2018-0427-0165	American Fuel & Petrochemical Manufacturers (AFPM)	Industry trade organization
EPA-HQ-OPPT-2018-0427-0166	National Roofing Contractors Association (NRCA)	Industry trade organization
EPA-HQ-OPPT-2018-0427-0169	Vinyl Institute	Chemical manufacturer/importer
EPA-HQ-OPPT-2018-0427-0170	B&C Consortia Management, L.L.C. (BCCM)	Industry trade organization

Submission Number	Commenter Name	Commenter Type
EPA-HQ-OPPT-2018-0427-0171	The Chemours Company	Chemical manufacturer/importer
EPA-HQ-OPPT-2018-0427-0172	California Communities Against Toxics et al.	Advocacy organization

[a] The first 9 (shaded) submissions were submitted between August 2020 and November 19, 2025 (*i.e.,* after final scoping and before publication of the draft risk evaluation for 1,2-dichloroethane).

2 OVERARCHING COMMENTS

Comments associated with this topic are summarized in the subsections below.

2.1 Potentially Exposed or Susceptible Subpopulations, Tribal and Fenceline Communities

2.1.1 Potentially Exposed or Susceptible Subpopulations

Summary: A public commenter (0160) stated that the Toxic Substances Control Act (TSCA) requires that risks to potentially exposed or susceptible subpopulations (PESS) be identified and addressed, Congress did not intend for these groups to be given less protection as the Draft Risk Evaluation for 1,2-Dichloroethane has done. The commenter said that instead of utilizing available data to characterize increased risks from 1,2-dichloroethane to all PESS, as TSCA mandates, EPA assumed that the application of the intraspecies uncertainty factor (UF_H) would address these risks. However, the commenter stated that the uncertainty factor (UF) is intended to merely account for variations in susceptibility within the general population of healthy adults, not designed to address the increased risks faced by specific sub-populations who experience greater exposure to a chemical than the general population and/or possess specific traits that increase their susceptibility to harm.

Similarly, a commenter (0172) said that EPA failed to adequately evaluate 1,2-dichloroethane risks to identified potentially exposed or susceptible subpopulations. The commenter stated that while TSCA excludes "tobacco or any tobacco product" from the definition of "chemical substance," smoking and exposure to second-hand smoke make people more susceptible to harm from 1,2-dichloroethane's conditions of use, mandating that EPA consider these background exposures. Instead, the commenter said that EPA applied a general 10× UF "to account for human variability" while simultaneously asserting that the increase in susceptibility is "not known." Additionally, the commenter said that EPA identified "individuals with preexisting conditions such as chronic kidney disease" as a PESS but did not consider their particular susceptibility to 1,2-dichloroethane or calculate any risks specific to that group. The commenter said that EPA again applied a 10× UF "to account for human variability," but wrote that "susceptible individuals, such as those with chronic kidney disease, may not be accounted for by standard approaches." The commenter also said that EPA failed to address increased risk to people with an aldehyde dehydrogenase-2 mutation, who are more susceptible to cancer, cardiovascular harm, and other serious health harms. The commenter said that EPA acknowledged that the aldehyde dehydrogenase-2 mutation is more likely in people of Asian descent but does not account for increased risks for East Asian populations near releasing facilities nor the more than 6 million people in the United States who are East Asian and may be exposed from any of its conditions of use.

EPA Response: EPA considers multiple PESS groups in its development of risk estimates (including women of childbearing age, all lifestages, individuals with pre-existing health conditions, and genetic predispositions). The Agency does not necessarily provide distinct risk estimates for each subpopulation, because some are already represented by the risk estimates presented while others are not quantifiable (*e.g.,* genetic predisposition, other health conditions). In the absence of quantitative information on the impact of genetic variability, pre-existing health conditions, lifestage, or other factors on susceptibility across the population, EPA applied an uncertainty factor of 10 to account for interindividual variability (Section 7.2 of the *Human Health Hazard Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026j)). Cigarettes release multiple chemicals, including acrolein and pyruvic aldehyde that have been shown *in vitro* to interact with 1,2-dichloroethane to inhibit plasma alpha-1-proteinase inhibitor. This suggests that smokers as well as individuals exposed to passive smoke may be susceptible to greater risk in developing emphysema (Ansari et al., 1988). Because EPA did not identify hazard data evaluating 1,2-

dichloroethane effects in animal models nor human data of co-exposed to cigarette smoke that would corroborate or dismiss this finding, the UF_H of 10 was not modified due to this uncertainty. Data indicate the kidneys as a target organ for 1,2-dichloroethane and thus the oral and dermal points of departure (PODs) used in the risk evaluation were based on kidney effects. As presented in the risk evaluation, individuals with chronic kidney disease may be susceptible due to 1,2-dichloroethane, however, studies were not identified that comorbidities increase the health effects due to 1,2-dichloroethane exposure. An identified metabolite of 1,2-dichloroethane is chloroacetaldehyde, it is a known substrate of aldehyde dehydrogenase-2 based on the work of Sharpe (1993) and it is a known DNA crosslinker according to Organisation for Economic Co-operation and Development (OECD) guidances. The main substrate for aldehyde dehydrogenase-2 is the similar acetaldehyde produced from ethanol consumption. People with the aldehyde dehydrogenase-2 polymorphism may potentially have higher risk to cancer incidences, cardiovascular injury, and other health effects due to increased aldehyde formation and decreased clearance of reactive aldehydes (Gross et al., 2015). Hazard data evaluating an animal model for this gene polymorphism was not identified; however, the aldehyde dehydrogenase-2 inhibitor disulfiram was shown to increase tumor incidences based on co-exposure but not to 1,2-dichloroethane or disulfiram alone. Additionally, increased blood levels of 1,2-dichloroethane by 5-fold as a result of this co-exposure and decreased metabolite formation suggest 1,2-dichloroethane accumulation and decreased urinary clearance in the rodent model (Cheever et al., 1990). Thus, the Agency acknowledges that there is uncertainty around the magnitude of variation in toxicokinetic and toxicodynamic factors across individuals.

The UF_H was established to account for uncertainty and variability that includes susceptible subpopulations, and research indicates that a factor of 10 (when considering both toxicokinetics and toxicodynamics) is sufficient in most cases (U.S. EPA, 2002b). Therefore, EPA expects that the UF_H used in the risk evaluation should account for a significant portion of the intraspecies variability that include susceptible subpopulations applicable to 1,2-dichloroethane. A refinement to the UF_H would be warranted in cases where the susceptible subpopulation is specifically defined (*e.g.,* through knowledge of the chemical's mode of action); however, the Agency does not have any reasonably available data that would support modifying the UF beyond the standard 10× as recommended by EPA Guidance (U.S. EPA, 2002b). Furthermore, EPA guidance on derivation of data-derived extrapolation factors (DDEF) requires a strong understanding of the mode of action for the endpoint of interest with relevant quantitative data informative of specific key events underlying the endpoint. This understanding must also include knowledge of the toxicokinetic exposure-response associated with the endpoint (U.S. EPA, 2014).

As described previously, there is insufficient mechanistic information supporting any mode of action and it is unclear whether any metabolite is more or less important. Therefore, the Agency relied on default dosimetric adjustments and did not establish a DDEF to derive points of departure for these endpoints in accordance with Agency guidance (U.S. EPA, 2014). EPA applied benchmark dose modeling to the hazard data within the assessment that allowed for the reduction of experimental uncertainty that can be attributed to study design and sample size resulting in high confidence in the results. Furthermore, to account for increased risks faced by PESS who experience greater exposure scenarios to 1,2-dichloroethane, EPA considered high-end exposure estimates for acute and intermediate inhalation and dermal exposures to workers and occupational non-users (ONUs; unless personal protective equipment [PPE] reported in the test order indicated this would be an overestimation; see Section 6.2.1 of the final risk evaluation) and the general population. By using Human Exposure Model (Version 5.0) modeling for the general population analysis in the final risk evaluation, EPA was able to identify and characterize risks to the general population and was able to identify populations that are likely living nearest to 1,2-dichloroethane emitting facilities (and thus considered PESS). The use of

high-end facility reported releases from 1,2-dichloroethane emitting facilities across multiple reporting years provides robust evidence that high-end exposures were captured during the HEM5.0 modeling (see Section 5.3.6.2.1 of the final risk evaluation).

2.1.2 Fenceline Communities

Summary: In a comment submitted before the publication of the *Draft Risk Evaluation for 1,2-Dichloroethane* (U.S. EPA, 2025e), a public commenter (0052) said EPA should not limit its analysis to only fenceline communities who "live within 100 to 1,000 meters from the emitting source(s)," but instead identify relevant communities by taking into account multiple exposure factors (*e.g.,* quantity or volume of the chemical released in a particular area, specific release pathways from the relevant facilities, individual chemical's capacity for transport in various environmental media, and the chemical's capacity for environmental persistence and uptake) and susceptibility factors (*e.g.,* a community's exposure to multiple chemicals with the same adverse health endpoints, prevalence of underlying disease in the community, and prevalence of psychosocial stress arising from factors such as poverty, food insecurity, healthcare inequity, and racial injustice). The commenter recommended that EPA, at a minimum, consider potentially exposed or susceptible sub-populations communities near high-volume chemical facilities in the Greater Houston Area; in and around Port Arthur, Texas; in and around Mossville, Louisiana; in and around the Rubbertown area of Louisville, Kentucky; and along the Mississippi River between Baton Rouge and New Orleans, Louisiana, in the area known as "Cancer Alley." The commenter concluded that EPA's current scope documents violate statutory and regulatory requirements to identify with specificity the relevant greater-risk subpopulations.

Similarly, a public commenter (0148) said EPA must incorporate fenceline communities near plastic plants using 1,2-dichloroethane into the risk evaluation where low-income residents already experience cumulative environmental burdens and community-level health disparities.

EPA Response: The Agency used its previously peer -reviewed approach to evaluate fenceline and community exposures and acknowledges that proximity alone does not define PESS. Using 1,2-dichloroethane facility-specific releases and fate/transport properties, EPA modeled ambient air with HEM5.0 at census block centroids out to 50,000 m (see *Environmental Media Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026g), Section 3.1). Between the publication of the scope and risk evaluation, the Agency identified 1,2-dichloroethane releasing facilities including the communities identified by the commenter. Using HEM 5.0, EPA conducted an aggregate analysis incorporating reported air releases from facilities that manufacture 1,2-dichloroethane and evaluated risks to the general population and PESS from 1,2-dichloroethane's conditions of use (COUs), including facilities in the regions cited by commenters when supported by release data. Although TSCA does not require a cumulative assessment across multiple chemicals or stressors, the Agency considered PESS and applied health protective assumptions- and methods (see Section 5.3.2. of the Risk Evaluation for 1,2-Dichloroethane). However, if EPA identifies potential non-chemical stressors that may be reasonably anticipated to impact risk estimates from chemical substance exposures, then the Agency may include a qualitative discussion of the non-chemical stressors and their potential impact on a case-by-case basis until such time that peer-reviewed, Agency-wide guidance for quantitative evaluation of non-chemical stressors is available.

2.1.3 Tribal Communities

Summary: A public commenter (0164) requested that EPA evaluate tribal exposures and risk to 1,2-dichloroethane in the final risk evaluation by applying appropriate tribal exposure factors, using an appropriate lifetime exposure value, evaluating all age groups, and aggregating exposures before determining risk. The commenter said that EPA failed to apply appropriate fish consumption rates,

consider additional tribal exposure pathways, aggregate exposures across pathways and conditions of use, and include the most vulnerable tribal groups from its analysis (*i.e.,* children and elders). The commenter added that grouping tribal fish ingestion with that of subsistence fishers is not appropriate.

EPA Response: EPA acknowledges that there are different fish consumption rates for different lifestages and has included children's tribal consumption rates from the tribes in Minganie and Lower North Shorre regions of Quebec, Canada, as a representation of possible children's fish consumption rates for children in the Navajo Nation in the final risk evaluation (see Section 4.4 of the General Population technical support document [TSD] and Section 5.1.2.3.4 of the 1,2-Dichloroethane Risk Evaluation). The assumption that children in the Navajo Nation have the same fish consumption rate as those in the Minganie and Lower North Shorre regions of Quebec, Canada, is conservative given regional dietary differences. Using this conservative fish consumption rate, the 1,2-dichloroethane exposure estimate to children (lifestages 3–5, 6–11, and 12–19 years) still did not result in risk below benchmark for exposures via fish consumption.

The Agency also considered adult (21+ years of age) tribal ingestion of fish in the Navajo Nation where 1,2-dichloroethane is released into surface waters. Risks to elders are also encompassed within the adult analysis and in lifetime cancer risk estimates (78-year exposure duration) in the final risk evaluation.

EPA does not have Navajo Nation-specific data regarding time of contact of water to estimate exposure. Therefore, EPA used the swimming scenario as a conservative estimate of dermal exposures and when added to oral exposures via fish ingestion, the total exposures (see Section 5.1.4 of the *Risk Evaluation for 1,2-Dichloroethane* (U.S. EPA, 2026m)) result in risk estimates that are still well above the non-cancer benchmark (see Section 5.3.7 in the *Risk Evaluation for 1,2-Dichloroethane* (U.S. EPA, 2026m)).

EPA did not identify inhalation exposures for the Navajo Nation from reported surface water releases.

EPA welcomes continued discussion with the tribes on the use of fish consumption information in risk assessment.

2.2 Byproducts

Summary: A public commenter (0172) said that EPA's assessment of risks from 1,2-dichloroethane byproducts is arbitrary, capricious, and inconsistent with TSCA, because EPA unlawfully excludes two known byproducts from consideration (*i.e.,* 1,1,2-trichloroethane and *trans*-1,2-dichloroethylene). The commenter wrote that TSCA requires EPA to evaluate each chemical's risk "under the conditions of use," which here includes the known byproducts of 1,2-dichloroethane manufacturing. Similarly, another public commenter (0160) stated that EPA should assess the risk from 1,1,2-trichloroethane and *trans*-1,2-dichloroethylene as part of its byproduct assessment, reasoning that even if the Agency does assess the byproduct risks in their individual risk evaluations, EPA must still consider their risk as byproducts from 1,2-dichloroethane manufacture in this risk evaluation. The commenter added that not including these risks could significantly change the risk management needed for 1,2-dichloroethane that then could not be fully addressed in the individual byproduct risk evaluations.

Another public commenter (0169) said that delaying the assessment of trans-1,2-dichloroethylene and 1,1,2-trichloroethane is inconsistent with the final scope for 1,2-dichloroethane, which established that EPA would assess all seven byproducts of 1,2-dichloroethane production (1,1-dichloroethane, 1,1,2-trichloroethane, trans-1,2-dichloroethylene, trichloroethylene [TCE], perchloroethylene [PCE], methylene dichloride, and carbon tetrachloride [CTC]) during the 1,2-dichloroethane risk evaluation. Similarly, a public commenter (0170) expressed surprise that EPA excluded an assessment of *trans*-1,2-

dichloroethylene as a byproduct of 1,2-dichloroethane production, because the final scope of 1,2-dichloroethane unequivocally stated that the *trans*-1,2-dichloroethylene byproduct would be assessed during the risk evaluation of 1,2-dichloroethane. This unannounced change in approach from the 2020 final scope creates confusion for stakeholders and raises concern about the predictability of EPA's future scoping decisions. The commenter suggested that EPA articulate and apply a more coherent policy for when and where it will consider byproducts in the scope of TSCA risk evaluations.

EPA Response: EPA acknowledges that 1,2-dichloroethane manufacture can produce *trans*-1,2-dichloroethylene (CASRN 156-60-5) and 1,1,2-trichloroethane (CASRN 79-00-5) as byproducts. As stated in the final risk evaluation's executive summary, the Agency will assess these chemicals in forthcoming, separate risk evaluations for *trans*-1,2-dichloroethylene and 1,1,2-trichloroethane.

TSCA requires EPA to evaluate risks "under the conditions of use" for each chemical substance. The Agency will consider the production of *trans*-1,2-dichloroethylene and 1,1,2-trichloroethane as byproducts of 1,2-dichloroethane manufacture as conditions of use in each chemical's respective risk evaluation. This ensures that each byproduct is evaluated with the best available science specific to that substance. Hazard values for *trans*-1,2-dichloroethylene and 1,1,2-trichloroethane are still under review and will be included in their forthcoming draft risk evaluations.

Because the toxicity assessments for *trans*-1,2-dichloroethylene and 1,1,2-trichloroethane are not yet complete, EPA determined that not evaluating the *trans*-1,2-dichloroethylene and 1,1,2-trichloroethane potential hazards within the 1,2-dichloroethane risk evaluation, while continuing to evaluate other byproducts (*e.g.,* 1,1-dichloroethane, trichloroethylene, perchloroethylene, methylene dichloride, and carbon tetrachloride), allows the Agency to apply updated hazard science and ensure a robust, chemical-specific analysis. EPA described the change in approach from the *Final Scope of the Risk Evaluation for 1,2-Dichloroethane; CASRN 107-06-2* (U.S. EPA, 2020) in the 1,2-Dichloroethane Draft Risk Evaluation (see Executive Summary (U.S. EPA, 2025e) and the supporting *Draft 1,2-Dichloroethane Byproducts Assessment* (see Summary and Section 1.1 (U.S. EPA, 2025a) and made it available for public comment. As explained in our response, this change reflected the information reasonably available at the time the 1,2-Dichloroethane Draft Risk Evaluation was published. EPA recognizes the concern that this decision could affect risk management for 1,2-dichloroethane. To mitigate this, the Agency plans for the draft risk evaluations for *trans*-1,2-dichloroethylene and 1,1,2-trichloroethane to be available for public comment and peer review prior of EPA issuing proposed risk management for 1,2-dichloroethane. The Agency will coordinate these actions and consider relevant information from the risk evaluations of *trans*-1,2-dichloroethylene and 1,1,2-trichloroethane when developing risk management for 1,2-dichloroethane, to avoid gaps or misalignment.

Deferring assessment of these two byproducts until their hazard evaluations are complete ensures use of the best available science because the hazard evaluations will reflect the most recent scientific information. If the formulation of these chemicals as byproducts is found to significantly contribute to the unreasonable risk of the chemical substance, EPA would address it in the respective chemical-specific rulemakings, rather than through the 1,2-dichloroethane rulemaking. This approach is neither arbitrary nor capricious; it reflects a structured, science-based sequencing that aligns with TSCA's best-available-science standard.

Summary: A public commenter (0163) expressed concern that EPA's assessment mischaracterizes the risks from the production of CTC and TCE as byproducts, based on a limited set of data. The comment

described that EPA relied on overly conservative assumptions of the concentrations of these substances. Specifically, the comment noted the following:

1. The draft risk evaluation ignores the information provided by the Vinyl Institute that these two substances are unlikely to be generated during ethylene dichloride (EDC) manufacture using the direct chlorination process.
2. Risk calculations are based on worst-case estimates of CTC and TCE produced in the process.
3. Expressed concern with the high-end exposure estimates because the draft risk evaluation appears to assume the concentrations found in process streams that compose only a small fraction of the total stream from the EDC manufacturing process.

The commenter (0163) also added that they are concerned that decoupling the consideration of byproducts from the primary chemical has the potential for a duplicative risk management process, which may increase the regulatory burden on the regulated community.

Another public commenter (0169) stated that EPA's risk determinations for byproducts are erroneous. Specifically, the comment noted the following:

- EPA has taken a radically conservative approach to estimating byproduct concentrations by relying on concentrations estimated for these byproducts in minor process streams, instead of the 0.0035% and 0.15% concentrations TCE and CTC, respectively, found in 1,2-dichloroethane manufacturing using the oxychlorination process.
- Moreover, EPA has also failed to account for the combined use of the oxychlorination process and the direct chlorination process at most 1,2-dichloroethane manufacturing facilities, and the fact that direct chlorination does not produce appreciable concentrations of TCE and CTC. Concentration data provided to EPA were high-end estimates of the byproducts in specific streams, and that EPA's approach to use of this information was not described in a way that permits review by commenters.
- EPA's Monte Carlo distribution is not provided in the docket and that EPA should rely on central tendency concentrations rather than high-end concentrations for evaluation of byproducts, including TCE and CTC. According to the commenter, it is inappropriate to base the high-end exposure on the light or heavy ends because this is an example of compounding conservatism.
- EPA appeared to make an error in the calculations for TCE presented for ONUs, noting that values presented different documents. Additionally, the commenter noted that EPA erroneously stated that the byproduct TCE significantly contributes to unreasonable risk through chronic, non-cancer dermal risk for workers at high-end exposures and that the basis for this conclusion is unclear.
- EPA inaccurately describes the scope of its risk findings with respect to both inhalation and dermal exposure to CTC in the Draft Risk Evaluation for 1,2-Dichloroethane, where EPA states that CTC contributes to unreasonable risk due to "chronic, non-cancer risk and cancer risk for operators, maintenance technicians, and laboratory technicians, at both central tendency and high-end inhalation and dermal exposures, as well as for ONUs at high-end inhalation exposures." The commenter said that EPA must correct its discussion of its findings in the Draft Risk Evaluation for 1,2-Dichloroethane to correctly reflect its exposure estimates, citing both Table 6-3 of the Draft Risk Evaluation for 1,2-Dichloroethane and Table 6-4 of the Draft Byproducts Assessment, which indicate that EPA's assessment:

    - only show chronic, non-cancer risk for one similar exposure group (SEG), operators, at both central tendency and high-end inhalation exposures; the remainder of the chronic, non-cancer inhalation risks were found at high-end exposure only;
    - only show cancer risk for logistics technicians at high-end exposure; and
    - dermal risks were only estimated (and thus, could only be found) for central tendency exposure.
- The TCE risk management rule only exempts byproduct TCE processed within the same site-limited, physically enclosed system that it was generated in, which places unrealistic conditions on the exclusion. The commenter stated that it is critical that EPA not repeat these mistakes as it evaluates byproduct TCE associated with 1,2-dichloroethane production. The commenter said that EPA must understand that even enclosed systems do not operate under an airtight, hermetic seal, and EPA must recognize the nuances of chemical manufacturing processes in evaluating any potential risks presented by byproduct TCE.

EPA Response: EPA acknowledges concerns from the public comments regarding EPA's approach to estimating byproduct concentrations. EPA has revised the *Byproducts Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026a) so that the methods EPA utilized are described in more clarity (see Section 4.1.1.3 Occupational Exposure Methodology). Specifically, EPA has updated this section to include more specificity on the byproduct concentrations utilized to estimate inhalation exposures of byproducts, including TCE) and carbon tetrachloride CTC. The byproduct concentrations mentioned in the public comments (0.0035% TCE and 0.15% CTC) were utilized in the calculation of "low-end exposure estimates," which were based on the weight percent of the byproduct in the unpurified 1,2-dichloroethane stream (as described in Section 4.1.1.3 of the Byproducts Assessment for 1,2-Dichloroethane). High-end concentrations were estimated for each of the byproducts based on the maximum weight percent of the byproduct in light- and heavy-end liquid streams.

Because inhalation risks were identified for TCE and CTC, EPA utilized Monte Carlo methods as a refined method to estimate inhalation exposures for these byproducts. EPA has provided more description of this analysis, including the underlying distribution type (see Section 4.1.1.3 of the *Byproducts Assessment for 1,2-Dichloroethane*). Additionally, EPA seeks to clarify that the monte-carlo modeling did not assume that each SEG had 50% exposure to the higher of the light and heavy ends, and 50% exposure to the unpurified 1,2-dichlorethane. The Monte Carlo had two distributions: (1) byproduct weight fraction and (2) inhalation exposure expressed as an 8-hour time-weighted average (TWA). The byproduct weight fraction was a uniform distribution ranging from the lowest expected concentration for the given byproduct to the highest expected concentration. For each SEG, EPA used a triangular distribution with the min/max 8-hour TWAs as the lower/upper bounds, and the 50th percentile as the mode.

EPA acknowledges concerns that high-end exposure estimates of the byproducts may be compounding conservatism. In the Risk Evaluation, EPA has indicated that for the byproducts analysis, the high-end estimates combined both highest exposures and highest byproduct weight percent and may be overly conservative for assessment of chronic risks for workers and ONUs. EPA believes that the methods utilized as well as the underlying confidence in the data (as described in Sections 5.3.4.1 and 5.3.8.2 of the Risk Evaluation) support the use of high-end exposures for assessment of non-cancer acute and intermediate risks and the central tendency for the assessment of non-cancer chronic and cancer risks for the evaluation of TCE and CTC risks (EPA notes that neither acute nor intermediate risks were identified for any of the byproducts).

EPA has reviewed the comments regarding erroneous calculations or inaccurate statements in the byproducts assessment and has made necessary corrections. Specifically, regarding TCE, EPA has corrected the reporting of risk estimates in the final risk evaluation, which shows no risk for dermal exposure to workers and inhalation exposure to ONUs from TCE produced as a byproduct during the manufacture of 1,2-dichloroethane. EPA notes that the inhalation risk estimates indicate that ONUs are shown to meet the benchmark MOE for chronic non-cancer at both the central tendency (MOE = 198) and high-end exposures (MOE = 44). EPA has updated the byproducts section of the risk determination for workers, removing the dermal and ONU inhalation risk that was stated in error. Additionally, EPA has corrected its discussion of findings related to CTC risks, specifically to clarify that inhalation chronic, non-cancer risks were observed at the central tendency and high-end for operators only; inhalation cancer risks were observed for logistics technicians at the high-end exposure only; and that dermal cancer risks to workers are only present at the central tendency (see Section 6.2 of the Final Risk Evaluation). EPA did not estimate high-end dermal exposures because the central tendency from the closed system monitoring data is a more representative and appropriate exposure estimate for a frequent, repeated dermal exposure (*i.e.,* chronic) and is health protective for risk estimation for closed system processes.

EPA acknowledges the comments on understanding the nuances of chemical manufacturing processes that while operating within enclosed systems they do not operate under an airtight, hermetic seal and the need to reflect this understanding in the risk evaluation. EPA uses data on emissions and inhalation exposures from chemical manufacturing facilities that supports that chemical manufacturing processes are not operated under an airtight, hermetic seal.

Summary: A public commenter (0172) said that EPA understates the risks of TCE (one of the byproducts of 1,2-dichloroethane) by ignoring strong scientific evidence linking TCE exposure to fetal heart defects. Instead of using this most sensitive and health-protective endpoint, EPA based its Byproducts Assessment on immune system effects, which occur only at higher exposure levels. The commenter said that this approach traces back to political interference in the earlier TCE risk evaluation, where White House staff directed EPA to rely on a less sensitive endpoint. The commenter said that EPA has since acknowledged that fetal cardiac defect studies are scientifically valid and should not be excluded. However, the commenter said that, despite this, the 1,2-dichloroethane Byproducts Assessment offers no justification for disregarding them and relies instead on the compromised prior TCE evaluation, which fails to consider TCE's most sensitive effect, leading EPA to depart from the best available science and understate the risks posed by 1,2-dichloroethane byproducts.
A public commenter (0169) stated that EPA's noncancer risk estimates for byproduct TCE in the EDC risk evaluation inappropriately rely on the TCE risk evaluation's use of Keil et al. (2009) immunotoxicity data to derive a POD for an existing chemical exposure limit (ECEL). Citing the TSCA best-available-science standard and prior stakeholder input from the TCE section 6 process, the commenter argued that Keil et al. (2009) is not suitable for this purpose and that EPA should not rely on Keil et al. (2009) or Johnson et al. (2003) in the EDC evaluation.

EPA Response: EPA's 2020 Risk Evaluation for richloroethylene (accessed May 5, 2026) was subject to peer review and public comment and was the result of a systematic review approach which investigated the reasonably available information in order to identify relevant adverse health effects. For TCE, the description of relevant adverse health effects starts on page 8 of the Trichloroethylene (TCE) Final Rule (accessed May 5, 2026). Therefore, EPA is not making changes to the risk evaluation and use of the health hazard information from the risk evaluation for evaluating the chemical's production as a byproduct is appropriate.

Summary: A public commenter (0169) argued that EPA's health hazard value for carbon tetrachloride (CTC) does not reflect the best available science. They said EPA's byproduct CTC cancer risk estimates rely on benign pheochromocytomas in rodents from Nagano et al. (2007), an endpoint whose relevance to humans is highly uncertain. The commenter asserted this endpoint should not be used for cancer risk calculations or to set an ECEL. Instead, they recommended a threshold approach based on liver tumors from the same Nagano study. They urged that, in the EDC risk evaluation, EPA should not rely on the pheochromocytoma endpoint.

EPA Response: EPA's 2020 Risk Evaluation for carbon tetrachloride (CTC) (including the use of the Nagano et al. (2007) study) was subject to peer review and public comment and was the result of a systematic review approach which investigated the reasonably available information in order to identify relevant adverse health effects. For CTC, the description of relevant adverse health effects starts on page of the Carbon Tetrachloride Final Rule (accessed May 5, 2026). Therefore, EPA is not making changes to the risk evaluation and use of the health hazard information from the risk evaluation for evaluating the chemical's production as a byproduct is appropriate.

Summary: A public commenter (0169) discussed the TCE risk evaluation and final risk management rule, concluding that now that EPA is evaluating the manufacturing, processing, and disposal of TCE formed as a byproduct of 1,2-dichloroethane production, this evaluation and determination should supersede any prior evaluation during the TCE risk evaluation and risk management processes.

EPA Response: EPA's evaluation of TCE produced as a byproduct during the manufacturing of 1,2 dichloroethane adds to, rather than replaces, the Agency's previous risk evaluation of TCE. EPA emphasizes that this risk evaluation only assesses the risk presented by TCE produced as a byproduct during the manufacturing of 1,2-dichloroethane—not the processing and nearly all disposal of the byproduct TCE. Furthermore, this risk evaluation is not intended to supersede any prior risk evaluation under TSCA section 6, but rather to provide a thorough analysis of the risks presented by the byproducts produced during the manufacture of 1,2-dichloroethane.

With the publication of this final risk evaluation and the identification of unreasonable risk, the Agency will be moving forward with risk management by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that the chemical substance no longer presents an unreasonable risk. During the risk management stage, EPA will consider a variety of relevant factors in choosing one or more of the available TSCA section 6(a) regulatory tools, including the extent to which these byproducts are already regulated under TSCA to avoid a duplicative risk management process.

2.3 Cumulative Risk

Summary: A public commenter (0172) said that by segmenting the consideration of 1,2-dichloroethane's byproducts into three separate risk evaluations, EPA arbitrarily understates the cumulative risks to people who are exposed to 1,2-dichloroethane byproducts in combination and in violation of TSCA. The commenter said EPA also ignores the cumulative effects and instead evaluates each byproduct in isolation. The commenter said that, instead, EPA must consider all risks associated with 1,2-dichloroethane's conditions of use, including all byproducts of 1,2-dichloroethane manufacturing, in the current risk evaluation. Another public commenter (0160) said that EPA is required to holistically assess the risks associated with manufacturing 1,2-dichloroethane, including all byproducts. The commenter said that EPA must correct its byproduct assessment to include these exposures and estimate the full risks from all byproducts of 1,2-dichloroethane manufacture.

EPA Response: A cumulative risk assessment across byproducts was considered but ultimately not performed based on the two principal considerations for grouping chemicals of toxicologic similarity and co-exposure over a relevant timeframe, as outlined in multiple guidance documents from EPA (2016, 2003b, 2002a, 2000, 1986), OECD (2018), and World Health Organization/International Programme on Chemical Safety (WHO/IPCS; (Meek et al., 2011)). With regard to the 1,2-dichloroethane byproducts, though there are co-exposures to the byproducts in the Manufacturing COU, there are different apical health outcomes associated with each of the identified byproducts; thus, assessing toxicologic similarity across the byproducts for both non-cancer and cancer outcomes introduces uncertainties to how risk can be combined. As outlined in the above guidances, evidence for toxicological similarity exists along a continuum and includes but may not be limited to identical toxicodynamics (*i.e.*, same molecular initiating event [MIE], downstream key events, and apical outcome), similar toxicodynamics (*e.g.*, different MIE, convergent toxicodynamic pathways leading to a common downstream effect, and same apical outcome), shared syndrome, shared apical outcome (MIE and other key events unknown), effect on the same target organ, and structural similarity or similarly shaped dose-response curves in comparable toxicity studies. Empirical evidence from mixture studies may provide support for establishing a cumulative risk assessment; however, when the reasonably available information is limited to an effect on the same target organ this approach may introduce too much uncertainty for risk estimates. Furthermore, chemicals that neither result in a common adverse effect nor possess common mechanism of toxicity also limits the utility in applying a "response additon," the joint risk of a common effect being approximated as the sum of the individual risks (2003b, 2000). In the case of the 1,2-dichloroethane byproducts, common adverse/apical effects, mechanisms of toxicity and modes of action were not identified so the "response addition" approach was not considered appropriate to perform a cumulative risk assessment.

Although the manufacture of 1,2-dichloroethane also produces *trans*-1,2-dichloroethylene (CASRN 156-60-5) and 1,1,2-trichloroethane (CASRN 79-00-5) as byproducts, these chemicals will be assessed in forthcoming risk evaluations for 1,1,2-trichloroethane and *trans*-1,2-dichloroethylene (accessed May 5, 2026), as stated in the Executive Summary of the 1,2-Dichloroethane Risk Evaluation. Derivation of the PODs for these chlorinated solvents are still under development and will be included in forthcoming draft risk evaluations for each of these chemicals. Completion of these chemical-specific risk evaluations will allow for a more comprehensive exposure assessment, which will include exposures to these chemicals as byproducts in the Manufacturing COU.

2.4 Conditions of Use and Accidental Releases

Summary: A public commenter (0160) requested that EPA quantitatively include reasonably foreseen accidental chemical releases and releases from distribution in commerce as part of the risk evaluation. The commenter cited recent analyses and requirements demonstrating the large quantity of accidental releases and emissions from start up, shutdown, and malfunctions (SSM) events. The commenter added that the TSCA program has long recognized that releases from distribution in commerce are subject to TSCA, and EPA should again consider them as part of the evaluation of 1,2-dichloroethane risks. Another commenter (0052), in a comment submitted before the publication of the Draft Risk Evaluation for 1,2-Dichloroethane, also expressed that EPA must consider exposures associated with accidental chemical releases, facility malfunctions, start-up/shutdown processes, and background exposure. A public commenter (0157) discussed exposure to 1,2-dichloroethane during distribution operations. The commenter recommended EPA incorporate distribution-specific exposure data where available and explicitly invite the submission of such data in order to ensure that worker exposure estimates align with the operational realities of chemical distribution.

EPA Response: EPA generally does not include exposures associated with extreme weather events within the scope of the risk evaluation. Releases are considered in risk evaluations if such events do lead to regular and predictable exposures associated with a given condition of use. Although accidents were not evaluated as COUs, releases from those events were included in the information that informed the 1,2-dichloroethane risk evaluation, including the Toxic Release Inventory [TRI]) database and ambient air monitoring information. The Agency used TRI-reported air emission data to estimate ambient air concentrations from COUs, using the American Meteorological Society/Environmental Protection Agency Regulatory Model (AERMOD) and HEM). TRI emission data include releases from SSM events, because the TRI release definition broadly covers any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment of any toxic chemical (40 CFR 372.3). Specifically, in Part II, Section 8.8, of the TRI reporting form, an owner/operator must report the quantity of any release of a toxic chemical into the environment or transferred off-site as a result of a remedial action, catastrophic event, or one-time event not associated with production processes.

EPA does consider the activities and releases from distribution in commerce as part of the evaluation; however, these are considered within each COU rather than within one Distribution in commerce COU. EPA's approach for quantitatively assessing releases and exposures for the remaining aspects of distribution in commerce consists of searching DOT and NRC data for incident reports pertaining to 1,2-dichloroethane distribution.

2.4.1 Conditions of Use

Summary: A public commenter (0157) said that EPA's evaluation does not clearly differentiate distribution-only activities within the 15 conditions of use and that clarifying whether warehouse handling, loading and unloading of sealed containers, and transportation are included among the conditions of use driving unreasonable risk determinations, in order to help ensure the final evaluation accurately reflects distribution exposures. The commenter added that chemical distributors do not manufacture 1,2-dichloroethane but usually handle it only in closed or sealed containers during short-term, task-based activities. The commenter states that these are short-duration, task-based activities that differ from the continuous or longer-term exposures associated with manufacturing or processing.

EPA Response: In Appendix E (the COU descriptions) of the *Risk Evaluation for 1,2-Dichloroethane* (U.S. EPA, 2026m), EPA describes the Distribution in commerce COU and has included the full TSCA section 3(5) definition of distribution in commerce. Furthermore, EPA added a new table to the Distribution in Commerce OES that describes distribution in commerce applicable to each OES. This information is provided in Table 3-8 of the *Environmental Release Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026h). Additionally, EPA considers activities conducted by third-party distributors that operate outside of the Manufacturing and Processing COUs (*e.g.,* Repackaging) to be part of Distribution in commerce COU.

Activities conducted by third-party chemical distributers (*e.g.,* warehouses not related to manufacturing or processing of 1,2-dichloroethane) may include loading/unloading, repackaging and transportation. Any activity at these sites that involves transfers of the chemical, such as repackaging into smaller containers, would be assessed under the Repackaging OES. Regarding loading/unloading, EPA expects all the products and/or articles to be transported in closed systems or otherwise to be transported in a form (*e.g.,* articles containing the chemical) such that there is negligible potential for releases except during an incident. Therefore, no occupational exposures are reasonably expected to occur and no separate assessment was performed for exposures from Distribution in Commerce OES.

2.5 Data to Be Considered by EPA/TSCA Requirements

Summary: In a comment submitted before the publication of the Draft Risk Evaluation for 1,2-Dichloroethane, a public commenter (0052) responded to EPA's publication of the 74th Report of the Interagency Testing Committee (ITC) by recommending that EPA implement its duties arising from the ITC's addition of the high-priority substances, including 1,2-dichloroethane, to the Priority Testing List (PTL) (0051). These recommendations included issuing test orders to fill the data gaps for the TSCA high-priority substances and requiring all manufacturers, importers, and processors to submit unpublished health and safety studies about the high-priority substances, pursuant to TSCA section 8(d). The commenter also suggested EPA use its authority under TSCA section 8(c) to issue data requests for every chemical undergoing risk evaluation to identify facilities, materials, or products that use or release the chemical and communities exposed.

The commenter said EPA should use its authority under section 4 of TSCA to obtain more information about human and environmental exposure and hazard to chemicals undergoing risk evaluation. For example, EPA should:

- seek quantitative empirical data on releases to air, water, and soil so it has an accurate understanding of exposure to human and ecological receptors;
- require manufacturers to conduct sampling of ambient air, surface water, and sediment near sites where risk evaluation chemicals are manufactured, processed, used, and disposed of to better characterize exposure;
- order manufacturers whose facilities are known or reasonably foreseen to release significant volumes of chemicals undergoing risk evaluation to conduct testing to measure their releases into air and water;
- direct manufacturers to contract with academic or other not-for-profit institutions to conduct a study with Institutional Review Board approval that is designed to obtain or generate information about indoor or residential exposures to chemicals undergoing risk evaluation—particularly in communities near facilities that are known or reasonably foreseen to release and/or transfer large volumes of any of these chemicals; and
- use its authority under TSCA section 4(a) to require hazard testing for all high-priority chemicals included on the Priority Testing List (PTL) of the TSCA Interagency Testing Committee (ITC).

Following the publication of the Draft Risk Evaluation for 1,2-Dichloroethane, multiple public commenters (0170, 0171) recommended incorporating data into the final risk evaluation that was submitted to EPA in compliance with a 2021 test order and 2006 consent order. One of the commenters, an industry trade organization (0170), added that they have a vested interest in ensuring that EPA's exercise of its TSCA section 4 test order authority is closely tied to a specific need for the information and that the information generated is used by EPA to inform its analyses and decisions in TSCA section 6 risk evaluations. A public commenter (0169) discussed the key data, studies, and references they provided as part of responses to the TSCA section 4 test orders and throughout the risk evaluation that were not considered by EPA.

Another public commenter (0155) recommended that EPA consider all data submitted by industry, including results of EPA mandated testing, rather than data generated by computer modeling.

EPA Response: EPA obtained and considered reasonably available information, defined as information the Agency possesses or can reasonably obtain and synthesize within statutory deadlines. The 1,2-dichloroethane draft scope document describes these sources, including peer-reviewed and gray literature databases; TSCA submissions under sections 4, 8(d), and 8(e); and FYI submissions. The

Agency sought public comment on the draft scope and considered submitted or otherwise identified information, as appropriate, in developing the subsequent draft risk evaluation. For 1,2-dichloroethane, EPA determined that multiple TSCA authorities and data sources (sections 4, 8(a), 8(d) and 8(e)) were the appropriate authorities under which to obtain the reasonably available information to conduct a risk evaluation that meets TSCA's scientific standards to support a determination under section 6.

Under section 8(d), EPA finalized a Health and Safety Data Reporting Rule in June 2021 (86 FR 34147) to obtain unpublished studies. Under section 4, the Agency issued test orders (EPA-HQ-OPPT-2018-0427-0050; EPA-HQ-OPPT-2018-0427-0069) for 1,2-dichloroethane (Stantec ChemRisk, 2024; BASF, 2021) and 1,1-dichloroethane (Stantec ChemRisk, 2023) to develop worker and ONU inhalation exposure data, worker dermal exposure data (Stantec ChemRisk, 2024) (Stantec ChemRisk, 2023), and earthworm reproductive hazard data (the latter was extinguished due to test infeasibility from volatility). Environmental hazard gaps for benthic organisms were addressed using section 4 test order data from analog substances (1,1-dichloroethane, 1,2-dichloropropane, and 1,1,2-trichloroethane; (U.S. EPA, 2025c; Smithers, 2024a, b)).

The Agency also exercised its TSCA section 4 authorities pre-Lautenberg to gather additional information on 1,2-dichloroethane, which is summarized in Section 3.6 of the *Human Health Hazard Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026j). EPA published a proposed test rule for Hazardous Air Pollutants (HAPs) under TSCA section 4 in June 1996 (61 FR 33 178, June 26, 1996). The rule proposed testing for 21 chemicals, including 1,2-dichloroethane, that are listed as HAPs under section 112 of the Clean Air Act (CAA), and solicited proposals for enforceable consent agreements (ECAs). As a result, EPA and the HAP Task Force entered into an ECA to test 1,2-dichloroethane for health effects relevant to conducting a residual risk assessment under the CAA. The testing program included development of pharmacokinetics and mechanistic data and a computational dosimetry model for route-to-route extrapolations, which would allow the use of data from studies conducted by the oral route of exposure to predict the effects of inhalation exposures. The testing is described in a Federal Register notice that published on June 3, 2003, announcing the ECA (68 FR 33125). Tier II HAPs testing described in the Federal Register notice was later modified to allow an extended one generation reproductive effects protocol with a neurotoxicity satellite to substitute for the reproductive and neurotoxicity testing protocols originally specified by the ECA. EPA subsequently finalized another TSCA section 4 test rule to require manufacturers (including importers) and processors of 34 chemicals, including 1,2-dichloroethane, to conduct *in vitro* dermal absorption rate testing (69 FR 22402).

EPA did not issue additional test orders or rules under TSCA section 4 to require human health hazard testing because the Agency had sufficient information to complete the 1,2-dichloroethane risk evaluation using a weight of scientific evidence approach. When preparing this risk evaluation, EPA obtained and considered reasonably available information, defined as information that the Agency possesses, or can reasonably obtain and synthesize for use in risk evaluations.. Specifically, EPA used TRI, NEI (National Emissions Inventory), and Discharge Monitoring Report (DMR) facility-reported releases to air, water, and soil to quantitatively assess exposure to general population and ecological receptors. In some cases, when information available to EPA was limited, the Agency relied on models. As stated above, EPA used TSCA section 4 to require worker inhalation and dermal exposure data and earthworm reproductive hazard data. Using empirical information and modeling together, EPA is confident that its risk estimates support its risk determination for 1,2-dichloroethane.

2.6 Peer Review and Public Comment Process

2.6.1 Requests for an Additional or an Extension of the Comment Period

Summary: A public commenter (0150) requested an extension to the comment period until February 6, 2026, and stated that the current comment period is insufficient for stakeholders to review the Draft Risk Evaluation for 1,2-Dichloroethane and supporting documents, and to prepare appropriate comments, because of the following:

- The Draft Risk Evaluation for 1,2-Dichloroethane and TSDs are exceptionally complex, lengthy, and present novel approaches.
- There is no SACC review of the entire Draft Risk Evaluation for 1,2-Dichloroethane.
- EPA's new test order industrial hygiene data requires heightened attention and analysis from commentors, especially absent SACC peer review.
- The new proposed TSCA Framework Rule spurs further complications for the 1,2-dichloroethane risk evaluation.
- Six federal holidays and holiday-related leave interrupted a substantial portion of the comment period.
- Similar to the D4 (Octamethylcyclotetrasiloxane) (Cyclotetrasiloxane, 2,2,4,4,6,6,8,8-octamethyl-) Draft Risk Evaluation comment period that was extended, the Draft Risk Evaluation for 1,2-Dichloroethane poses comparable complex issues.

Another public commenter (0158) stated that stakeholders need additional time to consider and provide information on updated conditions of use prior to finalization of the risk evaluation. The commenter stated that adding conditions of use without allowing time for stakeholders to evaluate the impact could lead to incomplete or incorrect risk management rules.

Several public commenters (0055, 0056, 0061, 0064, 0151) submitted multiple comments, some before the publication of the Draft Risk Evaluation for 1,2-Dichloroethane, requesting the docket remain open longer so that the public can submit use, hazard, exposure, and any other information that could help inform the risk evaluation. Additionally, the commenters said that EPA's Central Data Exchange was experiencing technical issues that presented a potential obstacle for providing new scientific information to EPA.

The commenter (0151) requested an extension of the comment period on the Draft Risk Evaluation for 1,2-Dichloroethane for an additional 30 days.

EPA Response: EPA appreciates the stakeholders for their continued engagement with the Agency and emphasizes that each step of the TSCA process for existing chemicals involves an opportunity for public comment. TSCA section 6(b)(4)(H) states that EPA "shall provide no less than 30 days public notice and an opportunity for comment on a draft risk evaluation…." 15 U.S.C. § 2605(b)(4)(H). By rule, EPA has provided an additional 30-days for public comment per 40 CFR 702.43(c). In accordance with 40 CFR 702.43(c), the Agency provided 60 days for public comments for the 1,2-dichloroethane draft risk evaluation, EPA also notes that, on November 22, 2024, the U.S. District Court for the District of Columbia entered two consent decrees establishing deadlines for completing risk evaluations for 20 High-Priority Chemicals and two manufacturer-requested risk evaluations (MRRE); which included EPA finalizing seven of the remaining High-Priority Chemicals (including 1,2-dichloroethane) by no later than December 31, 2025. *See Cmty. In-Power & Dev. Ass'n Inc., et al. v. EPA*, No. 1:23-cv-2715 (D.D.C.). The court-ordered deadline to transmit the final 1,2-dichloroethane risk evaluation to the Federal Register has already been extended once and is now May 5, 2026. To meet EPA's obligations

under the consent decree, the Agency was unable to extend the public comment period. EPA's responses to the extension requests are available in the docket (EPA-HQ-OPPT-2018-0427-0167; EPA-HQ-OPPT-2018-0427-0168).

EPA also disagrees with other reasons provided by the stakeholders for needing additional time. First, the risk evaluation has the typical number of technical support documents and pages as other TSCA risk evaluations. EPA also emphasizes that the Agency added only three COUs between scope and draft risk evaluation and no additional COUs between the draft and final risk evaluations; rather, the Agencies expanded the subcategories to include additional sectors reported to the Agency and to Chemical Data Reporting (CDR; see Appendix D of the *Risk Evaluation for 1,2-Dichloroethane* for more information on the COU additions and changes). Updates for clarity do not necessarily change the COU but provide more clarity as to what uses a COU covers.

2.6.2 SACC Peer Review Process

Summary: Several public commenters (0156, 0159, 0166, 0170, 0171) said EPA should have convened the SACC to review the risk evaluation, provide feedback to EPA, and provide an additional opportunity for public input, because the 1,2-dichloroethane risk evaluation differs in important ways from prior risk evaluations. A public commenter (0169) added that peer reviewing only portions of a risk evaluation is not a substitute for review of the complete draft and EPA should convene the SACC to review the Draft Risk Evaluation for 1,2-Dichloroethane, including new information provided since the 2024 review. Two public commenters (0163, 0169) recommended that EPA convene a SACC peer review of the full risk evaluation so that the Draft Risk Evaluation for 1,2-Dichloroethane is not vulnerable to subsequent legal challenge and represents the best available science.

EPA Response: EPA has a long-standing commitment to peer review in the TSCA program and EPA met that commitment in regard to the 1,2-dichloroethane risk evaluation. TSCA section 26(o) requires EPA to establish an advisory committee, known as the SACC, to provide independent advice and expert consultation with respect to the scientific and technical aspects of issues relating to the implementation of TSCA. EPA's Procedures for Chemical Risk Evaluation require that EPA "conduct peer review activities on risk evaluations conducted pursuant to 15 U.S.C. 2605(b)(4)(A)." 40 CFR 702.41. EPA expects to conduct these peer review activities (including deciding on the scope and type of peer review) "consistent with the applicable peer review policies, procedures, and methods in guidance promulgated by the Office of Management and Budget [OMB] and EPA, and in accordance with 15 U.S.C. 2625(h) and (i)." 40 CFR 702.41. In finalizing this rule, EPA explained that risk evaluations may use previously peer reviewed scientific approaches, models, and/or methods for similar chemicals or exposure scenarios and that "[b]oth the Peer Review Bulletin and the EPA Handbook clearly outline circumstances where additional peer review may not be necessary. An example would include work that has been previously peer reviewed in a manner consistent with the Peer Review Bulletin and the EPA Handbook." 89 FR 37028, 37042 (May 3, 2024). 40 CFR 702.41.

In the 2018 *Final Scope of the Risk Evaluation for 1,2-Dichloroethane; CASRN 107-06-2* (EPA-HQ-OPPT-2018-0427), EPA stated that the draft risk evaluation for 1,2-dichloroethane will undergo peer review. The *Draft Human Health Hazard Assessment for 1,2-Dichloroethane* (EPA-HQ-OPPT-2024-0114) was released for public comment in July 2024 and was peer reviewed by the SACC in September 2024. The 1,2-dichloroethane draft risk evaluation proceeded without additional external (SACC) peer review consistent with EPA and OMB guidance because all science questions needing peer review were addressed in the September 2024 peer review of the *Draft Human Health Hazard Assessment for 1,2-Dichloroethane* (EPA-HQ-OPPT-2024-0114) and in published risk evaluations as well as the *Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline*

Communities (accessed May 5, 2026). The EPA Peer Review Handbook (accessed May 5, 2026) states that: "[T]here are other circumstances when peer review of influential products may not be necessary. For example, peer review generally is not conducted […] for work that has been reviewed previously in a manner consistent with the OMB Peer Review Bulletin and this Handbook (*e.g.,* a cancer risk assessment methodology or an exposure modeling technique that was the subject of earlier peer review of appropriate technical merit would not generally undergo additional peer review even if the product supported a significant Agency decision)." The methods and analyses used in the 1,2-dichloroethane draft risk evaluation are not novel and have been reviewed in the development of the tools used in various agency work products or previous TSCA assessments. Specifically, the Agency has considered and incorporated SACC recommendations on these methodologies where relevant and appropriate.

- ***Ecological Risk***
  - *Eco Analog Selection:* To fill a data gap in 1,2-dichloroethane for sediment-dwelling invertebrates, data from analog chemicals were used. The methodology used—a tiered process with multiple lines of evidence (structural similarity, physical-chemical properties, environmental fate and transport similarity, and ecotoxicological similarity)—was also used in the risk evaluation for 1,1-dichloroethane and was peer reviewed by the SACC in September 2024 (see Charge question 2.a, EPA-HQ-OPPT-2024-0114). 1,1-Dichloroethane, 1,2-dichloropropane, and 1,1,2-trichloroethane were selected as analogs for 1,2-dichloroethane and data from these chemicals were used to help establish both acute and chronic benthic concentrations of concern.

- ***General Population Risk***
  - *Consumer Model:* EPA evaluated risks from consumer uses of imported articles containing 1,2-dichloroethane for inhalation exposures using the Agency's previously peer-reviewed Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones (IECCU) Model Version 1.1 (accessed May 5, 2026). That model was also used in the risk evaluation of 1-bromopropane and was peer reviewed by the SACC in September 2019 (Charge question 3, EPA-HQ-OPPT-2019-0235). Exposure infant mouthing methodology was used also in the separate risk evaluations of diisodecyl phthalate and diisononyl phthalate (DIDP/DINP) and was peer reviewed by the SACC in July 2024 (see Charge question 1.a.iii, EPA-HQ-OPPT-2024-0073).
  - *General Population Inhalation Exposures:* Exposures to the general population via the ambient air pathway were estimated using methods described in the *Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities (Fenceline Analysis)*, which was peer reviewed by the SACC in March 2022 (EPA-HQ-OPPT-2021-0415) and more recently during the 1,3-butadiene SACC in April 2025 (see Charge questions 2.a.iii and 6; EPA-HQ-OPPT-2024-0425). Exposures were also modeled using HEM, which was also peer reviewed during the 1,3-butadiene SACC in April 2025 (see Charge questions 2.a.ii; EPA-HQ-OPPT-2024-0425).

- ***Release Assessment***
  - *EPA Estimated Releases for Generic Facilities/Sites:* Estimated release methodologies for relevant conditions of use and occupational exposure scenarios (COUs/OESs) have been peer reviewed, most recently during the SACC meeting on risk evaluation for 1,3-butadiene in April 2025 (see Charge questions 4 and 6; EPA-HQ-OPPT-2024-0425). Similar methodologies/work were also conducted in the first 10 risk evaluations (Table 2-2)

- ***Occupational Risk***
  - *Inhalation Monitoring Data for 1,2-Dichloroethane:* An inhalation monitoring test order was issued for 1,2-dichloroethane. The methodology was used in the risk evaluation for 1,1-dichloroethane and was peer reviewed by the SACC in September 2024 (see Charge question 10; EPA-HQ-OPPT-2024-0114).
  - *Inhalation Monitoring Data for 1,1-Dichloroethane as a Byproduct:* An inhalation monitoring test order was issued for 1,1-dichloroethane. That test order and associated analyses were used in the risk evaluation for 1,1-dichloroethane and were peer reviewed by the SACC in September 2024 (see Charge question 10; EPA-HQ-OPPT-2024-0114), and the same data were used in the byproduct analysis for 1,2-dichloroethane because 1,1-dichloroethane is one of the byproducts.
  - *Surrogate Inhalation Monitoring Data:* Surrogate data (*e.g.,* data from a similar chemical or scenario) was used for inhalation monitoring in the 1,1-dichloroethane risk evaluation for occupational exposure. This work was peer reviewed by the SACC in September 2024 (see Charge question 10; EPA-HQ-OPPT-2024-0114). Similar methodologies/work were also done in the first 10 risk evaluations (Table 2-2).
  - *Dermal Modeling:* The Dermal Exposure to Volatile Liquids (DEVL) Model used is the same model used in the risk evaluation for 1,1-dichloroethane and was peer reviewed by the SACC in September 2024 (see Charge question 10; EPA-HQ-OPPT-2024-0114). That model was also used in the first 10 risk evaluations (Table 2-2.

- ***Byproducts (Produced During the Manufacture of 1,2-Dichloroethane) Risk***
  - *Use of Existing and Previously Peer-Reviewed Information:* EPA utilized physical-chemical and fate properties; environmental and human health hazard data; as well as release estimate exposures and associated risks from the following EPA risk evaluations and related documents for the byproducts risk:
    - *Risk Evaluation for 1,1-Dichloroethane*;
    - *Risk Evaluation for Carbon Tetrachloride*;
    - *Risk Evaluation for Methylene Chloride*;
    - *Risk Evaluation for Perchloroethylene*;
    - *Risk Evaluation for Trichloroethylene*;
    - *Carbon Tetrachloride: Fenceline Technical Support – Ambient Air Pathway;*
    - *Carbon Tetrachloride: Fenceline Technical Support – Water Pathway*;
    - *Methylene Chloride: TRI Release Data Sensitivity Analysis*;
    - *Methylene Chloride: Fenceline Technical Support – Water Pathway*;
    - *Perchloroethylene: Fenceline Technical Support – Air Pathway*;
    - *Perchloroethylene: Fenceline Technical Support – Water Pathway*;
    - *Trichloroethylene (TCE): Fenceline Technical Support – Ambient Air Pathway*; and
    - *Trichloroethylene: Fenceline Technical Support – Water Pathway*.
  - *Use of Inhalation Monitoring Test Order Data for 1,1-Dichloroethane:* As per the above, the methodology has been peer reviewed in the risk evaluation for 1,1-dichloroethane (see Charge question 10; EPA-HQ-OPPT-2024-0114).
  - *Use of Surrogate Inhalation Monitoring Test Order Data for the Other Byproducts:* EPA is using 1,2-dichloroethane test order data as a surrogate for trichloroethylene, perchloroethylene, methylene chloride, and carbon tetrachloride, adjusted by vapor pressure using the percent of concentrations of byproducts in the streams—as provided by industry. As per the above, the methodology was recently peer reviewed in the risk

evaluation for 1,1-dichloroethane by the SACC in September 2024 (see Charge question 10; EPA-HQ-OPPT-2024-0114).

- *Byproducts Releases:* EPA is using facility-reported releases for 1,2-dichloroethane and byproduct percent concentrations provided by industry. The methodology used to estimate 1,2-dichloroethane releases was peer reviewed in each byproduct's chemical-specific risk evaluation (Table 2-2) and was recently peer reviewed during the 1,3-butadiene SACC meeting in April 2025 (see Charge questions 1.a.i. and 6; EPA-HQ-OPPT-2024-0425).
- *Ecological Aquatic Risk:* A screening methodology was conducted in accordance with methodologies peer reviewed in the 1,1-dichloroethane risk evaluation by the SACC in September 2024 (see Charge question 1; EPA-HQ-OPPT-2024-0114).

Table 2-1. Summary of SACC Peer-Reviewed Charge Questions

Topic	Previous Peer Review(s) [a] (month year)	Relevant Charge Question(s)
Eco analog selection	1,1-Dichloroethane (September 2024)	2.a
Consumer model	1-Bromopropane (September 2019)	3
	Fenceline Analysis (March 2022)	Entire review
Estimated releases for generic facilities	1,3-Butadiene (April 2025)	4, 6
Estimated facility-reported releases	1,3-Butadiene (April 2025)	1.a.i, 6
General population inhalation exposures	Fenceline Analysis (March 2022)	Entire review
	1,3-Butadiene (April 2025)	2.a.ii, 2.a.iii, 6
1,1-Dichloroethane inhalation monitoring data	1,1-Dichloroethane (September 2024)	10
Surrogate inhalation monitoring data	1,1-Dichloroethane (September 2024)	10
Dermal modeling	1,1-Dichloroethane (September 2024)	10
Byproduct exposure – general population	1,3-Butadiene (April 2025)	2.a.ii
	Fenceline Analysis (March 2022)	Entire review
Byproduct exposure – eco exposure	1,1-Dichloroethane (September 2024)	1 [b]
	Carbon Tetrachloride (February 2020)	1
	Methylene Chloride (December 2019)	2
	Perchloroethylene (May 2020)	2
	Trichloroethylene (March 2020)	2
Exposure – infant mouthing	DIDP/DINP (July 2024)	1.a.iii

[a] EPA has advanced Agency methodologies to align with and have included the SACC's recommendations as appropriate in the approaches used in the 1,2-dichloroethane risk evaluation.
[b] Although the charge question was specific to the "storm scenario," the SACC did include other comments and recommendations about the screening methodology in response to the charge question.

Table 2-2. List of Previous Chemical Dockets for Byproduct Technical Support Document

Source	SACC Docket ID
Risk Evaluation for 1,1-Dichloroethane	EPA-HQ-OPPT-2024-0114
Risk Evaluation for Carbon Tetrachloride	EPA-HQ-OPPT-2019-0499
Risk Evaluation for Methylene Chloride	EPA-HQ-OPPT-2019-0437
Risk Evaluation for Perchloroethylene	EPA-HQ-OPPT-2019-0502
Risk Evaluation for Trichloroethylene	EPA-HQ-OPPT-2019-0500

2.6.3 Human Health Hazard Assessment

Summary: A public commenter (0151) said their initial review of the Draft Risk Evaluation for 1,2-Dichloroethane found that EPA failed to address stakeholder comments on the 2024 draft Human Health Hazard TSD for 1,2-dichloroethane. Similarly, another public commenter (0169) stated that scientific deficiencies identified by both the SACC and stakeholders remain unaddressed concerning the Draft Human Health Hazard Assessment and were not revised in the Draft Risk Evaluation for 1,2-Dichloroethane.

Some public commenters (0156, 0159, 0166, 0169) said EPA should have issued a revised Human Health Hazard Assessment for the Draft Risk Evaluation for 1,2-Dichloroethane so that commenters could better understand how EPA made its determinations and effectively comment on those conclusions.

EPA Response: EPA released the *Draft Human Health Hazard Assessment for 1,2-Dichloroethane* (EPA-HQ-OPPT-2024-0114) for public comment in July 2024, which was peer reviewed by the SACC in September 2024. Rather than issuing a revised hazard assessment at the time of the 1,2-dichloroethane draft risk evaluation, EPA considered SACC and stakeholder comments on the *Draft Human Health Hazard Assessment for 1,2-Dichloroethane* and integrated relevant updates and clarifications in the final risk evaluation and the *Human Health Hazard Assessment for 1,2-Dichloroethane* (Sections 4 and 5).

This approach is consistent with TSCA and the 2024 Risk Evaluation Procedural Rule, which provides for public comment and peer review of hazard materials and integration of revisions into the risk evaluation.

2.7 Legal and Regulatory

2.7.1 Best Available Science

Summary: Multiple public commenters (0169, 0160, 0171) discussed how the Draft Risk Evaluation for 1,2-Dichloroethane did not use the best available science as required under TSCA. One of the public commenters (0171) said that revisions are needed to meet the statutory requirements for conducting a risk evaluation, including the use of best available science and consideration of the weight of the scientific evidence.

A public commenter (0154) said the Draft Risk Evaluation for 1,2-Dichloroethane does not reflect the best available science required under the Lautenberg Act, as demonstrated by the following:

- EPA's criticism of the extended one-generation reproductive toxicity (EOGRT) study in the Draft Risk Evaluation for 1,2-Dichloroethane that is unfounded and refuted by the data presented in the EOGRT study report.

- EPA's criticism of the EOGRT study reflecting a lack of understanding of the equipment used in animal toxicity studies and the quality of data required to meet EPA's criteria for TSCA section 4 testing.
- Questions regarding the thoroughness of the systematic review process.

Similarly, another public commenter (0165) discussed how the Draft Risk Evaluation for 1,2-Dichloroethane does not comply with the requirements of Executive Order 14303 Gold Standard Science and TSCA section 26(h).

EPA Response: EPA's systematic review of studies for consideration for dose-response and the overall integration into weight of scientific evidence was supplemented by new data/information provided by the SACC, public comments and stakeholder submissions to the Agency. This information was incorporated, where applicable, to further EPA's approach in the use of the best available science. In evaluating the EOGRT study in the Draft Risk Evaluation of 1,2-Dichloroethane, systematic review identified this study as not suitable for dose-response. EPA has since further characterized this study in the final risk evaluation for 1,2-Dichloroethane and incorporated the findings within the weight of scientific evidence. EPA's approaches are consistent with the science standards in TSCA section 26(h) and Executive Order 14303, "Restoring Gold Standard Science" (90 FR 22601, May 23, 2025).

2.7.2 Precautionary Principles

Summary: A public commenter (0148) discussed the Precautionary Principles and regulatory obligations to act to prevent harm when credible scientific evidence indicates the potential for serious or irreversible damage, especially for vulnerable populations such as children. The Agency for Toxic Substances and Disease Registry (ATSDR) notes that children are most likely to be exposed to 1,2 dichloroethane through contamination of ambient air and drinking water, yet limited data exist on health impacts of such internal doses in children. Therefore, the commenter said that EPA should apply the highest degree of caution when evaluating the continued manufacture and use of 1,2-dichloroethane. The commenter reasoned that the combination of potential exposure, demonstrated risk, and incomplete information on health impacts of 1,2-dichloroethane demands a precautionary approach that uses protective default assumptions, rather than treating the absence of evidence as evidence of safety.

EPA Response: TSCA requires EPA to consider PESS and to use the best available science and reasonably available information when determining whether a chemical presents an unreasonable risk. EPA considered ATSDR information among the sources reviewed for 1,2-dichloroethane and recognizes the limited child-specific dose-response data. Where data are limited, the Agency uses health-protective defaults consistent with EPA's guidance and the 2024 Risk Evaluation Procedural Rule, including age-appropriate exposure factors (*e.g.,* inhalation, fish ingestion and drinking water intake rates; see Section 5.1.2. of the 1,2-Dichloroethane Risk Evaluation) from EPA's *Exposure Factors Handbook* and a default uncertainty factor of 10 (as used in the 1,2-dichloroethane final risk evaluation) to account for human variability (including children) due to a lack of data to indicate life-stage susceptibility to apply extrapolation factors (U.S. EPA, 2014, 2002b). Also, EPA used conservative exposure assumptions and upper-bound concentration estimates for child-specific exposure scenarios such as pica (see Section 5.1.2.3.3 of the 1,2-Dichloroethane Risk Evaluation) and several imported toys where there was evidence of 1,2-dichloroethane content (see 1,2-Dichloroethane Consumer TSD). TSCA is a risk-based statute that relies on the best available scientific information.

2.7.3 Framework Rule

Summary: A public commenter (0169) said that EPA states in the proposed revisions to the procedural framework rule for conducting existing chemical risk evaluations under TSCA that it "believes that

certain provisions of the 2024 final rule are not based on the best reading of TSCA and are thus impermissible under the Court's decision in *Loper Bright*." The commenter stated that the Agency should not rely on an admittedly flawed and unlawful Framework Rule or arbitrarily apply the unlawful regulation to the 1,2-dichloroethane risk evaluation in an effort to meet timing requirements. Instead, EPA should confirm its intent to apply the procedures of the revised Framework Rule to the 1,2-dichloroethane risk evaluation. As a part of these revisions, the commenter stated support for:

- removing the requirement to evaluate every exposure route and pathway, particularly when certain exposures are regulated under other EPA programs (*e.g.,* Clean Air Act [CAA], Clean Water Act [CWA], Safe Drinking Water Act); and
- moving away from the single risk determination approach.

The commenter stated that EPA should issue an order, as required under proposed 40 CFR 702.43(f), for each condition of use that the Agency finds does not present an unreasonable risk, such that preemption of future state regulations applies.

Similarly, a public commenter (0149) expressed their concern that the analysis will likely result in increased 1,2-dichloroethane releases due to the updated Procedures for Chemical Risk Evaluation Under TSCA, 90 FR 45690-01, published on September 23, 2025. The commenter requested that EPA provide a scientifically validated estimation of likely 1,2-dichloroethane release under the amended 40 CFR part 702 as compared to what release would have been under the earlier regulations cited in the Draft Risk Evaluation for 1,2-Dichloroethane.

EPA Response: EPA conducted the risk evaluation of 1,2-dichloroethane according to the current TSCA risk evaluation framework rule. The proposed framework rule cited by commenters has not yet been finalized. Until EPA does finalize that rule, the 2024 framework rule continues to apply, to the extent practicable, for risk evaluations initiated prior to June 3, 2024, which includes 1,2-dichloroethane. 40 CFR 702.31(c).

The current framework rule requires the Agency to make a single risk determination on a chemical substance. See 40 CFR 702.39(f)(1); see also 87 Fed. Reg. 37028 (May 3, 2024). TSCA section 6(b)(4)(A) specifies that a risk evaluation must determine whether "a chemical substance" presents an unreasonable risk of injury to health or the environment "under the conditions of use." In evaluating 1,2-dichloroethane's risk, the Agency considered exposures associated with each condition of use but did not make separate risk determinations. A single determination that a chemical substance presents an unreasonable risk does not mean that the entirety or whole of that chemical's uses—or even a majority of uses—presents an unreasonable risk. The 1,2-dichloroethane final risk evaluation considered the chemical's COUs (*i.e.,* the intended, known and reasonably foreseen circumstances under which the chemical is manufactured, processed, distributed in commerce, used or disposed of). The different exposure scenarios presented by different COUs are reflected in the risk evaluation's exposure assessment. In the 1,2-dichloroethane final risk evaluation, EPA listed the COUs that significantly contribute to the unreasonable risk, and any future risk management rule will likely focus on those COUs.

Although EPA is required to evaluate every exposure route and pathway under the current Framework Rule, EPA emphasizes that TSCA requires the Agency to coordinate with other EPA programs—especially when certain exposures are already regulated under other EPA programs. The other statutes administered by EPA, such as the CAA, the CWA, the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), the Safe Drinking Water Act, and the Resource Conservation and Recovery Act, primarily regulate risks to the general population and the environment.

Nevertheless, throughout the risk evaluation process and beyond, EPA's Office of Chemical Safety and Pollution Prevention has coordinated with other EPA offices and will continue to do so.

3 CHEMISTRY AND FATE AND TRANSPORT OF 1,2-DICHLOROETHANE

Comments associated with this topic are summarized in the subsections below.

3.1 Physical and Chemical Properties

No comments are associated with this topic.

3.2 Environmental Fate and Transport

No comments are associated with this topic.

3.3 Other Comments

No comments are associated with this topic.

4 RELEASES AND CONCENTRATIONS OF 1,2-DICHLORETHANE IN THE ENVIRONMENT

Comments associated with this topic are summarized in the subsections below.

4.1 Approach and Methodology

4.1.1 Air Release Modeling Approaches and/or Input Data

Summary: A public commenter (0160) said that EPA should model ambient air releases for the highest year of release from both TRI and NEI data. The commenter said that EPA chose to only use one year of release data from TRI (2018, or the highest year of release if there were no 2018 releases) and use only this release data for the HEM modeling. However, the commenter recommended that EPA should model ambient air exposures using the highest year of release for each facility, not the highest year of release across all facilities. The commenter said that EPA's reasoning for utilizing only TRI data in HEM is not compelling, and instead, EPA should use NEI data for ambient air modeling, as well as TRI as there are multiple facilities and OESs where NEI releases are reported to be higher than TRI releases. The commenter stated that EPA failed to use the highest years of releases, all datasets available, and all models, which resulted in underestimated ambient air concentrations that underestimate risks to the general population. The commenter reasoned that EPA should instead estimate risks for the highest potential exposures, as it is required to assess risks to potentially exposed and susceptible subpopulations.

EPA Response: EPA performed additional ambient air modeling using HEM5.0 that uses each facility's highest reported annual release as reported to TRI data from 2015 to 2024. For NEI data, EPA used data reported in 2014, 2017, and 2020 in this analysis. 2020 NEI data was the most recent data available at the time of the analysis. In the draft risk evaluation, EPA modeled all available data for 2014 and 2017 using AERMOD (U.S. EPA, 2025e). For this evaluation, EPA modeled, in HEM5.0, each facility that showed a risk greater than 1×10^{-6} based on the 95th percentile concentration at 10 m from the release location based on the analysis performed in the draft risk evaluation. EPA also modeled any releases that were new to the 2020 NEI if they were greater than the lowest release from 2014 and 2017 that resulted in a risk greater than 1×10^{-6} based on the 95th percentile concentration at 10 m from the release location. If a facility reported in multiple years and had total releases greater than the threshold described above, then EPA used the maximum release across all years in this analysis. This new analysis adds confidence that high-end exposures were characterized.

The results of the additional modeling are available in Section 3 of the *Environmental Media Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026g); Section 3 of the *General Population Exposure Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026i); and Sections 3.3.1, 5.1.2.1, and 5.3.6 of the *Risk Evaluation for 1,2-Dichloroethane* (U.S. EPA, 2026m).

4.1.2 Environmental Releases and Modeling Approaches

Summary: A public commenter (0155) stated that EPA's highly conservative, generic assumptions from environmental modeling used for releases and parameters for all key pathways of exposure to the environment (including sediment and air) can be improved with site-specific and/or more realistic, readily available data.

EPA Response: EPA's first preference was to assess releases using facility-specific release data for multiple years from TRI, DMR, and NEI data as described in both the Environmental Releases TSD and the risk evaluation. For 1,2-dichloroethane, EPA assessed releases for 14 OESs and there were facility-

specific release data available for 13 of 14. For three OESs (Industrial Application of Adhesives and Sealants; Industrial and Commercial Non-Aerosol Cleaning and Degreasing; and Commercial Laboratory Use), in addition to the available facility-release data, EPA also modeled releases to increase the amount of evidence and overall confidence in the assessment of the OES.

EPA used a probabilistic modeling approach with Monte Carlo set at 100,000 iterations to allow for a consideration of the range of the values of the parameters rather than a screening-level deterministic modeling approach using solely conservative default values for model parameters. EPA acknowledges that additional data could improve release modeling approaches. In the case of modeling releases for the Use of Adhesives and Sealants, EPA revised the value of weight percent to include a broader range of solvent weight percents in adhesives in refining the approach used in the draft risk evaluation where EPA used only the high-end value that came from one SDS. EPA did review all the comments received to determine if there were any data provided that could be added to inform the release modeling but did not find any additional data.

For estimation of risk to the general population and the environment via ambient air, EPA used facility reported site-specific data where available. EPA relied only on releases from generic facilities/sites for OESs for which there were not facility reported releases to air, or when there were a limited number of facility reported releases that were not representative of the overall OES. When modeling ambient air concentrations from generic facilities/locations in AERMOD, EPA performed the modeling using two meteorological stations: Lake Charles, Louisiana, and Sioux Falls, South Dakota. These two meteorological stations were chosen because they represent meteorological datasets that tend to provide central tendency (Sioux Falls) and high-end (Lake Charles) concentration estimates relative to the other stations within the Integrated Indoor-Outdoor Air Concentrations Model- based on a sensitivity analysis of the average concentration conducted in support of Integrated Indoor-Outdoor Air Calculator (IIOAC) development (U.S. EPA, 2019). EPA also used two land cover scenarios, urban and rural, when estimating ambient air concentrations from releases at generic facilities/sites. Stack parameters are based on an analysis of available data done as part of the development of the Integrated Indoor-Outdoor Air Calculator. Therefore, when EPA relied on data from generic facilities/sites, EPA used realistic assumptions that cover a range of potential locations, land covers, and are based on available data.

EPA estimated 1,2-dichloroethane risk of exposure to the general population and the environment via surface water based on facility reported, site-specific releases, receiving water body and effluent monitoring data via the Discharge Monitoring Reports. Corresponding site-specific receiving water body flow data was from the U.S. Geologic Survey (USGS) NHDPlus resulting in facility-specific surface water concentrations and exposures at the facility's point of discharge.

Summary: A public commenter (0169) said that EPA's preliminary determination that releases from the Manufacturing condition of use present an unreasonable risk to the environment is erroneous because the releases that drive this conclusion are sourced from a single facility in Louisiana from 2016, when extraordinary rain events led to significantly higher releases. The commenter said that releases from extreme weather events should be excluded as not reasonably foreseen in order to be consistent with the statutory text and good policy (*i.e.,* exclude exposures associated with catastrophic accidents, extreme weather events, and other natural disasters from the scope of risk evaluations). The inclusion of these incidents would require an overly broad interpretation of the term "conditions of use," and would lead to condition of use determinations based on hypothetical scenarios and would inevitably introduce extremely conservative assumptions and projections. The commenter provided the following arguments to further support their position:

- The EPA should exclude exposures associated with extreme weather events from the scope of risk evaluations as not reasonably foreseen as a matter of course;
- The Eagle US 2 LLC – Lake Charles Complex data from 2016 reflects extreme weather events in March and August 2016 that should not be characterized as representative of normal operation conditions;
- The data used by EPA (DMR data) conflicts with other data provided by the same source for the same period (TRI data). The TRI dataset was determined to be of "High" quality whereas the DMR data was determined by EPA to be of "Medium" quality. Notably, there is no indication as to why the release rate for one year from one facility was selected to represent the Manufacturing OES even though it was greater than the 95th percentile (high-end estimate) across all facilities;
- EPA appropriately distinguished those extreme weather-driven releases associated with Hurricane Laura in 2020 from the Manufacturing OES routine manufacturing release calculations, using the flow rate of the Calcasieu River at the time of the event instead of the 7Q10 flow rate, recognizing that this category of release does not represent normal operating conditions.
- Even if not classified as an excludable extreme weather event, the estimates used by EPA can be excluded as an unrepresentative outlier that are not indicative of realistic releases as the annual release of 4,865 kg/year is greater than all TRI-reported releases from 2015–2023 and greater than most DMR-reported releases from 2015 to 2025.
- The Interquartile Range method does not reliably identify outlier release events in small datasets and EPA should consider using alternative outlier detection methods such as Dixon's Q Test, which is designed for small samples sizes (3–30 observations) with skewed distributions and is robust in identifying departures from normality.

Conversely, a public commenter (0172) said that EPA unlawfully ignores 1,2-dichloroethane exposures associated with extreme weather events, facility malfunctions, and other "known" and "reasonably foreseen" but unplanned releases. The commenter said that instead of considering these incidents in the Draft Risk Evaluation for 1,2-Dichloroethane, EPA arbitrarily considered only water release data associated with unplanned releases from a single facility, unlawfully ignoring other reasonably available information for characterizing 1,2-dichloroethane releases and exposures associated with extreme weather events as well as facility malfunctions, accidents, and other unplanned releases. The commenter said that had EPA considered reasonably available information from federal and state databases, the Agency would have discovered evidence of repeated unplanned releases of 1,2-dichloroethane, citing multiple instances of the accidental release of 1,2-dichloroethane, including among others from a pipeline at the Conoco docks in Westlake, Louisiana, which released more than 1.6 million lb of 1,2-dichloroethane in March 1994. The commenter identified several other specific examples of accidental releases in Louisiana. The commenter asserts these incidents are reasonably foreseeable because between 1993 and 2025, Louisiana documented approximately 70 unplanned release incidents involving 1,2-dichloroethane. The commenter also said that 1,2-dichloroethane is particularly prone to unplanned releases associated with extreme weather events since it is overwhelmingly manufactured, used, and released in a region that is highly susceptible to hurricanes and other extreme weather events, which are both foreseeable and worsening. Eleven of the 15 facilities with the highest reported air releases nationwide are located in Louisiana or Texas, accounting for more than 80 percent of the total air releases. The commenter said that the Draft Risk Evaluation for 1,2-Dichloroethane disregards readily available information documenting substantial, recurring unplanned releases of 1,2-dichloroethane into the environment, which understates exposures to 1,2-dichloroethane in fenceline communities and violates TSCA.

EPA Response: EPA generally does not include exposures associated with extreme weather events within the scope of the risk evaluation. However, when specific chemical information is available to the Agency and can provide additional characterization of facility operations and associated exposures, EPA considers this as part of a fact-specific, chemical-specific analysis. The Eagle US 2 LLC – Lake Charles Complex facility submitted 6 years of release data with the largest releases associated with storm events (see Table 4-2 in the 1,2-Dichloroethane Environmental Media Assessment). Based on the chemical- and facility-specific data received, EPA considered the exposures associated with these storm events. The Agency presented the data that are reflective of the range of releases and corresponding conditions, particularly the frequency of storm events in Louisiana. EPA also considered the 2020 releases resulting from extreme storm events separately and considered the 2021 releases as representative of normal operating conditions.

Because the facility noted storm-related impacts, in the draft risk evaluation, EPA excluded 2020 data coincident with Hurricane Laura from routine assessment and instead used 2016—the second highest release year without storm-affected release days. As provided by the facility and as presented in Table 4-2 of the *Environmental Media Assessment for 1,2-Dichloroethane*, the largest releases for 2016 did not occur during storm events. In the draft risk evaluation, EPA derived an average daily discharge by dividing the annual load as reported in the EPA Pollutant Loading Tool of 4,849.67 kg/year by 350 operating days (13.9 kg/day). Facility-reported daily releases in May and December 2016 (63.8 and 37.3 kg/day, respectively) exceeded this value, indicating that the 13.9 kg/day value EPA used in the draft risk evaluation did not overestimate facility releases. See Section 4.1 of the *Draft Environmental Media Assessment for 1,2-Dichloroethane* (U.S. EPA, 2025d).

For the final risk evaluation, EPA considered the highest releases across 2015 to 2024 and identified the year 2021 as the highest release excluding the 2020 releases related to Hurricane Laura. Therefore, the Agency used the 2021 release and corresponding plant flow rate which led to surface water concentration below the concentration of concern. See Section 4.1 of the *Environmental Media Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026g).

EPA is including a storm scenario using the 2020 release related to Hurricane Laura for this specific facility because there are available release data showing releases of 1,2-dichloroethane across multiple storm events over the release years assessed. The storm scenario described in the *Risk Evaluation for 1,2-Dichloroethane* is specific to this facility and is not a generic scenario that applies to other possible storm releases at other facilities. As the commenter noted, the storm scenario uses the flow rate of the Calcasieu River at the time of the event instead of the 7Q10 flow rate (*i.e.,* the lowest 7-day average flow that occurs (on average) once every 10 years) of the receiving water body (Bayou d'Inde) as EPA estimated that under these conditions the adjacent Calcasieu River would overwhelm the Bayou d'Inde flow. See Section 4.1.1 of the *Environmental Media Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026g).

For the final risk evaluation, EPA updated releases for all OESs to 9 years of data from 2015 to 2024 (see *Environmental Release Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026h)). However, EPA does not average surface water releases across years, instead it relies on annual, facility-reported-data. Within the Manufacturing OES, releases from each facility vary and are independent of each other, since processes and operations may be different. For both the draft and final risk evaluation, all facility releases were considered (U.S. EPA, 2026q) and the facility with releases resulting in the highest surface water concentration per OES was presented in Table 4-1 in the *Environmental Media Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026g) and in Table 3-11 of the *Risk Evaluation for 1,2-Dichloroethane*.

Six manufacturing facilities had aquatic risk quotients (RQs) greater than 1 in the draft risk evaluation, not just the Louisiana facility referenced by the commenter, although RQ values for that facility were presented in the 1,2-Dichloroethane Draft Risk Evaluation (see Section 4.3.3) to represent the Manufacturing COU as it resulted in the highest aquatic media concentrations. The estimated concentration using facility plant flow was 27.3 µg/L, which is the highest concentration compared to the average concentration of 3.85 µg/L across 25 facilities in the Manufacturing COU. For the Louisiana facility (National Pollutant Discharge Elimination System [NPDES] permit no. LA0000761) referenced by commenter 0169, the Agency used for the final risk evaluation two facility-reported sources: (1) DMR 2015 to 2024 data as presented in the EPA Pollutant Loading Tool, and (2) facility-submitted 1,2-dichloroethane release data for 2016 to 2022 provided to the Agency via correspondence that the Agency presented in Table 4-2 in the *Environmental Media Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026g).

EPA prioritizes medium- and high-rated data sources. Differences in data-source ratings primarily reflect the "methodology documentation" and "metadata completeness" criteria (U.S. EPA, 2026d, 2021). TRI submissions require facilities to identify the method used to estimate releases and provide contextual information on chemical use at the site, whereas DMR reports under NPDES focus on effluent measurements and typically include fewer metadata elements about estimation methods. This results in higher scores for TRI in those categories. DMR was highly rated across several metrics and, unlike TRI (which covers all media), offers water-release-specific granularity (see *Data Quality Evaluation and Data Extraction Information for Environmental Release and Occupational Exposure for 1,2-Dichloroethane* (U.S. EPA, 2026d)).

EPA does not conduct a statistical analysis on facility specific release data. Each facility's release is an independent event that is a function of that facility's condition of use. EPA assesses the amount of release, the corresponding environmental and human exposures and the associated risks for either each facility or for a representative facility per OES as reported to EPA databases.

As noted above, EPA generally does not include in the scope of the risk evaluation catastrophic accidents, extreme weather events, and other natural disasters if such events do not lead to regular and predictable exposures associated with a given condition of use. Although storms, accidents, and other background exposures were not evaluated as TSCA COUs, releases from those events were included in the information that informed the 1,2-dichloroethane risk evaluation, including the TRI database and ambient air monitoring information. EPA used TRI-reported air emission data to estimate ambient air concentrations from TSCA COUs, using the IIOAC and HEM. TRI emission data include releases SSM events, since the TRI release definition broadly covers any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment of any toxic chemical (40 CFR 372.3).

Summary: A public commenter (0169) said that EPA modeled two release duration scenarios for Manufacturing OES: a 350-day continuous scenario and a 21-day pulse scenario. The commenter said that EPA appropriately used the 350-day continuous release scenario rather than the 21-day pulse scenario to support its risk determination conclusions. However, the commenter said that EPA should replace the use of the 21-day pulse assumption in its sensitivity analysis with a data-driven, short-term release scenario informed by operational patterns by leveraging the DMR monthly discharge data to identify realistic variability in release over 21-consective days overtime.

EPA Response: EPA's publicly available Pollutant Loading Tool within the Enforcement and Compliance History Online (ECHO) database captures reported NPDES permit Discharge Monitoring

Report data. This data is not reported consistently among facilities and reflects the varying permit monitoring requirements among discharging facilities. Some facility effluent monitoring data is reported in the Pollutant Loading Tool annually, others, quarterly and only sometimes monthly data is captured. Given the lack of consistently available monthly effluent monitoring data, EPA instead utilizes annual data and therefore, is continuing to include the 21-day release scenario, which is based on the chronic aquatic hazard study duration.

Summary: A public commenter (0169) said that EPA estimated a surface water concentration of 3,420 µg/L for the Manufacturing OES based on the 2016 DMR release rate at the Eagle US 2 LLC facility (13.9 kg/day) with modeled 7Q10 drought-flow conditions. The commenter said that this combination of facility-specific release data with worst-case drought hydrology does not represent a realistic refined assessment, but rather an inconsistent hybrid that generates concentration estimates not representative of actual exposure conditions. The commenter recommended that EPA conduct refined, facility-specific hydrologic assessments for the routine assessment, as the Agency did for the storm scenario presented in Section 4.1.1. of the Draft Environmental Media Assessment (TSD) for 1,2-Dichloroethane using facility-specific release and surface water conditions, in order to calculate concentration estimates that reflect realistic co-occurrence of release and flow conditions, consistent with EPA's commitment to use "actual exposure levels."

EPA Response: EPA's estimates of 1,2-dichloroethane concentrations in surface waters are based on several flow metrics of facility-specific permit designated receiving waterbodies. The flow rate used for aquatic assessments is either the 7Q10 of the receiving water body, or where the facility plant flow rate exceeded the hydrologic flow, the facility plant flow rate was applied as the flow in the receiving water body (see Section 4.1 of the *Environmental Media Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026g). This combination of facility-specific releases and facility-specific receiving water body flows, including low flows, represent relevant conditions for the aquatic exposures and environmental risk assessment. Other flow metrics such as the 30Q5 (*i.e.,* the lowest 30-day average flow that occurs (on average) once every 5 years) and harmonic mean are utilized in general population exposure scenarios (see Sections 5.1.2.2 and 5.1.2.3 in the *Risk Evaluation of 1,2-Dichloroethane*). For the Manufacturing OES, EPA had facility-specific release data across 5 years as well as the receiving water body data as identified in the NPDES permit as well as the flow metrics from NHDPlus for the draft risk evaluation (see Section 4.1 of the *Draft Environmental Media Assessment for 1,2-Dichloroethane* (U.S. EPA, 2025d)). For the final risk evaluation, the facility plant flow rate was collected from the ECHO Application Programming Interface and used (see Table 4-1 in *Environmental Media Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026g)) to compare to the facility's receiving water body hydrologic flow. If the hydrologic flow was less than plant flow then EPA used plant flow to estimate 1,2-dichloroethane concentrations. Using plant flow captures where the receiving water body is primarily driven by the facility's effluent plant flow.

Summary: A public commenter (0169) stated that although Tier II water modeling conducted in the Variable Volume Water Model (VVWM) in Point Source Calculator (PSC) includes refinements for physical and chemical properties of 1,2-dichloroethane, hydrological assumptions (*e.g.,* water body size, flow rate) were not refined. Therefore, the Tier II modeling retains screening level hydrology, which when paired with annual-average releases does not represent realistic chronic exposure scenarios.

EPA Response: As the commenter noted, the final tier surface water modeling relies on the VVWM in PSC. The addition of the physical and chemical properties within the PSC tool considers partitioning of 1,2-dichloroethane from the water column into sediment and provides sediment and pore water concentration estimates. Further refinement of the flow rate is not required for the final tier of the

assessment because facility-specific receiving water body flow rates are used in all tiers. EPA uses facility-specific flow rates at the point of the effluent discharge (either receiving water body flow rate or the facility plant flow rate, whichever is greater) in each tier of the assessment. Regarding the water body size, generally the receiving water body flow is the dominant factor in affecting the concentration of 1,2-dichloroethane in the receiving water body water column, and not water body size. Lastly, there was no reasonably available information on industrial release patterns, more granular flow conditions, or receiving water body size to better represent each of the nearly one hundred site conditions releasing 1,2-dichloroethane. See Section 4.1 of the *Environmental Media Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026g).

Summary: A public commenter (0169) said that there was a lack of modeling validation against measured data. The commenter discussed the Water Quality Portal data and EPA's estimated flow statistics (*i.e.,* 30Q5, harmonic mean, 7Q10) as examples. The commenter said that, in the case of the flow data used, EPA did not validate the modeled flow estimates against available measured data from U.S. Geologic Survey (USGS) gauges or facility DMR data where available. The commenter recommended that EPA should

- transparently show how measured DMR effluent concentrations compare to estimated water concentrations (accounting for dilution factors and the influence of facility treatment requirements);
- clarify whether differences between TRI-reported releases and DMR-measured effluent concentrations indicate that onsite wastewater treatment systems reduce 1,2-dichloroethane concentrations before discharge, and if so, whether this treatment effectiveness is reflected in the surface water concentration estimates;
- clarify how measured effluent concentrations translate to estimated receiving water concentrations when accounting for facility effluent flow rates and receiving water flow rates, and whether the substantial month-to-month variability observed in DMR data affects the representativeness of annual-average concentration estimates; and
- present a validation comparison for facilities with available DMR data showing measured effluent concentration ranges, facility effluent flow rates, receiving water flow rates, calculated receiving water concentrations based on measured effluent, estimated receiving water concentrations from Table 4-1, and explanations of any substantial differences.

EPA Response: EPA did not compare and validate all of the modeled facility-specific receiving water body concentration estimates and the corresponding effluent concentrations as effluent concentrations are only downloaded and used in a higher tier analysis. Four facility modeled surface water concentrations were considered for Tier 2 analysis where the effluent monitoring concentrations were reviewed. Two facility effluent concentrations were similar to those modeled (*e.g.,* for NPDES PA0080594, modeled was 1,730 µg/L and effluent monitoring was 2,200 µg/L) and two facility effluent concentrations were significantly lower (*e.g.,* NPDES IL0000141, modeled was 467 µg/L and effluent concentration was 5 µg/L)

The requirements for reporting releases in TRI versus DMR are different and as the commenter indicated, TRI releases frequently are reported as before onsite treatment. EPA utilized both data sources to capture facility releases, however, the universe of facilities reporting releases to surface waters in DMR is larger and the amount of 1,2-dichloroethane released is direct releases to the receiving water body after treatment. As treatment efficiency is not reported in either database, EPA relies on the DMR reported releases after treatment without the need for treatment efficiencies as treatment processes and efficiencies vary significantly among facilities.

EPA accounts for effluent flow rates and receiving water body flow rates by comparing the two flow rates (if the data has been provided to ECHO) and using the greater flow rate in estimating receiving water body concentration of released 1,2-dichloroethane from a given facility. If the effluent plant flow is greater than the receiving water body, EPA will then use the effluent plant flow to estimate the surface water concentration thereby more accurately characterizing small receiving waterbodies that are effluent driven. As described below, for the final risk evaluation, EPA is implementing a tiered approach, considering facility reported effluent concentrations for the highest year of release across 10 years in the final tier. When effluent concentration is considered, the month-to-month variability, which is dependent on permit requirements for monitoring frequency, is used directly as the highest concentration found in the receiving water body—particularly in cases where the receiving water body is primarily effluent driven irrespective of annual releases. As the commenter suggested, EPA is incorporating the use of effluent monitoring data. This data has been applied as part of a tiering assessment as follows.

As an initial tier, EPA uses the Enforcement and Compliance History Online Pollutant Loading Tool (accessed May 5, 2026) to inform facility reported releases and corresponding receiving water body information for the hundreds of multi-year records. However, the Pollutant Loading Tool that captures Discharge Monitoring Report data is not consistent among facilities. Some facility effluent monitoring data are reported in the Pollutant Loading Tool annually, others quarterly or monthly. The facility release data were combined with the corresponding receiving water body flows in NHDPlus. The NHDPlus database provides modeled flows for stream reaches without USGS gages, allowing targeted estimations of concentrations at the point of release. The modeled flows in this dataset are adjusted to align with available data from the USGS gage network.

For the final risk evaluation, EPA also downloaded reported plant flow data from the Pollutant Loading Tool and if the plant flow was higher than the hydrologic flow in NHDPlus, EPA used the higher facility plant flow to estimate 1,2-dichloroethane surface water concentrations at the point of discharge. Surface water concentration estimates were then compared to environmental (*i.e.*, RQ>1) or human exposure concentrations. If there was an exceedance, EPA then conducted an additional tiered assessment by downloading if available, the facility's 1,2-dichloroethane effluent monitoring data which was used to represent concentration of 1,2-dichloroethane in the receiving water body and for subsequent environmental and human exposure estimates (see Table 4-1 in the *Environmental Media Assessment for 1,2-Dichloroethane*.

The basis for reporting releases or discharges of 1,2-dichloroethane to surface waters may be different between TRI and DMR. Though EPA mainly relies on DMR data, as releases are after treatment per NPDES permit requirements, EPA does consider TRI data for those facilities reporting to TRI. TRI-reported releases and DMR-measured effluent concentrations indicate that onsite wastewater treatment systems reduce 1,2-dichloroethane concentrations before discharge.

Summary: A public commenter (0169) provided revised surface water concentration calculations in Table 8 of the comment using alternative assumptions (*i.e.,* flow rates and release rates) in their submission. The alternative water release numbers proposed were an average of the chosen Louisiana facility (Eagle US 2 facility in Westlake, Louisiana) from 2017 to 2019, the central tendency across all Manufacturing OES facilities, or the high-end estimate across all Manufacturing facilities. The alternative flow rates proposed were the harmonic mean flow or Calcasieu River flow rates obtained from USGS and NHDPlus. The commenter said that combining lower release rates with greater flow rates (such as those reported for the Calcasieu river) result in the lowest RQs and that these revised calculations would change the risk conclusion because the chronic environmental RQs for aquatic organisms would be less than 1 for the Manufacturing condition of use. The commenter added that if

similar updates were made for the Disposal and other conditions of use, those RQs would decrease as well.

EPA Response: The Eagle US 2 facility in Westlake, Louisiana is located near the Calcasieu River, but releases into low-flowing Bayou d'Inde, thus using the higher flow rates upstream of this facility for the Calcasieu River would not be representative of the flow rate of the receiving water body. The 7Q10 flow rate used by EPA in the draft risk evaluation is the 7Q10 of the receiving water body, which is site-specific and is the flow rate recommended for aquatic life by EPA's Office of Water (OW) per EPA's Water Quality Standards Handbook (accessed May 5, 2026).

For the draft risk evaluation, EPA estimated the concentration of 1,2-dichloroethane at the point of release to the receiving water body based on the reported receiving water body (Bayou d'Inde) as found. in the ECHO Application Programming Interface and used the Bayou d'Inde hydrologic flow rate as reported in NHDPlus. However, for the final risk evaluation, EPA expanded the analysis to include the facility plant flow rate as well as the receiving water body flow. If the plant flow was greater than the receiving water body hydrologic flow, the plant flow was used to estimate 1,2-dichloroethane surface water concentrations. For the Eagle US2 facility, the facility plant flow was greater than the Bayou d'Inde hydrologic flow and therefore, the plant flow was used in the assessment. The use of the facility plant flow resulted in an RQ less than 1 for that facility. See supplemental file *Surface Water Concentration Estimates for 1,2-Dichloroethane* (U.S. EPA, 2026n).

Summary: A public commenter (0169) said that EPA used Point Source Calculator's (PSC) standard "farm pond" scenario with static water instead of site-specific flowing stream characterization to model sediment concentrations, which subsequently mischaracterized Manufacturing OES receiving water bodies. The commenter said that since the farm pond scenario employed by EPA does not account for sediment resuspension or downstream transport process, overestimation of benthic exposure and risk is likely, particularly when using default scenario values reflective of a static pond. The commenter added that the farm pond scenario's complete exclusion of transport processes (including episodic storm-driven resuspension, tidal exchange, and near-field mixing) overestimates steady-state benthic exposure and risk under typical conditions.

EPA Response: The Agency acknowledges some of the conservative assumptions associated with the use of the EPA Point Source Calculator (PSC). The PSC model is an updated model of the EPA Office of Pesticide VVWM and includes the parameter of receiving water body flow rate. Thus, EPA's application of PSC included the use of site-specific flow rates. The use of the farm pond parameters was specific to the water column and benthic chemistry and physical properties (suspended solids, organic carbon, sediment density, etc.), rather than referring to a still water body. See Section 4.4 of the *Environmental Media Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026g) for a description of the modeling approach for estimating concentrations in sediment.

Generally, the receiving water body flow is the most important factor in estimating water column, sediment and pore water concentrations. Therefore, the use of receiving water body flow characterizes the fate of 1,2-dichloroethane beyond a static farm pond. In addition, for relevant general population exposures, EPA conducted a downstream analysis, that is, in estimating concentrations of 1,2-dichloroethane at drinking water intake locations (see Section 5.1.2.3.1 in the 1,2-Dichloroethane Risk Evaluation).

4.2 Environmental Releases

4.2.1 Other Comments

Summary: A public commenter (0169) said that EPA should improve documentation traceability by clearly identifying in the technical assessment documents which specific facility, year, and data source are used to derive key input parameters such as the release rates/pollutant load (in kg/day), rather than requiring reviewers to cross-reference multiple supplemental files. The commenter identified several instances in the Draft Risk Evaluation for 1,2-Dichloroethane where transparency and information traceability should be improved, such as why the 2016 DMR annual discharge for Eagle US 2 LLC – Lake Charles Complex in Westlake, Louisiana, is the basis of the release estimate used for exposure calculations related to the Manufacturing OES.

EPA Response: To avoid repetitiveness across documents, EPA includes cross-referencing to technical support documents and supplemental files that contain the detailed information the commenter has requested. The Agency added facility-specific NPDES numbers and pollutant loads within the technical support documents and the final risk evaluation (*e.g.,* see Table 4-1 in *Environmental Media Assessment for 1,2-Dichloroethane,* Table 4-4 in *General Population Exposure Assessment for 1,2-Dichloroethane* and Table 3-11 in *Risk Evaluation for 1,2-Dichloroethane*).

In the draft risk evaluation, EPA downloaded DMR data for all facilities releasing 1,2-dichloroethane from 2015 to 2020. All facilities releases were then mapped to a condition of use/OES. All release data for the draft are in the *Draft Water Releases for 1,2-Dichloroethane* (U.S. EPA, 2025f). EPA presented in the Draft risk evaluation, the facility releases that result in the highest receiving water body concentration per OES. Thus, the 2016 release data for the Eagle US 2 LLC – Lake Charles Complex in Westlake, Louisiana, was the facility with the highest receiving water concentration in the Manufacturing OES across the 5 years of all facility releases and representing the highest concentration within the Manufacturing OES.

For the final risk evaluation, EPA downloaded a total of nine years of release data from 2015 to 2024. EPA used the same methodology as described above in the draft evaluation for the final evaluation. That is, all facility releases are compiled in and mapped to the corresponding COU/OES in the supplemental file, *Water Releases for 1,2-Dichloroethane* (U.S. EPA, 2026q). For each COU/OES, EPA presents in the facility releases with the highest receiving water body concentration within all the facilities within the same COU/OES. EPA chose the 2021 DMR annual discharge for the Eagle US 2 LLC – Lake Charles Complex in Westlake, Louisiana, facility for the final risk evaluation as it was the highest release year without storm events coinciding with the highest receiving water body concentration. In addition, the facility provided EPA with release patterns from 2016 to 2022. Releases in 2021 (330 lb) are similar to those in 2016 (316.79 lb), which provides evidence that the 2021 releases are representative across the 9 years of releases that EPA assessed for the Eagle 2 LLC facility and the corresponding Manufacturing OES (see Section 4.1 in the *Environmental Media Assessment for 1,2-Dichloroethane*).

Summary: A public commenter (0169) observed a miscalculation in the supplemental file *Draft Water Releases for 1,2-Dichloroethane* on the sheet "OES Summary." They noted that formulas used to calculate central tendency and high-end values included multiplication by 0.453592, which is the conversion factor from lb to kg, but that conversion is not necessary because the formula was based on data already in kg units.

EPA Response: EPA thanks the public commenter for pointing out the error and has removed the conversion in the "OES Summary" worksheet of the *Water Releases for 1,2-Dichloroethane* file and updated the 50th and 95th percentile surface water discharges per OES in the *Environmental Release Assessment for 1,2 Dichloroethane* (see Table 4-1) and *Risk Evaluation for 1,2-Dichloroethane* (see Table 3-6).

5 ENVIRONMENTAL RISK ASSESSMENT

Comments associated with this topic are summarized in the subsections below.

5.1 Environmental Exposures

Summary: A public commenter (0169) said that in order to assess aquatic hazard and risk to aquatic species, EPA determined that empirical data on 1,2-dichloroethane needed to be supplemented by data on sediment-dwelling species from analogs, including 1,1-dichloroethane. However, since chronic exposure in sediment to 1,1-dichloroethane is infeasible, EPA issued a TSCA section 4 test order for 1,1-dichloroethane requiring the conduct of an acute exposure duration study using Organisation for Economic Co-operation and Development (OECD) 233 but did not include OECD 233 in either test order issued for 1,2-dichloroethane. The commenter said that if EPA believes that 1,1-dichloroethane is an analog for 1,2-dichloroethane in environmental risk assessment, then EPA must conclude that chronic 1,2-dichloroethane exposure to benthic and sediment-dwelling organisms will not occur.

EPA Response: EPA identified 1,1-dichloroethane, 1,2-dichloropropane, and 1,1,2-trichloroethane as appropriate analogs for use in the environmental hazard and risk assessment for 1,2-dichloroethane. 1,1-Dichloroethane and 1,2-dichloropropane had acute exposure duration benthic hazard data for *Chironomus riparius* (Smithers, 2024a, b). The best analog with chronic exposure duration benthic hazard data was 1,1,2-trichloroethane (Smithers, 2023). 1,1,2-Trichloroethane did not have acute duration benthic hazard data available. 1,1-Dichloroethane has a higher vapor pressure than both 1,2-dichloroethane and 1,1,2-trichloroethane, suggesting it will more readily volatilize from water than 1,2-dichloroethane and 1,1,2-trichloroethane. The analog appendix, Appendix A in the *Draft Environmental Hazard Assessment for 1,2-Dichloroethane* (U.S. EPA, 2025c), noted that confidence was increased in 1,1-dichloroethane as an analog based on methods used in the specific study selected for read-across (acute toxicity study in *Chironomus riparius;* (Smithers, 2024b)) to mitigate impacts from volatilization (such as chemical measurement, chemical renewal, capping test vessels). Given the difference in vapor pressure between 1,1-dichloroethane and 1,2-dichloroethane, and the fact that the 1,1-dichloroethane study deemed appropriate to read-across to 1,2-dichloroethane used an acute exposure duration (Smithers, 2024b), the Agency cannot draw the conclusion that chronic exposure to benthic and sediment-dwelling organisms will not occur solely based on the chemical properties of one of the selected analogs.

5.2 Environmental Hazards

5.2.1 Analog Selection

Summary: Several public commenters (0156, 0159, 0166, 0169) said that the environmental risk assessment conducted by EPA for 1,2-dichloroethane is flawed. The commenters said that EPA selected three analogs (1,1-dichloroethane, 1,2-dichloropropane, and 1,1,2-trichloroethane) to assess 1,2-dichloroethane's environmental hazard using tools and framework that were appropriate, however, the process lacked transparency regarding tool settings and analog selection criteria. The commenter stated that EPA should communicate how many analogs were identified using each tool. Moreover, the commenters requested that EPA provide additional details to explain how the initial list of analogs was narrowed to only three analogs after applying the flowchart, since it appears that there could be additional analogs that match the EPA criteria.

EPA Response: Selection criteria were stated throughout Appendix A Analog Selection for Environmental Hazard in the *Draft Environmental Hazard Assessment for 1,2-Dichloroethane* (U.S. EPA, 2025c). The following considerations were noted in the draft assessment:

1. Analog candidates that appeared in three out of four programs and were structurally similar were identified as potential analog candidates (19 chemicals identified).
2. Analog candidates with log octanol:water partition coefficient (log KOW) and vapor pressure within one log unit relative to 1,2-dichloroethane continued to be considered as potential analog candidates (7 of the previous 19 chemicals).
3. Analog candidates with readily available (*i.e.,* completed data evaluation and extraction) measured benthic hazard data continued to be considered as potential analog candidates (3 of the previous 7 chemicals).
4. Analog candidates with similar physical and chemical and environmental fate properties relevant to water, sediment, and soil continued to be considered as potential analog candidates (3 of the previous 3 chemicals).
5. Analog chemicals with ecotoxicological similarity to 1,2-dichloroethane continued to be considered as potential analog candidates (3 of the previous 3 chemicals).

The three analogs ultimately selected (1,1-dichloroethane, 1,2-dichloropropane, and 1,1,2-trichlorothane) were the only analogs that had gone through the entire systematic review process from literature search through data evaluation and extraction, and thus those three analogs proceeded beyond the structural similarity and Log KOW and vapor pressure screening to additional steps shown in the analog flowchart (Figure_Apx A-1). The step of determining if there is available measured analog hazard data is a step in the analog flowchart which occurs after vapor pressure screening and before comparing additional physical, chemical, and fate properties.

Further clarity was added to the final *Environmental Hazard Assessment for 1,2-Dichloroethane* as described below (U.S. EPA, 2026f). Throughout Appendix A of the final *Environmental Hazard Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026f), EPA has added further clarification by including the ready availability of measured benthic hazard data in the list of reasons why these three analogs were ultimately selected for use in the environmental hazard and risk assessment for 1,2-dichloroethane. Additionally, EPA has released with the final assessment a supplemental file that lists the settings used for each of the four structural similarity tools (Analog Identification Methodology [AIM], QSAR Toolbox, Cheminformatics Search Module, and GenRA), along with the full list of analogs generated, including those that were only identified by one or two of the tools as being structurally similar to 1,2-dichloroethane (see *Tool Settings and Analog List for Environmental Hazard Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026p)).

5.2.2 Modeling Approaches

Summary: A public commenter (0169) said that EPA used the web-based Interspecies Correlation Estimation (Web-ICE) application and the Species Sensitivity Distributions (SSD) Toolbox to estimate acute toxicity and derive a hazardous concentration threshold for 5% of species (HC5) for 1,2-dichloroethane, entering EC50/LC50 values for *Daphnia magna*, fathead minnow, and rainbow trout and supplementing with predicted data for other species. The commenter said that EPA reported an HC5 of 17.86 mg/L and used the lower bound (11.909 mg/L) as the acute concentration of concern. The commenter questioned why EPA relied on the SSD Toolbox rather than Web-ICE's SSD module, which can accept many surrogate species and directly generate HC5s. The commenter said that three trial runs in Web-ICE (including proxy entries for midge, frog, salamander, and brine shrimp) produced much lower HC5s (≈2.0–2.2 mg/L). The commenter said that because the SSD Toolbox HC5 incorporated Web-ICE-predicted LC50s, it compounds uncertainty from both Web-ICE predictions and the Toolbox fitting, and thus may be less conservative and less accurate than HC5s produced directly by Web-ICE. The commenter agreed with deriving an HC5 but concluded that EPA's chosen method may underestimate risk compared with Web-ICE's SSD outputs.

EPA Response: The approach of incorporating both empirical and Web-based Interspecies Correlation Estimation (Web-ICE)-predicted hazard EC50/LC50 values (effect concentration at which 50% of test organisms exhibit an effect/lethal concentration at which 50% of test organisms die) in SSDs derived using the SSD Toolbox has been used in prior risk evaluations and was reviewed by the SACC for the *Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP)* (see *Peer Reviewers' comments on the draft RE of TCEP Letter Review*; EPA-HQ-OPPT-2023-0265-0055). The reviewers stated that this approach is scientifically sound. Entering empirical data for a different surrogate species when the tested species is not available as a surrogate in Web-ICE (*e.g.,* entering *Artemia salina* empirical data as *Streptocephalus proboscideus* in Web-ICE) introduces additional uncertainty as the tested species is used to generate predicted toxicity values for additional species. EPA derived a similar HC5 of 2.1 mg/L for 1,2-dichloroethane that is similar to the HC5s presented by the commenter when using the Web-ICE SSD module without entering the empirical data for species not listed as surrogates in Web-ICE (*Chironomus riparius, Lithobates pipiens, Ambystoma gracile,* and *Artemia salina*). However, the HC5 value of 2.1 mg/L was derived prior to applying the data filters recommended to select robust models with increased accuracy in predictions in U.S. EPA (2024b) and described in both the draft and final environmental hazard assessments for 1,2-dichloroethane (U.S. EPA, 2026f, 2025c). After applying the recommended data filters, the Web-ICE-derived HC5 was 16.5 mg/L, which closely aligns with the SSD Toolbox-derived HC5 of 17.9 mg/L. Using the SSD Toolbox to derive the SSD increases confidence in the resulting SSD and HC5 (hazard concentration that is protective of 95% of the species in the SSD) as this tool allows the assessor to select between multiple models and fitting methods, ensuring that the best model fit is achieved for a given dataset.

Summary: A public commenter (0169) said that EPA derived the algal concentration of concern (CoC) of 12.4 mg/L using the 72-hour 1,2-dichloroethane EC50 value in *Raphidocelis subcapitata* of 124 mg/L and applied an assessment factor of 10. The commenter said that since there are several species of algae, another approach to derive algal concentration of concern (COC) is by using Web-ICE's SSD module for algal species, which includes data for 15 algal species. The commenter encouraged EPA to also consider adding the SSD approach since it was also used for other aquatic species.

EPA Response: EPA had data for one algal species from a study (CITI, 1996a) with an overall quality determination (OQD) of high for the 1,2-Dichloroethane Draft Risk Evaluation. An additional high-rated algal study (Wang et al., 2021) with two species was incorporated in the final risk evaluation (see Section 2 of the *Environmental Hazard Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026f). In the Model Validation section of the Web-ICE v4.0 User Manual (U.S. EPA, 2024b) it is stated that the uncertainty analysis of algal ICE models is ongoing. Because there was only high-quality empirical data available for three species, Web-ICE algal predictions have not yet been validated, and a minimum of eight species are required to develop an SSD, EPA used a deterministic approach to set the algal COC.

5.2.3 Hazard Calculations and Values

Summary: A public commenter (0169) said that EPA used the lower 95 percent confidence interval (CI) of the HC5 (11.909 mg/L) as the acute CoC to represent hazard to aquatic invertebrates and vertebrates in the draft assessment, and that the rationale for this decision was not entirely clear. The commenter requested that EPA provide additional details on how it was determined that using the lower 95 percent confidence interval of HC5 as the acute CoC was appropriate, including relevant references to support this decision.

EPA Response: As the commenter stated, EPA used the lower 95% confidence interval of the HC5 as the acute concentration of concern in the *Draft Environmental Hazard Assessment for 1,2-Dichloroethane* (U.S. EPA, 2025c). As requested, EPA has clarified the justification for using the lower

95% confidence interval (CI) as the acute aquatic COC instead of applying an assessment factor in section 4 of the *Environmental Hazard Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026f) and has provided supporting citations (Raimondo et al., 2025; Awkerman et al., 2014). Notably, Raimondo et al (2025) found that using the lower 95% CI of the HC05 as the COC reduces aleatory uncertainty.[1]

Summary: A public commenter (0169) said that 1,2-dichloroethane toxicity in midges (chironomids) was extrapolated from available data for the analogs 1,1-dichloroethane and 1,2-dichloropropane, but the available toxicity data (LC50 of 147 mg/L) for another analog (1,1,2-trichloroethane) was not used. The commenter said that it is unclear why EPA has not identified the lack of toxicity studies in midges as a knowledge gap for 1,2-dichloroethane and did not issue a test order for toxicity testing in midges.

EPA Response: The Agency has evaluated the 1,1,2-trichloroethane midge study submitted for consideration by the commenter with an LC50 of 147 mg/L (Roghair et al., 1994) and assigned an OQD of uninformative, due to the study authors reporting that measurement of test concentrations for 1,1,2-trichloroethane was unreliable, and thus EPA has not incorporated this value in the SSD. EPA noted in the *Final Scope of the Risk Evaluation for 1,2-Dichloroethane* (U.S. EPA, 2020) that the Agency would consider read-across from analog chemicals to characterize the potential hazards of 1,2-dichloroethane and also noted in the March 24, 2022 TSCA section 4(a)(2) test order for 1,2-dichloroethane that "Identification of the reasonably available information for 1,2-dichloroethane included consideration of existing data for the parent chemical and analogous chemicals for aquatic and terrestrial exposure pathways." TSCA section 4(a)(2) test orders were issued earlier (January 2021) for analog candidate chemicals 1,1-dichloroethane, 1,2-dichloropropane, and 1,1,2-trichloroethane, thus there was not a need to fill the benthic data gap with additional toxicity testing in midges with the target chemical 1,2-dichloroethane.

Summary: A public commenter (0169) said that while several toxicity studies were identified for 1,2-dichloroethane, some of the identified studies were not mentioned in the Draft Environmental Hazard Assessment for 1,2-Dichloroethane (Table 10 in the comment). The commenter said it was unclear if the studies were missing (*i.e.,* not identified by EPA) or were determined to be of low quality and not included. The commenter added that, in some instances, the study was included by EPA but not all toxicity thresholds were recorded in Table 2-1. The commenter encouraged EPA to verify that the contents of Table 2-1 of the Draft Environmental Hazard Assessment for 1,2-Dichloroethane are complete.

EPA Response: In the first paragraph of Section 2 of the *Draft Environmental Hazard Assessment for 1,2-Dichloroethane* (U.S. EPA, 2025c) EPA stated that the studies summarized in Table 2-1 were those assigned OQDs of high or medium and which were considered the most relevant for quantitative assessment. Table 2-1 was intended to be a summary table and not to include all extracted data from all studies in the dataset. The Agency has revised the third paragraph of Section 1 of the *Environmental Hazard Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026f) to clarify that details for all studies, including those considered uninformative for quantitative assessment, are available in supplemental files (*Data Quality Evaluation Information for Environmental Hazard for 1,2-Dichloroethane* and *Data Extraction Information for Environmental Hazard and Human Health Hazard Animal Toxicology and Epidemiology for 1,2-Dichloroethane* (U.S. EPA, 2026c, e)). EPA compared the values and studies submitted by the commenter in Table 10 of their comment with the studies included in the 1,2-dichloroethane dataset and determined that four of the listed studies had not been included in the dataset for the draft risk evaluation: Stauffer Chem Co. (1973), Roghair et al (1994), Bazin et al (1987), and

[1] Aleatory uncertainty accounts for the variation of inputs and fit parameters.

Call et al (1980). These four studies have now undergone systematic review. The 1,2-dichloroethane data reported by Stauffer Chem Co. (1973) received an uninformative rating and was incorporated qualitatively into the assessment (for details of the data evaluation see *Data Quality Evaluation Information for Environmental Hazard for 1,2-Dichloroethane* (U.S. EPA, 2026e)). The study by Roghair et al (1994) also received an uninformative rating as the results were based on nominal concentrations due to "unreliable analytical results" and thus was not incorporated into the assessment as it only contained data for 1,1,2-trichloroethane. The full reference was not available for Bazin et al (1987), thus this reference was not incorporated in the assessment. The study reported in Call et al (1980) was also reported in Richter et al (1983) and had already been evaluated and extracted from Richter et al (1983) and used quantitatively in the draft assessment. Additional toxicity values from citations already in the evaluated dataset were added to Table 2-1 in the final assessment (Smithers, 2024a, b; CITI, 1996a, b). Reasons for not incorporating additional studies and toxicity data into the summary table submitted by the commenter included the following:

- The data was already present in Table 2-1 from the submitted citation;
- The same data were available from multiple sources and had already been evaluated and extracted from a different source;
- The study did not meet population, exposure, comparator or scenario, and outcomes (PECO) screening criteria; or
- The study received an OQD of low or uninformative.

Summary: A public commenter (0169) said that EPA used chronic values (ChV) for chronic exposure assessment in daphnids and midges, however, other than defining ChV as "chronic value", no explanation was provided on how ChV is calculated. The commenter requested that EPA include the formula used for ChV (see original comment for formula).

EPA Response: EPA has added the formula used to calculate chronic values as Equation 1-1 in Section 1 of the *Environmental Hazard Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026f).

Summary: A public commenter (0169) agreed that there is limited information available for terrestrial vertebrate studies with mammalian or avian wildlife species for either 1,2-dichloroethane or its analogs. The commenter noted that similar to Table 3-1 in the *Draft Environmental Hazard Assessment for 1,2-Dichloroethane*, only a few studies that captured no-observed-effect levels/lowest-observed-effect levels (NOELs/LOELs) only for 1,2-dichloroethane were available in ECOTOX, with no information on acute toxicity. However, the commenter said that their review of the information available for 1,2-dichloroethane in the CompTox Chemicals Dashboard, three acute oral LD50 values (lethal dose at which 50% of test organisms die) in mice, rats, and rabbits (413, 670, 860 mg/kg, respectively), one acute inhalation LC50 in rats (7.08×10^3 mg/m^3), and one acute dermal LD50 in rabbits (2.08×10^3) were identified. The commenter said that the oral LD50 values can be used to classify 1,2-dichloroethane as moderately to slightly toxic using EPA's categories for terrestrial organisms. Additionally, the commenter said that the three oral LD50 values can be entered into the Web-ICE SSD module for wildlife to derive an HD5 value of 21.43 mg/kg. The commenter encouraged EPA to consider these additional pieces of information, because the current assessment only considers toxicity reference value and ChV for mammals and birds, respectively.

EPA Response: EPA did not quantitatively assess dermal or inhalation risk to terrestrial wildlife, as it is expected that these routes of exposure are minor compared to exposure via ingestion (U.S. EPA, 2003a). Additionally, EPA does not typically assess acute hazard durations (*e.g.,* <3 days) for terrestrial wildlife as part of TSCA risk evaluations, as it is expected that chronic exposure durations are more realistic in

the terrestrial environment for existing chemicals. Exposures for wildlife species (mammals and birds) to chemicals released to the environment are primarily via ingestion in food, soils, sediments and via inhalation (U.S. EPA, 1993). As mammals and birds are not immobile and range across habitats to forage for food, acute exposures are not expected that would be associated with a receptor remaining fixed in one point where an acute (one time) release would occur.

5.3 Environmental Risk Characterization

Summary: A public commenter (0163) said that EPA's modeling results suggest risk to aquatic organisms from exposure from surface water, benthic pore water, and sediment, and reaches this conclusion despite acknowledging that "[1,2-dichloroethane] is not expected to persist in aquatic surface water or sediments as it volatilizes from water." The commenter said that the Draft Risk Evaluation for 1,2-Dichloroethane suggests that sufficiently high release rates may cause "sediment concentrations to cause partitioning to sediment pore water," without providing empirical evidence to support the suggestion. The commenter said that a sediment stability study conducted in accordance with a 2021 test order issued under TSCA section 4 demonstrated that 1,1-dichloroethane, applied to sediment, had minimal affinity to associate with the sediment, indicating that that chronic exposure via sediment to evaluate hazard to benthic organisms is unachievable and that any exposure to 1,1-dichloroethane would predominantly occur via the aqueous phases and would only be acute in nature. The commenter said that despite EPA's own conclusions regarding 1,2-dichloroethane's volatility and the information available from the 2021 study for 1,1-dichloroethane suggesting that exposure to 1,2-dichloroethane in sediment and pore water is limited, EPA relied on data from the two other, less similar analogs, to assess risk to benthic organisms. The commenter added that since surface water monitoring data are limited, the Draft Environmental Risk Evaluation for 1,2-Dichloroethane is based on point-of-release concentrations in effluent data from NPDES permits to estimate aqueous concentrations near facilities releasing 1,2-dichloroethane. For the manufacturing condition of use, the estimate for 1,2-dichloroethane concentrations in surface water relies on releases at a single facility during a period when rain events led to dramatically higher releases than normal; therefore, EPA's estimates are "several orders of magnitude" greater than concentrations available from ambient surface water monitoring data." The commenter said that EPA's analysis should be viewed as speculative at best and its draft conclusions relative to environmental risks presented by 1,2-dichloroethane manufacturing and disposal as a worst-case, screening assessment.

A few public commenters (0156, 0159, 0166) said that there are significant flaws with the environmental exposure assessment, particularly as it relates to assumptions of releases to the environment and parameters used to predict environmental concentrations. The commenter (0163) said that these concerns are most striking in the estimates of releases to water representative of a storm event to characterize the manufacturing condition of use, coupling high release estimates with assumptions of very low (drought-like) water flow. The commenter said that reliance on more realistic estimates of releases (through facility data from years without major storm events) and/or more realistic estimates of water flow (such as from site-specific information) likely would reduce the predicted water concentrations by at least 500-fold and dramatically impact EPA's environmental risk determinations. The commenter added that there are also highly conservative and/or generic assumptions regarding releases and parameters around environmental modeling for all key pathways of exposure to the environment, including sediment and air, that could be improved with site-specific and/or more realistic, readily available data.

EPA Response: In the final *Risk Evaluation for 1,2-Dichlorethane* (U.S. EPA, 2026m) EPA has revised the statement "[1,2-dichloroethane] is not expected to persist in aquatic surface water or sediments as it volatilizes from water" to "1,2-Dichloroethane is expected to have low degradation rates under most

environmental conditions, and ongoing releases could sustain its presence in aquatic and terrestrial environments. Fugacity modeling indicates that when constantly released to either soil or water, it will primarily remain in the media of release (100% release to water = 82.8% partitioning to water; 100% release to soil = 71.1% partitioning to soil) (U.S. EPA, 2026n). Volatilization from soil and water can mitigate persistence, consistent with its Henry's law constant (1.54×10^{-3} atm-m^3/mol) and vapor pressure (78.9 mmHg), although it is also water soluble (8,600 mg/L) and thus some portion will remain dissolved in water." to better reflect the properties of 1,2-dichloroethane as already summarized in Section 2 of the *Draft Risk Evaluation for 1,2-Dichloroethane* (U.S. EPA, 2025e) and in the *Draft Chemistry and Fate and Transport Assessment for 1,2-Dichloroethane* (U.S. EPA, 2025b). EPA has robust evidence that there are ongoing releases of 1,2-dichloroethane to water based on facility reported releases to DMR and TRI. The suggestion that 1,2-dichloroethane can partition to sediments and the associated pore water is based on the well-established understanding of environmental partitioning rather than monitoring data: 1,2-dichloroethane has high water solubility and relatively low sorption (low organic carbon:water partition coefficient [K_{OC}]), so under sustained, elevated concentrations in overlying water, a concentration gradient would drive diffusive flux into the upper sediment. Given its weak sorption, 1,2-dichloroethane would remain primarily in the dissolved phase (*i.e.,* pore water) rather than strongly bound to solids. Since EPA did not have data on concentrations in sediment near direct discharges to water, the Agency used an equilibrium partitioning approach for volatile organic chemicals in sediment to estimate concentrations in pore water (Fuchsman, 2003).

EPA identified 1,1-dichloroethane, 1,2-dichloropropane, and 1,1,2-trichloroethane as appropriate analogs for use in the environmental hazard and risk assessment for 1,2-dichloroethane. The analog with chronic exposure duration benthic hazard data was 1,1,2-trichloroethane (Smithers, 2023). 1,1-Dichloroethane has the highest vapor pressure and Henry's Law constant across the three analogs and 1,2-dichloroethane, suggesting it will more readily volatilize from water than 1,2-dichloroethane and 1,1,2-trichloroethane (vapor pressure: 1,1-dichloroethane 227 mmHg, 1,2-dichloroethane 78.9 mmHg, 1,2-dichloropropane 40 mmHg, 1,1,2-trichloroethane 23 mmHg; HLC 1,1-dichloroethane 5.6×10^{-3} atm-m^3/mol, 1,2-dichloropropane 2.82×10^{-3} atm-m^3/mol 1,2-dichloroethane 1.54×10^{-3} atm-m^3/mol, 1,1,2-trichloroethane 8.2×10^{-4} atm-m^3/mol). See Appendix A of the *Environmental Hazard Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026f).

There are several facilities releasing 1,2-dichloroethane that are mapped to the Manufacturing COU. However, as the commenter noted, the facility with effluent releases resulting in the highest receiving water body concentrations provided the worst-case scenario. For this facility located in Louisiana by the Calcasieu River, but releasing into low-flowing Bayou d'Inde, EPA did not rely on DMR data representing the highest effluent releases in 2020 for aquatic exposure and risk estimates. For that particular year, there were several storms that affected the amount of 1,2-dichloroethane released and EPA instead characterized the data separately as a storm scenario.

The next highest year of 1,2-dichloroethane effluent release as reported by the facility in DMR was 2016 for draft risk evaluation and based on communications with the facility (see Table 4-2 in the *Environmental Media Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026g)), no specific storms were associated with any of the releases that year. In addition, 2023 releases were similar in magnitude as those in 2016 so that EPA's environmental analysis represents impacts of actual releases of 1,2-dichloroethane.

In the final risk evaluation, EPA obtained the plant flow rate for this facility from ECHO Application Programming Interface (API). As the facility plant flow rate exceeded the hydrologic flow, the facility

plant flow rate was applied as the flow in the receiving water body. This refinement reduced the estimated surface water concentration below the concentration of concern.

6 HUMAN HEALTH RISK ASSESSMENT

Comments associated with this topic are summarized in the subsections below.

6.1 Human Exposures

Comments associated with this topic are summarized in the subsections below.

6.1.1 Occupational Exposure

6.1.1.1 General Comments

Summary: A public commenter (0160) recommended EPA use 95th percentile exposure estimates instead of central tendency estimates to calculate worker risks. The commenter stated that EPA based unreasonable risk determinations on central tendency estimates when monitoring data for workers were not available, but EPA used high-end estimates when monitoring data were available. The commenter said that EPA should not utilize different exposure estimates based on the availability of monitoring data, and EPA's use of central tendency exposures for workers is not protective of PESS.

EPA Response: Estimation of risks for chronic non-cancer and cancer effects includes values for the exposure concentration (central tendency and high-end), the exposure frequency in days/yr and the working years. EPA's default values for working years is 31 years as a central tendency and 40 years as a high-end and the default value for exposure frequency is to assume daily exposure up to 250 days/yr. EPA also incorporated industry available data on working years as well, where available. When the exposure concentrations are based on sufficient monitoring data, EPA believes it is appropriate to use both the central tendency and high-end exposure estimates with the default or industry provided values for exposure frequency and working years to estimate these risks. When the exposure concentrations are estimated from methods of lower confidence, such as from modeling, EPA believes that the combination of the 95th exposure concentration along with the default values for working years and assumption of daily frequency is overly conservative and therefore the central tendency is used in these cases to assess chronic risks. In such cases, EPA has examined the underlying assumptions and inputs of the exposure model to determine the most reasonable level of expected exposure based on all available data. EPA does not disregard high-end exposures, but rather, EPA considers how the range of exposure estimates was developed for each COU individually and determines the applicability of the high-end or central exposure estimates.

Summary: A public commenter (0161) encouraged EPA to better understand the context in which material/chemical is used to better control exposures and recommended performance based versus prescriptive measures. The commenter stated that overly prescriptive measures can lead to unintended adverse consequences to worker health such as heat stress, loss of dexterity, tripping hazards, ergonomic issues, and others. This comment was issued in response to EPA solicitation of comments on exposure controls and use of personal protective equipment (PPE) used during the manufacture, processing, and use of 1,2-dichloroethane.

EPA Response: EPA calculates an occupational exposure level (OEV) in the risk evaluation, the risk evaluation does not specify how the OEV is to be achieved for facilities within an OES (*e.g.,* the risk evaluation does not require performance based or prescriptive measures).

With the publication of this final risk evaluation and the identification of unreasonable risk, EPA will move forward with risk management by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that the chemical substance no longer presents an unreasonable risk.

During the risk management stage, EPA will consider a variety of relevant factors in choosing one or more of the available TSCA section 6(a) regulatory tools, including the extent to which overly prescriptive measures as mentioned by the commenter (0161) can be avoided through a flexible, performance-based approach.

Summary: A public commenter (0169) expressed agreement with EPA's approach to characterize occupational exposure potential by similar exposure group (SEG), rather than for each OES as a whole.

EPA Response: EPA appreciates this commenter's support of EPA's use of exposure groups**.** EPA's preferred practice is to use the metadata that is available in sources of occupational exposure data, such as test orders, to identify exposure groups and assess exposure by exposure group. Where available, EPA utilized SEG-specific information to estimate exposures and risks.

Summary: Several public commenters (0155, 0156, 0159, 0166, 0169, 0170) stated that though the Vinyl Institute Consortium provided EPA with demographic data specific to the occupational setting as part of the Test Order Response, the Agency did not utilize this data in the risk evaluation. One comment (0155) stated that demographic data specific to the industrial setting is more accurate than Bureau of Labor Statistics population studies estimating the number of working years. In their public comment, the Vinyl Institute (0169) provided a summary of the demographic data (length of service). Specifically, the Vinyl Institute comment reported a mean length of service of 8.9 and 10.6 years for the total workforce for manufacturing and manufacturing as a byproduct, respectively. A maximum length of service of 33 years and 40 years for manufacturing and manufacturing as a byproduct, respectively, were also reported in the public comment. The Vinyl Institute public comment (0169) stated that the EPA "must refine these estimates based on the demographic data it requested and received from the VI Test Order."

EPA Response: EPA acknowledges that the Vinyl Institute Consortium (VI) provided demographic information as part of their test order submission, and that EPA requested such information as part of the test order. At the time, such information was claimed as confidential business information (CBI), and as such EPA was not able to incorporate this information in the draft risk evaluation in a way that would be protective of the CBI claims. EPA reviewed the information provided in VI's public comment and found the limited non-redacted information to be too limited in scope to incorporate into the risk evaluation. For example, the public comment provided limited summary statistics for select OESs. EPA requested that VI submit additional demographic information without CBI claims and received this information in a letter dated March 18, 2026 (EPA-HQ-OPPT-2018-0427-0181). EPA has reviewed this information and found it sufficient for incorporation into the risk evaluation.

Specifically, this information provided by Vinyl Institute has been incorporated as a value for "working years" utilized in the cancer calculations for the following OESs: Manufacture of 1,2-Dichloroethane (Intentional); Manufacture of 1,2-Dichloroethane (as an Unintentional Byproduct); Processing as a Reactant; and Byproducts Produced During the Manufacture of 1,2-Dichloroethane. For more information on the calculations in which this information was utilized, including example calculations, please see Appendix B and C of the *Occupational Exposure Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026k). Working years are not included in acute and intermediate exposure risk calculations. While working years are included in chronic, non-cancer exposure risk calculations, the working years variable is canceled out in the calculations, and as such does not impact the resulting risk estimates. Specifically, for the chronic non-cancer effects, the exposure dose over the working years is averaged over the working years. Working years is in both the numerator and denominator and arithmetically cancels out the working years (or exposure duration) term. For cancer effects, the exposure dose over the

working years is averaged over the lifetime years, which includes the years with no exposure. EPA uses a default of 78 years to represent the lifetime years when calculating exposure for cancer risk estimation. (Appendix B of the *Occupational Exposure Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026k)). The incorporation of the industry provided demographic data can be found in Sections 4.1.1.4 of the *Byproducts Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026a), 3.1 and 3.3 of the *Occupational Exposure Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026k), and 5.1.1 of the *Risk Evaluation for 1,2-Dichloroethane* (U.S. EPA, 2026m).

Although EPA has incorporated the industry demographic data into the risk evaluation, for the OESs where industry data was provided, EPA also provides risk estimates using the working years based on U.S. Bureau of Labor Statistics (BLS) data for comparison. The risk determinations for the COUs evaluated with these OESs are based on the risk estimates derived from industry submitted data. The BLS working year estimates are intended to capture a worker's tenure by the end of their career and include total tenure with an industry. BLS data are not industry or site specific but are considered high quality for a variety of reasons (including a robust and well-defined collection methodology). EPA utilized BLS data for all other OESs where industry-provided data was not available.

Summary: A public commenter (0163) said that EPA's evaluation of the production of 1,2-dichloroethane as a byproduct relies on data that is not representative of the range of manufacturing scenarios that may produce 1,2-dichloroethane unintentionally. As demonstrated in the Agency's assessment of byproducts from EDC manufacture, percent-by-weight is not typical of concentrations when EDC is formed as a byproduct. Instead, these percent-by-weight concentrations are generally much lower than suggested by the Vinyl Institute data. The commenter is aware of processes conducted by at least one of its members in which the quantity of EDC inadvertently produced as a byproduct is on the order of one percent or less of the waste stream and where this stream is contained in a closed process system designed to prevent potential environmental releases. Such situations present a markedly different level of risk from those assessed by the Agency and should be incorporated into the draft risk evaluation. The commenter said that EPA must consider levels below which such byproducts do not pose an unreasonable risk of injury and should not include them in unreasonable risk determinations that advance to the risk management phase.

A public commenter (0171) stated that "we support the following comments developed by ACC's Chlorine Panel", which included the statement that EPA should appropriately consider the risk from the production of 1,2-dichloroethane as a byproduct. Additional details were not provided in this comment.

EPA Response: EPA received personal breathing zone monitoring data on manufacturing of 1,2-dichloroethane as a byproduct from the Vinyl Institute Consortium, which represented two sites, where 1,2-dichloroethane was produced as a byproduct at specific reported concentrations (95–100%). Both sites were included in the inhalation monitoring study. EPA is not aware of additional occupational full-shift exposure monitoring data that would be specific to manufacturing 1,2-dichloroethane as a byproduct at other concentrations. However, in response to comments, EPA did assess the "one percent" scenario suggested by the commentor, although the commentor did not provide monitoring data specific to that scenario. EPA evaluated a scenario where the concentration of 1,2-dichloroethane in the byproduct stream would be as low as 1%, than the concentration in the byproduct stream at the facilities where the inhalation monitoring was done. To evaluate this scenario, EPA estimated the airborne exposure concentrations of the "one percent" scenario using the same method described in Equation 4-1 of Section 4.1.1.3 of the *Byproducts Assessment for 1,2-Dichloroethan*e. EPA used a mole fraction of 0.95 for the inhalation monitoring data (95% scenario) and 0.01 for the mole fraction in the 1% scenario, based on information on weight percent provided in the test order and the public comments ((Stantec ChemRisk, 2024); EPA-HQ-OPPT-2018-

0427-0163). For dermal exposure, EPA used the same method described in Section 2.4 of the *Occupational Exposure Assessment for 1,2-Dichloroethan*e. This analysis resulted in lower inhalation exposures and associated risk estimates for this low weight percent scenario (1% weight) by two orders of magnitude compared to the test order inhalation monitoring data. The results of this analysis are presented in the *Risk Calculator for Occupational Exposure for 1,2-Dichloroethane* (U.S. EPA, 2026l). EPA acknowledges that there is uncertainty associated with adjusting the inhalation data from 95 to 1%.

With the publication of this final risk evaluation and the identification of unreasonable risk, EPA will be moving forward with risk management by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that the chemical substance no longer presents an unreasonable risk. During the risk management stage, EPA will consider a variety of relevant factors in choosing one or more of the available TSCA section 6(a) regulatory tools when determining how to address risk from this COU.

6.1.1.2 Personal Protective Equipment (PPE) and Other Controls

Summary: Two public commenters (0160, 0172) stated that EPA cannot consider PPE throughout the risk evaluation. The commenters wrote that mixing risk management with risk evaluation underestimates risks, improperly biases risk management decisions, and is unlawful. One commenter (0172) said that Congress separated the risk evaluation and risk management processes to ensure that EPA determines whether a chemical poses unreasonable risk based only on health and environmental effects. Additionally, the commenters (0160, 0172) said that EPA's proposed approach would allow for developing risk estimates based on widespread use of PPE, which is inconsistent with TSCA's mandate that chemicals' risks are evaluated in a manner consistent with the best available science. The commenters stated that robust evidence indicates that PPE usage in occupational settings is limited and often ineffective, and EPA's own SACC criticized EPA's approach of assuming PPE use. One of the commenters (0172) expressed that consideration of PPE is also fundamentally inconsistent with the occupational hierarchy of controls, which only permits the consideration of PPE as a last resort.

In contrast, another public comment (0169) described that EPA did not properly account for personal protective equipment used in the workplace, noting that EPA should "incorporate available information on PPE usage – to do otherwise would leave the final risk evaluation legally unsound". This comment indicated that "EPA must incorporate the information it has received on PPE usage (respirators and dermal protection). Another public comment (0163) described that "EPA's evaluation includes a number of assumptions about the use of personal protective equipment that are not consistent with industry practice that further compounds the conservative nature of its exposure analysis". A public commenter (0162) additionally recommended EPA consider PPE in the final risk evaluation, in alignment with the proposed Risk Evaluation Framework Rule.

EPA Response: EPA recognizes a range of opinions in the public comments regarding consideration of PPE within the evaluation of risk. However, EPA's Risk Evaluation Framework Rule states that EPA's "consideration of occupational exposure scenarios will take into account reasonably available information, including known and reasonably foreseen circumstances where subpopulations of workers are exposed due to the absence or ineffective use of personal protective equipment. EPA will not consider exposure reduction based on assumed use of personal protective equipment as part of the risk determination." 40 CFR 702.39(f)(2). When characterizing the risk to human health from occupational exposures during risk evaluation under TSCA, EPA conducts baseline assessments of risk and makes its determination of unreasonable risk in a manner that takes into consideration reasonably available information (*e.g.,* test order information, site visits) regarding the use of respiratory protection or other PPE. This allows EPA to make unreasonable risk determinations based on the available information regarding workers. Additionally, when the Agency receives information demonstrating the use of PPE

and what types, it can be used to inform EPA's risk evaluation so that it can reflect real working conditions which can be incorporated into the exposure scenarios. In determining whether unreasonable risk is presented, EPA's consideration of occupational exposure scenarios took into account reasonably available information on the implementation and use of occupational exposure control measures such as PPE. As described in Section 6.2.1 of the risk evaluation, EPA specifically considered reasonably available information about PPE use for four COUs associated with Manufacturing and Processing as reactant. For the other occupational COUs, EPA did not have reasonably available information regarding use of PPE for those COUs

EPA acknowledges that the test order submission from the Vinyl Institute provided detailed information regarding the use of controls, including respiratory protection, for workers in facilities that manufacture and process 1,2-dichloroethane (Stantec ChemRisk, 2024). EPA agrees with public comments (0163, 0169) that this information should be further incorporated into the risk evaluation. In response to these comments, EPA has performed a more detailed summary and analysis of the information on controls and PPE provided in the Vinyl Institute test order submission Final Study Report. Specifically, EPA has updated Sections 3.1.5 and 3.3.5 of the Occupational Exposure TSD to include a more detailed summary of the PPE, engineering controls, and administrative controls that were documented in the Final Study Report.

Additionally, EPA has made several changes to the risk evaluation to better incorporate the updated review and analysis of the available information on PPE.

Changes to Appendix K (Information on Personal Protective Equipment): This section has been updated to provide descriptive information on the PPE EPA received from the test order and other sources. Discussion of this information (such as the confidence or representativeness) is now provided in the Risk Characterization for Occupational Exposure (Section 5.3.3.1).

Changes to Section 5.3.3.1 (Occupational Inhalation Exposure Risk Characterization): This section has been updated to provide a discussion of reported use of respiratory protection for each OES. EPA has incorporated reasonably available information on respiratory protection usage by workers into each OES and included a discussion on whether or not the information can be used to refine the risk estimates.

Specific to the three OESs that were included in the test order submission from the Vinyl Institute (Intentional Manufacturing; Manufacturing as an Unintentional Byproduct; and Processing as a Reactant), EPA has performed a detailed review of respiratory protection utilized by workers within each SEG and each OES covered in the Vinyl Institute test order submission. Use of respiratory protection and other PPE was documented during the full, task, and short-term sampling performed as part of the test order (see Appendix N-Raw Sample Results of the Final Study Report). EPA has included a discussion on how this informs our confidence in the risk estimates at the central-tendency and/or high-end exposures in Section 5.3.3. While EPA does not quantify the exposure reduction that may result from the use of PPE, EPA does include an indication of the respirator APF needed to mitigate risk (see Table 5-27 of the Risk Evaluation). Additionally, for certain SEGs, EPA considered reasonably available information on PPE, which influenced EPA's reliance on high-end exposure estimates in the risk determination (see Section 6.2.1).

Although EPA provided inhalation risk estimates with the level of PPE that would mitigate the unreasonable risk if applied, as described previously, EPA based its risk determination on risk estimates without PPE. Although EPA believes that the information on PPE is informative for characterization of

the risk estimates, EPA does not have sufficient information to be able to determine if current PPE practices are consistent with the level of PPE required to mitigate exposures so that they do not exceed applicable benchmarks. For example, while EPA has evidence that certain workers wear PPE for specific high-exposure tasks, the PPE reduction tables assume a worker is wearing PPE for a full-shift exposure, and the APFs are based on 8-hour TWA exposures. As such, while the table may indicate an APF of 10 needed based on an 8-hour TWA exposure, there could be scenarios where an APF of 1,000 is needed only for a short-term exposure period during a shift. EPA acknowledges that use of respiratory protection during high-intensity tasks may significantly reduce overall full-shift exposure if these tasks contribute to a large percentage of the potential exposure during a shift. EPA has considered how the use of PPE affects confidence in the exposure estimates (*e.g.,* consistent use of PPE at high-end exposures indicates that the risk estimates are likely an overestimate), and for certain SEGs, EPA considered reasonably available information on PPE, which influenced EPA's reliance on high-end exposure estimates in the risk determination (see Section 6.2.1).

Consideration of dermal PPE is addressed in a subsequent public comment response.

Summary: A public commenter (0169) expressed that various U.S. Occupational Safety and Health Administration (OSHA) regulations explicitly require employers to assess workplaces for hazards and select appropriate PPE. The commenter wrote that EPA stated that there is a lack of regulatory standards for glove protection factors for dermal exposure, but this is not correct. The commenter said that the OSHA PPE standard for hand protection establishes selection criteria for selecting and providing hand protection relevant to employees' work areas. Additionally, the comment described that OSHA provides guidance to the regulatory community with recommendations on the protective qualities of various types of gloves, and that manufacturers may also use similar rating systems, as well as information on breakthrough time, permeation rate, and general recommendations regarding suitability for submersion, splash protection, or intermittent contact. The commenter noted that this information provided the basis for a quantitative protection assessment of gloves during the selection process. The commenter recommended EPA incorporate the use of gloves and other dermal protection into its modeling and not assume that significant dermal exposure to workers can occur.

Another public comment (0163) stated that EPA's analysis of dermal exposures also does not incorporate the use of chemical-resistant gloves, asserting that there are no regulatory standards for glove protection factors. The comment described that the Occupational Safety and Health Administration's (OSHA) standard for hand protection (cited as 59 29 CFR 1910.138, Appendix B to Subpart I) establishes selection criteria for providing dermal protection for workers.

EPA Response: EPA agrees with the comments that OSHA provides regulatory standards and recommendations on the selection of hand protection for workers. EPA has clarified the statement ("lack of regulatory standards for glove protection factors for dermal exposure") to reflect that OSHA has not established quantitative protection factors for the selection of gloves, which would be equivalent to the APFs OSHA provides for respiratory protection selection. EPA notes that references to the OSHA hand protection standard were included in Appendix F of the Draft Occupational Exposure technical supporting document. EPA has also included a reference to the OSHA regulatory standard on hand protection (29 CFR 1910.138) in the final risk evaluation and supporting documents.

While the public comment indicated that information from OSHA guidance documents or glove manufacturers could provide a basis for a quantitative protection assessment of gloves, neither of the provided references provided a quantitative protection assessment. The public comment (0169) cited to an OSHA guidance document [OSHA, *Personal Protective Equipment* (2003)*,* OSHA 3151-02R at 25-

26], that provided a four-tier rating system on protective qualities of various gloves against various chemicals. EPA identified a version of this document from 2023 and noted that the ratings provided were qualitative. Specific to 1,2-dichloroethane (referred to as ethylene dichloride in the guidance document), a rating of fair was provided for neoprene and butyl gloves, and a rating of poor was provided for latex/rubber and nitrile gloves. The manufacturers guide provided by the public comment included breakthrough times and permeation rates, as well as qualitative ratings for other factors related to glove usage (as described in the public comments).

The public comment described that SDS from Vinyl Institute members recommend use of Viton or PVA gloves. The test order report indicated that workers wear leather, neoprene, nitrile or heavy duty nitrile, or viton/butyl gloves, depending on the area and tasks being performed. In response to this comment, EPA has reviewed the information on glove use provided in the Vinyl Institute test order Final Study Report and provided a more detailed summary and description of this information in Section 5.3.3.2 (Occupational Dermal Exposure Risk Characterization) of the Risk Evaluation. Specifically, for the OESs where EPA received detailed information on the use of gloves by workers, EPA has further reviewed this information to understand how this may affect the risk estimates. However, EPA did not have sufficient information to assume the use of 1,2-dichloroethane chemically resistant gloves in the risk determination for any COU.

EPA uses a modeling approach to estimate the potential dermal contact with the skin in the workplace. The model does not incorporate the use of protective gloves. The dermal model is explained in full detail in Section 2.4 (Dermal Exposure Approach and Methodology) and Appendix D (Dermal Exposure Assessment Method) of the Occupational Exposure TSD. EPA recognizes that protective gloves are worn to mitigate the amount of dermal contact with the skin and considers data on PPE use to be part of the occupational exposure assessment. EPA's practice for dermal exposure assessment is to combine the quantitative estimates of dermal exposure from modeling with the confidence we have in the use of gloves from the available data. EPA has incorporated reasonably available information on dermal PPE usage, including information from test order submissions (Stantec ChemRisk, 2024). EPA considers information on glove usage, including selection criteria, employee training, change out procedure, and use during specific tasks, as relevant to information the risk evaluation. Available information on PPE is summarized in Section 3 of the Occupational Exposure TSD. Additionally, EPA has updated the Section 5.3.3.2 (Occupational Dermal Exposure Risk Characterization) of the Risk Evaluation to include on how this may inform our confidence in the dermal risk estimates. EPA does not quantify the exposure reduction that may result from the use of dermal PPE.

Summary: A public commenter (0158) discussed exposure risk in the automotive industry, noting that EPA assessed risks from such facilities the same as assessing risk from chemical manufacturing facilities. The commenter wrote that multiple chemicals are usually present in facilities that manufacture complex durable goods, so exposure controls are routinely put in place that address all potential exposures to any chemical that may be present. The commenter stated that the automotive sector uses the industrial hygiene hierarchy of controls to manage risks from potential chemical exposures, and the combination of automated systems, controlled environment, and appropriate PPE ensures a high level of safety. The commenter provided examples of the types of exposure controls used in high pressure spraying operations in the automotive sector, including automated robotic spray systems, enclosed booths, airflow requirements, downdraft systems, and PPE such as National Institute for Occupational Safety and Health (NIOSH) Approved Powered Air Purifying Respirator (PAPR). The commenter also provided a graphic of the paint application process and the engineering controls used at different steps of that process in their facilities.

The commenter said that, if EPA believes that certain workplace risks are not being adequately controlled, they should identify real and actual risks and coordinate with OSHA to update and enforce its requirements and compliance program. The commenter stated that TSCA should not be used in place of OSHA requirements.

EPA Response: EPA appreciates the information submitted in this public comment, which included specific information on PPE and controls used in the automotive sector. EPA did not include the manufacture of automobiles in the risk evaluation, and as such EPA does not have an applicable OES for which to incorporate this information. It is EPA's practice to consider reasonably available information on occupational exposure controls and PPE for each specific OES, and EPA does not assume that selection of controls will be the same across OESs. EPA refers the commentor to the updated Sections 5.3.3 and 5.3.8.2 ("Risk Estimates for Workers" and "Occupational Exposure Risk Estimates"), which includes a discussion of how the available information on PPE may be used to refine risk estimates for each OES.

Following issuance of the risk evaluation for 1,2-dichloroethane, the Agency will initiate risk management rulemaking to mitigate identified unreasonable risk associated with 1,2-dichloroethane under the COUs by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that 1,2-dichloroethane no longer presents such risk. EPA would also consider whether such risk may be prevented or reduced to a sufficient extent by action taken under another federal law, *e.g.,* the Occupational Safety and Health Act, such that referral to another agency under TSCA section 9(a) or use of another EPA-administered authority to protect against such risk pursuant to TSCA section 9(b) may be appropriate. EPA will examine a number of considerations when developing any risk management activities from COUs that are determined to be significantly contributing to unreasonable risk.

Summary: Several public comments provided information on use of controls, including PPE, utilized in occupational settings relevant to 1,2-dichloroethane (0157, 0161, 0165).

A public commenter (0157) discussed exposure to 1,2-dichloroethane during distribution operations. The commenter said that distribution operations generally involve handling 1,2-dichloroethane in closed or sealed containers and performing short-duration, task-based activities. The comment described that these activities are typically conducted under established controls, including closed-system transfers, local exhaust ventilation, and use of PPE consistent with OSHA requirements. The comment noted that the established controls reduce the potential for inhalation and dermal exposure compared with open-process manufacturing or processing operations. The commenter wrote that dermal exposure is generally uncommon in distribution settings because containers remain sealed and chemical-resistant gloves and other protective equipment are routinely used.

One public commenter (0161) responded to EPA's solicitation of comments on exposure controls and use of personal protective equipment (PPE) used during the manufacture, processing, and use of 1,2-dichloroethane. This public commenter encouraged EPA to better understand the context in which material/chemical is used to better control exposures and recommended performance based versus prescriptive measures. The comment described that in real-world exposure scenarios often industrial hygiene professionals will be controlling exposures to a number of chemicals being handled at the same time. Thus, evaluations of single chemical exposures (*i.e.,* in a vacuum without consideration of any other exposure conditions) is not preferrable when evaluating chemical exposures and evaluating risk.

A public commenter (0165) described that workers at every 1,2-dichloroethane/vinyl chloride monomer (VCM) production site in the United States wear personal protective equipment (PPE) in accordance with OSHA, NIOSH, and state regulations when conducting maintenance on the processing units. This public commenter (0165) also discussed how 1,2-dichloroethane is a critical catalyst moderator in the manufacture of ethylene oxide and asserted that the only way a worker could be exposed to 1,2-dichloroethane is from an accidental release when lines are connected or disconnected, but that workers wear PPE when connecting and disconnecting lines.

EPA Response: The Agency recognizes that information on PPE use is an important part of occupational exposure information and has included reasonably available information on PPE when it is available. The above summarized comments provided generic information acknowledging that PPE and other controls are utilized in occupational settings relevant to 1,2-dichloroethane. The information provided is consistent with more specific information provided by the inhalation monitoring test order study for these OES (Manufacturing; Processing as a Reactant). In response to these and other comments, EPA has updated the risk evaluation to include specific information on usage of PPE and other controls from test order submissions and other sources, as summarized in Section 3 (Occupational Exposure Assessment by OES) of the Occupational Exposure Assessment for 1,2-Dichloroethane and Appendix K (Information on Personal Protective Equipment) of the Risk Evaluation. Additionally, Section 5.3.3 (Risk Estimates for Workers) has been updated to include a discussion of how the available information on PPE may be used to refine risk estimates for each OES.

Summary: A public commenter (0162) provided an overview of their use of 1,2-dichloroethane as a catalyst moderator in the ethylene oxide manufacturing process and described that the only potential for exposure is with the discrete task of connecting and disconnecting EDC totes, which is very limited (*e.g.,* 20 minutes every 2–6 weeks). The comment noted that when this occurs, ONUs are kept out of the work area and workers are wearing PPE. The public comment provided additional information on PPE usage during specific tasks, such as the use of full-face respirators worn during tote changeout tasks.

EPA Response: EPA has incorporated this information into Section 3.3.5 of the Occupational Exposure Assessment TSD and Appendix K ("Information on Personal Protective Equipment" of the Risk Evaluation. Additionally, Section 5.3.3 ("Risk Estimates for Workers") has been updated to include a discussion of how the available information on PPE may be used to refine risk estimates for each OES.

6.1.1.3 Inhalation Exposure

Summary: Several public commenters (0155, 0156, 0159, 0163, 0165, 0166, 0169, 0170) expressed that data from the 1,2-dichloroethane TSCA test order was used to characterize inhalation exposures for 4 of the 14 OESs evaluated, but EPA only used the full-shift personal breathing zone samples in calculating risk estimates. These comments noted that the Vinyl Institute provided short-term (15 minute) and task length inhalation monitoring data and qualitative data contextualizing this data, including information on task frequency and controls (including PPE).

One public comment (0169) described that the Agency specifically required the EDC Consortium to include short-term sampling in the test order study plan. The comment described that EPA presented the short-term and task length exposure data in the Draft Occupational Exposure Estimate for 1,2-dichloroethane but noted that it was unclear if and where EPA considered the data in its estimation of occupational exposure risk. The public comment (0169) indicated that "[T]he Agency should clarify use of this requested occupational exposure data in the risk evaluation and note how it is considered in calculating potential occupational exposure risks for each OES of relevance" (0169: p. 21).

The public comment (0169) stated that "If EPA did not utilize this data, VI urges EPA to consider the short-term and task length sample data, when combined with information on frequency and duration of tasks, to evaluate the appropriateness of the high-end estimates of long-term exposure to confirm that infrequent tasks with comparatively high exposure potential are not contributing unduly to full-shift TWA exposure estimates." (0169: p. 21). This public comment also stated that this analysis could aid in informing future risk management decisions.

Two public comments (0163, 0169) noted that EPA assumed 250 exposure days per year, which assumes uniform exposure to EDC on each working day. These commenters described that the Vinyl Institute provided detailed information on frequency of tasks and average task duration in its Test Order response. One commenter (0169) noted that seemingly little of this information was considered in characterization of acute or short-term exposure potential for comparison to applicable health benchmarks. The other commenter (0163) noted that the industry information on frequency and duration of tasks could be used to generate more realistic assumptions about exposure.

Additionally, as part of their comment on the use of the short-term sampling, a public comment (0169) noted that "Task length data, including both the concentration and duration, may provide a more appropriate value for estimation of acute inhalation exposures than the use of a full-shift TWA exposure estimate, particularly for acute benchmarks that are reflective of 15-minute (*e.g.*, a short-term exposure limit [STEL]) or peak/ceiling exposures (rather than acute 8-hour exposures)" (0169: p .21).

One public commenter (0169) expressed agreement with EPA's approach to characterize occupational exposure potential by similar exposure group (SEG) rather than for each OES as a whole.

EPA Response: EPA agrees that duration and frequency of tasks are important considerations for exposure assessment, and that short-term and task-based inhalation monitoring can be informative for contextualizing full-shift inhalation monitoring results. Further, EPA agrees with commenters that the test order provided detailed information on frequency of tasks, and that such information could be utilized to create more realistic assumptions about exposure. EPA reviewed Table 3 of the Vinyl Institute Test Order report and noted that many of the SEG specific tasks occurred on a daily basis, multiple times per shift. The data on task duration was quantitative, the data on exposure frequency included descriptors such as "daily" or "weekly", from which EPA was able to infer that the exposure frequency for individual SEGs could be up to 250 days/yr. EPA requested that the Vinyl Institute submit an analysis of task-based data that was previously claimed as CBI, and this information was received upon request (EPA-HQ-OPPT-2018-0427-0181).

EPA has made the following updates to incorporate this information:

Occupational Exposure TSD: The Agency completed an updated review of the available information on short-term and task-based samples from the Vinyl Institute Final Study Report (Stantec ChemRisk, 2024). Specifically, EPA has further summarized the short-term and task-length monitoring data by SEG, and provided updated Tables 3-3, 3-6, and 3-15 in the occupational exposure TSD. Additionally, EPA has added additional summary of the qualitative information on worker task duration and frequency to Sections 3.1.1 and 3.3.3 of the Occupational Exposure TSD. These updates are also reflected in the Risk Evaluation (see Sections 5.1.1 and 5.3.3).

Additionally, in response to the public comments, EPA has utilized the updated analysis (described above) to provide additional characterization of the high-end risk estimates for chronic inhalation exposure. EPA has maintained 250 working days per year as the default estimate for exposure but

recognizes that uniform exposure does not occur on a daily basis for all 250 working days. EPA also recognizes that there is variation in full-shift and task-based exposure concentrations within each OES and SEG covered in the inhalation monitoring study, and that not all tasks are performed on a daily basis. For example, EPA conducted a more detailed review of exposures for the logistics technician SEG in the Manufacturing OES. According to the information submitted by the Vinyl Institute, loading/offloading tasks from barges and other vehicles occur 50 days per year, and concentrations during these tasks ranged from 0.48 to 8400 ppb (n = 13, # non-detects [ND] = 0) (EPA-HQ-OPPT-2018-0427-0181). The highest full-shift sample concentration (0.29 ppm, D-FS-LGT-01) was associated with a 15-minute short-term sample (8.4 ppm, D-STEL-LGT-01A) collected during a barge loading task. The barge loading task was reported to occur once per week. Based on the available information, EPA believes that the loading/offloading tasks contribute significantly to the full-shift exposures in this SEG, and that such tasks occur with a frequency less than 250 days. As such, the high-end estimates of chronic exposures are likely to overestimate exposures for these workers, and EPA has revised the language in the risk characterization in acknowledgement of this key consideration.

Additionally, EPA has evidence to show that workers within a given SEG, who perform the same tasks, have variation in their exposures. For example, EPA performed a more detailed review of maintenance technicians in the Manufacturing OES. According to the summary statistics provided by Vinyl Institute, maintenance technicians conduct "line breaks and equipment opening" tasks on average 128 days per years, and between three and 250 days per year (EPA-HQ-OPPT-2018-0427-0181). Measured concentrations during these tasks ranged from 2.1 to 22,000 ppb (n = 28, #ND = 0). EPA expects that while some maintenance technicians may conduct line break and equipment opening tasks on a daily basis, such exposures will vary widely, and it is unlikely that exposures at the high-end will occur during every shift. Additionally, based on the available information, workers in this SEG wore respiratory protection during the higher-exposure measurements associated with line break and equipment opening tasks.

Based on the available information, EPA has evidence to suggest that chronic high-end risk estimates for these OES are conservative, as these assume that workers are exposed at the high-end, inhalation, 8-hour TWA concentration during every work shift. Specifically, the high-end inhalation estimates may incorporate tasks that occur with a frequency less than 250 days per year. Additionally, within each SEG, there is a range of task-based exposures, and workers are not likely to experience the same high-end exposure for a task on a daily basis. EPA believes that the chronic, central tendency estimates are more reflective of chronic worker exposures, as these capture the distribution of potential worker estimates at both the low and high-end. These updates have been reflected in the risk characterization. EPA acknowledges that it is appropriate to compare 15-minute exposures against an appropriate 15-minute benchmark, such as a 15-minute STEL. For 1,2-dichloroethane, EPA did not perform this comparison, as EPA believes that the full-shift exposures are appropriate for comparison against acute 8-hour exposure benchmark.

EPA acknowledges the comments supporting EPA's use of exposure groups. EPA's preferred practice is to use the metadata that is available in sources of occupational exposure data, such as test orders, to identify exposure groups and assess exposure by exposure group.

Summary: A public commenter (0165) stated that the Stantec ChemRisk report was not available in the docket as of January 14, 2026, and that there was no way for commenters to compare the inhalation exposure information in the Draft Risk Evaluation to the information submitted by the Vinyl Institute. Additionally, the comment described that there was no way to verify the accuracy of the exposure data presented in Table 5-4 and Table 5-5 of the Draft Risk Evaluation.

Additionally, this comment expressed concern that the risk evaluation uses the value of 7.3 ppm to represent exposure to workers over an 8-hour shift to 1,2-dichloroethane from a closed system where the product is not even isolated. The comment indicated that the source or context for the value could not be derived. The commenter stated that EPA should only base manufacturing and processing as an industrial intermediate exposure estimates on reasonably foreseen tasks related to maintenance on processing units.

Additionally, this comment (0165) described that Table 5-21 of the Draft Risk Evaluation erroneously places the COU of Catalyst moderator under the OES of Processing as a Reactant. The comment notes that this OES should only apply if 1,2-dichloroethane reacts with other chemicals in the processing unit. The commenter explained that ethylene oxide only contains an ethylene molecule and an oxygen atom bonded to both of the carbons of ethylene functionality. There are no chloride functional groups, so 1,2-dichloroethane acts as a catalyst moderator and not as a reactant.

The commenter (0165) wrote that 1,2-dichloroethane is used in a closed system to produce ethylene oxide, so the only pertinent information related to inhalation exposures would be fugitive emissions and accidental releases. The commenter additionally said that the value of 7.3 ppm is not representative of fugitive emissions from a closed-system processing unit, accidental releases are not reasonably foreseeable, and thus, should not be considered within the scope of a TSCA risk evaluation. The commenter (0165) also discussed how 1,2-dichloroethane is a critical catalyst moderator in the manufacture of ethylene oxide. The commenter stated that 1,2-dichloroethane is fed from a pressurized tote into a closed system, and that the totes are changed out every 2 to 6 weeks, depending on the activity level and age of the catalyst, and each change-out takes about 20 minutes. The annual use rate use of the catalyst is around 14,000 lb. The commenter explained that the ethylene oxide processing units are large and typically outdoors, as are the totes. The commenter explains that the 1,2-dichloroethane is generally consumed in the process, but a small amount can remain and be either treated on site or remain in a recycle-stream that feeds back into the process. The commenter asserts that the only way a worker could be exposed to 1,2-dichloroethane is from an accidental release when lines are connected or disconnected. A similar public commenter (0162) also provided an overview of their use of 1,2-dichloroethane as a catalyst moderator in the ethylene oxide manufacturing process, as well as data from their most recently conducted occupational industrial hygiene monitoring (2017 and 2019).

The public commenter (0165) also submitted comments on processing 1,2-dichloroethane as a reactant as an intermediate to manufacture vinyl chloride monomer (VCM). This commenter discussed how the manufacturing of 1,2-dichloroethane and the processing of the chemical as an intermediate to make VCM are intertwined, explaining that VCM is manufactured in an interconnected two-step process, where 1,2-dichloroethane is first produced, and then in the second step, the 1,2-dichloroethane undergoes dehydrochlorination to produce VCM. The commenter also described that a closed-loop, continuous system incorporates both processes. The commenter described tasks during which workers may have exposures and concluded that the likelihood of exposure to 1,2-dichloroethane under the manufacturing and processing as an intermediate condition of use is negligible.

EPA Response: EPA acknowledges the comments on the mapping of the Catalyst moderator COU and the preference that this COU be assessed as an OES. EPA has included additional details provided by the commenter on the catalyst moderator use in the risk evaluation. Specifically, information relevant to processing description was added to the Environmental Release TSD (Section 3.3.1) and information relevant to occupational exposure (including the results of industrial hygiene monitoring and description of worker activities) was added to the Occupational Exposure TSD (Sections 3.1.1, 3.3.1, and 5).

According to the commentor, the exposure frequency for the task of change out of the totes for catalyst use is every 2 to 6 weeks. The exposure frequency in days/yr is a parameter that impacts the estimates of chronic non-cancer and chronic cancer risks. EPA assesses exposure and risk by SEG and Test Order data from manufacturing and processing facilities indicate that SEGs perform multiple tasks and frequencies can range from daily to weekly to monthly with each SEG having tasks that can be performed daily. EPA uses 250 days/yr as a default for exposure frequency for each SEG. A site-specific refinement can be done by using the maximum days/yr for an SEG at the site if it is different from the EPA default. EPA has included language in both the Weight of Scientific Evidence Table 5-13 and in Section 5.3.3.1.4 of the Occupational Exposure Risk Characterization, on variability in exposure frequency and that the actual number of exposure days per year for an SEG may be less than 250 and tasks with high exposure potential may be performed on a less than daily frequency. EPA acknowledges commenter's description of manufacturing and processing of 1,2-dichloroethane in a closed-loop, continuous system, and their qualitative assessment that exposure potential is negligible. The Agency agrees that these features (closed-loop continues systems) can reduce exposure potential and has added this qualitative information on system type and data on the use of PPE to the occupational exposure risk characterization of the Risk Evaluation (Section 5.3.3). While the commenter (0165) described tasks during which workers may have exposures, they did not provide any additional exposure data, such as inhalation monitoring data.

EPA also acknowledges commenters' concerns regarding availability of the underlying data used to assess inhalation exposures. The Stantec ChemRisk referenced in the comment was made available to the public during the public comment period as it was uploaded to the public docket (EPA-HQ-OPPT-2018-0427-0141) on December 9, 2025.

EPA has reviewed the exposure value that was presented in the public comments (7.3 ppm). This value is described in Table 5-4 of the Draft Risk Evaluation and Table 3-2 of the Occupational TSD. According to the Stantec ChemRisk Final Study Report provided by the Vinyl Institute, 7.3 ppm (7,300 ppb) was identified as the 95th percentile full-shift inhalation exposure for operators in the manufacturing SEG (Table 9 of the Final Study Report (Stantec ChemRisk, 2024)). EPA has reviewed this exposure value in more detail and determined that the 95th percentile is not associated with a single sample but is interpolated between multiple values (per the statistical methods used to calculate a 95th percentile). EPA has reviewed the two full-shift samples closest to this value (D-FS-OP-4, D-FS-OP-6) and noted that they are described as representing routine daily tasks occuring in manufacturing settings. One full-shift sample (DS-FS-OP-4) has an associated short-term sample (DS-FS-OP-04A) that was collected during closed loop sample collection of low to moderate concentration. Respirator usage (full-face air-purifying respirator with organic vapor cartridges) was noted to have occurred during this short-term sample. EPA has no information to suggest that accidental releases occurred during the test-order sampling study. Additional information has been added to the risk characterization.

EPA estimates inhalation exposure based on monitoring data at the facilities where the chemical is manufactured, processed and used. EPA evaluates occupational risks using both the central tendency (50th percentile) and high-end (95th percentile) exposure estimates which is why the 95th percentile estimate of 7.3 ppm for operators' exposure from the test order data during manufacturing of 1,2-dichloroethane as an intended product was used in the risk evaluation. EPA used the data in the test order, which includes the results of the inhalation monitoring, as well as information on exposure controls, and metadata on the exposure groups such as the tasks they perform, task frequency, duration and PPE. EPA based the assessment of occupational exposure on the monitoring results, and the detailed metadata.

Occupational industrial hygiene monitoring data provided by the commenter (0162) were incorporated into the Occupational Exposure TSD (see Section 3.3.3).

Summary: Two public commenters (0163, 0169) stated that EPA's estimates of repackaging exposures rely on data from a 1976 NIOSH report, rather than current inhalation monitoring data submitted in response to a 2021 test order. One of the commenters (0163) looked at the NIOSH information and noted that it is based on two data points from an unspecified number of workers collected in 1959. One of the commenters (0169) specifically said that the logistics technician SEG characterized in the submitted inhalation monitoring report reflected data collected in 2024, had a robust sample size, and characterized a subset of tasks considered within the Repackaging OES; however, EPA still chose to use data provided in the 1976 NIOSH report. Additionally, this comment described several reasons why the NIOSH 1976 data is unlikely to reflect current occupational controls or practices consistent with repackaging activities conducted today. This comment described that EPA utilized the test order for several other COU within the risk evaluation.

EPA Response: Upon further review of the study, EPA acknowledges that the 1976 NIOSH data should not be used for estimating exposure, especially since the actual monitoring reported in this study was conducted in the 1950s and is not reflective of current work conditions. Due to these limitations, EPA is no longer utilizing the 1976 NIOSH report in the final risk evaluation. EPA has updated the risk evaluation to incorporate inhalation data for logistics technicians at manufacturing and processing facilities from the Vinyl Institute test order (see Section 3.2.3 of the Occupational Exposure TSD).

EPA agrees that the logistics technician data can be used for the Repackaging OES and has made this addition for the scenario of bulk repackaging.

6.1.1.4 Dermal Exposure

Summary: Many public commenters (0156, 0159, 0163, 0166, 0169, 0170) stated that EPA relied on the dermal absorption fraction (0.3%) extracted from the LabCorp OECD 428 dermal absorption study submitted by the 1,2-dichloroethane Consortium in response to the test order. The commenters said that this estimate represents an upper bound estimate, which overestimates dermal absorption for most individuals. Additionally, the commenters wrote that, in spite of available concentration-dependent absorption fractions, EPA relied only on data for neat 1,2-dichloroethane, which results in an unscientifically conservative estimate of dermal exposure that overestimates risk. Another public commenter (0163) added that the study conducted in response to the test order reported an average absorption of 0.18%, and EPA's analysis does not incorporate the use of chemical-resistant gloves, even though the OSHA standard for hand protection establishes selection criteria for providing dermal protection for workers. Another public commenter (0170) added that the test order for TDCE required the same OECD 428 study.

EPA Response: EPA acknowledges that the value for fraction absorbed can vary by weight fraction. Although, the average absorption from the Labcorp Early Development, 2024 OECD 428 dermal absorption test order was calculated as 0.18% for the neat scenario (+/- 0.08 standard deviation), EPA derived the upper-bound (95% upper confidence limit) of 0.3% as a conservative estimate to account for the mass losses and the high variability in the neat test preparation. The SACC recommended correcting the data for mass losses as being appropriate. EPA has updated the dermal exposure approach and methodology to include a dermal absorption fraction range of 0.16 to 0.3%. This range is based on an adjustment informed by considerations pertaining to calculated coefficient of variation greater than 25% (calculated between ~30 and 100% from the test order) and mass balance of the calculated fraction absorption values across the various test preparations of 1,2-dichloroethane (neat and the 1, 10 and 50%

1,2-dichloroethane test preparations in 1,1,2-trichloroethane) (IOMC ED, 2022). As described in Section 2.4 (Dermal Exposure Approach and Methodology) of the Occupational Exposure TSD, EPA refined its approach by applying variable fraction absorption values (based on the neat and 1, 10 and 50% 1,2-dichloroethane in the vehicle of 1,1,2-trichloroethane) to the various exposure scenarios that were of greater representativeness to the 1,2-dichloroethane weight fractions being modeled. Fraction absorption values are summarized in Table 2-1 of the Occupational Exposure TSD. The use of adjusted fraction absorbed values increases confidence in the appropriate use of the test order data.

EPA recognizes that the use of protective gloves provides a barrier to mitigate dermal contact with the skin but is not aware of a method to reduce estimates of potential dermal exposure quantitatively based on glove use. EPA's practice, therefore, is to use a modeling approach to estimate potential dermal contact and to consider the available data on glove use by exposure groups, the potential for dermal contact based on the worker activity descriptions and the frequency and duration of potential exposure in characterizing the dermal risk to workers.

Summary: A public commenter (0161) stated that industrial hygiene professionals often use safety data sheets to train their workers about how to work with and handle a chemical that they may come in contact with over the course of their normal job duties. The commenter said that they have several resources that provide guidance on estimating dermal exposures, including American Industrial Hygiene Association (AIHA) Mathematical Models for Estimating Occupational Exposure to Chemicals (2nd edition), which specifically addresses dermal exposure modeling. The commenter stated that Frasch et al. (2014) identified several limitations that should be considered when applying a fractional absorption approach, and Lynch et al. (2023) compared results of the fractional absorption modeling approach to a flux-based approach and found 2- to 20-fold higher estimates of exposure with the fractional approach. The commenter additionally said that the industrial hygiene SkinPerm dermal absorption model uses a permeability coefficient approach. The commenter recommended EPA better characterize the exposure determinants that may dictate which dermal exposure estimation approach is preferred for a given chemical and its conditions of use.

EPA Response: EPA notes the suggestions on resources on models. Flux would not be an appropriate term to estimate the absorption of 1,2-dichloroethane, and the study of Frasch et al 2014 is in agreement with a fractional absorption approach for highly volatile chemicals. 1,2-dichloroethane evaporates rapidly so the duration of absorption does not allow for steady flux. Rather, the flux during the short absorption time is transient and may vary considerably over the few minutes that 1,2- dichloroethane is absorbing. There is no accurate way to assign one flux value, determine the duration of that flux, or determine time dependent flux for such a short absorption event.

Highly volatile chemicals like 1,2- dichloroethane exhibit relatively consistent ratios of evaporation to absorption for finite doses, and this yields relatively consistent values of fractional absorption. This principle is demonstrated by the "chi" value in dermal modeling which Frasch incorporates for estimating absorption of volatile chemicals. The consistency in fractional absorption across dermal loads is evident from the test order data and from IHSkinPerm modeling. For instance, the IHSkinPerm model estimates 0.693% absorption for a neat dose of 2.1 mg/cm^2 and 0.698% absorption of a 1-percent formulation dosed at 1.4 mg/cm^2. Even with different loading conditions the percent absorption values are consistent. The Lynch 2023 paper specifically states: "The review and alternative exposure analyses indicate that the current TSCA modeling approach may generate total dermal absorbed doses for chlorinated chemical manufacturing and feedstock use scenarios that are 2- to 20-fold higher than those generated by IHSkinPerm." However, EPA is relying on the test order empirically-derived value of 0.3% absorption from a guideline study rather than a modeling approach value of 0.693%.

From the test order data, EPA did not choose the most conservative value measured, the highest uncorrected raw data replicate value 0.37% utilizing 1,1,2-trichloroethane as the COU vehicle. Instead, the assessment utilized the value of 0.3% absorption for neat 1,2-dichloroethane after correction based on SACC and OECD guidance (highest neat 1,2-dichloroethane uncorrected measurement was 0.33%). This absorption is over 2 times less than the modeled absorption by IHSkinPerm at 0.69%. The lower absorption measurements in the isopropylmyristate (IPM) vehicle do not reflect COU worker exposures, thus are not appropriate for risk calculations since industry identified 1,1,2-trichloroethane as the COU vehicle. The various COUs must match the corresponding testing concentration results. The uncorrected mean raw absorption measurements for 1,2-dichloroethane were 0.07%, 0.13%, and 0.19% at concentrations of 1%, 10%, and 50% utilizing 1,1,2-trichloroethane as the COU vehicle and 0.18% for neat 1,2-dichloroethane. Thus, the assessment absorption value of 0.3% brackets the uncorrected raw replicate absorption measurements in the OECD 428 guideline study. Lost mass balance, low sample number and high data variability add uncertainty that the reported mean value accurately represents the dermal absorption. The SACC and OECD 428 guidance recommended that the data be corrected for lost mass as being appropriate which was incorporated to calculate the absorption value of 0.3% for neat 1,2-dichloroethane (OECD, 2004) and (EPA-HQ-OPPT-2024-0114-0086) . The absorption testing incorporated a vapor trap to quantify this compartment, so the lost mass cannot be assumed to be completely from evaporation. EPA acknowledges that there are potential mass losses during the assembly and disassembly of the apparatus is not captured by the vapor trap nor collected in the receptor fluid. Given the challenges in performing the absorption test with a volatile chemical such as 1,2-dichloroethane, the data had high variability with coefficients of variation from 31% to 100% of the mean value. The ratio of the lost mass for 1,2-dichloroethane was 61-fold or higher than the mean absorption value which justifies the correction recommended by the SACC and OECD guidances. The other alternative recommended by the SACC was to utilize the higher IHSkinPerm model value of 0.693% absorption. EPA prefers high quality empirically-derived data over modeled estimates. For the final risk evaluation, EPA incorporated the variability in fraction absorption by weight percent as warranted by the 1,2-dichloroethane concentrations for the OES.

Summary: A public commenter (0169) expressed support for using a probabilistic modeling approach for dermal exposure modeling. The commenter stated that probabilistic methodology is more appropriate for determining the potential for unreasonable risk through dermal exposure than deterministic methods. Moreover, the commenter wrote that EPA appears not to have considered probabilistic estimates of dermal absorption fraction, and they should incorporate probabilistic estimates in the final risk evaluation.

EPA Response: EPA acknowledges the commentor for the comments on the probabilistic approach and that this could be applied to the fraction absorption parameter as well. For the final risk evaluation, EPA incorporates the variability in fraction absorption by weight percent as warranted by the 1,2-dichloroethane concentrations for the OES.

6.1.1.5 Conditions of Use

Summary: A public commenter (0152) expressed support for the use of the OSHA Laboratory Standard as the gold standard to manage laboratory exposures. The commenter stated that they have used the implementation of recent TSCA rules to gather data about the broad effectiveness of existing engineering controls, and they provided extensive data on laboratory exposures to methylene chloride to EPA. The commenter said that the data demonstrate that a properly designed Chemical Hygiene Plan, as required by the OSHA Laboratory Standard, is more than sufficient to eliminate unreasonable risk from laboratory use.

Additionally, the commenter stated that EPA's determination that 1,2-dichloroethane poses an unreasonable risk when used as a laboratory chemical was not based on exposure data associated with laboratory use as defined in the OSHA Laboratory Standard. The commenter said that EPA used exposure data from quality assurance/quality control (QA/QC) laboratories as the basis for estimating exposures from laboratory use of 1,2-dichloroethane. The commenter remarked that there are two reasons to believe that these are not valid proxies of laboratory exposures: (1) OSHA's definition of laboratory use exempts QA/QC laboratories; and (2) academic laboratories are workplaces where only small quantities of hazardous chemicals are used. The commenter said that EPA obtained exposure data for the use of 1,2-dichloroethane in processing as a reactant, but this is likely to produce an overestimate of laboratory exposures. The commenter finally stated that if EPA continues to base its risk estimate for research laboratory use of 1,2-dichloroethane on exposures from QA/QC laboratories, it should only require implementation of a Workplace Chemical Protection Program for laboratories that use 1,2-dichloroethane as an aerosol. The commenter recommended EPA consider the financial and operational impact of any future rule requirements on academic laboratory facilities.

EPA Response: The 1,2-dichloroethane test order monitored the SEG of laboratory technicians at manufacturing and processing facilities. EPA used this data in assessing the OESs of Manufacture and Processing as a Reactant. EPA did not identify any 1,2-dichloroethane monitoring data at commercial laboratories. Therefore, EPA relied on other sources of data, recognizing that there would be uncertainty in applying the data to the OES of Commercial Use of 1,2-Dichloroethane as a Laboratory Chemical. Sources of data that EPA used included the test order laboratory technician data; one source of data for this COU. EPA also used inhalation monitoring data for methylene chloride used in academic laboratories cited by the commentor. EPA adjusted for differences in vapor pressure and mole fraction between the surrogate chemical and the chemical being assessed when using surrogate data. Use of surrogate data increases our overall confidence in the assessment of this OES.

Any proposed Workplace Chemical Protection Program would be developed as part of risk management rulemaking following the final unreasonable risk determination and would be subject to public notice and comment as part of the rulemaking process.

6.1.1.6 Derived Occupational Exposure Value (OEV)

Summary: Two public commenters (0163, 0169) discussed EPA's proposed OEV. The commenters wrote that the identified OEV is well below established occupational limits and recommended that EPA apply a less conservative UF for human-to-human (intraspecies) variability than is used for the general population. The commenters said that, while a UF_H of 10 is considered appropriate for the general population, its application to a worker population is overly conservative because worker populations are considered less sensitive overall. The commenters stated that occupational regulatory agencies in the European Union use UF_H values of 3 or 5 for derivation of OEVs as summarized in Schneider (2022). The commenters additionally recommended EPA develop a chronic OEV on the basis of the cancer effect observed at a threshold, rather than applying a linear extrapolation approach to the Nagano et al. tumor data. Based on a threshold approach using the benchmark concentration lower bound of 4 ppm, the commenters proposed an OEV of 1.1 to 1.7 ppm, applying a total UF of 10 to 15, which incorporates a UF_H of 3 to 5. The public commenter (0169) said that for workers, an approximate 80- to 120-fold difference exists between an acceptable exposure concentration set on the basis of the existing non-threshold dose response assessment (*e.g.,* equivalent to 1×10^{-4} risk level) and one based on a threshold approach, which is consistent with the difference between the commenter's proposed OEVs of 1.1 to 1.7 ppm and EPA's OEV of 0.014 ppm. The commenter (0169) also said that the decisions made by EPA on the human health risk assessment have significant impact on the risk calculations and overall

conclusions regarding unreasonable risk associated with 1,2-dichloroethane. The commenters stated that this proposed value is better aligned with existing occupational exposure limits. As an example, commenter (0169) said that EPA's decision to treat 1,2-dichloroethane as a non-threshold carcinogen significantly lowered the acceptable exposure concentrations for relevant populations, including workers and the general population. Finally, the commenters remarked that the cancer effect represents the most sensitive threshold effect, so a chronic OEV developed on the basis of cancer would be health protective of other adverse effects associated with 1,2-dichloroethane exposure.

EPA Response: EPA believes that its use of a 10× UF_H is the most appropriate and defensible approach for this particular risk evaluation. EPA considers multiple PESS groups in its development of risk estimates (including women of childbearing age, all lifestages, individuals with pre-existing health conditions, and genetic predispositions). EPA also includes workers as PESS as per TSCA section 3(12) that states that "the term [Potentially Exposed or Susceptible Subpopulations]…means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." This risk evaluation considers PESS throughout the human health risk assessment, including in the exposure assessment, hazard identification, dose-response analysis, and as summarized in the hazard characterization. EPA does not necessarily provide distinct risk estimates for each subpopulation, because some are already represented by the risk estimates presented while others are not quantifiable (*e.g.,* genetic predisposition, other health conditions). In the absence of quantitative information on the impact of genetic variability, pre-existing health conditions, or other factors on susceptibility across the worker population, EPA applied an uncertainty factor of 10 to account for interindividual variability in the 1,2-dichloroethane risk evaluation. EPA acknowledges that there is uncertainty around the magnitude of variation in toxicokinetic and toxicodynamic factors across individuals and whether the factor of 10 is sufficient to protect potentially susceptible subpopulations, however, data were not identified to determine if a reduction was applicable nor were data identified to determine if a higher value was applicable for this risk evaluation.

The UF_H was established to account for uncertainty and variability that includes susceptible subpopulations, and research indicates that a factor of 10 (when considering both toxicokinetics and toxicodynamics) is sufficient in most cases (U.S. EPA, 2002b). EPA expects that the UF_H used in the risk evaluation accounts for a significant portion of the intraspecies variability that includes all susceptible subpopulations applicable to 1,2-dichloroethane, including those in occupational scenarios. A refinement to the UF_H would be warranted in cases where the susceptible subpopulation is specifically defined (*e.g.,* through knowledge of the chemical's mode of action), however, EPA does not have any reasonably available data that would support modifying the UF beyond the standard 10×. A 2002 report to EPA (U.S. EPA, 2002b) recommends that reduction of the intraspecies UF from a default of 10 be considered only if data are sufficiently representative of the exposure/dose response data for the most susceptible subpopulation(s). EPA guidance on derivation of data-derived extrapolation factors (DDEF) requires a strong understanding of the mode of action for the endpoint of interest, with relevant quantitative data informative of specific key events underlying the endpoint. This understanding must also include knowledge of the toxicokinetic exposure-response associated with the endpoint (U.S. EPA, 2014). There is insufficient mechanistic information supporting any mode of action for 1,2-dichloroethane and it is unclear whether any particular metabolite for 1,2-dichloroethane is more or less important. Therefore, EPA relied on default dosimetric adjustments and did not establish a DDEF to derive PODs for these endpoints in accordance with agency guidance (U.S. EPA, 2014).

In accordance with EPA's 2005 Carcinogen Guidelines, an appropriate cancer classification with a weight-of-the-evidence descriptor for 1,2-dichloroethane would be "likely to be carcinogenic to humans,". EPA is not considering 1,2-dichloroethane to possess a definitive mutagenic mode of action nor has EPA identified an alternative mode of action due to limited conclusive data that would suggest the application of the threshold approach for cancer dose-response assessment. Additional information related to mode of action would provide additional confidence in the cancer classification. Additionally, at this time, EPA does not have sufficient mode of action information for this risk evaluation to move away from linear low dose extrapolation. If EPA had additional information on the mode of action in this risk evaluation, a non-linear mode of action could have been considered. At this time, EPA does not have sufficient mode of action information to move away from linear low dose extrapolation. The cancer hazard assessment in Section 5 of the 1,2-dichloroethane human health hazard assessment integrates evidence across multiple data sources. EPA did not derive a chronic OEV based on the cancer threshold approach but considers the derived cancer OEV based on the default linear low-dose approach as health protective of the non-cancer adverse effects associated with 1,2-dichloroethane exposure. EPA considers all reasonably available mode of action information and analyses, particularly for non-genotoxic chemicals, to inform the use of non-linear cancer modeling in EPA risk evaluations. In the case of this risk evaluation, however, sufficient information was not available to EPA to inform a non-linear cancer analysis. EPA welcomes further dialog on this issue for application to chemical assessments as it continues to evolve its TSCA risk evaluation program.

6.1.1.7 Other Comments

Summary: A public commenter (0161) stated that exposure of ONUs is generally less than that of workers directly handling the substance, but some ONUs may have higher peak or average exposures than production workers. The commenter specifically stated that workers engaged in maintenance, repair, and/or cleaning of machines or containers with the substance being evaluated are likely to have higher peak or even average exposures than production workers. The commenter recommended that EPA obtain, examine, and present data related to the occupational exposures of workers engaged in maintenance, cleaning, and/or repair separately.

EPA Response: EPA acknowledges that it is important to evaluate exposures to workers engaged in maintenance, cleaning, and repair of machines or containers, where possible. A primary difference between workers and ONUs is that workers may handle the chemical and have direct contact with the chemical, while ONUs may be working in the general vicinity of workers but do not handle the chemical and do not have direct contact with the chemical being handled by the workers. Activities such as maintenance, repair and equipment cleaning may lead to direct contact with the material. Therefore, potential exposures from these occupational activities are characterized by worker exposure levels rather than ONU exposure levels, which generally would account for higher peak or average exposure levels.

In the 1,2-dichloroethane risk evaluation, EPA evaluated and presented inhalation monitoring exposure data for maintenance technicians as part of the Manufacturing; Manufacturing as a Byproduct; and Processing as a Reactant OESs. Additionally, maintenance supervisors and coordinators were included in the ONUs evaluated for these OES. Information on these SEGs, including worker activities and inhalation exposure monitoring, is provided in Sections 3.1 and 3.3 of the occupational exposure TSD.

Summary: A public commenter (0172) wrote that EPA assumed that a full shift was 8 hours per day, but EPA had test-order data from facilities that described "full shift" samples as being 8 to 12 hours. The commenter stated that it was an error to evaluate exposures over an 8-hour period, if EPA had information showing that workers work up to 12 hours per day.

EPA Response: In response to this comment, EPA provided clarification in the final Risk Evaluation and supporting documents that the length of the shift can be up to 12 hours. It is EPA's understanding that the test-order reported full-shift samples that were collected over the full duration of a worker's shift on the day they were sampled. The full-shift sampling durations ranged from 230 to 726 minutes for manufacturing (n = 162), 290 to 678 minutes for manufacturing as a byproduct (n = 53), and 411 to 730 minutes for processing as a reactant (n = 53). According to the Final Study Report, shift durations ranged from 8 to 12 hours for operator/process technicians, maintenance technicians, logistics/distribution technicians, and laboratory technicians. Occupational non-user shift duration ranged from 5 to 12 hours. Due to the variation in the sampling durations and shift lengths within a given COU and SEG, EPA believes that the full-shift samples are representative of a worker's 8-hour TWA exposure. EPA utilized the full-shift sampling concentrations as reported in the test order final study report and assumed a standard working schedule of five days per week (250 days per year) in calculating chronic risk estimates. As such, the chronic risk estimates are representative of a 40 hour work week. EPA does not have evidence to suggest that workers in this industry typically work more than an average 40-hour per week schedule. For example, the test order describes that some facilities in this industry utilize rotating schedules that allow workers to alternate between different work shifts and activities, such that they may have three days off between certain work shifts and are not working 5 days per week.

Summary: A public commenter (0169) said that the TCE risk management rule only exempts byproduct TCE processed within the same site-limited, physically enclosed system that it was generated in, which places unrealistic conditions on the exclusion. The commenter stated that it is critical that EPA not repeat these mistakes as it evaluates byproduct TCE associated with 1,2-dichloroethane production. The commenter said that EPA must understand that even enclosed systems do not operate under an airtight, hermetic seal, and EPA must recognize the nuances of chemical manufacturing processes in evaluating any potential risks presented by byproduct TCE.

EPA Response: EPA understands the nuances of the chemical manufacturing process that while operating within enclosed systems they do not operate under an airtight, hermetic seal and the need to reflect this understanding in the risk evaluation. EPA uses data on emissions and inhalation exposures from chemical manufacturing facilities which supports that chemical manufacturing processes are not operated under an airtight, hermetic seal.

Summary: A public commenter (0161) stated that industrial hygiene professionals often encounter exposure data reported by laboratories as "0," non-detect, or below the limit of detection (LOD; censored data). The commenter said that AIHA has several resources to assist industrial hygiene professionals on how to handle censored data, and it is typically not the preferred practice to remove data with results reported as "0," non-detect, or below the LOD. The commenter expressed that, if data is collected at a particular site, it is reasonable to assume that the chemical is present at the site.

EPA Response: EPA acknowledges that if data for a particular chemical substance is collected at a particular site, it is reasonable to assume that the chemical is present at the site. EPA has modified its procedures for OSHA Chemical Exposure Health Data (CEHD) data to be consistent with this point. EPA recognizes that the treatment of non-detect data should be according to standard procedures and has included this detail in the tables where inhalation monitoring data are presented.

Summary: A public commenter (0169) expressed that EPA reported that it mapped 19 conditions of use to 11 OESs, and the definition of OESs was informed by systematic review, industry outreach, and public comments. The commenter wrote that the Draft Occupational Exposure Estimate refers back to

the Draft Risk Evaluation for 1,2-Dichloroethane in various locations, and it often references incorrect table numbers. The commenter recommended EPA review and confirm referenced table numbers and correct errors in references between documents.

EPA Response: EPA reviewed and updated the cross referencing in the 1,2-dichloroethane Occupational Exposure TSD to ensure that table numbers and references to the Risk Evaluation are accurate.

6.1.2 Consumer Exposure

Summary: A public commenter (0169) stated that EPA preliminarily determined that exposure to consumer articles does not significantly contribute to the unreasonable risk of 1,2-dichloroethane based on a screening level assessment of two peer-reviewed studies: Danish EPA (2018) and Doucette et al. (2010). The commenter expressed agreement with EPA's preliminary determination that exposure to consumer articles does not represent an unreasonable risk, but the commenter stated that the use of overly conservative estimates fails to properly represent real-world consumer exposure scenarios. Additionally, the commenter expressed concern that EPA relied on data from a small sample of consumer articles that are unlikely to be representative of the consumer articles available in the United States today. The commenter stated that a robust assessment would require use of consumer article data representative of the products available to consumers in the United States today and use of estimates that realistically capture consumer exposure risk, but there is no need for further assessment given EPA's conservative, screening level-type approach did not identify an unreasonable risk.

EPA Response: As the commenter noted, EPA used conservative assumptions to parameterize the models used to estimate exposures to articles emitting 1,2-dichloroethane. For both the draft and final risk evaluations, EPA employed a tiering methodology to the consumer assessment with the initial tier relying on a small sample of articles and conservative assumptions for duration and frequency of exposures. If the estimates had resulted in risk estimates below the benchmark for acute and/or chronic exposures, EPA would then have refined the assessment and reevaluated the assumptions and revised the least certain parameters to less conservative values.

6.1.3 General Population Exposure Pathways

6.1.3.1 General Comments

Summary: A public commenter (0160) recommended EPA use monitoring data more fully to estimate risks. The commenter said that EPA concluded that its models for estimating general population risks are sound based on comparison to monitoring data from one location in Calvert City, but a comparison of monitored releases from one facility is not sufficient to reflect all real-world exposures to 1,2-dichloroethane in the ambient air. The commenter stated that recent studies have found that monitored concentrations are frequently above the modeled concentrations, so EPA should consistently use more monitoring data to estimate general population risks.

EPA Response: In the additional modeling of concentrations of 1,2-dichloroethane in the ambient air using TRI data from 2015 to 2024, EPA added Ambient Monitoring Technology Information Center (AMTIC) monitoring locations that were within 50,000 m of release locations as user added receptors to HEM5.0 to more directly compare modeled and monitored data. The results of this comparison are available in Section 7.1 of the *Environmental Media Assessment for 1,2*-Dichloroethane (U.S. EPA, 2026g). The results of the new modeling effort allow for comparison of concentrations resulting from releases reported to TRI to multiple monitoring stations across the country.

Summary: A public commenter (0172) expressed concern that EPA failed to consider numerous other 1,2-dichloroethane exposures to the general population, which must be addressed in the final risk evaluation. The commenter specifically said that EPA must expand its assessment of the risk of 1,2-dichloroethane ingestion while swimming, in order to include children under 6 years of age. Additionally, the commenter recommended EPA expand its assessment of the risk of 1,2-dichloroethane ingestion from soil to children younger than three.

EPA Response: EPA does not have data to support including children under age six in the swimming scenario that assumes an hour a day in the receiving water body (see Section 4.2 in the *General Population Exposure Assessment for 1,2-Dichloroethane*).

For younger children, as presented in Sections 4.1 and 4.3 of the *General Population Exposure Assessment for 1,2-Dichloroethane,* oral exposures to 1,2-dichloroethane are assessed via drinking water (including for infants as well as toddlers and young children) and soil ingestion via pica.

6.1.3.2 EPA's Modeling Approach

Summary: A public commenter (0169) expressed agreement with EPA's preliminary determination that the 1,2-dichloroethane conditions of use do not present unreasonable risk to the general population. The commenter said that EPA appropriately decided to skip the screening-level tier in predicting ambient air concentrations and proceed directly to the highest-tier modeling approach. The commenter stated, however, that EPA modeled ambient air concentrations using the American Meteorological Society/EPA Regulatory Model with generic source parameters and co-located emissions for TRI facilities, and EPA also applied worst-case meteorology for generic scenarios and assumed flat terrain for all scenarios. The commenter expressed that EPA's reliance on generic parameters and co-located sources, combined with conservative temporal patterns, result in modeled concentrations that are more representative of screening-level analyses than refined assessments.

EPA Response: EPA agrees that using facility-specific data for use in modeling of ambient air concentration provides more refined estimates than use of default/generic/assumed values. When using releases reported to either NEI or TRI, EPA used the available facility-reported parameters as inputs to HEM5.0; however, data for all modeling parameters are not consistently reported for all facilities. Therefore, EPA used default/generic/assumed values only for parameters when they were not available TRI or NEI. Section 3.1 of the *Environmental Media Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026b) provides specific information about the input parameters used.

EPA agrees that the co-located emissions as reported to TRI are a source of uncertainty in the ambient air analysis. To mitigate some of this uncertainty, EPA used NEI data to refine locations of TRI release locations to better reflect actual emission locations. EPA also modeled emissions reported to NEI, which does not report co-located emissions at each facility.

EPA agrees that the lack of release-specific parameters (*e.g.*, stack height, stack temperature, plume velocity) in TRI is a source of uncertainty in the ambient air analysis. When modeling TRI releases, EPA used emissions parameters that tend to result in high-end exposures to be health protective. EPA also modeled facility reported emissions from NEI. NEI provides source-specific parameter values used in modeling (*e.g.*, stack height, stack temperature, plume velocity).

EPA agrees that use of local metrological data results in refined estimated exposure values. HEM 5.0 automatically uses meteorological data from the nearest meteorological station available in the dataset.

For four OESs, EPA relied on releases from generic facilities/sites for the ambient air analysis. Because these releases are not directly associated with physical locations, EPA must assume a release location, emissions parameters (*e.g.*, stack height, stack temperature, plume velocity), and land use. EPA did not only use high-end meteorology data or land use. EPA conducted the modeling using two meteorological stations: Lake Charles, Louisiana, and Sioux Falls, South Dakota. These two meteorological stations were chosen because they represent meteorological datasets that tend to provide central tendency (Sioux Falls) and high-end (Lake Charles) concentration estimates relative to the other stations within the Integrated Indoor-Outdoor Air Concentrations Model (IIOAC) based on a sensitivity analysis of the average concentration conducted in support of IIOAC development. EPA also conducted the modeling assuming both rural and urban land uses. EPA did assume flat terrain for generic facilities/locations. This is an appropriate assumption given that EPA does not have facility-specific data or locations for generic facilities/sites. EPA also used emissions parameters (*e.g.*, stack height, stack temperature, plume velocity) that tend to result in high-end exposures to be health protective. EPA acknowledges that each of these assumptions contributes to the uncertainty associated with the estimated inhalation risks to the general population from generic facilities/sites, which is reflected in the low confidence rating associated with the modeling of generic facilities/locations (U.S. EPA, 2026i).

Summary: A public commenter (0172) stated that EPA's air exposure modeling underestimates risks to fenceline communities because EPA's HEM analysis is flawed. First, the commenter said that EPA acknowledges that SACC recommended the use of 78 years of exposure in calculating risks across a lifetime, but EPA assumed an exposure duration of only 70 years in its HEM modeling. The commenter remarked that EPA is omitting 8 years, which is more than 10%of relevant exposures to 1,2-dichloroethane. EPA has not explained how the shorter duration is consistent with the SACC's recommendation or is protective of potentially exposed or susceptible subpopulations.

Second, the commenter expressed concern that EPA uses only TRI data from 2018. The commenter stated that EPA should have evaluated risks to individuals living near a facility using emissions data reflecting the year with the highest emissions from that specific facility, rather than the highest year of overall emissions. EPA's HEM analysis did not capture higher years of emissions for multiple facilities for which even 2018 data showed cancer risks exceeding 1×10^{-6}. The commenter provided several specific examples of facilities that emitted higher amounts in other years.

Additionally, the commenter said that EPA must analyze more recent emissions data in the final risk evaluation. The commenter said that this information is "reasonably available" and must be considered under TSCA section 26(k).

Third, the commenter wrote that EPA only modeled TRI-reported releases, which does not account for the facilities for which other data from NEI capture high-end exposures. The commenter provided an example of a specific facility that, under another dataset (NEI), showed far greater releases than reported under TRI.

Finally, the commenter expressed that EPA calculates risks from a facility's TRI coordinates, which may not be the actual release location. The commenter notes that because the TRI coordinates may not represent the release point within a much larger facility it may result in an underestimation of risk (because individuals actually live closer to the emitting portion of the facility than EPA assumed) or an underestimation of the number of people exposed to risks exceeding EPA's benchmarks. The commenter stated that if EPA does not know the specific location of the facility's release point, EPA must either collect precise coordinates of emissions or use the facility boundary

closest to the nearest residences. The commenter recommended EPA revise its HEM analysis using more appropriate inputs.

The commenter also states that EPA ignored elevated risks that were calculated outside of its HEM model. They note that when discussing estimated inhalation cancer risks via ambient air, EPA notes that it "determined that . . . the OES of Waste handling, disposal, and treatment (POTW) had a facility with general population living within 100 m and a risk estimate above 1×10^{-6} at an area distance of 100 to 1,000 m." The commenter states that EPA did not discuss this OES or the corresponding Disposal COU in discussing the basis for its proposed "no unreasonable risk" determination to the general population or fenceline communities or even in identifying the COUs for which there were facility releases that resulted in an increased cancer risk.

EPA Response: EPA used lifetime average daily concentrations (LADC) when calculating inhalation cancer risks to the general population when using results from AERMOD. LADC was calculated using the equation below.

$$LADC = \frac{AAC \times ET \times EF \times ED}{AT}$$

Where:

AAC	=	Annual average air concentration (µg/m^3)
ET	=	Exposure time (24 hours/day)
EF	=	Exposure frequency (365 days/year)
ED	=	Exposure duration (78 years)
AT	=	Averaging time (24 hours/day × 365 days/year × 78 years)

Since a lifetime of 78 years was assumed in both the exposure duration, which is in the numerator, and averaging time, which is in the denominator, the choice of lifetime length did not affect the estimated inhalation cancer risks in this assessment. In HEM5.0, the cancer risk is calculated using the equation below.[2]

$$CR_t = \sum_{i,k} AC_{i,k} \times URE_k$$

Where:

$\Sigma_{i,k}$	=	The sum over all source i and pollutant types k
$AC_{i,k}$	=	Ambient concentration (µg/m^3) for pollutant k at the given receptor
URE_k	=	Cancer unit risk estimate (1/(µg/m^3) for pollutant k (cancer risk for an individual exposure to 1 µg/m^3 over a lifetime)

As demonstrated by the above equation, lifetime is not a factor in calculating cancer risk in HEM5.0. The URE, which is equivalent to the inhalation unit risk, assumes exposure over an entire lifetime. Therefore, the choice for lifetime length does not impact the estimated risks in this evaluation.

In the final risk evaluation, EPA used HEM5.0 to estimate ambient air concentrations and calculate risks using data reported to both TRI and NEI. TRI emissions are reported on an overall facility basis and

[2] HEM 5.0 User Guide: https://www.epa.gov/system/files/documents/2025-05/hem5.0-users-guide.pdf (accessed April 23, 2026)

process level information is not reported to TRI; therefore, it is not appropriate to apply process level parameters to TRI emissions. To account for process level information and release locations, EPA used facility specific information as reported to NEI to model ambient air concentrations using HEM5.0. Additionally, when estimating ambient air concentrations using HEM5.0 and TRI reported data, EPA did refine release locations by using the coordinates of the highest releasing stack as reported to NEI for facilities that reported to NEI as the input for TRI emissions. For facilities that did not report to NEI, EPA did use satellite images to ensure that the modeled release locations were within the facility boundaries. EPA therefore used the data available in TRI to refine release locations. The locations of process level emissions were accounted for by using NEI data.

EPA performed additional ambient air modeling using HEM5.0 that uses each facility's highest reported annual release as reported to TRI data from 2015 to 2024. For NEI data, EPA considered releases from the years 2014, 2017, and 2020. In the draft risk evaluation, EPA modeled all available data for 2014 and 2017 (U.S. EPA, 2025e). For this evaluation, EPA modeled each facility that showed a risk greater than 1×10^{-6} based on the 95th percentile concentration at 10 m from the release location. EPA also modeled any releases that were new to the 2020 NEI if they were greater than the lowest release from 2014 and 2017 that resulted in a risk greater than 1×10^{-6} based on the 95th percentile concentration at 10 m from the release location. EPA did not model releases that were assigned to the OES of Use in Fuels and Related Products or if the Source Classification Code (SCC) level one code was "internal combustion engine" or "external combustion engine," even if they met the previously stated criteria, as they were considered to part of the OES of Fuels and Related Products, which was not quantitively evaluated in this evaluation (U.S. EPA, 2026h).

The results of the additional modeling are available in Section 3 of the *Environmental Media Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026g), Section 3 of the *General Population Exposure Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026i), and Sections 3.3.1, 5.1.2.1, and 5.3.6 of the *Risk Evaluation for 1,2-Dichloroethane* (U.S. EPA, 2026m).

EPA acknowledges that the Agency inadvertently left out the Disposal COU in discussing the basis for the proposed no unreasonable risk determination to the general population even though there were facility releases that resulted in an increased cancer risk for this COU. EPA has corrected this error in the final risk determination. However, given that the cancer risk estimates for facilities associated with the Disposal COU are at the lower end of the 1×10^{-6} to 1×10^{-4} range (only as high as 3.80×10^{-6}), EPA does not consider the general population exposures from this COU to significantly contribute to the unreasonable risk. EPA has updated the risk determination to clarify that while a general population risk estimate for the Disposal COU is within the cancer range, EPA did not determine that the general population exposures from this COU significantly contribute to the unreasonable risk.

Summary: A public commenter (0172) wrote that EPA ignores elevated risks that were calculated outside of its HEM model, specifically for the Disposal COU. The commenter said that EPA noted that it determined that the Waste Handling, Disposal, and Treatment OES had a facility with a general population living within 100 meters and a risk estimate above 1×10^{-6} at an area distance of 100 to 1,000 m, but EPA does not discuss this OES when discussing the basis for its proposed no unreasonable risk determination to the general population or fenceline communities.

EPA Response: In the risk determination, EPA emphasizes that these estimates and cancer risk benchmarks are not treated as a "bright line" and other risk-based factors are considered (*e.g.,* confidence in the hazard and exposure characterization, duration, magnitude, uncertainty, and populations exposed) for the purpose of making an unreasonable risk determination. Given that the

cancer risk estimates for facilities associated with the Disposal COU are at the lower end of the 1×10^{-6} to 1×10^{-4} range (as high as 3.80×10^{-6}), EPA does not consider that the general population exposures from this COU significantly contribute to the unreasonable risk. EPA has updated the risk determination to clarify that while a general population risk estimate for the Disposal COU is within the cancer range, EPA did not determine that the general population exposures from this COU significantly contribute to the unreasonable risk.

6.1.3.3 Exposure Through Water

Summary: Two public commenters (0160, 0172) expressed concern that EPA ignored exposures to 1,2-dichloroethane from groundwater despite stating that 1,2-dichloroethane is "widespread in groundwater across the United States." One commenter (0172) wrote that people may be exposed to contaminated groundwater when it enters their drinking water supply or by vapor intrusion, and wildlife may be exposed as well. The commenter remarked that EPA analyzed surface water used as drinking water, but this does not account for communities that have drinking water supplies that are fed from groundwater. The commenters (0160, 0172) said that EPA did not assess 1,2-dichloroethane in groundwater because "there is no evidence that the 1,2-dichloroethane in groundwater is from TSCA COU activities or releases" and is most likely present due to "the anaerobic transformation to 1,2-dichloroethane from other chlorinated solvents" in groundwater. The commenters assert that EPA has not shown that the 1,2-dichloroethane is not associated with a COU. The commenters also said that, even if 1,2-dichloroethane's presence in groundwater is not associated with a TSCA condition of use, EPA must consider these background exposures in evaluating whether exposures to 1,2-dichloroethane from TSCA conditions of use contribute to unreasonable risk. The commenters remarked that TSCA mandates EPA to use the best available science and to assess all risks to PESS, so EPA's failure to account for 1,2-dichloroethane exposures from groundwater is unjustified.

EPA Response: EPA reviewed the occurrence of 1,2-dichloroethane in drinking water systems where the source water is groundwater (U.S. EPA, 2024c). Of the 47,689 systems with groundwater as source water, 3 systems had occurrence of 1,2-dichloroethane at greater than the maximum contaminant level (MCL) of 5 µg/L and represented less than 0.01% of the population served.

As described in Section 3.3.3 of the *Risk Evaluation of 1,2-Dichloroethane*, monitoring data from the Water Quality Portal show that 1,2-dichloroethane is detected in groundwater at numerous locations across the United States. While disposal of 1,2-dichloroethane to landfills could contribute to groundwater via leachate under certain conditions (as indicated by the Delisting Risk Assessment Software [DRAS] modeling and described Section 6.2.2 of the *Environmental Media Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026g)), 1,2-dichloroethane may also be present as a transformation product formed under anaerobic conditions from higher-chlorinated solvents—particularly 1,1,2-trichloroethane and 1,1,2,2-tetrachloroethane—commonly associated with legacy disposal practices. Given the limited geographic scope of contemporary 1,2-dichloroethane releases and the prevalence of legacy chlorinated-solvent sites, observed detections likely reflect a combination of direct disposal and in situ formation from legacy sources. EPA acknowledges that the source of background concentrations of 1,2-dichloroethane in groundwater is likely from legacy sources. However, based on the conservative DRAS modeling results and the water quality portal concentration data, EPA does not expect groundwater concentrations to significantly contribute to exposures and risks from groundwater exposures.

Summary: A public commenter (0160) expressed that EPA should more fully assess general population exposures from surface water. The commenter specifically said that EPA estimated surface water concentrations and compared the estimations to the Safe Drinking Water Act Maximum Contaminant

Level (MCL) of 5 ppb, and EPA determined that the downstream surface water concentration is well below the drinking water limit for all facilities releasing 1,2-dichloroethane upstream. The commenter stated that two conditions of use had surface water concentration estimates under one dilution scenario that were above the MCL, however. The commenter expressed that EPA should not dismiss the exposure estimates that fall above the MCL without quantifying the risks from drinking water sources supplied by 1,2-dichloroethane contaminated surface water, taking into account assumptions such as volatilization and drinking water treatment.

EPA Response: For the final risk evaluation, EPA compiled and used facility releases of 1,2-dichloroethane as reported between 2015 and 2024 (see Section 3.3.2.1) to assess general population exposures and risks. As described in Section 5.1.2.3.1 of the *Risk Evaluation for 1,2-Dichloroethane*, surface water concentrations at the point of discharge above 5 µg/L were included in the downstream analysis. The highest downstream surface water concentration at a drinking water intake location was 0.4 µg/L—well below 5 µg/L.

Summary: A public commenter (0169) discussed exposure to 1,2-dichloroethane through wastewater. The commenter stated that EPA preliminarily determined that the disposal condition of use significantly contributes to the unreasonable risk for 1,2-dichloroethane, and EPA characterized its confidence level for the "Waste Handling, Treatment, and Disposal – WWT OES" as moderate. The commenter said that EPA's approach lacks scientific rigor, as the preliminary unreasonable risk finding is predicated on inhalation exposure assessed by a singular non-U.S. study, Lehtinen and Veijanen (2011). The commenter stated that Lehtinen and Veijanen (2011) only present data in summary form, and they provide very little information about where the samples were taken, which makes it difficult to discern the representativeness of the study to U.S. operations or to compare the data to existing wastewater treatment data. The commenter expressed that EPA should rely on actual 1,2-dichloroethane exposure information for wastewater treatment, and EPA should use the test order data and information provided in these comments to assess risk from wastewater disposal instead of Lehtinen and Veijanen (2011). The commenter added that process knowledge indicates that wastewater should not be assessed by EPA to be a significant source of inhalation exposure. Finally, the commenter said that, in terms of implications for EPA's general population exposure assessment on wastewater, the data indicate that releases to the environment from wastewater are quite low for the manufacturing and processing as a reactant conditions of use.

EPA Response: EPA acknowledges the comments on the limitations of the exposure data from the singular non-U.S. study and has incorporated the test order data and information provided in the comments in the final risk evaluation to assess exposures to 1,2-dichloroethane at wastewater treatment facilities. EPA has included the results of the Lehtinen and Veijanen (2011) study in the *Occupational Exposure Assessment for 1,2-Dichloroethane* (see Section 3.11.3) as a discussion point, but these values were no longer utilized in the risk evaluation.

Summary: A public commenter (0148) stated that EPA must evaluate the risks of 1,2-dichloroethane within the wider context of polyvinyl chloride (PVC) and chlorinated polyvinyl chloride (CPVC) use, because 1,2-dichloroethane is the starting point for these materials. The commenter said that, while 1,2-dichloroethane is not present in finished PVC pipe, its hazards cannot be separated from the materials that comprise many potable water distribution systems.

Commenter (0148) said that multiple significant and diverse research findings underscore that 1,2-dichloroethane presents serious hazards throughout the vinyl supply chain, from manufacturing of PVC and CPVC, to the installation of derived products, including community and building plumbing systems.

The commenter highlighted several authoritative sources of information supporting this claim, including assessments from the ATSDR and the National Toxicology Program.

Another public commenter (0159) stated that the advocacy group, Safe Piping Matters (SPM), incorrectly claims in its public comment that while 1,2-dichloroethane is not present in finished PVC, its hazards cannot be separated from the materials that comprise many potable water distribution systems. The commenter said that this claim by SPM is in direct contradiction to exposure-based risk assessment principles. The commenter added that Safe Piping Matters failed to demonstrate that the 1,2-dichloroethane exposure to leachate from PVC water drinking systems is more than the amount necessary to induce an adverse effect in humans, illustrating another example of the overuse of the precautionary principle in needlessly regulating safe uses of chemicals.

EPA Response: Commentor (0148) is in agreement with EPA's understanding that 1,2-dichloroethane is not present in finished PVC pipe, which is also supported by the public comment from the Vinyl Institute (EPA-HQ-OPPT-2018-0427-0040) and is referenced in the conditions of use table in the risk evaluation. The commenter also states that "emerging research shows that degradation of polymers in pipe walls releases microplastic fragments and chlorinated byproducts", however, the commenter did not provide release data, concentration data of said releases, or specific releases of 1,2-dichloroethane that EPA could consider. Moreover, EPA agrees with the response from another commenter (0159), that the other commenter (0148) did not demonstrate the extent of potential exposures to 1,2-dichloroethane leaching from PVC in drinking water systems nor if that exposure is greater than the amount necessary to induce an adverse effect in humans. EPA did not make edits to the drinking water assessment for the final risk evaluation regarding this commentor's request.

6.1.3.4 Exposure to Byproducts

Summary: A public commenter (0172) said that EPA understates exposure to 1,2-dichloroethane's byproducts. First, the commenter stated that EPA relied on wholly unsupported public comments from the Vinyl Institute to estimate the levels of 1,2-dichloroethane byproducts in various product streams, even though the Vinyl Institute offers no support for their estimates. The commenter stated that the unsubstantiated claims of a trade association are not science. Additionally, the commenter expressed concern that EPA evaluated all releases of 1,2-dichloroethane byproducts based on TRI data from 2018. The commenter said that reliance on 2018 data will understate exposures for facilities whose releases peaked in later years, and rather, EPA should determine the risks to fenceline communities from 1,2-dichloroethane byproducts based on a facility's highest year of reporting over a multi-year lookback period. Finally, the commenter stated that EPA understates risks to PESS by relying on unsupported assumptions and inputs to calculate 1,2-dichloroethane byproduct exposures. The commenter specifically remarked that EPA assumes a maximum exposure duration of 33 years for exposure in drinking water and fish, and this assumption is both inappropriate and internally inconsistent, given EPA assumed 57 and 62 years of drinking water and fish consumption exposures, respectively, in its non-byproduct 1,2-dichloroethane analyses.

EPA Response: The weight percent of 1,2-dichloroethane byproducts in various product streams is a parameter in estimating inhalation and dermal exposure to the byproduct chemicals. In the final risk evaluation, EPA provided more detail on the method that was used by the Vinyl Institute to estimate the weight percent values.

For the byproducts analysis, EPA performed additional ambient air modeling using HEM5.0 that uses each facility's highest reported annual release as reported to TRI data from 2015 to 2024. The results of

the additional modeling are available in the Sections 2.2.1.2 and 6.2 of the *Byproducts Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026a).

EPA estimated each of the byproduct exposures based on scaling from 1,2-dichloreothane exposures for both drinking water and fish consumption, thereby keeping the same assumptions for chronic years of exposures for the byproducts as for 1,2-dichloroethane.

6.1.3.5 Tribal Exposure

Summary: Two public commenters (0164, 0172) expressed concern that EPA did not adequately evaluate risks from 1,2-dichloroethane to Tribal people. The commenters wrote that the only exposure pathway EPA considered was tribal fish consumption, and it used a rate that is too low and not representative of tribal diets. The commenters remarked that EPA used a fish ingestion rate of 216 g/day for tribal fish consumption, without a high-end rate and a heritage rate. The commenters said that this does not capture the exposures tribal people experience. One of the commenters (0172) said that high-end tribal fish consumption rates are readily available and should be incorporated in the final risk evaluation. Additionally, the commenter said that EPA identified a heritage fish ingestion rate for Tribal populations (1,646 g/day), but EPA did not consider exposures reflecting heritage fish ingestion rates, which is unreasonable.

EPA Response: As presented in Section 3.3.2 of the *Risk Evaluation for 1,2-Dichloroethane*, EPA utilized reasonably available facility-specific 1,2-dichloroethane release data and conducted refined analyses based on location of releases and resultant exposures. As described in Section 5.1.2.3.4 of the *Risk Evaluation for 1,2-Dichloroethane,* EPA's available tribal heritage fish ingestion rates are provided from nations located in the northwestern United States. Releases and exposures via fish ingestion occurred in Navajo Nation areas in Arizona and New Mexico where fish ingestion rates are not at the same levels as those nations in the upper Northwest and thus, tribal ingestion rates were considered conservative for Navajo Nation members.

Summary: Two public commenters (0164, 0172) stated that EPA did not evaluate risks to tribal children, despite determining that exposure to toddlers and children in the general population from eating fish is high, which is not acceptable. One of the commenters (0164) additionally wrote that the risks to tribal elders were also not evaluated.

EPA Response: EPA acknowledges that there are different fish consumption rates for different lifestages and as described in Section 5.1.2.3.4 of the *Risk Evaluation for 1,2-Dichloroethane* utilized available children's tribal consumption rates from the tribes in Minganie and Lower North Shorre regions of Quebec, Canada as a representation of possible children's fish consumption rates for children in the Navajo Nation. The assumption that children in the Navajo Nation have the same fish consumption rate as those in the Minganie and Lower North Shorre regions of Quebec, Canada, is very conservative but a 1,2-dichloroethane exposure estimate to children (lifestages 3–5 and 6–11 years) still did not result in risk below benchmark via that exposure pathway (see Section 5.3.6.5 of the *Risk Evaluation for 1,2-Dichloroethane*).

EPA considered adult (21+ years of age) tribal ingestion of fish in Navajo Nation where 1,2-dichloroethane is released into surface waters. For elders, risks from this exposure pathway are captured among the adult population as it considers that age group and in the cancer risk as that is lifetime (78 years) exposures.

Summary: A public commenter (0164) expressed that tribal exposures other than fish consumption need to be included in the TSCA risk evaluation. The commenter said that Tribes have unique lifeways that place them at different risk due to multiple exposure pathways not experienced by the general population. The commenter stated that tribal lifeways include differences in diet, housing, worker safety protocols, local water, drinking, bathing, ceremonial use, cultural activities, subsistence activities, and recreational activities. The commenter requested that EPA perform an exposure analysis using tribal inhalation rates in the final risk evaluation. Additionally, the commenter said that tribal exposure factors from drinking water are different, and many tribal communities live near unlined landfills.

EPA Response: EPA considered exposures on tribal lands and has evidence of 1,2-dichloroethane releases to surface waters from publicly owned treatment works (POTWs) in the Navajo Nation (see Section 5.1.2.3.4 of the *Risk Evaluation for 1,2-Dichloroethane*). EPA does not have evidence of industrial facility releases to ambient air in the same location as these surface water releases.

Summary: A public commenter (0172) stated that EPA arbitrarily limits its analysis of tribal populations' exposure and risk to a single facility representing a single condition of use – the Chinle Wastewater Treatment Facility. The commenter wrote that it is arbitrary to assume that tribal populations engage in subsistence fishing exclusively on tribal lands, and EPA did not determine whether conditions of use beyond wastewater disposal contribute to unreasonable risk to tribal populations. The commenter expressed that the discharge data indicate that other facilities discharge greater quantities of 1,2-dichloroethane than wastewater treatment facilities, so EPA cannot dismiss those risks without evidence that they are not relevant to tribal populations.

EPA Response: EPA purposefully identified facilities discharging to receiving waterbodies on tribal lands and specifically, the facility that results in the highest concentration of 1,2-dichloroethane in the receiving water body. This facility represents the highest oral and/or dermal tribal exposure anticipated from any of the COUs.

EPA estimated exposures to 1,2-dichloroethane via subsistence level of fish ingestion from discharges for all COUs/OESs not just on tribal lands and included facilities outside tribal lands, that is, across all of the United States that discharge greater quantities of 1,2-dichloroethane than wastewater treatment facilities. EPA does not have specific location data of tribal populations outside of tribal lands to correlate the location of 1,2-dichloroethane discharges to the location of tribal population exposures outside of tribal lands.

Summary: A public commenter (0164) quoted language on tribal populations' connection to the land and Tribe-specific fish ingestion from the risk evaluation for Butyl benzyl phthalate, which the commenter stated was also included in risk evaluations for TCE, di-2-ethylhexyl phthalate, diisobutyl phthalate, and dibutyl phthalate. The commenter recommended EPA include this language in the Draft Risk Evaluation for 1,2-Dichloroethane.

EPA Response: EPA used the swimming scenario as a conservative estimate of dermal exposures and when added to oral exposures via fish ingestion, the total exposures are still well above the non-cancer benchmark (see Section 5.1.4.1 in the *Risk Evaluation for 1,2-Dichloroethane*). The exposures to tribal communities were specific to the Navajo Nation where 1,2-dichloroethane releases and exposures occur.

6.1.4 Aggregate and Sentinel Exposure

6.1.4.1 Aggregate Exposure

Summary: Two public commenters (0160, 0172) expressed that EPA systematically underestimates exposures to 1,2-dichloroethane by failing to aggregate exposures from multiple routes and conditions of use, which is unlawful. The commenters stated that EPA's failure to aggregate exposures violates TSCA's mandate to evaluate risks to PESS, TSCA's mandate to protect against risk posed by combinations of activities, and TSCA's mandate to use the best available science. One of the commenters (0172) also stated that EPA is required to aggregate exposure because TSCA section 6(a) directs EPA to regulate when it finds from a risk evaluation that there are unreasonable risks posed by "the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance . . . or . . . *any combination of such activities*." (emphasis in original). The commenter asserts that EPA cannot eliminate unreasonable risks caused by "any combination of" activities if EPA solely determines the risks posed by individual conditions of use in isolation. One of the commenters (0172) added that the Framework Rule requires consideration of aggregate exposures.

Both commenters (0160, 0172) acknowledged that EPA considered aggregate inhalation exposures from multiple facilities that release 1,2-dichloroethane in the same area but said that EPA did not aggregate exposures from multiple exposure routes and pathways or from multiple conditions of use, as required. The commenters state that EPA's rationale for not aggregating routes of exposure, that the endpoints are different and dependent on the route of exposure, is not true. Commenters (0160, 0172) expressed that there are effects seen for some of the same health endpoints across all routes of exposure. The commenter added that, if the sensitivity endpoints differ between routes of exposure, it is difficult to determine if that is due to lack of data or due to a true difference. The other commenter (0172) stated that 1,2-dichloroethane inhalation and oral exposures in rodents produced similar tumors across two studies, and EPA also ignores immunosuppression, neurotoxicity, and other systemic effects associated with both inhalation and oral exposures and that rather than solely focusing on the most sensitive endpoint of each exposure route, EPA must also quantitatively assess the aggregate risk to other affected organs.

One commenter (0172) also stated that EPA must aggregate exposures from different pathways. For example, the commenter notes that the draft risk evaluation does not combine exposures from drinking water in addition to inhalation of ambient air. The commenter asserts that although EPA may characterize concentrations of 1,2-dichloroethane as low in one type of media, it cannot disregard a known exposure pathway for individuals, especially when those may combine with other exposures to contribute to 1,2-dichloroethane's overall risks.

Additionally, the commenters wrote that EPA must aggregate risks for those who are part of multiple subpopulations, such as those who both work and live near facilities releasing 1,2-dichloroethane or face the same exposure pathway from multiple activities or conditions of use. They note that the SACC has urged EPA to consider the risks from combined occupational and environmental exposures to chemical substances, given that, "[i]n many fenceline communities, members of the community also work at the polluting facility and so may have occupational exposures that also contribute to . . . toxicological risk[]." As an example, one commenter (0172) stated that EPA failed to consider aggregate exposures from drinking water that are a result of 1,2-dichloroethane releases to surface water from multiple facilities, instead "evaluat[ing] independently for each facility-intake linkage" the amount of 1,2-dichloroethane that is expected to be in finished drinking water even though "multiple facility releases can be upstream of the same [public water system] intake."

EPA Response: As the commenter notes, TSCA section 6(a) provides that "*If* the Administrator determines…that any combination of such activities, presents unreasonable risk," which allows for the possibility of an unreasonable risk finding based on a combination of activities (emphasis added). However, it does not require one or suggest that EPA would have been required to assess any specific combination of activities in any particular chemical risk evaluation. This is consistent with TSCA section 6(b)(4)(F)(ii), which requires EPA to "describe *whether* aggregate" exposures were considered—allowing for the possibility of an aggregate assessment without requiring one. The TSCA Risk Evaluation Framework Rule does require that EPA "include an aggregate exposure assessment in the risk evaluation, or will otherwise explain in the risk evaluation the basis for not including such an assessment." 40 CFR 702.39(d)(8). EPA has explained below where the 1,2-dichloroethane risk evaluation includes an aggregate exposure assessment and has provided responses explaining the basis for not including other types of aggregate assessment suggested by commenters.

EPA did not disregard exposure pathways for individuals and considered all pathways depicted in Figure 1-6 of the *Risk Evaluation for 1,2-Dichloroethane*, the conceptual model for general population exposures. EPA quantitatively assessed exposures associated with each of the many pathways represented in Figure 1-6.

EPA considered aggregate general population inhalation exposures across different facilities in the *1,2-Dichloroethane Risk Evaluation* by adding concentrations from multiple facility releases to ambient air thereby aggregating exposures to the general population. EPA quantitatively aggregated ambient air concentrations emitted from facilities within 50 km of each other irrespective of each facility's COUs (Section 5.1.4.1 of the Risk Evaluation).

However, EPA did not aggregate inhalation exposures for workers and the general population because EPA does not have specific evidence of workers with 1,2-dichloroethane exposures and their location of residence to assume that all fenceline populations are also exposed as workers. Even if EPA did have such evidence, inhalation exposures are the primary route of exposure and risk for workers and the current analysis is expected to be protective of worker total exposures. If there are individuals who live at the fenceline and are workers, the risk evaluation already has determined unreasonable risk for nearly all workers, independent of fenceline exposures which are lower than occupational exposures.

EPA also reviewed estimated surface water concentrations from individual facility releases and though there are clusters of releasing facilities in areas such as the Mississippi River and the Delaware River, the concentrations at the point of discharge are low and fate processes such as volatilization would quickly lower the concentration downstream even at another facility effluent discharge location. Therefore, aggregating drinking water estimates from multiple facility releases as suggested by commenters would not result in different estimates from the drinking water downstream dilution analysis results as presented in Section 5.1.4.1 of the *Risk Evaluation for 1,2-Dichloroethane* (U.S. EPA, 2026m).

Additionally, as described in Section 7.1 of the final *Human Health Hazard Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026j), EPA considered the extent to which it is biologically appropriate to aggregate cancer or noncancer risks across exposure routes for different durations. EPA evaluated each health effect identified from 1,2-dichloroethane based on duration for each route of exposure and integrated these findings in a weight of scientific evidence approach to inform dose-response considerations as described in the final *Human Health Hazard Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026j). For non-cancer, EPA considered each health effect (immunosuppression, neurotoxicity, and other systemic effects associated with both inhalation and oral exposures) and considered selection

of the endpoint that represents the best available science for each exposure route and duration that would be health protective of the other health effects identified.

The inhalation and oral/dermal routes have different acute noncancer health effects; therefore, acute exposures and risks from these routes were not aggregated. Moreover, inhalation exposure to the general population is the major route of exposure and the relative contribution from oral and/or dermal exposures is significantly less. Therefore, EPA does not consider that risks from any pathway of exposure were missed, underrepresented or not considered. EPA does acknowledge, however, that the acute dermal point of departure was extrapolated from oral and that both routes of exposure result in systemic effects. EPA therefore, as a screening assessment, aggregated acute oral exposures from fish ingestion, incidental ingestion from swimming and acute dermal exposures also from swimming (see Section 5.1.4.1 of the *Risk Evaluation for 1,2-Dichloroethane*) and estimated total exposures and the corresponding risk (MOE = 765; See Section 5.3.7) which was well above the benchmark of 30. These exposures are conservative because of uncertainties with the collocation of exposures that were not considered for this assessment.

Intermediate and chronic non-cancer PODs are based on systemic effects and EPA concluded that it is reasonable to anticipate that intermediate and chronic exposures and risks across oral, dermal, and inhalation routes may be additive. Similarly, for chronic cancer EPA concluded that exposures and risks across oral, dermal, and inhalation routes may be additive. The oral and dermal cancer slope factors were derived from the inhalation unit risk by route-to-route extrapolation. However, given the extent to which there is uncertainty around the extent to which incidence of specific systemic tumor sites or noncancer effects may vary across routes of exposure, there is uncertainty in quantifying aggregate cancer risks across routes. Given that uncertainty, EPA is not relying on quantitative aggregate risk estimates as the basis for risk conclusions in this assessment.

Downstream drinking water analysis demonstrates low 1,2-dichloroethane concentrations which are expected to result in low concentrations of the 1,2-dichloethane in fish tissue and low oral exposures. Therefore, aggregated chronic non-cancer oral exposures were not assessed for these exposure pathways.

6.1.5 Cumulative Exposure

Summary: Several public commenters (0052, 0160, 0172) discussed the need for a cumulative risk assessment that accounts for exposure to chemicals that are released or used together with 1,2-dichloroethane. The commenters wrote that TSCA's best available science standards require EPA's risk evaluations to account for exposures to multiple chemicals. Additionally, one commenter (0172) expressed that EPA's obligation to consider cumulative risks arises from TSCA's mandate that EPA specifically assess risks to PESS. This commenter wrote that EPA's failure to consider cumulative exposures and risks affected EPA's determination of 1,2-dichloroethane's unreasonable risks, because when cumulative exposures to 1,2-dichlorethane and byproducts are taken into account, exposed workers and communities will experience greater risk than from 1,2-dichloroethane alone. One commenter (0160) stated that it is particularly important to consider chemicals that are commonly used and/or released with 1,2-dichloroethane and share common uses and toxic endpoints.

EPA Response: EPA considered multiple chemical releases in the *Byproduct Assessment for 1,2-Dichloroethane.* However, EPA did not conduct a cumulative assessment since each byproduct chemical formed during 1,2-dichloroethane manufacturing has different hazard effects. This is different from where EPA has conducted cumulative assessment, namely for phthalates where those chemicals within the assessment had the same effect (U.S. EPA, 2025h).

Summary: A public commenter (0160) discussed cumulative risk from production and use of 1,2-dichloroethane and vinyl chloride. The commenter said that 1,2-dichloroethane is commonly used to produce vinyl chloride, and over 90%of produced 1,2-dichloroethane is converted to vinyl chloride. The commenter additionally wrote that 1,2-dichloroethane and vinyl chloride have been shown to cause similar health effects, so considering cumulative health effects could reveal health endpoints that are more sensitive than currently identified.

EPA Response: EPA published the *Draft Scope of the Risk Evaluation for Vinyl Chloride* in January 2025, the final scope document has not been published, and the subsequent vinyl chloride risk evaluation will assess the hazards, exposures and risks associated with each condition of use, including production and use of vinyl chloride. Since the final scoping document for vinyl chloride is not yet complete, identification of the points of departure have not been established, nor have exposure scenarios been characterized, EPA determined that there is not enough information at this time to consider a cumulative assessment.

Summary: A public commenter (0172) wrote that EPA's failure to consider cumulative exposures is particularly problematic given that EPA previously determined that 1,2-dichloroethane is an appropriate hazard analog for 1,1-dichloroethane, with similar properties and toxicity. The commenter said that facilities release both chemicals in high volumes, and there is ample evidence that exposure to 1,2-dichloroethane occurs alongside exposures to other chemicals with the same health effects. The commenter stated that EPA must conduct a cumulative risk assessment to evaluate the risks presented by co-exposures to 1,2-dichloroethane, 1,1-dichloroethane, and other chemicals that cause the same health effects.

EPA Response: The *Environmental Release Assessment for 1,2-Dichloroethane* presents data that total release volumes of 1,2-dichloroethane are greater than 1,1-dichloroethane. The *Byproduct Assessment for 1,2-Dichloroethane* shows that exposures to workers to 1,2-dichloroethane via the Manufacturing COU in which byproducts are formed is the main risk driver and that occupational exposures under this COU present unreasonable risk. EPA did identify 1,2-dichloroethane as an appropriate hazard analog for 1,1-dichloroethane based on similarities in chemical structure and physical, chemical and environmental fate and transport (see Section 4.2.1.1 of the Risk Evaluation for 1,1-Dichloroethane). However, the toxicological data for 1,1-dichloroethane was very limited and prevented a robust analysis of the toxicologic relative toxicity between 1,1-dichloroethane and 1,2-dichloroethane. The Agency did not assess cumulative exposures between 1,1-dichloroethane and 1,2-dichloroethane based on this limitation.

Summary: One commenter (0160) said that EPA should not compare byproduct releases to previous chemical-specific risk evaluations to determine the reasonableness of its assessment, as EPA must fully assess the risk from 1,2-dichloroethane and its byproducts without making arbitrary comparisons to other releases of the byproduct chemicals.

EPA Response: As described in the Byproducts Assessment TSD (U.S. EPA, 2026a), for this risk evaluation, EPA estimated releases of each assessed byproduct for the 1,2-dichloroethane Manufacturing COU using TRI and DMR data (2015–2024) plus byproduct concentration information provided in public comments. The Agency then compared these estimated byproduct releases to reported releases for the Manufacturing COU in the previously published chemical-specific risk evaluations and the *Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities* and fenceline technical support document for each chemical; the estimated byproduct

releases are lower (see Section 2.1.3 of the Byproducts TSD). These estimated byproduct releases-not reported releases for the Manufacturing COU in the previously published chemical-specific risk evaluations-were used to model inhalation exposures and assess general population risks near 1,2-dichloroethane manufacturing facilities.

Summary: In a comment submitted before the publication of the Draft Risk Evaluation for 1,2-Dichloroethane, a public commenter (0052) recommended EPA consult with the White House Environmental Justice Advisory Council, the National Environmental Justice Advisory Council, and EPA's Office of Environmental Justice and Office of Research and Development as it develops the methodology for cumulative risk assessments.

EPA Response: EPA conducted an intra-agency and inter-agency review of the *Draft Risk Evaluation for 1,2-Dichloroethane*, incorporating comments from Offices within the Environmental Protection Agency and across the federal government. Additionally, in May 2023, EPA's *Draft Proposed Principles of Cumulative Risk Assessment Under the Toxic Substances Control Act* (Draft TSCA CRA Principles document) was peer reviewed by the Science Advisory Committee on Chemicals (SACC). EPA also provided an opportunity for review for the Office of Research and Development as well as the Office of Water, Office of Pesticide Programs, Office of General Counsel, and Office of Children's Health Protection at EPA as it developed the Draft TSCA CRA Principles document.

6.1.6 Other Comments

Summary: A public commenter (0160) stated that there are no genetic susceptibilities or other biological differences between workers and the general population. The commenter said EPA should approach exposures and risks consistently for all human exposures, using high-end exposures.

EPA Response: EPA's exposure assessment relies on a hierarchy of data availability. For workers, EPA is relying on inhalation monitoring test order data specific to occupational exposure scenarios. For the general population which are exposed to 1,2-dichloroethane through various pathways, EPA estimates exposures based on reported releases and subsequent media concentrations.

Summary: A public commenter (0161) wrote that it is important to consider how the bioavailability of a chemical can change based on how it is used, handled, or processed. The commenter stated that a chemical could pose a completely different exposure risk in its "neat" state than when it is heated, aerosolized, or is involved in an exothermic reaction.

EPA Response: EPA acknowledges that the chemical formulation and form of 1,2-dichloroethane is important in estimating exposures. EPA has received test order inhalation monitoring data that spans a variety of Occupational Exposure Scenarios in which the state of the chemical, particularly during manufacturing or processing in which the chemical is likely in its neat form.

6.2 Human Health Hazards

6.2.1 Carcinogenicity

Summary: Multiple public comments (0156, 0159, 0162, 0163, 0166, 0169) said that EPA's Draft Hazard and Dose-Response Assessment for 1,2-Dichloroethane does not reflect the best available science or the full weight of evidence. The commenters said that EPA's evaluation of potential risk to workers relies on studies suggesting kidney, respiratory, and reproductive effects and cancer in laboratory animals exposed to 1,2-dichloroethane, and that the proposed determination of unreasonable risks is based on the occurrence of mammary and other tumors in rats reported in a study by Nagano et

al. (2006). For cancer, the commenters state that EPA incorrectly treats 1,2-dichloroethane as a non-threshold carcinogen despite substantial evidence supporting a threshold mode of action, including a negative OECD 488 *in vivo* mutagenicity study and other literature showing lack of *in vivo* genotoxicity. For example, one commenter (0163) disagreed with EPA that that the occurrence of tumors in multiple tissues is "suggestive" of a genotoxic mode of action (MOA), asserting instead that the evidence provided in Nagano et al. (2006) is indicative of DNA damage (*i.e.,* DNA adduct and DNA damage) - not mutagenicity. The commenters said that using a threshold approach based on tumor formation in Nagano et al. (2006) would increase acceptable exposure benchmarks by roughly three orders of magnitude.

The commenters said that relying on cancer as the key endpoint for chronic toxicity for 1,2-dichloroethane would likely utilize a point of departure (POD) that is protective of the effect identified for Zhang, et al. (2017), but with reduced uncertainty due to the chronic nature of testing under Nagano, et al. (2006). One of the commenters (0162) added that the weight-of-evidence should have led EPA to consider 1,2-dichloroethane as a threshold carcinogen. Another one of the commenters (0163) added that the weight-of-the-evidence for tumorigenesis via the inhalation route of exposure is equivocal and is coupled with a lack of micronucleus effects (genotoxicity) in animals exposed via the inhalation route of exposure. The commenter stated that for the inhalation route of exposure, an appropriate cancer classification with a weight-of-the-evidence descriptor applied in accordance with EPA's 2005 Carcinogen Guidelines would be "suggestive evidence of carcinogenic potential," with a threshold approach to risk assessment. Another commenter (0169) said given the uncertainty of 1,2-dichloroethane-induced carcinogenicity in general (*i.e.,* uncertainties in Nagano, et al. (2006)), and the strong evidence supporting a non-mutagenic mode of action (MoA) for 1,2-dichloroethane if it is carcinogenic, the commenter recommended EPA to consider a threshold MoA for 1,2-dichloroethane for cancer dose-response assessment.

EPA Response: As part of the public comment period for the draft 1,2-dichloroethane risk evaluation, EPA received several studies to supplement the peer-reviewed literature search that was conducted in 2019. Additionally, based on recommendations by the SACC and public commenters, the Agency performed an updated human health literature search that was completed in April 2025. Relevant studies identified by this April 2025 literature update aligned with those provided during the November 2025 to January 2026 public comment period; thus, EPA is confident the literature update represents the best available science for 1,2-dichloroethane. These studies include information on non-cancer health effects associated with reproductive, hepatic, renal, and neurotoxicity (Section 4), as well as cancer (Section 5) in the *Human Health Hazard Assessment for 1,2-Dichloroethane*. These studies were incorporated into the hazard identification and weight of scientific evidence for dose-response considerations.

EPA treated 1,2-dichloroethane as a non-threshold carcinogen based on available information as it relates to genotoxicity and mutagenicity in summary tables within Appendix B of the *Human Health Hazard Assessment for 1,2-Dichloroethane* (U.S. EPA, 2026j). Overall, genotoxicity was identified across a wide range of *in vitro* model systems. These results were observed to be predominantly positive in model systems employing exogenous metabolic activation, although results from model systems in the absence of metabolic activation were also observed to be positive, albeit mixed. *In vitro* assays examining gene mutation were also predominantly positive in the absence of exogenous metabolic activation. *In vivo* evidence of genotoxicity and gene mutation were slightly mixed, wherein micronuclei formation was observed to be predominantly negative across rodent model systems with a single study in the bone marrow of male Wistar rats observed to be positive for micronuclei formation (Lone et al., 2016). Two studies involving genetically engineered mouse models (MutaMouse and Big Blue Fischer 344 rats from the unpublished OECD 488 study referenced by the commenter) are discussed as part of

the weight of evidence consideration and were both negative for gene mutation. Combined these data support the characterization of genotoxic activity depicted throughout the existing literature and provide a mixed characterization for the requirement of metabolic activation in promoting mutagenic endpoints.

As the available metabolic data suggests the potential for biotransformation of 1,2-dichloroethane, the available data indicate a complex role for metabolism in the production of reactive metabolic products. There also appears to be no clear association among routes of exposure among *in vivo* model systems and positivity among genotoxic or mutagenic endpoints. As a potential for the induction of DNA damage through DNA alkylation, the production of direct-acting reactive metabolites (episulfonium ion), and reactive oxidative species is indicated in the available database, a more complete understanding of the relative contribution of metabolic processing in the generation of these events is needed to understand their overall contribution to genomic mutation. In total, these data describe the induction of DNA damage, genotoxicity, and gene mutation after 1,2-dichloroethane exposure and a complex and incompletely characterized role for metabolism in the production of a variety of identified reactive metabolic products. As such significant uncertainty exists surrounding the mode of action. There are uncertainties regarding the source of reactive metabolites, their DNA binding capabilities, and subsequent potential genotoxicity or mutagenicity. The available evidence suggests that 1,2-dichloroethane exposure leads to DNA damage, but the uncertainties surrounding the relative contribution of each of the three potential DNA damaging pathways (DNA alkylation, CYP450-mediated ROS production, and glutathione-mediated episulfonium ion generation) prevents identification of the causal moiety. Without a mode of action (including molecular initiating event and subsequent key events leading to tumorigenesis), EPA is using the default approach of linear low-dose extrapolation. EPA has not conducted a mutagenic mode of action framework analysis.

In accordance with EPA's 2005 Guidelines for Carcinogen Risk Assessment, the appropriate cancer classification is the weight-of-the-evidence descriptor for 1,2-dichloroethane of "likely to be carcinogenic to humans." This conclusion is supported based on indeterminate evidence in humans and robust evidence in animals exposed by oral, inhalation, and/or dermal routes demonstrating the following: evidence for mammary gland tumors in two species (rats and mice) and two sexes (of rats), evidence for liver tumors in both sexes of mice, evidence of lung tumors in both sexes of mice, and evidence of hemangiosarcomas in male mice. Evidence for other tumor types occurring at increased incidence in animals exposed to 1,2-dichloroethane (subcutaneous fibromas, peritoneal mesotheliomas, squamous cell carcinomas of the stomach, and endometrial stromal polyps) was judged to be indeterminate.

Summary: A public commenter (0169) said that EPA's cancer dose-response assessment for 1,2-dichloroethane relies heavily on Nagano et al. (2006), but several issues raise doubts about using that study as the basis for modeling. The commenter said that these concerns include: EPA's choice to model combined mammary and subcutaneous tumors, the high rate of spontaneous mammary tumors in control female rats (a tumor type some authorities do not consider reliable for carcinogenicity), and the fact that increased tumors were seen only at the highest exposure (which likely approached the maximum tolerated dose [MTD]). The commenter said that more recent data (OECD 488 study, Charles River 2022) indicate that 160 ppm, the top dose in Nagano et al., is near or at the MTD. The commenter added that other long-term inhalation studies (Cheever et al., 1990; Maltoni et al., 1980) did not observe tumor increases at similar or lower concentrations, supporting a possible threshold mode of action. The commenter reasoned that, given these uncertainties and inconsistencies, the results from Nagano et al. should be interpreted cautiously and weighed alongside the broader evidence base when evaluating 1,2-dichloroethane's carcinogenic potential.

One commenter (0163) said that several reports have confirmed that mammary gland tumors are a benign, commonly observed, and spontaneous neoplasm in female F344 rats, including those used in Japanese, and that some authoritative bodies such as the European Food Safety Authority no longer regard the occurrence of mammary gland tumors in female rats as indicative of an agent's carcinogenic potential. The commenter states this is supported by Nagano, et al. because the incidence rates reported for the control animals in the study exceeded those provided for the fifteen historical inhalation studies for every mammary gland tumor type except the fibroadenomas. Based on the tumor data reported by Nagano et al. the commenter states that the dataset does not meet the minimum criteria for the use of the MS-Combo module of EPA's benchmark dose (BMD) software.

In regards to EPA's use of the MS Combo Model, the same commenter noted that while the different tumors associated with 1,2-dichloroethane may be independent in the sense that one does not cause another, they are likely still correlated in that they are a function of a very high dose that may significantly compromise the overall health of the animals. The commenter quoted the peer review report for the MS Combo module, which states "the summation approach is not valid if elevations in the incidence rate of different tumor types occur in a correlated manner." The commenter expressed concern that EPA does not have access to the individual animal data, so it is not known whether the same or different test animals developed tumors in the various target organs.

EPA Response: EPA's cancer dose-response assessment for 1,2-dichloroethane based on the Nagano et al. (2006) inhalation study was benchmark dose modeled using the combined mammary and subcutaneous tumors as these data indicated a positive trend in tumor incidences in the female rats that reached exceeded the maximum tumor incidences of historical controls at 40 and 160 ppm and reached statistical differences at 160 ppm. Additionally, the tumor incidence within the control group of this study did not exceed the maximum tumor incidences of the historical control data and within the background range of incidences for the F344/DuCrj statin of rats used in the study. As indicated in Nagano et al. (2006), the MTD criteria developed by the NCI and IARC guidelines for the 2-year rodent carcinogenicity study, indicate that the highest dose should not induce toxic manifestations that are predicted to reduce the lifespan of the animals except as the result of neoplastic development or a 10% or greater retardation of body weight gain, compared with the control (Montesano et al., 1986; Sontag et al., 1976). Nagano et al. (2006) further affirms that the present data of both the 2-year survival rates and the terminal body weight decrements did not result in overt manifestation of chronic non-neoplastic lesions in the 1,2-dichloroethane-exposed animals thus fulfilling the MTD criteria. This indicates that the highest concentrations of 160 ppm 1,2-dichloroethane employed in Nagano (2006) for rats did not exceed the MTD in accordance with the prediction from the subchronic 13-week inhalation exposure study and did not compromised the overall health of the animals. This study, along with Maltoni et al. (1980) and Cheever et al. (1990), were evaluated in the cancer-dose-response assessment for 1,2-dichlorethane. Maltoni et al. (1980) reported no definite carcinogenic effects induced by inhalation exposure to 5, 50 or 250/150 ppm 1,2-dichloroethane vapor for 78 weeks in Sprague-Dawley rats, though survival rates were low and variable at an exposure duration shorter than that of Nagano et al. (2006). Cheever et al. (1990) reported no significant increase in incidences of any tumor in Sprague-Dawley rats exposed to 50 ppm 1,2-dichloroethane vapor for 2 years. This was the only non-control exposure group. Although the exposure concentration was lower than the highest concentration of 160 ppm used in Nagano et al. (2006) to demonstrate tumor induction by 1,2-dichloroethane, incidences of subcutaneous fibromas and mammary gland tumors were respectively increased in male and female F344 rats exposed to 40 ppm 1,2-dichloroethane in Nagano et al (2006).

Although there is a positive trend in tumor incidences with increased exposure concentration to 1,2-dichloroethane, EPA assumed that the different tumor types are independent of each other due to a lack

of evidence to support a mode of action that would suggest causation. To elucidate whether tumor occurrences were due to hormone-secreting tumors promoting the occurrence of secondary tumors by enhancing cell proliferation in those secondary tumor sites, EPA evaluated considerations of hormone-mediated tumorgenicity in this assessment based on the findings of LeBaron (2021), where prolactin, a hormone known to result in mammary tissue proliferation and tumor formation was not increased nor was an increase in mammary epithelial tissue proliferation observed based on 1,2-dichloroethane exposure via inhalation. Additionally, individual animal data was not available to determine tumor co-occurrence within the Nagano (2006) study. The MS-Combo model characterized total cancer risk where 1,2-dichloroethane increased incidence of multiple tumor types was run using the incidence data for the individual tumors and the polydegrees identified in the model runs for the individual tumors. For 1,2-dichloroethane, the tumors observed in Nagano et al. (2006) were considered independent of each other as emphasized in the comments provided in the External Peer Review of EPA's MS-COMBO Multi-tumor Model (accessed May 5, 2026) from 2011 that outline considerations for the valid use of the model. The approach in using the MS-Combo model is also consistent with prior National Research Council (NRC) conclusions that an approach based on counts of animals with one or more endpoints would tend to underestimate risk when tumors occur independently across sites (NRC, 1994). These documents identify that the multistage potency-summation approach is valid under the condition of an independent occurrence of different tumor types but not valid if elevations in the incidence rate of different tumor types occur in a correlated manner. Evidence of correlation could not be determined due to a lack of the individual animal data from Nagano (2006). Due to a lack of evidence of tumor dependency, the MS-Combo model was used.

Summary: A public commenter (0169) said that EPA did not consider important new scientific evidence when determining whether a linear cancer dose-response model is appropriate for 1,2-dichloroethane. The commenter said that after EPA's cutoff for included studies, the Vinyl Institute submitted two key pieces of information:

- A 2022 Good Laboratory Practices OECD 488 *in vivo* mutagenicity study showing that 1,2-dichloroethane did not induce mutations in lung, liver, bone marrow, or mammary tissue of transgenic rats exposed up to 150 ppm, which are levels comparable to the tumor-producing concentrations used in Nagano et al. (2006). This strongly indicates 1,2-dichloroethane does not act via a direct genotoxic mechanism.
- LeBaron et al. (2021), a high-quality study examining early key events in 1,2-dichloroethane-related mammary tumors, found no evidence of genotoxicity, increased cell proliferation, changes in prolactin, or other early tumor-related biological changes, even at 200 ppm (higher than the tumor-producing concentration in Nagano et al.).

The commenter stated that these studies provide strong evidence that 1,2-dichloroethane is a non-genotoxic carcinogen, supporting a threshold MOA rather than a linear extrapolation approach. The commenter said that EPA did not incorporate these findings into the Draft Risk Evaluation for 1,2-Dichloroethane, despite being aware of them.

EPA Response: EPA performed an updated literature search through April 2025 for human health data and has integrated the findings of these two studies along with other studies identified in public comments into the weight of scientific evidence for the cancer hazard assessment in Section 5 of the 1,2-dichloroethane human health hazard TSD. Additionally, these studies have been considered in the threshold vs. linear low-dose extrapolation approach discussion in Section 5 of the 1,2-dichloroethane human health hazard TSD.

6.2.2 Reproductive Effects

Summary: A public commenter (0154) said that EPA's criticism of the EOGRT study conducted on 1,2-dichloroethane is unfounded. The commenter said that EPA's Draft Human Health Hazard Assessment for 1,2-dichloroethane excluded a validated EOGRT study, even though it was conducted under a TSCA section 4 Enforceable Consent Agreement (ECA) and previously accepted by EPA. The commenter said that EPA claimed dosing in the study was unreliable due to evaporation and water spillage, but the study's analytical and consumption data show stable dosing and minimal leakage. The commenter noted that the SACC also recommended EPA reconsider its dismissal of the study. The commenter said that the EOGRT study found no adverse reproductive or developmental effects in rats up to high exposure levels, including no effects on sperm or reproductive organs. Despite this, EPA based its reproductive toxicity concerns largely on a separate study with notable weaknesses. The commenter claimed that EPA overlooked key Tier II ECA data, including the EOGRT study and physiologically-based pharmacokinetic modeling, and recommended that EPA assess the reproductive toxicity of 1,2-dichloroethane on the basis of the weight of all the available scientific information, including the EOGRT study.

EPA Response: EPA has integrated the findings of the EOGRT study in the hazard identification for reproductive effects in Section 4.1.3.2.1 and summarized the physiologically based pharmacokinetic (PBPK) modeling for 1,2-dichloroethane in Section 3.6 of the 1,2-dichloroethane human health hazard TSD. Although EPA ultimately did not use this study for derivation of the intermediate oral POD, the NTP 1991 study that was selected for dose-response, based on the weight of scientific evidence, indicates greater confidence in the resulting renal effects due to oral exposure to 1,2-dichloroethane based on multiple study concordance at similar dosing and is summarized in Section 4.1.1.2.1 in the hazard characterization for renal effects in the 1,2-dichloroethane human health hazard TSD.

Summary: Multiple commenters (0156, 0159, 0162, 0163, 0166) discussed chronic non-cancer inhalation effects and said that EPA relied almost exclusively on a single study (Zhang et al., 2017) reporting reduced sperm concentration, even though multiple other reproductive toxicity studies (including the WIL Research (2015) EOGRT study) found no adverse effects on sperm or reproduction. The commenters said that pharmacokinetic modeling shows the NOAEL for sperm effects is at least tenfold higher than EPA's selected POD. One of the commenters (0163) requested that EPA re-evaluate its use of the Zhang et al. study for non-cancer risk evaluation of 1,2-dichloroethane, and carefully consider, and clearly explain, its choice for benchmark response level in benchmark dose modeling for cancer or non-cancer endpoints. This same commenter noted that the ATSDR rejected the Zhang et al. results as part of its most recent assessment of 1,2-dichloroethane. One of the commenters (0166) said that the WIL Research (2015) study included a companion pharmacokinetic evaluation to correlate exposures in drinking water to inhalation concentration (Sweeney and Gargas, 2016). The commenter said that this pharmacokinetic study suggested that the NOAEL for effects on sperm were at least an order of magnitude higher than the POD selected by EPA based on Zhang, et al.

EPA Response: EPA evaluated the findings from Zhang et al., 2017 and integrated data from a subsequent study by Zhang et al., 2024 that provided mechanistic information that indicated the role of pyroptosis in the resulting decreased sperm concentration in the male mice for which the intermediate/chronic inhalation POD is based. The application of the PBPK model in extrapolating from the EOGRT study for derivation of an intermediate inhalation POD raises uncertainties related to the model parameterization assumptions that were minimized by using the route-specific POD from Zhang et al. 2017. Additionally, the benchmark dose response level for the Zhang et al. 2017 study is based on consideration that decreased sperm concentration is biologically significant in humans. As stated in EPA's Guidelines for Reproductive Toxicity Risk Assessment (U.S. EPA, 1996), human males are

particularly susceptible to chemicals that reduce numbers or quality of sperm and "statistically significant changes in measures of sperm count, morphology, or motility as well as number of normal sperm should be considered adverse effects." The Agency selected a benchmark response (BMR) of 5% for sperm concentration to be protective of male reproductive effects, based on scientific literature. For instance, use of a BMR 5% for degeneration of seminiferous tubules and azoospermia (no measurable sperm in semen) was considered a biologically relevant endpoint (Blessinger et al., 2020). When evaluating male phthalate syndrome, for example, Blessinger et al. (2020) used a BMR of 5% for all endpoints associated with zero to moderate impacts on fertility. These endpoints included germ cell degeneration or depletion in seminiferous tubules ranging from 5 to 75% level of severity (Blessinger et al., 2020; Lanning et al., 2002). A number of 28-day inhalation studies in mice also provided a robust evidence of effects on liver, nervous system, and male reproductive effects with respect to apical outcomes (*e.g.,* pathology, motor activity), mechanistic understanding, and blood concentration measurements during and after exposure (Zhang et al., 2024; Zhong et al., 2022; Liang et al., 2021; Huang et al., 2020; Zeng et al., 2018; Wang et al., 2017; Zhang et al., 2017). These studies support dose-response analysis and show that sperm effects in (Zhang et al., 2017) of male mice are the most sensitive with a LOAEL of 25 ppm and biologically relevant endpoint to inform the intermediate POD.

In an evaluation of the 2024 ATSDR Toxicological Profile for 1,2-Dichloroethane, the intermediate-duration studies identified an exposure level of 86 ppm (350 mg/m^3) as a "serious" LOAEL for neurological effects from (Zhong et al., 2022) and male reproductive effects from (Zhang et al., 2017). In both of these studies, male mice via whole-body exposure to 0, 100, 350, or 750 mg/m^3 (0, 25, 86, or 173 ppm) for 6 hours/day for 28 continuous days. In counter to the public comment, ATSDR did not reject the Zhang (2017) but considered it along with another study by Liang (2021) as support for their selection of critical effects for derivation of the intermediate inhalation minimum risk level (MRL) that had the same study exposure scenarios (male mice via whole-body exposed to 0, 100, 350, or 750 mg/m^3 for 6 hours/day for 28 continuous days) as Zhang (2017)and Zhong (2022). ATSDR relied on similar neurological effects from Zhong (2022) and Liang (2021) for the derivation of the intermediate inhalation MRL. The Zhang (2024) study considered by EPA was not included as a second line of evidence to support sperm effects in the 2024 ATSDR Toxicological Profile for 1,2-Dichloroethane. As noted by ATSDR, male reproductive effects have only been evaluated in a single study (Zhang et al., 2017) and not corroborated in contrast to the integration of this study with others in identifying the sperm effects as a biological relevant effect due to 1,2-dichlorethane inhalation.

EPA reviewed the study by Sweeney (2016, 2015) that performed a route-to-route extrapolation of the extended one-generation reproductive toxicity study by WIL Research (2015) and indicated that the no observable adverse effect level (NOAEL) of 155 mg/kg-day for sperm effects via drinking water in adult male rats would be equivalent to a continuous inhalation exposure of 62 ppm. Based on the mouse study by Zhang (2017), EPA used the analytical concentrations of the study (0, 102.7, 356.04 and 707.01 mg/m^3) and converted these exposure concentrations for a continuous duration (0.075, 25.675, 89.010, and 176.75 mg/m^3) that was then subjected to benchmark dose modeling. Based on these data, had a NOAEL approach been used, rather than the more refined BMD modeling, for the Zhang (2017) study, a NOAEL of 89 mg/m^3 (22 ppm) would have been identified. It is important to note that the PBPK model was a rat-specific oral-to-inhalation extrapolation so a comparison of these NOAEL of sperm effects across species is not appropriate.

Summary: A public commenter (0169) said that EPA relied on Zhang et al. to set the chronic inhalation benchmark for 1,2-dichloroethane, despite multiple high-quality reproductive toxicity studies showing no adverse effects. The commenter said that EPA dismissed the extended one-generation reproductive toxicity study (WIL Research, 2015) claiming dosing uncertainty. The commenter said that this study

found no effects on sperm parameters, with a NOAEL equivalent to 62 ppm, far above EPA's benchmark derived from Zhang et al. One commenter (0163) considered the supplemental data quality file assessment for this study and noted that EPA rated all of the twenty-five study evaluation metrics as medium or high, including all metrics for both exposure and outcome assessment, except for one – reduced water consumption in the exposed groups. This commenter noted that a reduction in water consumption may not influence the outcome of a given study, and that any available no-effect levels from such a study would be appropriate for EPA's consideration. The commenter noted that the SACC indicated that the analysis by Sweeney and Gargas (2016) took into account the lower water intake in the WIL Research study to compare it to the results of oral studies and that Sweeney and Gargas reported that the inhalation equivalent, no-effect level associated with the WIL Research study is 62 ppm (270 mg/m^3), which is considerably higher than the POD of 5.2 ppm (21.2 mg/m^3).The commenter addressed EPA's prior response regarding this study, *i.e.,* that there are multiple concerns for dosing accuracy due to high rates of chemical evaporation and the failure to quantify water spillage, by noting that the final report by WIL Research indicated that post-storage concentrations were no less than 90%of the pre-storage value and showing that there were very few exclusions of water consumption data because of spillage or leakage.

The commenter stated that EPA also ignored additional negative findings from Rao et al. (1980) and failed to consider confounding stress-related biological responses in Zhang et al., which may influence sperm outcomes. A follow-up study by Zhang et al. (2024) reported substantially lower sperm morphology abnormalities than the 2017 paper, suggesting variability and raising questions about the reliability of the dose-response relationship used by EPA. The commenter said that by disregarding robust negative studies and relying solely on a single, inconsistent mouse study, EPA selected an overly conservative POD that does not reflect the weight of scientific evidence. The commenter recommended that EPA base all chronic inhalation risk assessments for 1,2-dichloroethane on the tumor threshold identified in the long-term Nagano et al. (2006) study. Although EPA derived similar PODs from Nagano (16.2 mg/m³) and Zhang et al. (21.2 mg/m³), the Nagano POD carries far less uncertainty because it comes from a chronic, well-designed two-year study. The commenter said that using Nagano as the basis for chronic risk assessment would raise the benchmark by roughly tenfold, provide a more scientifically reliable estimate of risk, and reduce the likelihood of EPA incorrectly concluding that chronic inhalation exposures present an unreasonable risk.

EPA Response: EPA has integrated the findings of the EOGRT with other studies including Zhang et al. 2024 and Rao et al (1980) with other studies provided via public comment that evaluated reproductive/ developmental effects in Section 4.1.3.2.2 of the hazard identification for reproductive/developmental hazard identification and the weight of scientific evidence. Analysis of the Zhang et al. (2024) indicated that lower sperm morphology abnormalities (~18%) than those abnormalities identified in Zhang et al. (2017) were identified these increases in abnormalities were considered by EPA as biologically significant in both studies and supportive of selection of Zhang et al. (2017) for dose-response.

The selection of the Zhang et al. 2017 for derivation of the chronic inhalation benchmark was based on a comparison and evaluation of the utility of the available chronic inhalation studies identified within the 1,2-dichloroethane database for dose-response. Section 4.2.2.3 of the 1,2-Dichloroethane Human Health Hazard TSD outlines the rationale for not selecting a study of chronic duration.

Considerations of the utility of WIL Research (2015) for dose-response were based on the totality of the metrics outlined in the systematic review protocol (U.S. EPA, 2021). A reduction in water consumption is considered a key consideration that can influence the outcome of a study as this can affect dose administration. Additionally, water consumption reductions can result in dehydration that can affect

biological processes that can confound the assessment of systemic health outcomes. Additionally, WIL Research (2015) calculated water consumption based on historical control water consumption and an averaging over an exposure interval which is not as explicit a dosing regimen as daily oral gavage of known concentration or where water consumption is measured daily within a study. As indicated in the study, food and water consumption though reported was not statistically analyzed. The study authors did note that concentration-dependent reductions in water intake throughout the study period were likely due to issues with palatability. Water intake was reduced by >20% in the mid-and high-dose groups, and there were corresponding reductions in body weights. The authors noted that many of the effects observed (decreased body weights, organ weight changes, etc.) stemmed from the reduced water intake and likely dehydration.

In accordance with EPA's 2005 Carcinogen Guidelines, EPA is not considering 1,2-dichloroethane to possess a definitive mutagenic mode of action nor has EPA identified an alternative mode of action based on limited conclusive data that would suggest the application of the threshold approach for cancer dose-response assessment. "It is the Agency's long-standing science policy position that use of the linear low-dose extrapolation approach provides adequate public health conservatism in the absence of chemical-specific data indicating differential early-life sensitivity or when the mode of action is not mutagenic" (U.S. EPA, 2005a). EPA is therefore not using the Nagano et al. 2006 study for the chronic non-cancer POD based on a tumor threshold. EPA considered the use of the study for the non-cancer chronic POD, however, the data for non-cancer health effects were not reasonably available for dose-response considerations.

6.2.3 Other Comments

Summary: A public commenter (0163) said that the SACC raised multiple concerns regarding which studies and data EPA did or did not use during its evaluation. The commenter also said that they recommended that EPA consider several additional studies in the 1,2-dichloroethane risk evaluation that had not been included in the Draft Human Health Hazard Assessment, and it is not clear whether these studies were considered in preparing the Draft Risk Evaluation for 1,2-Dichloroethane.

EPA Response: The initial literature search for 1,2-dichloroethane was completed in September 2019, however, EPA has added references to the systematic review pool since 2019. EPA performed an updated literature search for studies to be included in the 1,2-Dichloroethane Human Health Hazard Assessment in April 2025. Additionally, references of interest for 1,2-dichloroethane (both peer-reviewed and gray literature) that had been identified by assessors were included in systematic review, screened for relevance, and proceeded to data quality evaluation and extraction if they met the screening criteria. In addition to assessor identified references, EPA also added to the systematic review pool for 1,2-dichloroethane studies that were submitted to the Agency under various TSCA authorities (*e.g.*, TSCA section 8(d)). Finally, references that EPA received through public comments for 1,2-dichloroethane also went through the systematic review steps as described in the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances* (U.S. EPA, 2021) and the *Systematic Review Protocol for 1,2-Dichloroethane* (U.S. EPA, 2026o). With all these sources of information, EPA determined to have enough information for the risk evaluation for 1,2-dichloroethane.

6.3 Human Health Risk Characterization

Summary: A public commenter (0160) said that EPA discounts risks to workers by using a less protective cancer benchmark for workers than for any other subpopulation. The commenter said that EPA also does not explain in detail how it will determine whether a specific cancer risk within that range (less than the 1×10^{-4} NIOSH benchmark) will present an unreasonable risk, nor does it explain which PESS will be subject to the less protective cancer risk of greater than 1×10^{-6}. The commenter

recommended that EPA should instead use the more protective benchmark of 1×10^{-6} for all populations moving forward.

EPA Response: EPA relied on NIOSH guidance (Whittaker et al., 2016) when choosing the 10^{-4} cancer risk benchmark to evaluate risks to workers from 1,2-dichloroethane exposure. NIOSH's mandate, on pg. iii of Whittaker et al. (2016), is to: "… describe exposure levels that are safe for various periods of employment, including but not limited to exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience." Although NIOSH guidance, p. 20, states that: "exposures should be kept *below* a risk level of 1 in 10,000, *if practical* [emphasis added]" EPA adheres to the 1 in 10,000 benchmark during the risk evaluation stage for TSCA chemicals for workers. It is important to note that, consistent with other cancer risk benchmarks, 1×10^{-4} is not treated as a bright line, and EPA uses discretion to make unreasonable risk determinations based on other considerations or factors as appropriate. See Section 5.1.1.2 of the Risk Evaluation for additional information. EPA has consistently applied a cancer risk benchmark of 1×10^{-4} for assessment of occupational scenarios under TSCA. For the cancer risk assessments for the general population, EPA considers an increased cancer risk above benchmarks ranging from 1 in 1,000,000 to 1 in 10,000 (*i.e.,* 1×10^{-6} to 1×10^{-4}), which is also not treated as a bright line.

7 UNREASONABLE RISK DETERMINATION

Comments associated with this topic are included in the subsections below.

7.1 Unreasonable Risk Determination for Human Health

Comments associated with this topic are included in the subsections below.

7.1.1 Unreasonable Risk to Workers

7.1.1.1 Specific Conditions of Use

Summary: A public commenter (0165) said that the unreasonable dermal risk to workers in the Draft Risk Evaluation for 1,2-Dichloroethane for the manufacturing, processing as an intermediate, and use as a catalyst moderator for ethylene oxide production is based on unrealistic and unlikely accident scenarios. The commenter raises several concerns with the Draft Dermal Monte Carlo Exposure Model for 1,2-Dichloroethane, specifically that it assumes an accidental release each day for 250 days per year, "that dermal exposures occur to some portion of the hands plus some portion of other body parts (*e.g.,* arms) such that the total exposed surface area is approximately equal to the surface area of one to two hands" because workers are not wearing any PPE, and that workers leave 1,2-dichloroethane on their skin for an entire 8-hour work shift. The commenter also noted that the unreasonable risk determination was based on the "high-end" for "all COUs for which the use is known to take place in closed systems."

The commenter described the details of 1,2-dichloroethane production and its use in a closed system and said that EPA's dermal exposure models are critically flawed because the modeling assumptions are purely hypothetical and do not in any way reflect the real-world usage.

For the COU as a Catalyst moderator in a closed system, the commenter explained that dermal exposures would occur only from accidental releases when lines are connected or disconnected. They note that, at the upper-bound, the frequency of these change-outs is more like a range of 26 times per year (every two weeks), with the lower bound 8 times per year (every six weeks) and the duration each time is only 20 minutes, while the model assumes the task to be 8 hours. The commenter also asserts that as accidental releases these are hypothetical, unlikely events and therefore are not a condition of use as they are not reasonably foreseen.

The commenter said that replacing EPA's assumptions with the correct frequency and duration values would produce a different modeling result for dermal exposures. The commenter asked why the dermal exposure model used for the Draft Risk Evaluation for 1,2-Dichloroethane uses default values and not the correct values provided by Dow Chemical.

EPA Response: EPA acknowledges that in the absence of dermal exposure monitoring data, it relies on the use of the DEVL Model to estimate dermal exposure. The model uses chemical-specific values for fraction absorption to account for the high percentage of the potential dose that would evaporate vs the percentage that would absorb to the skin. The model also uses chemical-specific data on the weight percent of the chemical in the OES being assessed in estimating the potential dermal dose.

There is generally limited data on dermal exposure at industrial and commercial facilities to compare to the DEVL Dermal Model results.

EPA's practice to quantitatively estimate dermal exposure for volatile liquids using the DEVL model and then consider information on the nature of the OES, such as use in closed systems and data on the use of PPE at the facility in the characterization of the potential dermal risk. EPA's preference is to use chemical-specific data on the frequency of exposure in the risk estimates. The test order provided descriptions of the exposure frequency such as "daily" or "weekly". Each of the SEGs had tasks that could be performed on a daily basis. EPA used this information to assume up to 250 days/yr of exposure for each SEG. If data on the maximum number of days/yr for an individual worker in an SEG was available, this data could be used in place of the assumption of 250 days/yr.

Modeling assumes one contact event/day and does not assume that workers leave the chemical on the skin for the full 8-hour shift. Following a contact event, a volatile chemical simultaneously evaporates from and absorbs into the skin. The DEVL Model assumes that the dose is likely to deplete before the end of the workday.

EPA uses the central tendency from the dermal exposure modeling as a more appropriate exposure estimate for the risk determinations for chronic non-cancer and cancer effects. Use of the high-end dermal estimate in combination with high-end estimates of exposure frequency and working years may result in overly conservative estimates for the risk determination.

Summary: A public commenter (0169) said that the industrial use of lubricants and grease and aerosol degreasing conditions of use do not appear to reflect any actual use, despite EPA's determination that the OES of "Industrial Application of Lubricants and Greases" significantly contributes to unreasonable risk using EPA's aerosol degreasing model. The commenter said that EPA did not identify inhalation exposure monitoring data associated with the use of 1,2-dichloroethane in lubricant and grease applications or aerosol degreasing and thus, relied on estimated inhalation exposure models. The commenter said that EPA used its aerosol degreasing (Brake Servicing Near-Field/Far-Field) exposure model for both OESs, however, EPA does not provide clear support that this model is representative of application methodologies for these OESs. The commenter said that EPA's modeling results rely heavily on concentration information from a limited set (<2) of example product concentrations and it is unclear whether this information and, thus, the modeled air concentrations (or the distributions of inhalation concentrations) are representative of the products covered by these OES. The commenter added that EPA's modeling uses a 100%release scenario, which assumes that all of the 1,2-dichloroethane used in the scenario will be released to the air, as well as assuming 250 days/year of use and exposure. The commenter said it is unclear whether either of these assumptions are representative of actual air concentrations and/or potential work and exposure patterns of the industries and sites that use these products. The commenter stated that more information on the products, application, facilities, and work practices associated with the OESs is needed to appropriately estimate potential inhalation exposure for these OESs.

EPA Response: EPA acknowledges the commenter for their feedback on the OESs for the Lubricants and greases COU and Aerosol degreasing COU. As discussed in Section 5.3.3 of the risk evaluation, the Agency has slight to moderate confidence in these MOEs for both the non-cancer and cancer exposures because of the uncertainties in the modeled exposure values. While EPA does not make risk determinations based on slight confidence, the moderate confidence in the modeling for both COUs allows the Agency to do so, and both COUs were found to significantly contribute to unreasonable risk for 1,2-dichloroethane. EPA is required by TSCA to assess all reasonably foreseeable COUs and specifically requested more information on these COUs in the request for comment. Had actual inhalation exposure monitoring data and/or more chemical-specific data for modeling parameters been provided to EPA, the Agency would have considered that data in lieu of modelling and default assumptions.

EPA used the Brake Servicing Near Field/Far-Field exposure model for the following OES: (1) Industrial Use of Lubricants and Greases, and (2) Commercial Aerosol Products.

For the industrial use of lubricants and greases, EPA relied on multiple streams of evidence. A safety data sheet for a solid film lubricant was identified containing 5-10% 1,2-dichloroethane. In addition, a comment submitted by the DOE (2025) confirmed this concentration, and a comment from the AIA (EPA-HQ-OPPT-2018-0427-0005) further confirmed the use of 1,2-dichloroethane in lubricants within the aerospace industry. The technical data sheet indicates that the identified product is applied via spray. EPA used the brake servicing model as an analogous scenario for this OES since it models aerosol use. The concentration data for this scenario is reasonable and based on identified products for the OES. EPA has moderate confidence that this modeling approach is applicable due to similarity in expected worker activities and application methods for lubricant application and aerosol brake servicing. However, there is uncertainty in the representativeness of all potential air concentrations for this scenario, since this is based on typical exposure and work patterns that occur for brake services. This uncertainty is reflected in our weight of scientific evidence rating of slight to moderate for the assessment.

For the commercial use of aerosol products, EPA had evidence from two safety data sheets identifying 1,2-dichloroethane use as a process cleaner and general solvent at 90-100% concentration. The application method was unspecified, so EPA assumed aerosol application as a conservative estimate and then assumed non-aerosol cleaning/degreasing as a separate OES. EPA used the brake servicing model as an analogous scenario due to the assumed aerosol application method. EPA has a slightly lower confidence in the applicability of this modeling approach since EPA could not determine the primary application method of 1,2-dichloroethane as a cleaning/degreasing product. This uncertainty, in addition to the uncertainties listed above for lubricants and greases, is reflected in the weight of scientific evidence rating of slight to moderate.

For both OES, due to expected aerosol use and chemical volatility, 100% of the chemical is assumed to be released to air. The 250 days/yr assumption is based on a typical worker schedule of 5 days/week and 50 weeks/year.

EPA updated Sections 3.7 and 3.9 of the Occupational Exposure Assessment for 1,2-dichloroethane to make clear the evidence for these COUs and the assessment decisions made.

7.1.1.2 Other Comments

Summary: A public commenter (0157) said that if EPA determines that 1,2-dichloroethane poses an unreasonable risk under one or more conditions of use, then EPA must develop TSCA section 6(a) regulations to address those risks and that any such measures should be tailored to actual distribution, manufacturing, and/or processing practices, including clearly specified PPE requirements, engineering controls appropriate for closed-container handling, and hazard communication.

EPA Response: With the publication of this final risk evaluation and the identification of unreasonable risk, EPA will be moving forward with risk management by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that the chemical substance no longer presents an unreasonable risk. During the risk management stage, EPA will consider a variety of relevant factors in choosing one or more of the available TSCA section 6(a) regulatory tools, including the activities that would be involved in each condition of use, the availability of engineering and other controls to reduce exposure, the limitations of respirators, the availability of substitutes, etc. EPA encourages the commenter to submit information about exposure controls implemented during distribution activities during the TSCA section 6(a) rulemaking notice and comment period.

Summary: A public commenter (0169) said that EPA's determination that there is potential for unreasonable risk to humans based on inhalation and dermal exposure to workers under most conditions of use, is strongly influenced by overlapping conservative decisions and assumptions that EPA made with respect to both the exposures to and the proposed hazards and associated dose response of 1,2-dichloroethane.

EPA Response: EPA has added information to the occupational exposure risk characterization (Section 5.3.3) regarding the strengths and limitations of the underlying data used to develop the estimates of occupational exposures. EPA acknowledges the comment and concern of combining multiple conservative assumptions in estimates of exposure, and the occupational exposure risk characterization (Section 5.3.3) describes how this topic was considered in the estimates for each OES that was assessed.

7.1.2 Proposed No Unreasonable Risk to the General Population

Summary: A public commenter (0160) said that EPA estimated risks to the general population, including those living downwind of chemical manufacturing facilities as high as 2.78×10^{-4}, which is almost 300 times the generally recognized acceptable risk benchmark of 1×10^{-6} for the general population. The commenter said that this level presents an unreasonable risk, yet EPA states that this elevated risk is not unreasonable because not that many people will face the elevated risk. The commenter said that EPA falsely claimed that its framework for determining acceptable cancer risks is similar to that used other EPA programs, in particular under the CAA and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). However, the commenter said that EPA's approach for TSCA would allow risks almost 300 times greater than the 1×10^{-6} cancer benchmark used under CERCLA. The commenter said that under the CAA, EPA considers a cancer risk of less than 1×10^{-6} generally acceptable and a risk of greater than 1×10^{-4} generally unacceptable. The commenter stated that where there are sensitive subpopulations or those more highly exposed, EPA will generally use the 10^{-6} benchmark rather than the higher 1×10^{-4} benchmark that EPA intends to use for TSCA.

EPA Response: EPA's cancer risk call for the general population is based upon a variety of factors, including the 1×10^{-6} to 1×10^{-4} range that is similar to the generally acceptable cancer risk ranges used under the CAA and CERCLA. While the commenter argues that estimated cancer risks to the general population, including those living downwind of chemical manufacturing facilities with risks as high as 2.78×10^{-4} constitute unreasonable risk, EPA explained in Section 6.2.3 of the draft risk evaluation that the HEM modeling did not indicate that individuals live in those areas with such high risk estimates, and that the highest risk estimates for areas in which individuals are living and could be exposed ranged from 1.70×10^{-5} to 4.45×10^{-5}. For this final risk evaluation, EPA reran the HEM modeling using TRI and NEI data from more recent years and found the highest risk estimates for the general population to be between 1.73×10^{-5} and 2.93×10^{-5} for the highest-releasing facilities. EPA also emphasizes that these estimates are not treated as a "bright line" and other risk-based factors are considered (*e.g.,* confidence in the hazard and exposure characterization, duration, magnitude, uncertainty, and populations exposed) for the purpose of making an unreasonable risk determination. As discussed in Section 6.2.3 of the final risk evaluation, the process of determining unreasonable risk is made on a case-by-case basis, and the risk estimates, along with other considerations, inform the determination that 1,2-dichloroethane does not present unreasonable risk to the general population.

Summary: A public commenter (0172) said that EPA's proposed determination that 1,2-dichloroethane poses no unreasonable risks to fenceline communities is flawed and unsupported. The commenter said that:

- EPA has not adequately explained why it is appropriate to use a cancer risk benchmark

range of 1 in 1,000,000 to 1 in 10,000 for identifying unreasonable risk to fenceline communities, which they state is a departure from the previously adopted benchmark in the fenceline screening methodology and was endorsed by the SACC;

- The record contradicts EPA's assertion that the cancer risk calculations are "biased toward high exposures;"
- EPA provided no basis for judging the maximum cancer risks it calculated to be "low." To the contrary, the maximum calculated risks exceed risk levels that EPA previously has found unacceptable for the general population and EPA articulated no reasoned basis for now judging those risks to be so "low" as to warrant no regulation;
- EPA articulated no reasoned basis for characterizing the fenceline community population facing cancer risks above 1 in 1,000,000 as so "small" as to warrant no regulatory protection under TSCA. The commenter notes that this conclusion is inconsistent with cancer risk findings for worker and ONU populations that are smaller, but appropriately EPA concluded those populations had unreasonable risk;
- EPA's attempt to dismiss elevated cancer risks because they affect a discrete population misunderstands and disregards its obligation under TSCA to protect against unreasonable risk to "potentially exposed or susceptible subpopulation[s]";
- EPA did not explain how considering the absolute number of expected cancers within a given population is consistent with TSCA's mandate to determine whether a chemical substance poses an unreasonable risk of harm—an inherently probabilistic inquiry—or with EPA's practice in prior risk evaluations, which, the commenters allege never relied on estimated cancer incidence within exposed populations to determine whether the risks of developing cancer that those individuals face are unreasonable; and
- EPA's invocation of its risk assessment approaches under the CAA and CERCLA does not salvage EPA's proposed determination that 1,2-dichloroethane poses no unreasonable risks to fenceline communities. EPA's effort to "better align" its assessment of risks from ambient air pollution under TSCA with those under the CAA or CERCLA is misguided, because the differences in the approach mandated under TSCA compared to other statutes reflect intentional features of that unique statute. The commenter also notes that it is unclear which part of EPA's analysis is meant to be bolstered by the references to the other statutes. Additionally, the commenter points to the interpretative principle that when Congress uses different language from a prior statute, courts presume that Congress intended to convey a different meaning. TSCA requires EPA to identify and eliminate any "unreasonable risk of injury to health" presented by the chemical under review, while the Clean Air Act's risk-based provisions for hazardous air pollutants require EPA to "provide an ample margin of safety to protect public health." The commenter also states that EPA cannot pick-and-choose different features of the CAA or CERCLA to support a particular outcome while disregarding other features of the assessments under the other statutes, e.g. consideration of cumulative risk. The commenter states that the National Contingency Plan, which "provide[s] the organizational structure and procedures for . . . responding to . . . releases of hazardous substances, pollutants, and contaminants" under CERCLA, establishes "a cumulative [cancer] risk level of 10^{-6} . . . as the starting point (or initial 'protectiveness' goal) for determining the most appropriate risk level that [remedial] alternatives should be designed to attain." The use of 10^{-6} expresses EPA's preference for remedial actions that result in risks at the more protective end of the risk range, but EPA

has departed from that target based on "site-specific factors." However, EPA's list of those factors does not include the number of people exposed to elevated cancer risk or the estimated number of increased cancer incidences. The commenter states that EPA routinely adopts remedies under CERCLA that protect fewer people than are exposed to unreasonable risk levels of 1,2- dichloroethane.

EPA Response: EPA's cancer risk call for the general population is based upon a variety of factors, including the 1×10^{-6} to 1×10^{-4} range that is similar to the generally acceptable cancer risk ranges used under the CAA and CERCLA. While the commenter argues that estimated cancer risks to the general population, including those living downwind of chemical manufacturing facilities with risks as high as 2.78×10^{-4} constitute unreasonable risk, EPA explained in Section 6.2.3 of the draft risk evaluation that the HEM modeling did not indicate that individuals live in those areas with such high risk estimates, and that the highest risk estimates for areas in which individuals are living and are could be exposed ranged from 1.70×10^{-5} to 4.45×10^{-5}. For this final risk evaluation, EPA reran the HEM modeling using TRI and NEI data from more recent years and found the highest risk estimates for the general population to be between 1.73×10^{-5} and 2.93×10^{-5} for the highest-releasing facilities. EPA also emphasizes that these estimates are not treated as a "bright line" and other risk-based factors are considered (*e.g.,* confidence in the hazard and exposure characterization, duration, magnitude, uncertainty, and populations exposed) for the purpose of making an unreasonable risk determination. The process of determining unreasonable risk is made on a case-by-case basis, and the risk estimates, along with other considerations, inform the risk determination.

EPA asserts that the Agency has sufficiently explained in Section 6.2.3 of the draft and final risk evaluations why the 1×10^{-6} to 1×10^{-4} benchmark range adopted in the draft risk evaluation for 1,2-dichloroethane is the more appropriate benchmark for identifying unreasonable risk to fenceline communities. In the risk determination, EPA describes how the range is not considered a "bright line" and that other factors, such as the locations of populations living near releasing facilities as well as the potential biases toward high exposures, relatively low maximum cancer risks, low cancer, incidence, and a small exposed population are also important factors. In this way, EPA explains that the Agency considers a multitude of factors when determining unreasonable risk.

7.2 Other Comments

Summary: A public commenter (0153) said that the risk evaluation should recognize that 1,2-dichloroethane does not pose unreasonable risk due to its presence as a byproduct, impurity, or contaminant in other chlorinated substances. The commenter requested that EPA address that 1,2-dichloroethane may be present as a byproduct, impurity, or other contaminant in chlorinated substances that EPA is addressing separately (*i.e.,* PCE, 1,1-dichloroethane, TCE, methylene chloride, and CTC). The commenter said that EPA's risk evaluations for these chemical substances have not determined that there is unreasonable risk from 1,2-dichloroethane potentially present in them, and that risk management rules for these substances cover any potential risks from trace contaminants, such as 1,2-dichloroethane, by ensuring that exposure is far below levels that could pose unreasonable risk. The commenter stated that it needs to be clear in this risk evaluation and the subsequent risk management rule that uses of other chlorinated products including PCE, which may contain trace levels of 1,2-dichloroethane, do not pose unreasonable risk from 1,2-dichloroethane and will not be covered under the 1,2-dichloroethane risk management rule. The comment noted that this would be best accomplished through a de minimis exemption along with an exemption for uses in which 1,2-dichloroethane is present solely as a byproduct, impurity, or other contaminant.

EPA Response: In the Risk Evaluation, EPA found unreasonable risk from 1,2-dichloroethane manufactured as a byproduct. EPA's previous risk evaluations for other chemicals did not assess or determine assess risk from the production of 1,2-dichloroethane as a byproduct during the manufacture of those other chemicals.

With the publication of this final risk evaluation and the identification of unreasonable risk, EPA will be moving forward with risk management by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that the chemical substance no longer presents an unreasonable risk. During the risk management stage, EPA will consider a variety of relevant factors in choosing one or more of the available TSCA section 6(a) regulatory approaches.

Summary: A public commenter (0160) said that EPA should not use uncertainty or "conservative assumptions" to discount exposures and risks. The commenter stated that EPA has dismissed exposures and risks due to uncertainty or because of "conservative assumptions." The commenter said that uncertainty in risk estimates does not equate to risk estimates that equal zero, and by treating them as zero and dismissing the potential risks, will likely result in risk management decisions that do not fully mitigate the unreasonable risk as required under TSCA section 6(a). The commenter said that in the absence of information on more susceptible individuals, the solution is not to dismiss the risks they face but to try to address the uncertainty with assumptions that are necessary to assess and address risk, since the alternative (*i.e.,* waiting for or generating data on these susceptible individuals) is unacceptable. As an example, the commenter said that an important exposure modeling approach that EPA often mischaracterizes as a "conservative assumption" is the use of high-end exposure concentrations instead of central tendency estimates. The commenter said this approach is not conservative because it accounts for exposures across the population, including potentially exposed and susceptible subpopulations. The commenter reasoned that EPA should not use arbitrary bright lines of uncertainty when making risk determinations but rather should consider all relevant hazard and exposure data in its risk evaluations and determinations.

EPA Response: EPA considered potentially exposed and susceptible individuals throughout the risk evaluation, including in the exposure assessment, hazard identification, and dose-response analysis. EPA's practice is to estimate both central tendency (50th percentile) and high-end (95th percentile) exposures to inform the risk assessment. Whether a high-end exposure estimate is an overly conservative estimate depends on the underlying data. Where we have representative monitoring data with the key metadata, use of both the central tendency and the more conservative high-end estimate for chronic risks may be appropriate. When the exposure estimates have a lot of uncertainty, using the more conservative high-end exposure estimate in combination with other conservative assumptions may result in an overly conservative risk estimate and EPA may elect to assess the risks with the central tendency exposure. EPA has added information to the occupational exposure risk characterization (Section 5.3.3) of the final risk evaluation to be more transparent on the underlying data associated with the occupational exposure estimates.

8 SYSTEMATIC REVIEW

Summary: In regard to the use and validation of the SWIFT-Review literature screening tool, a public commenter (0169) said EPA did not provide a list of the 5% of studies that were deemed false negatives, and there are no studies tagged as false negative within the Health Assessment Workspace Collaborative database or within any of EPA's other risk evaluation documents. The commenter requested that a list of these false negative studies be made clear and transparent for stakeholder and SACC review, and that EPA include a discussion of how these studies were incorporated into the risk evaluation.

EPA Response: As described in the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances* (U.S. EPA, 2021) and the *Systematic Review Protocol for 1,2-Dichloroethane* (U.S. EPA, 2026o), EPA validated references relevant for determining chemical-specific peer-reviewed reference sets for the characterization of physical and chemical properties, environmental fate and transport properties, occupational exposure and environmental releases, general population, consumer, and environmental exposure, and environmental and human health hazard. EPA manually screened the references found in the overall peer-reviewed search results that did not undergo title and abstract (TIAB) screening (*i.e.*, references that were not identified using a discipline-specific search string). If a reference that did not undergo further review after TIAB screening was found to meet the screening criteria for a respective discipline (*e.g.*, physical and chemical properties, environmental fate and transport properties, occupational exposure and environmental releases, general population, consumer, and environmental exposure and environmental and human health hazard) and identified for the chemical of interest, it was flagged as a false negative. This analysis validated and verified the use of the search terms in SWIFT-Review, as it showed that less than 5% of references were false negatives across disciplines.

This method was repeated for several of the TSCA High Priority Substances to build confidence in our discipline-specific search strings. EPA understands that references can be missed during systematic review; this is expected as part of any systematic review effort conducted by any group. The validation exercise that EPA performed was to test the robustness and validity of the method to identify references across disciplines, and a less than 5% false negative rate was deemed reasonable. During this validation, if EPA found any references that were "missed" among the less than 5% identified as false negative, they were added to the SR pool. While one could make the argument that a significant reference could have been among the false negatives based on the search terms in SWIFT-Review, as a measure to remediate any time before the publication of a final risk evaluation EPA has continuously considered new and/or additional references identified after the initial and/or updated literature search efforts for systematic review. Missed references may be caught when EPA routinely adds to the pool of systematic review references that assessors identify of relevance. EPA has also routinely added to the pool of systematic review references that were recommended by the SACC and public comments, as described in the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances* (U.S. EPA, 2021) and the *Systematic Review Protocol for 1,2-Dichloroethane* (U.S. EPA, 2026o).

Summary: A public commenter (0169) addressed inconsistencies in EPA's literature search period. The commenter said that the search for peer-reviewed literature was conducted in 2019; however best practice is to conduct or update the literature search no more than six to twelve months prior to publication date. The commenter concluded that with over six years of time between the literature search and the release of the Draft Risk Evaluation for 1,2-Dichloroethane, EPA missed "hundreds" of potentially relevant published articles with the most up to date data. The commenter added that despite EPA's statement that the search of the peer-reviewed literature was completed in September 2019, some animal toxicological literature published after 2019 was included in EPA's Draft Risk Evaluation for 1,2-Dichloroethane. The commenter requested EPA update the literature search prior to publication of

the final risk evaluation to ensure that the risk evaluation is comprehensive in its consideration of the available evidence on whether 1,2-dichloroethane presents unreasonable risk to human health or the environment. If EPA convenes a SACC review of the Draft Risk Evaluation for 1,2-Dichloroethane, the commenter recommended EPA complete the updated literature search prior to convening the SACC and provide the revised Draft Risk Evaluation for 1,2-Dichloroethane to the SACC.

EPA Response: The initial literature search for 1,2-dichloroethane was completed in September 2019, however, EPA has added references to the systematic review pool since 2019. References of interest for 1,2-dichloroethane (both peer-reviewed and gray literature) that had been identified by assessors were included in systematic review, screened for relevance, and proceeded to data quality evaluation and extraction if they met the screening criteria. In addition to assessor identified references, EPA also added to the systematic review pool for 1,2-dichloroethane studies that were submitted to the Agency under various TSCA authorities (*e.g.,* TSCA section 8(d)). Finally, references that EPA received through public comments for 1,2-dichloroethane also went through the systematic review steps as described in the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances* (U.S. EPA, 2021) and the *Systematic Review Protocol for 1,2-Dichloroethane* (U.S. EPA, 2026o). With all these sources of information, EPA determined to have enough information for the risk evaluation for 1,2-dichloroethane.

Summary: A public commenter (0169) stated that EPA relied on the 2021 Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances Version 1.0, which created an objective scoring system of studies reflecting study "reliability" only. The commenter said the Criteria for Reporting and Evaluating Ecotoxicity Data scoring system documented by Moermond et al. (2016) can provide insights not only on study reliability but also relevance. The commenter suggested EPA consider scoring studies for reliability as well as relevance, such that studies deemed both reliable and relevant are prioritized over other studies.

EPA Response: EPA described a scoring system for data quality evaluation in Section 5 and Appendices K through T of the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances* (U.S. EPA, 2021). An update to the scoring system is described in Section 2 of the *Systematic Review Protocol for 1,2-Dichloroethane* (U.S. EPA, 2026o) where EPA clarified the implementation of metric rating and overall quality determination that is based on categorical rating and not quantitative methodologies. The overall quality determination speaks to the quality of the information/data and already folded into the quality determination is not just reliability but also applicability and relevance of the information/data.

If the commenter was referring to determining relevance prior to data quality determination, EPA already employs a relevance-driven eligibility criteria (*e.g.,* PECO) during the title/abstract and full-text screening steps described in Section 3 of the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances* (U.S. EPA, 2021) to exclude irrelevant (off topic) studies before they are evaluated for risk of bias, quality, and reporting.

Summary: A public commenter (0154) discussed the *in vitro* dermal adsorption study EPA required in a consent order stating that the study was considered a data gap based on the results of EPA's systematic review for the Draft Risk Evaluation for 1,2-Dichloroethane. However, it is unclear how EPA reached that decision, given that a study using the same protocol involving 1,2-dichloroethane was submitted to EPA on June 24, 2005, to satisfy the TSCA section 4 test rule "In Vitro Dermal Absorption Rate Testing of Certain Chemicals of Interest to the Occupational Health and Safety Administration." The commenter

concluded that the lack of awareness of studies conducted for TSCA section 4 test rules for the TSCA risk evaluations raises questions on the thoroughness of the systematic review process.

EPA Response: EPA identified this study via its systematic review process and it was included in the *Draft Data Quality Evaluation and Data Extraction Information for Dermal Absorption for 1,2-Dichloroethane* submitted to the docket (EPA-HQ-OPPT-2018-0427-0094) during the public comment period. The Agency has included the rationale as the consideration of this study and the justification as to the issuance of the TSCA section 4 test order and use in the Occupational Dermal Exposure Assessment in Section 5.3.3.2. Additionally, the permeability coefficients and absorption rates from DuPont Haskell Laboratory (2005) was also characterized in the *Human Health Hazard Assessment for 1,2-Dichloroethane* in Section 3.1.3.

9 OTHER COMMENTS ON THE DRAFT RISK EVALUATION

Summary: In a comment submitted before the publication of the Draft Risk Evaluation for 1,2-Dichloroethane, a public commenter (0057) provided primary data, government reports, and a summary of current regulations and restrictions. The commenter concluded that EPA should:

- revise the literature review process to capture information from states that may not be available in the peer-reviewed literature;
- consider the impacts of states and other entities actions in reducing exposure to priority chemicals and avoid taking action that would preempt such actions; and
- recognize that current regulatory actions by states reduce exposures to priority chemicals and that, therefore, TSCA actions preempting state regulations could increase exposure over time.

EPA Response: As described in Section 4.3 of the *Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances* (U.S. EPA, 2021), EPA performs literature searches not only for peer-reviewed, but also for gray literature, which would include any reports or documents reported by states on a High Priority Substance under TSCA. Not all states might have information/data reported on a High Priority Substance such as 1,2-dichloroethane, particularly if there are no facilities or environmental releases of the chemical of interest in that state. As part of the gray literature search, the Agency may check gray literature sources that are available for California (*e.g.*, California Office of Environmental Health Hazard Assessment), New York (*e.g.*, New York State Department of Health), New Jersey (*e.g.*, New Jersey Department of Health and Senior Services), and Washington (*e.g.*, Washington State Department of Ecology).

Summary: A public commenter (0144) said EPA needs to start considering what they scrutinize and the chilling effect it has on future chemical investments in the U.S. and upstream / downstream impacts.

EPA Response: Under TSCA, risk evaluations assess health and environmental risk under the conditions of use and may not consider costs or other nonrisk factors. Economic and investment impacts are addressed during risk management (section 6(a)), where EPA conducts economic analyses and considers feasibility, alternatives, timing, and supply chain effects with stakeholder input. The Agency recognizes the importance of regulatory certainty and encourages stakeholders to submit data on potential impacts and feasible alternatives during the risk management process.

EPA has worked diligently over the past several years to provide stakeholders with multiple notifications regarding the Agency's review of 1,2-dichloroethane in an effort to obtain necessary stakeholder input. EPA has continued to conduct outreach during and after the comment period, including meeting with several of the commenters, to discuss topics of concern and/or clarify information provided during the comment period. Summary memos for these meetings are in the docket. The Agency has worked to finalize risk evaluations and risk management rules consistent with statutory direction and timeframes.

Summary: A public commenter (0153) said that they are not aware of any current intentional manufacturing, processing, or use of 1,2-dichloroethane in petroleum refinery operations to produce fuel and fuel products. However, the commenter said that 1,2-dichloroethane is important in the supply chain because chemical companies use it to produce ethylene oxide, which in turn is used to make various products including fuel additives and lubricants. The commenter said that it is important that such uses

are allowed to continue. Additionally, the commenter said that it is possible that chemical substances used in refineries such as PCE could contain 1,2-dichloroethane as a contaminant.

EPA Response: EPA did not identify current intentional manufacturing, processing, or use of 1,2-dichloroethane in petroleum refinery operations to produce fuels or fuel products. Although "Fuels and related products" was identified during scoping, upon further investigation EPA decided not to quantitatively assess releases and exposures for these uses. The rationale is provided in Section 1.2 of both the Environmental Release Assessment and the Occupational Exposure Assessment (U.S. EPA, 2026h, k). Consistent with this, we are removing these releases from the updated modeling for the Final Risk Evaluation.

EPA acknowledges that 1,2-dichloroethane can play a role in broader chemical supply chains, including for products that may be used as fuel additives or lubricants. Under TSCA, the risk evaluation focuses on 1,2-dichloroethane's conditions of use and associated exposures; it does not determine whether uses "continue."

EPA will consider exposures due to impurities under the applicable conditions of use. We encourage submission of any specific data or documentation on impurity levels and associated releases to the docket.

Summary: Some public commenters (0155, 0166, 0171) expressed support for comments provided from another stakeholder (*e.g.,* Vinyl Institute's [VI] Ethylene Dichloride Consortium [Consortium], American Chemistry Council's Chlorine Panel) outlining the key technical issues that EPA must address in revising and finalizing this risk evaluation.

EPA Response: EPA has considered the referenced comments and addressed the issues raised by Vinyl Institute's Ethylene Dichloride Consortium and the American Chemistry Council's Chlorine Panel in the topic-specific responses in this document and updated the analysis in the final risk evaluation and supporting TSDs as noted in this document.

10 COMMENTS NOT RELEVANT TO THE DRAFT RISK EVALUATION

Summary: A few public commenters submitted comments before the publication of the Draft Risk Evaluation for 1,2-Dichloroethane, which included the following:

- comments in response to the Federal Register notice published by ATSDR soliciting public nominations of substances for Toxicological Profile development (0053) that urge ATSDR to develop Toxicological Profiles for 43 chemicals listed on EPA's TSCA Work Plan for Chemical Assessments: 2014 Update and urged EPA to consult with ATSDR for assistance in developing methodologies to conduct the cumulative risk evaluations required by TSCA; and
- results of a literature review that collected and evaluated the literature on workplace safety trainings and certification programs (0060).

EPA Response: The issues raised by these commenters are not relevant to the Risk Evaluation for 1,2-Dichloroethane under TSCA section 6(b). Accordingly, no changes were made to the risk evaluation in response to these comments.

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APPENDICES

Appendix A SUMMARY OF AND RESPONSE TO EXTERNAL PEER REVIEW AND PUBLIC COMMENTS ON THE HUMAN HEALTH HAZARD TECHNICAL SUPPORT DOCUMENT FOR 1,2-DICHLOROETHANE

The draft 1,2-Dichloroethane Human Health Hazard Assessment was peer reviewed by the Science Advisory Committee on Chemicals (SACC) with the draft 1,1-Dichloroethane Risk Evaluation September 17-19th, 2024. The SACC report was published November 27th, 2024, and EPA published the 1,1-dichloroethane risk evaluation on June 23rd, 2025, which included a response to public and SACC comment on the 1,1-dichloroethane risk evaluation and 1,2-dichloroethane human health hazard assessment. A summary of the charge to the SACC for the 1,2-dichloroethane human health hazard assessment, the summary of SACC and public comments and EPA's response to the SACC and public comment for each charge question are provided below. Please see the charge to the SACC (EPA-HQ-OPPT-2024-0114-0055) and response to comments published with 1,1-dichloroethane risk evaluation (EPA-HQ-OPPT-2018-0426-0089) for details. EPA received additional public comment on the 1,2-dichloroethane human health hazard assessment when the draft risk evaluation for 1,2-dichloroethane was published for public comment on November 19, 2025. In some instances, EPA has made additional updates to the 1,2-dichloroethane human health hazard assessment, which are briefly noted below as an "Updated EPA Response" and where those updates are relevant to specific charge questions and prior EPA responses. Refer to Section 6.2 of this document to see a summary of public comments and EPA's current, full responses from the draft 1,2-dicholorethane risk evaluation public comment period on these issues (November 19, 2025, to January 20, 2026).

Table_Apx A-1. Index of Comment Submissions Sorted by Submission Number

Submission Number	Commenter Name
EPA-HQ-OPPT-2024-0114-0052	American Chemistry Council
EPA-HQ-OPPT-2024-0114-0053	Vinyl Institute
EPA-HQ-OPPT-2024-0114-0059	Stantec Consulting Services, Inc. on behalf of Vinyl Institute
EPA-HQ-OPPT-2024-0114-0060	Anonymous (withdrawn)
EPA-HQ-OPPT-2024-0114-0061	Nuclear Energy Institute
EPA-HQ-OPPT-2024-0114-0062	Environmental Defense Fund
EPA-HQ-OPPT-2024-0114-0063	American Chemistry Council
EPA-HQ-OPPT-2024-0114-0064	National Tribal Toxics Council
EPA-HQ-OPPT-2024-0114-0065	People for the Ethical Treatment of Animals (PETA)
EPA-HQ-OPPT-2024-0114-0066	Vinyl Institute
EPA-HQ-OPPT-2024-0114-0067	Vinyl Institute
EPA-HQ-OPPT-2024-0114-0068	University of California, San Francisco Program on Reproductive Health and the Environment
EPA-HQ-OPPT-2024-0114-0069	Louisiana Environmental Action Network et al. (Part 1 of 3)
EPA-HQ-OPPT-2024-0114-0070	Louisiana Environmental Action Network et al. (Part 2 of 3)
EPA-HQ-OPPT-2024-0114-0071	Louisiana Environmental Action Network et al. (Part 3 of 3)

Submission Number	Commenter Name
EPA-HQ-OPPT-2024-0114-0078	Stantec Consulting Services, Inc. on behalf of Vinyl Institute

A.1 Charge Question 4 – Oral, Non-Cancer (Acute)

The charge question asked for comments on the use of Storer et al. (1984), the benchmark dose modeling and alternative studies.

A.1.1 Review of Storer et al. (1984)

Summary: A public commenter, in multiple submissions to the docket (0053, 0066, 0067), requested that SACC and EPA consider the quality of the Storer et al. (1984) study and the applicability of the results for use in the dose response assessment for 1,1- or 1,2-dichloroethane. The commenter (0053) specifically suggested that the SACC consider that different scientific studies with varying exposure regimens have identified different effects associated with 1,2-dichloroethane exposures, and that there is a lack of scientific consensus regarding kidney effects from 1,1-dichloroethane exposure. The commenter (0066) also stated that there is no clear consistency of effects on the kidney associated with 1,1-dichloroethane exposures.

The SACC stated that its members expressed different opinions on the study quality, protocol, conduct, and data interpretation of Storer et al. (1984). One SACC member noted that the sample sizes, dosing regimen, and control groups were appropriately defined. The SACC member also said that the sample size was sufficient; however, a higher number of animals would increase statistical significance. The SACC member also said that the use of oral gavage as the route of administration is not an ideal representation of human oral exposure, but it is relevant, and the dose can be delivered in quantity as intended. Another SACC member said that the study did not meet today's standards. The SACC member said that the experimental design was set up for a typical analysis of the variance (ANOVA) with multiple comparisons test for significance, but this design does not allow for fitting a dose-response curve with confidence intervals for ECx values, thereby preventing the derivation of EC10, EC20, and EC50 values with confidence intervals. The SACC member said that there are currently multiple tools for conducting data analysis for exposure-response datasets.

The SACC concurred that the findings of Storer et al. (1984) could be relevant to the assessment of acute toxicity for 1,2-dichloroethane analogs, but it remains unclear whether these findings have any significance for the acute toxicity of 1,1-dichloroethane. The SACC said that "1,2-dichloroethane may not be the best analog to determine acute oral toxicity of 1,1-dichloroethane." The SACC said that 1,1-dichloroethane has been shown to be less potent than 1,2-dichloroethane in inducing toxicity responses, including kidney toxicity, and kidney toxicity may not be a relevant endpoint for acute oral toxicity determination. Some SACC members provided arguments for the relevance of the kidney toxicity endpoint, saying:

- "This finding was further supported by another study where absolute kidney weight was significantly increased in male rats exposed to 1,2-dichloroethane by gavage for 13 weeks (5 days per week);
- Kidney effects have also been observed in mice administered a lethal intraperitoneal injection of 1,1-dichloroethane; the effects included increased glucose and protein in the urine and tubular swelling;
- In the study by Hofmann et al. (1971), renal injury was observed in cats that were intermittently exposed to 1,000 parts per million (ppm) of 1,1-dichloroethane for 6 hours per day over 13 weeks, following an initial 13-week period of exposure to 500 ppm under the same conditions."

Other SACC members argued against the relevance of the kidney toxicity endpoint, stating:

- "Relative kidney weights were not affected by 1,1-dichloroethane in acute/subacute studies and elevated serum enzyme levels, histopathological changes, and abnormal urinalyses were not manifested;
- The absence of a nephrotoxic effect in other species and in other studies where 1,1-dichloroethane was administered orally suggests that the observed effect may be species-specific or influenced by factors unique to the study conditions;
- 1,1-dichloroethane is not considered a potent hepatotoxic, nephrotoxic, or carcinogenic agent, as available evidence indicates that its toxicity in the liver, kidneys, and potential for cancer development is low."

Overall, the SACC said that "the acute kidney response to 1,2-dichloroethane in mice does not accurately represent 1,1-dichloroethane response in mice and moreover, human response to both of these chemicals due to significant differences in metabolism, renal physiology, and dose-response relationships."

The SACC provided several recommendations for EPA:

- "While EPA provides transparent data and technical analyses, some sections lack clear scientific interpretation. The EPA should revise Section 5.2.6.1.2 (lines 7526–7542) and other relevant sections where technical work is presented but not fully explained by including additional explanations that emphasize the 'why.' This additional context could strengthen the presentation and improve stakeholder and public understanding. For example, explain the importance of doses tested in Storer et al. (1984) to highlight that the closely spaced dose levels provide a stronger basis for dose-response modeling compared to other studies (*e.g.,* Morel et al. (1999)). Similarly, clarify why benchmark dose (BMD) modeling of serum [blood urea nitrogen] is mentioned, as it offers a formal analysis of the observed trend, which the original study did not include.
- Lines 6619-6622: The two sentences here regarding the Zabrodskii et al. (2004) study should be re-worded/clarified. The Zabrodskii et al. (2004) study did not identify the isomer used and was therefore labeled 'Uninformative'. However, because this assessment is applying read-across from [1,2-dichloroethane], this study remains relevant for hazard identification.
- A weight-of-evidence approach that integrates data from multiple *in vitro* and *in vivo* studies can provide a more robust and comprehensive basis for deriving the acute oral POD for 1,1-dichloroethane and [1,2-dichloroethane].

To better assess human risk, it would be more appropriate to incorporate *in vitro* human kidney models and PBPK modeling (it will be more efficient and cost effective). The PBPK models can be defined based on kinetic constants derived from *in vitro* studies and then reverse translate the obtained *in vitro* concentration-response curves to predict *in vitro* dose-response curves."

EPA Response: EPA applied a read-across approach and weight of scientific evidence to support the selection of the POD and this justification has been further described in the Risk Evaluation to emphasize the relevance of the selection of the renal endpoint identified in Storer et al. (1984). The Zabrodskii et al. (2004) study that was identified as "uninformative" was incorrectly characterized in the draft risk evaluation and the systematic review rating has been updated in the Risk Evaluation to the actual systematic review rating of "medium." This study has been further described in the hazard identification and weight of scientific evidence conclusions in the Risk Evaluation (Section 5.2.3). EPA acknowledges that the acute oral toxicity data for 1,1-Dichloroethane is limited to one *in vivo* study that was rated as "medium" in the systematic review conducted to inform the dose-response analyses.

Updated EPA Response: The 1,2-dichloroethane human health assessment technical support document has been revised with these updates.

A.1.2 Benchmark (BMC) Analysis and Response Level

Summary: A public commenter, in multiple submissions to the docket (0066, 0067), expressed concern regarding the use of appropriate PODs, BMD modeling, and uncertainty factors in the dose response assessments for either 1,1- or 1,2-dichloroethane. The commenter requested that EPA consider the applicability and potential impacts of bolus dosing on the identified potential effects.
In another submission to the docket (0053), the commenter discussed that EPA only used information relevant to the gavage dosing regimen, adding that this may reduce the applicability of the dose response relationship to dermal exposures which are unlikely to involve bolus dosing.

EPA Response: EPA considered both drinking water and gavage studies. The selection of the studies that are the basis of the oral PODs were categorized into a subset of studies that were characterized as potential candidates based on systematic review. Studies that were rated as "uninformative" for dose-response based on key metrics that resulted in greater uncertainty to the delivered dose were not considered appropriate for POD selection.

Summary: The SACC stated that EPA neglected to acknowledge that the preferred approach to model selection includes consideration of the underlying biological process and said that it is appropriate that the statistical considerations of the analysis guide the selection of the model. The SACC recommended that EPA "add discussion/acknowledgement of the limit biological data/knowledge." The SACC also suggested that in Lines 1834 to 1836 of the Supplemental Information File: Benchmark Dose Modeling Results for 1,1-Dichloroethane (U.S. EPA, 2024a), "EPA should cite the guidance that supports the statement 'A [benchmark response (BMR)] of 10 percent relative deviation … was also selected because EPA considers a 10 percent change in relative kidney weight to be biologically significant.'"

EPA Response: The use of a BMR of 10% is consistent with EPA policy (U.S. EPA, 2012). EPA considered the biological processes and data variability in selection of model and BMR values.

A.1.3 Alternative Studies

Summary: The SACC said that the literature review did not identify any alternative studies suitable for use in deriving an acute oral POD for 1,1-dichloroethane and 1,2-dichloroethane. However, the SACC said that there are new types of studies that may enable improvements in data quality, analysis and interpretation. The SACC suggested "that these types of studies would improve the quality of the data and add information on modes of action."

The SACC provided several recommendations:

- "*In vitro* tests can be used to study the effects of [1,1-dichloroethane] and [1,2-dichloroethane] on various organs by utilizing primary cells or cell lines from different origins, including kidney, liver, respiratory, and intestinal models, as well as brain organoids, incorporating metabolically competent 3D tissue models.
- Metabolism and biotransformation, lipid peroxidation and oxidative stress, deoxyribose nucleic acid damage, inflammation, fibrosis, change in morphology and barrier function, changes in specific marker expression, cytokine and gene expression can be analyzed by multiple methods.
- Effect on human kidney could be tested on *in vitro* proximal tubule kidney epithelial tissue model by modeling kidney specific toxicity and acute kidney injury.

[Central nervous system] depression could be due to lipophilicity and crossing blood-brain barrier and it can be tested with *in vitro* assays on Blood-Brain models, brain organoids."

EPA Response: EPA used the best available information in deriving an acute oral POD. As part of the weight of scientific evidence approach, EPA integrated identified *in vitro* and mechanistic evidence where applicable with evidence identified in humans and from laboratory animals into the overall confidence statements for each health effect identified. The suggestions provided from the SACC refer to these types of studies which were considered if identified in the literature review. EPA, as part of the literature review, considers the incorporation of alternative studies within this process as a means to present the best available science and provide a comprehensive evaluation regarding the data across data streams.

A.2 Charge Question 5 – Oral, Non-Cancer (Short-Term and Chronic)

The charge question asked for comments on the use of (Munson et al., 1982), the use of (NTP, 1991), alternative studies and use of short-term and sub-chronic studies for assessing chronic exposure.

A.2.1 Review of Munson et al. (1982)

Summary: In multiple submissions to the docket (0066, 0067), a public commenter stated that it is inappropriate to use the results of the 14-day gavage study to inform potential hazards associated with 1,2-dichloroethane exposure, adding that Munson et al. (1982) confirms that chronic exposures to 1,2-dichloroethane via drinking water are unlikely to cause immunotoxic effects. The commenter recommended that EPA follow the ATSDR's reasoning with respect to use of the gavage study and reevaluate the conclusion that 1,2-dichloroethane is immunotoxic. The commenter additionally requested that EPA reconsider the use of Munson et al. (1982) for derivation of benchmarks for 1,1- and 1,2-dichloroethane. The commenter (0067) stated that accurate prediction of toxicity and dose response via the oral route is essential for the 1,2-dichloroethane draft risk evaluation, given anticipated use of the oral benchmarks for the prediction of dermal risk for workers exposed to 1,2-dichloroethane.
In contrast, a public commenter (0062) requested that EPA use the 14-day gavage study from Munson et al. (1982) in selection of the oral non-cancer short-term and chronic PODs, consistent with the best available science.

EPA Response: In response to the comments on the use of the Munson et al. (1982) study, EPA reevaluated the oral data available for 1,1- and 1,2-dichloroethane to develop its reasoning and justification for either maintaining the study as the basis for the intermediate/chronic oral POD or shifting to a different study and POD. The oral data for the intermediate and chronic oral exposure durations were plotted as a dose-response array and categorized by health effects in the RE that illustrates that several studies show adverse effects to the kidneys at similar dose levels and agreed that the most appropriate endpoint for 1,2-dichloroethane oral exposures are effects to the kidneys instead of the originally proposed POD based on immunotoxicity. The POD was changed from Munson et al. (1982) in the draft to an NTP (1991) oral gavage study in rats based on increased relative kidney weight effects. Due to limited data to support the continued use of the Munson et al. (1982) study for dose-response and as the basis for the POD for both the intermediate and chronic oral POD, EPA still considers this heath effect as sensitive and of concern thus an integration of evidence for the immunological endpoint in the hazard identification (Section 5.2.3.1.1) is presented in the risk evaluation. See Section 5.2.6 of the final risk evaluation for the justification on the revision to the oral intermediate/chronic POD from immunotoxicity to renal toxicity.

Summary: The SACC expressed concern that the ORD and ECRAD had different opinions on Munson et al. (1982). The SACC said it agreed with the ORD decision to not select this study, as there are

scientific issues related to human relevance, dose selection, metabolism, and unknown mechanistic understanding. For example, the SACC said that the study "only focused on short term exposures, which might not be relevant since it is likely that much of this exposure for humans is occupational, suggesting that it could be more long term/chronic exposures in humans." Additionally, the SACC said that the study "notes that the sub-chronic 90-day exposure is believed to produce an adequate manifestation of chemical toxicity, except for mutagenic and reproductive effects." The SACC said that this is a critical limitation. "If there are reproductive effects, this would represent a critical population who is uniquely susceptible to chemicals." Also, the SACC said that the impact on female rats was not shown, and it is unclear if the dosage administered for dichloroethane reflects human level exposures.

The SACC said that "EPA must weigh and explain the related uncertainties/considerations including the route of exposure, the type of effect observed and whether that effect would have longer-term or chronic consequences. These considerations then inform the adjustments/uncertainty factors that are reflected in the Margin of Exposure used for risk characterization."

With regards to the statistical analysis, the SACC said that there are limitations if the goal is to set concentrations for estimating the initiation of effects. In other words, the benchmark dose lower confidence limit (BMDL) using regressing methods to estimate a level equal to a preset limit. The SACC said that the selection of a no observed effect level is not equivalent. The SACC also said that they could not find any indication of the statistical power of the analyses that used ANOVA, and no indication of effective concentration (EC) values below the EC50 could be found. The SACC said they understand that during the 1980s to mid-1990s, computing regressions was more challenging, but it was possible to make these calculations using programs from various EPA and other laboratories during that time.

Lastly, the SACC said that the ATSDR (2024) Toxicological Profile for 1,2-dichloroethane was finalized in July 2024 and "should be reviewed and the draft risk evaluation updated accordingly."

EPA Response: Although immunotoxicity was identified as a health effect concern due to 1,2-dichloroethane exposures, EPA reevaluated the oral data available for 1,1- and 1,2-dichloroethane to further develop the weight of evidence for this health effect. The oral data was plotted as a dose-response array that was included in the final risk evaluation, and it was agreed that the most appropriate endpoint for 1,2-dichloroethane oral exposures are effects to the kidneys based on refined hazard characterization and weight of scientific evidence conclusions. The POD was changed from Munson et al. (1982) (immunotoxicity) in the draft to an NTP (1991) oral gavage study for relative kidney weight effects. See Sections 5.2.6 and 5.2.7 of the final risk evaluation for details pertaining to the weight of evidence conclusions in the selection of the updated POD for the intermediate and chronic oral durations.

EPA has reviewed the ATSDR (2024) Toxicological Profile as a source for potential refinement in the selection of the PODs proposed in the risk evaluation and assist in the hazard characterization of additional studies that may inform the weight of scientific evidence. The risk evaluation incorporates studies identified in the ATSDR (2024) Toxicological Profile for 1,2-Dichlorethane for hazard characterization for both 1,1- and 1,2-dichloroethane to support the analog selection and identified POD for hazard as the most appropriate and human health protective.

A.2.2 Alternative Studies

Summary: A public commenter (0053) recommended that EPA expand charge question 5 to direct the SACC to consider Munson et al. (1982) and NTP (1991) as additional resources for sub-chronic or

chronic studies to characterize the dose response of 1,2-dichloroethane. The commenter stated these studies use a dosing regimen and duration that is more consistent with the target benchmarks than the study currently in use by EPA. In another submission to the docket (0067), the commenter suggested EPA reconsider other available studies, including those involving drinking water administration, in deriving oral exposure limits for 1,2-dichloroethane.

EPA Response: EPA did not change the charge question as a result of this comment, as EPA felt that charge question 5 was sufficiently broad for the SACC to consider the issues raised by the commenter. All identified studies underwent SR to consider their appropriateness for dose-response derivation. In the final RE, EPA uses a weight of scientific evidence and best available science approach. Any studies provided to EPA during SACC meeting or final report or submitted via public comments were considered, evaluated and integrated into the final RE as appropriate.

Summary: The SACC expressed concerns because ORD and ECRAD also had different opinions on the NTP (1991) study. The SACC stated that it was more appropriate to use the NTP (1991) study as compared to the Munson et al. (1982) study for deriving short term and chronic PODs. As such, the SACC recommended "using the NTP (1991) study for deriving PODs." The SACC also had a number of editorial comments:

- "On p. 273, lines 7660–7663, 'EPA's independent convergence on Munson et al. (1982) for the non-cancer oral, short-term POD selection is validated by the ATSDR (2022) Toxicological Profile for 1,2-Dichloroethane, which also identified immunosuppression as the most sensitive human health protective endpoint.' What does 'independent convergence' mean? The SACC recommends rewording with direct/simpler language. EPA selected findings from this study for the non-cancer oral, short-term POD. The 'validated by' language here is misleading because ATSDR did not rely on the 14-day study from Munson et al. (1982) for its [minimal risk level]. The ATSDR (2024) report does provide support for concern about the immunological endpoint; it is noted to be one of the 'most sensitive targets of [1,2-dichloroethane] oral exposure' ((ATSDR, 2024), p. 2).

Reviewers also had concerns regarding the statistical analysis of the NTP (1991) study, and these concerns and suggestions are reflected in our response to charge question 5a."

EPA Response: In reviewing the NTP (1991) study identified by ORD based in systematic review, EPA identified the rat study cohort based on dosage via drinking water as not suitable for derivation for dose-response due to uncertainties in 1,2-dichloroethane exposures due to evaporation and spillage concerns during the study duration. EPA did, however, use the NTP (1991) study based on the rat cohort administered 1,2-dichloroethane via oral gavage that was presented in the same study to develop the updated POD for the oral/dermal intermediate and chronic durations now based on increased relative kidney weight. The previously presented POD for the intermediate and chronic oral POD based on Munson et al. (1982) observed in mice, based on an immunological endpoint, is presented in the final risk evaluation in the hazard characterization for immunological effects. The weight of scientific evidence though limited for immunological effects, is still an endpoint of consideration even though no longer the basis of the intermediate or chronic POD. This is a similar conclusion to that presented by the ATSDR (2024) Toxicological Profile for 1,2-Dichloroethane that indicated immunotoxicity as the most sensitive endpoint. EPA has refined the language to be more direct regarding the considerations regarding the immunological endpoint and the subsequent refinement to the POD to the renal toxicity. Specifically, EPA has changed the immunosuppression description to remove the terms "convergence" and "validated."

A statistical analysis of the NTP (1991) study performed and the data were amenable to benchmark dose modeling and this value is proposed POD presented in the final risk evaluation for 1,1-dichloroethane for the intermediate and chronic oral durations.

A.2.3 Uncertainty

Summary: The SACC stated that the use of short-term and sub-chronic studies to assess the potential for chronic, long-term exposure to 1,1-dichloroethane can introduce significant uncertainty, including the following:

- "Potential for uncertainty may arise from extrapolating data from animal studies to humans and the absence of epidemiologic studies.
- Short-term and sub-chronic studies tend to involve higher doses than the lower doses used in chronic studies. Effects observed at high doses might not manifest or might manifest differently at lower chronic exposures. Short-term and sub-chronic studies may not capture the full spectrum of effects that may develop from prolonged, low-level exposure. Also, delayed effects may not be observed in examining acute or early toxic responses. It may be necessary to adjust for the possibility of identifying a lower POD for chronic toxicity when extrapolating from a study of shorter duration.
- Biological mechanisms leading to toxicity in chronic exposures can differ from those occurring in short-term exposures."

The SACC emphasized that because there is inevitably uncertainty associated with using short-term and sub-chronic studies for assessing chronic, long-term exposure to 1,1-dichloroethane, EPA should instead ask how best to quantify the amount of uncertainty. The SACC recommended that "EPA should work to quantify the uncertainty in extrapolations from shorter-term duration to those of longer durations."

EPA Response: EPA included uncertainty factors to account for extrapolation from animals to humans as well as within the human population as described in Section 5.2.6.1.1 that were carried through from the draft to final risk evaluations. Additionally, a UF_S of 10× was retained from the draft to final risk evaluation to account for the uncertainty of extrapolating from an intermediate to a chronic duration (Section 5.2.6.1.1). EPA reviewed studies for the chronic duration that would minimize uncertainty associated with extrapolation from an intermediate duration and these studies are described in Section 5.2.6.1.4. Due to the identified the uncertainties and limitations of the chronic studies identified and evaluated that precluded their use for the chronic POD, a rationale for their use instead of the intermediate duration studies and the applied uncertainty factor for the duration adjustment was provided.

A.2.4 Other Comments

Summary: A public commenter (0068) applied World Health Organization (WHO) International Programme on Chemical Safety (IPCS) methodology to 1,2-dichloroethane chronic oral exposures using the POD values reported by EPA to estimate risk-specific doses for several levels of incidence. The commenter found lower bound (95% confidence) chronic human inhalation doses of 0.002 mg/kg-d, 0.0012 mg/kg-d, 0.0006 mg/kg-d, 0.0003 mg/kg-d, and 0.0001 mg/kg-d at which immunosuppression is expected in 1, 0.5, 0.1, 0.01, and 0.001 percent of the population, respectively. The commenter also estimated that EPA's current approach results in acceptance of exposures producing an upper bound risk level 3,000 times higher than the typical target risk level for protection of carcinogenic risks. The commenter provided a complete analysis of the 1,1- and 1,2-dichloroethane non-cancer risk using IPCS methodology in a technical appendix. The commenter stated that an "important caveat" to the calculations is that values used to represent human variability may be understated, and if variability is underestimated, then the risk at each dose will be underestimated. The commenter requested that EPA

apply the WHO framework to these endpoints and additional noncancer endpoints to better inform its risk characterization and risk determination for both 1,1- and 1,2-dichloroethane.

EPA Response: EPA sees value in considering the methodology for use in future risk assessments for hazard characterization and informing risk management decisions. Although methods have been proposed, EPA does not have peer-reviewed approaches to apply these methods under TSCA.

A.3 Charge Question 6 – Inhalation, Non-Cancer (Acute)

The charge question asked for comments on the use of Dow Chemical (2006), the selection of the BMR, BMC analyses, and alternative studies.

A.3.1 Review of Dow Chemical (2006)

Summary: A public commenter (0062) stated that EPA should use the BMDL from Dow Chemical (2006) for the inhalation non-cancer acute POD. The commenter discussed that the selection of the BMDL or the no-observed-adverse-effect level (NOAEL) for the POD must be reviewed using scientific judgment, and that the BMD modeling for nasal lesions in Dow Chemical (2006) has strong goodness of fit metrics.

In contrast, a public commenter (0053) stated that the Dow Chemical (2006) study is not publicly available for review.

EPA Response: EPA agrees with public commenter (0062) on the use of the BMDL for the inhalation non-cancer acute POD. The findings from the Dow Chemical (2006) study were published in a peer-reviewed journal by Hotchkiss et al. (2010) and are available for review.

Summary: The SACC said that the Dow Chemical (2006) study is acceptable and in-line with TSCA expectations and requirements, and that the conduct of the study was well-documented and in-line with studies of similar nature. The SACC asked EPA to explain the use of the continuous (24 hours/day) exposure to determine an "acute" POD. The SACC said that Table 5-43 stated that the adverse effect in the 8-hour acute study is degeneration with necrosis of the olfactory neuroepithelium and that this effect is neurological in nature. Moreover, in the recent ATSDR (2024) assessment for 1,2-dichloroethane, this same study effect was determined to be respiratory in nature. Therefore, the SACC said that a rationale is needed to consider this adverse effect as neurological versus respiratory tract toxicity, as there was no evidence presented in the animal study that there were direct neurological consequences following the necrosis of the nasal epithelium. Finally, the SACC provided an editorial comment regarding a discrepancy in the worker human equivalent concentration values in Tables 6-1 and 5-49. The SACC also stated that various points of clarification are needed: "the determination that degeneration with necrosis of the olfactory neuroepithelium effect is neurological in nature since there appears to be no evidence of a direct neurological effect from the Dow Chemical (2006) study; the high uncertainty in the [BMD] model fitting, warrants obtaining more data or use of the NOAEL/[lowest-observed-adverse-effect level (LOAEL)] approach."

EPA Response: EPA converted all studies identified for dose-response to a 24-hour duration as input into BMD modeling. This method was applied to allow for a comparison of HED/HEC values across studies so that the output from the modeling can be compared between the studies of differing duration (*i.e.,* 4- vs. 6-hour, etc.). The initial duration normalization that is representative of a continuous (24-hour) duration was applied to general population scenarios and subsequently adjusted to the worker (8-hour) duration for the respective occupational scenarios.

EPA has incorporated language to better characterize the necrosis to the olfactory as respiratory in nature as definitive effects to olfactory capacity were not evaluated as part of the study (Section 5.2.3.1.2 of the Risk Evaluation).

EPA has corrected the discrepancy in the worker human equivalent concentration in the tables referenced by the SACC.

EPA has provided more information about BMD modeling and the suitability of this approach in the risk evaluation (Section 5.2.6.1) and *Risk Evaluation for 1,1-Dichloroethane – Supplemental Information File: Benchmark Dose Modeling* (U.S. EPA, 2025g).

Updated EPA Response: The 1,2-dichloroethane human health assessment TSD has been revised with these updates.

A.3.2 BMC Analysis and Response Level

Summary: A public commenter, in multiple submissions to the docket (0053, 0066, 0067), stated that the Dow Chemical (2006) dataset is not well-suited for BMD modeling per EPA's own technical guidance given the lack of data at the desired benchmark response level. The commenter (0066, 0067) recommended that EPA instead utilize a NOAEL/LOAEL approach to dose response modeling. Additionally, the commenter (0053) stated that the SACC should comment on EPA's departure from its 2012 BMD Technical Guidance. The commenter (0067) requested that EPA reevaluate its methodology for BMD modeling to confirm the appropriate identification of a benchmark. The commenter (0053) also stated that the uncertainty factor of 10 for human-to-human variability in a worker population is overly conservative and requested (0066) that EPA consider revising its use.

EPA Response: EPA has provided more information about BMD modeling and the suitability of this approach in the risk evaluation (Section 5.2.6.1) and *Risk Evaluation for 1,1-Dichloroethane – Supplemental Information File: Benchmark Dose Modeling* (U.S. EPA, 2025g). EPA used an uncertainty factor of 10 for human-to-human variability in worker population to be health protective, since there was insufficient data available to justify derivation of a different uncertainty factor.

Summary: The SACC agreed that BMD modeling should be carried out for females or males separately (4- and 8-hour studies) and for the combined males and females 4-hour acute exposure study. However, in each case the models failed to predict a BMDL because of the high uncertainty at the lower end of the dose response curve (10 percent effect level). The SACC said that the combined male and female 4-hour study, even for the best fit model (the Multistage 3) where the Akaike information criterion is the lowest, the BMDL was lower than the NOAEL. The SACC said that, based on the EPA BMD modeling guidance, where there is greater uncertainty in the model fitting, it is warranted to obtain more data or use the NOAEL/LOAEL approach. The SACC questioned why EPA converted exposures to a 24-hour equivalent before carrying out the modeling to identify the "acute" POD, because in doing so, the concentration at which an effect was observed is artificially lowered. The SACC agreed that extrapolation of the 4-hour or 8-hour to longer or shorter durations, can be done, but it depends on the study design, the feasibility of the endpoint with the exposure pattern, and the limit to be derived. The SACC said that EPA should consider deriving different PODs for occupational and general populations, as exposure profiles are different for each population of interest.

EPA Response: EPA has provided more information about BMD modeling and the suitability of this approach in the Risk Evaluation (Section 5.2.6.1) and *Risk Evaluation for 1,1-Dichloroethane – Supplemental Information File: Benchmark Dose Modeling* (U.S. EPA, 2025g). EPA converted all

studies identified for dose response to a 24-hour duration as input into BMD modeling and considered this approach appropriate for the studies used in the risk evaluation. This method was applied to allow for a comparison of HED/HEC values across studies so that the output from the modeling can be compared between the studies of differing duration (*i.e.,* 4-hour vs. 6-hour, etc.). The initial duration normalization that is representative of a continuous (24-hour) duration was applied to general population scenarios and subsequently adjusted to the worker (8-hour) duration for the respective occupational scenarios.

Updated EPA Response: The 1,2-dichloroethane human health assessment technical support document has been revised with these updates.

A.3.3 Alternative Studies

Summary: A public commenter (0053) suggested that the Hotchkiss et al. (2010) study appears to be a peer-reviewed version of the Dow Chemical (2006) study and is of high quality and was conducted under Good Laboratory Practices.

EPA Response: As indicated by the commenter, Hotchkiss et al. (2010) is a peer-reviewed publication based on Dow Chemical (2006) study. EPA evaluated the Dow Chemical (2006) study as it is the source of the data that was extracted in Hotchkiss et al. (2010). EPA has included within evidence integration both citations in the instances when common data between the two sources was evaluated and extracted.

Updated EPA Response: The 1,2-dichloroethane human health assessment technical support document has been revised with these updates.

A.4 Charge Question 7 – Inhalation, Non-Cancer (Short-Term and Chronic)

The charge question asked for comments on the use of Zhang et al. (2017), the selection of the BMR, BMC analyses, and alternative studies.

A.4.1 Review of Zhang et al. (2017)

Summary: A public commenter, in multiple submissions to the docket (0053, 0066, 0067), requested that EPA and SACC consider the consistency of findings for reproductive toxicity when evaluating the appropriateness of Zhang et al. (2017) for the identification of a POD for 1,2-dichloroethane. The commenter (0066, 0067) added that there is currently no evidence of repeatability of the study results. The commenter also discussed that while EPA states in the 1,2-dichloroethane draft human health hazard assessment and 1,1-dichloroethane draft risk assessment that fertility of human males is known to be sensitive to changes in sperm numbers and quality, Zhang et al. (2017) did not examine potential effects on fertility across generations.

EPA Response: EPA has further developed the hazard identification and Weight of Scientific Evidence narratives to better characterize why this study was selected as the POD for the intermediate and chronic durations (Sections 5.2.6.1.3 and 5.2.6.1.4).

Updated EPA Response: The 1,2-dichloroethane human health assessment technical support document has been revised with these updates.

Summary: The SACC stated that there are a number of shortcomings identified in the Zhang et al. (2017) study, however, a number of these issues, including male only evaluations and limited endpoints evaluated within the study, are addressed in the other studies found in Table 5-45. The SACC said that it

is unclear whether this study was done according to a standardized guideline or done under good laboratory practices. The SACC submitted several comments regarding "questionable" details of the study: "the study reports that all mice were housed and acclimated but details such as individually or as exposure groups was not stated; The study used whole body dynamic inhalation chambers. This type of exposure allows "grooming" and ingestion of exposure chemical. Under these conditions the inhaled dose would underestimate the total dose received; It is unclear how particles in the lung bronchi indicate more than 90 percent of the aerosol particles in the [1,2-dichloroethane] exposure chambers were less than or nearly equal to 1.1 micrometers."

The SACC submitted several comments regarding the "appropriateness" of the study:

- "It appears that the study was done to determine the mode of action [(MOA)] for changes in sperm, not to determine a NOAEL.
- This study does not meet the standard for analysis of short term/subchronic and chronic noncancer inhalation POD derivation. The following endpoint deficiencies are noted:
    - Male mice only, no females
    - Incomplete evaluation of standard endpoints for assessment of toxicity and for deriving POD for short and chronic inhalation exposures
- Standard organ evaluations are lacking (gross evaluation, organ weights and histology, including no evaluation of the respiratory tract for this inhalation study knowing that this material can cause respiratory tract irritation at shorter duration and lower concentrations). Clinical chemistry is lacking. Clinical observations are lacking. Hematological parameters are lacking.
- For derivation of health protective limits this 4-week study is used to support short-term/subchronic and chronic with addition of 3× and 10× uncertainty factors, respectively. Please provide the guidance followed by EPA for duration [uncertainty factor] for extrapolating from a 4-week study to chronic and subchronic durations. Typically, a 10× [uncertainty factor] is used for extrapolating a 90-day study to chronic exposure duration. The current approach is inconsistent with that.

The SACC questions if the 4-week exposure duration of the Zhang et al. (2017) study is adequate to demonstrate the health effect."

EPA Response: EPA acknowledges that a nose-only study would be the preferred method for inhalation; however, EPA determined that the dosing methods used in the Zhang et al. (2017) study were sufficient since 1,1-dichloroethane will rapidly volatilize, making inhalation the major pathway. The objective of the study was to monitor at the effects of 1,2-dichloroethane on the male reproductive system and to elucidate underlying mechanisms of toxicity, via the inhalation route of exposure, thus females were not included in the study. The study was not intended to be a classical inhalation study with respiratory tract evaluations nor neurotoxicity endpoints. The study provided functional sperm parameters for POD selection, such as sperm concentration (the basis of the intermediate and chronic inhalation point of departure), spermatozoa malformations, histology of the testes and epididymis, seminiferous tubule diameter and geminal epithelial height were measured as well as mechanism of action data. The study measured hormones (testosterone, luteinizing hormone, follicle stimulating hormone, etc.) in plasma as part of their clinical chemistry panel. Additionally, body weight and testis/body weight ratio was evaluated at 1 and 4 weeks. EPA has provided greater clarification of the application of the uncertainty factors to the Zhang et al. (2017) study (Section 5.2.6.1.1 and 5.2.6.1.4). EPA has confidence in the use of this study to characterize the health effects identified in Zhang et al. (2017). A dose response array for inhalation non-cancer studies for 1,2-dichloroethane that was added to Section 5.2.6.1.5 to illustrate that the effects observed in Zhang et al. (2017) are protective of other human health outcomes.

Updated EPA Response: The uncertainty factor to account for the uncertainty of extrapolating from an intermediate to a chronic duration was changed from 10× to 1× in the final human health hazard assessment technical support document and risk evaluation for 1,2-dichloroethane. This change was based on an evaluation of the health effects seen in studies for the intermediate and chronic durations. Although there are a large number of available toxicology studies across durations, life stages, and laboratory animal species via the inhalation route, the available chronic duration studies in rat and mice are limited in the endpoints measured (Nagano et al., 2006; IRFMN, 1987) and/or reporting of non-cancer effects (Cheever et al., 1990; Spencer et al., 1951). As a result, EPA has selected an intermediate-term study for use in chronic risk assessment. Despite these limitations, as described below, a holistic evaluation of the inhalation toxicology database supports a conclusion that the subchronic to chronic uncertainty factor is not needed for 1,2-dichloroethane for the inhalation route. Further details pertaining to the rationale for preclusion of identified 1,2-dichloroethane chronic inhalation studies is presented in greater detail in Section 4.2.2.6 of the *Human Health Hazard Assessment for 1,2-Dichloroethane*.

The 104-week Nagano (2006) study reported limited non-cancer effects. Among the noncancer effects reported in the study neither growth rate nor food consumption were suppressed in any 1,2-dichloroethane exposure group up to 90 or 160 ppm in mice or rats, respectively. In addition, the authors report in the text (but not tabulated) that no exposure related changes in any hematological, biochemical, or urinary parameter were found in any 1,2-dichloroethane-exposed group.

There are a series of 28-day inhalation studies in mice which provide a robust evaluation of effects on liver, nervous system, and male reproductive effects in mice with respect to apical outcomes (*e.g.,* pathology, motor activity), mechanistic understanding, and blood concentration measurements during and after exposure (Zhang et al., 2024; Zhong et al., 2022; Liang et al., 2021; Huang et al., 2020; Zeng et al., 2018; Wang et al., 2017; Zhang et al., 2017). These studies support dose-response analysis and show that sperm effects in (Zhang et al., 2017) of male mice are the most sensitive with a LOAEL of 25 ppm and robust endpoint to inform the intermediate POD. EPA notes that in the (Cheever et al., 1990) chronic study at 50 ppm, evidence of male reproductive effects (an increased incidence of unspecified testicular lesions (24 versus 10% in controls) observed at gross necropsy) thereby show some consistency between the 28-day and chronic studies. The dose-response information across durations, combined with the rapid elimination following inhalation, support a conclusion that the subchronic to chronic uncertainty factor is not needed for 1,2-dichloroethane for the inhalation route.

A.4.2 BMC Analysis and Response Level

Summary: A public commenter (0053) stated that the benchmark response of 5 percent and the uncertainty factor of 10 for human-to-human variability in the worker population are overly conservative.

In additional submissions to the docket (0066, 0067), the commenter expressed concern regarding the BMD modeling of data in Zhang et al. (2017) in the risk evaluation. The commenter stated that EPA's rationale for the choice of the BMCL5 must be explained by the Agency, adding that use of a $BMDL_{10}$ is more supported based on past EPA risk evaluations. The commenter (0066) also recommended EPA consider revising its use of the uncertainty factor of 10 and instead using one in the range of 3-5.
A public commenter (0068) applied WHO IPCS methodology to 1,2-dichloroethane chronic inhalation exposures using the POD values reported by EPA to estimate risk-specific doses for several levels of incidence. The commenter found lower bound (95% confidence) chronic human inhalation doses of 0.4 ppm, 0.3 ppm, 0.1 ppm, 0.05 ppm, and 0.02 ppm at which decreased sperm concentration is expected in 1, 0.5, 0.1, 0.01, and 0.001%of the worker population, respectively. The commenter also stated that the analysis found an upper bound risk at an inhalation exposure of 0.07 ppm of 0.025 percent. The

commenter provided a complete analysis of the 1,1- and 1,2-dichloroethane non-cancer risk using IPCS methodology in a technical appendix. The commenter stated that an "important caveat" to the calculations is that values used to represent human variability may be understated, and if variability is underestimated, then the risk at each dose will be underestimated. The commenter requested that EPA apply the WHO framework to these and additional noncancer endpoints to better inform its risk characterization and risk determination for both 1,1- and 1,2-dichloroethane.

EPA Response: EPA chose the benchmark response of 5%as it is considered to be biologically significant for humans and set an uncertainty factor of 10 for human-to-human variability in the worker population as data were not identified that would justify a lower uncertainty factor. EPA concluded that a BMR of 5%to be appropriate for the severity of effects that can result in significant reproductive effects, including decreased fertility and viability. EPA acknowledges that the modeling is not ideal because the BMD is low on the dose-response curve compared with the doses tested in the study. However, BMD modelers identified the importance of choosing a BMR *a priori*. EPA has identified publications in previous risk evaluations that support the use of this BMR based on germ cell degeneration or depletion in seminiferous tubules (Blessinger et al., 2020; Lanning et al., 2002). Even if the effects are not life-threatening to the parents, the possibility of decreased viability in offspring is of concern.

EPA sees value in considering the WHO methodology (Guidance Document On Evaluating And Expressing Uncertainty In Hazard Characterization) (WHO, 2018) for use in future risk assessments for hazard characterization and informing risk management decisions. While methods have been proposed, EPA does not have peer-reviewed approaches to apply these methods under TSCA.

Summary: The SACC said that clarification is recommended for the selection of the BMR.

EPA Response: EPA has provided the biological relevance of the benchmark response selected in the risk evaluation in the final benchmark dose response supplemental file (U.S. EPA, 2025g).

A.4.3 Alternative Studies

Summary: A public commenter, in multiple submissions to the docket (0053, 0066), stated that Rao et al. (1980) did not identify effects on fertility, gestation or survival in male or female rats exposed to 150 ppm, adding (0066) that EPA failed to appropriately weigh the negative findings in this study. The commenter (0053) said that additional studies that may provide insight into potential inhalation toxicity associated with 1,2-dichloroethane exposure include Zhong et al. (2022), Liang et al. (2021), and Nagano et al. (2006). Additionally, the commenter (0066, 0067) discussed Campbell et al. (2009) and Sweeney and Gargas (2016).

EPA Response: The developmental endpoints in the Rao et al. (1980) study were not identified but this study also identified mortality in the maternal rats which is not usually considered a sensitive endpoint. EPA has further developed its weight of scientific evidence based on incorporation of these studies into the hazard identification, where appropriate.

Summary: The SACC said that EPA should review the four acute inhalation studies and two repeat dose studies on 1,2-dichloroethane on the ECHA's chemical database website for their possible use in a weight-of-evidence approach. The SACC did not identify any additional studies for 1,1-dichloroethane. The SACC submitted additional recommendations in response to Charge Question 7.c.:

- "Provide clearer justification of using this study for determining a POD including the exposure conditions (whole body chambers), aerosol particle deposition, exposure duration in relation to duration of spermatogenesis.
- Discuss and account for potency differences.
- Clarify the application [uncertainty factors] for extrapolation of the 4-week duration to short-term and chronic durations.
- Add more thorough discussion/consideration of the uncertainty around and implications of the read-across.
- At least a brief mention of the rationale for the selection of the BMR to the Draft Human Health Hazard Assessment Technical Support Document… As stated in the Supplemental Information File: Benchmark Dose Modeling Results in Section 2.1.1.2.4.1, lines 2197-2198, 'A BMR of five percent relative difference… was also selected because EPA considers a five percent change in sperm concentration to be biologically relevant.' This statement in the Supplemental Information File needs to include a reference to the relevant EPA guidance document.

The SACC cautioned that if study and endpoint are not suitable or appropriate then the BMC analysis is not warranted or informative."

EPA Response: EPA has reviewed relevant studies on the ECHA chemical database website and incorporated them in the hazard characterization where appropriate.

In some strains of rats and mice, production of normal sperm can be reduced by up to 90%or more without compromising fertility (Working, 1988; Robaire et al., 1984; Meistrich et al., 1982; Aafjes et al., 1980). However, less severe reductions can cause reduced fertility in human males who appear to function closer to the threshold for the number of normal sperm needed to ensure full reproductive competence. This difference between test species and humans suggests that results from a test species may not fully represent toxicity in humans due to chemical exposure.

Due to limited data for 1,1-dichloroethane, assessing potency between 1,1- and 1,2-dichloroethane is difficult as similar testing models, durations and common health effects are needed to determine potency differences.

The application of an uncertainty factor for extrapolation from the 4-week duration to chronic duration was based on an evaluation of chronic studies via the inhalation which, due to study limitations and underlying uncertainties as outlined in Section 5.2.6.1.4, were not identified as suitable for use as the chronic POD. Thus, application of the uncertainty factor for subchronic-to-chronic duration extrapolation (UFs) was applied to this 4-week short-term study. Details for the application of this uncertainty factor are described in Section 5.2.6.1.1 and 5.2.6.1.4 of the risk evaluation.

Updated EPA Response:
As stated in EPA's Guidelines for Reproductive Toxicity Risk Assessment (U.S. EPA, 1996), human males are particularly susceptible to chemicals that reduce numbers or quality of sperm and "statistically significant changes in measures of sperm count, morphology, or motility as well as number of normal sperm should be considered adverse effects". The Agency selected a benchmark response of 5% to be protective, based on scientific literature. When evaluating male phthalate syndrome, Blessinger et al. (2020) used a BMR of 5% for all endpoints associated with zero to moderate impacts on fertility. These endpoints included germ cell degeneration or depletion in seminiferous tubules ranging from 5 to 75% (Blessinger et al., 2020; Lanning et al., 2002).

The uncertainty factor to account for the uncertainty of extrapolating from an intermediate to a chronic duration was changed from 10× to 1× in the final human health hazard assessment technical support document and risk evaluation for 1,2-dichlorethane. This change was based on an evaluation of the health effects seen in studies for the intermediate and chronic durations. Although, there are a large number of available toxicology studies across durations, life stages, and laboratory animal species via the inhalation route, the available chronic duration studies in rat and mice are limited in the endpoints measured (Nagano et al., 2006; IRFMN, 1987) and/or reporting of non-cancer effects (Cheever et al., 1990; Spencer et al., 1951). As a result, EPA has selected an intermediate-term study for use in chronic risk assessment. Despite these limitations, a holistic evaluation of the inhalation toxicology database supports a conclusion that the subchronic to chronic uncertainty factor is not needed for 1,2-dichloroethane for the inhalation route.

The 104-week Nagano (2006) study reported limited non-cancer effects. Among the non-cancer effects reported in the study neither growth rate nor food consumption were suppressed in any 1,2-dichloroethane exposure group up to 90 or 160 ppm in mice or rats, respectively. In addition, the authors report in the text (but not tabulated) that no exposure related changes in any hematological, biochemical, or urinary parameter were found in any 1,2-dichloroethane-exposed group.

There are a series of 28-day inhalation studies in mice which provide a robust evaluation of effects on liver, nervous system, and male reproductive effects in mice with respect to apical outcomes (*e.g.,* pathology, motor activity), mechanistic understanding, and blood concentration measurements during and after exposure (Zhang et al., 2024; Zhong et al., 2022; Liang et al., 2021; Huang et al., 2020; Zeng et al., 2018; Wang et al., 2017; Zhang et al., 2017). These studies support dose-response analysis and show that sperm effects in (Zhang et al., 2017) of male mice are the most sensitive with a LOAEL of 25 ppm and robust endpoint to inform the intermediate POD. EPA notes that in the (Cheever et al., 1990) chronic study at 50 ppm, evidence of male reproductive effects (an increased incidence of unspecified testicular lesions (24 versus 10% in controls) observed at gross necropsy) show some consistency between the 28-day and chronic studies. The dose-response information across durations, combined with the rapid elimination of 1,2-dichloroethane following inhalation, support a conclusion that the subchronic to chronic uncertainty factor is not needed for the inhalation route.

A.5 Charge Question 9 – Cancer Assessment

The charge question asked for comments on the use of 1,2-dichloroethane as an analog to support 1,1-dichloroethane, the use of NTP (1978) mouse and rat data, the use of Nagano et al. (2006), and assessment of oral cancer risk.

A.5.1 Review of NTP (1978)

Summary: A public commenter, in multiple submissions to the docket (0052, 0063), stated that EPA is quantifying cancer risk for 1,1-dichloroethane by reading across from 1,2-dichloroethane, even though 1,2-dichloroethane is more potent. However, the commenter said that an alternative approach would be for EPA not to quantify the cancer risk of 1,1-dichloroethane at all, or to use a threshold approach. The commenter said that the Integrated Risk Information System (IRIS) cancer classifications for both 1,2- and 1,1-dichloroethane were performed prior to the 2005 Guidelines for Carcinogen Risk Assessment, when the descriptors for carcinogenic potential were also updated. However, the commenter said that "possible human carcinogen" may be analogous to the 2005 Guideline descriptors of "suggestive evidence of carcinogenic potential" or "inadequate information to assess carcinogenic potential." The commenter said that in practice, they are unaware of EPA conducting any kind of quantitative assessment for "inadequate information." The commenter, along with another public commenter (0066) suggested that the SACC should consider if the data for 1,1-dichloroethane, including limitations of

read-across from 1,2-dichloroethane, are sufficient to derive cancer toxicity values via a (linear) dose-response assessment, as a threshold approach, or if the data are sufficient to derive cancer toxicity values at all. A public commenter (0066) also stated that there are significant concerns regarding the extrapolation of the dose response from 1,2-dichloroethane to 1,1-dichloroethane owing to clear differences in potency. Specifically, the commenter, in two submissions to the docket (0066, 0067) said that based on the cancer risk values, the cancer unit risk (inhalation route) value for 1,1-dichloroethane was 13-fold lower than for 1,2-dichloroethane; the cancer slope factor (oral route) for 1,1-dichloroethane was 8-fold lower than for 1,2-dichloroethane; and the cancer slope factor (inhalation route) for 1,1-dichloroethane was 13-fold lower than for 1,2-dichloroethane.

Another public commenter (0062) stated that although concerns have been raised about the age of the NCI (1978) mouse study, an OPPT/Existing Chemicals Risk Assessment Division analysis comparing the NTP study with the current 2018 OECD Combined Chronic Toxicity/Carcinogenicity Studies guidelines did not find differences in the methodology that would have impacted the outcome of the study. The commenter also said that the mice developed tumors both benign and malignant at lower doses than estimated since there was a loss of 1,2-dichloroethane due to volatilization. If anything, the commenter said that a higher incidence of tumors cannot be ruled out with full-strength concentration of 1,2-dichloroethane in the drinking water.

A public commenter (0053) said that EPA and the SACC should carefully consider the utility of the NTP studies for both 1,1-dichloroethane and 1,2-dichloroethane (NCI, 1978; NTP, 1978). For example, for the rat studies, reduced survival due to colony pneumonia may preclude the use of the data from these studies based on both EPA and OECD guidelines for survival, according to the commenter. However, another public commenter (0062) stated that that the pneumonia may be of low confounding impact. The commenter explained that the overall tumor incidence, the organs affected, and the presence of multiple tumors in the NTP (1978) rat study is similar to the results observed in the Nagano et al. (2006) rat study, which was an inhalation study. The commenter concluded that the similarities between two very different exposure routes strengthen the rationale to use the NTP (1978) rat study in a qualitative manner to support the quantitative derivation of the oral slope factor from the mouse study. Another public commenter, in multiple submissions to the docket (0066, 0067) stated that, despite the similarities between the two NTP studies in design and execution, EPA considered the 1,2-dichloroethane mouse study to be of sufficient quality for use in subsequent dose response assessment, while the 1,1-dichloroethane mouse study was excluded from consideration for evaluating hazard and dose response of 1,1-dichloroethane. Therefore, the commenter said there is a "logical inconsistency" in the interpretation of this study by EPA, with EPA using the 1,1-dichloroethane NTP study to justify analog identification but considering it insufficient for characterization of 1,1-dichloroethane carcinogenicity. The commenter (0067) said that the OCSPP and the ORD within EPA disagreed with the Agency's decision that the NTP (1978) study was appropriate for use to characterize 1,2-dichloroethane carcinogenicity. The groups found deficiencies in both NTP (1978) studies including: reduced survival in rats, including controls, due to high incidences of pneumonia; variable dosing regimen in mice resulting in potential challenges with identification of a tumorigenic dose; inconsistency with current guidelines; and quality control concerns.

EPA Response: Read across is a standard process at the EPA when the chemical database is insufficient (*i.e.,* OPPT, PPRTV, etc). There are insufficient mechanistic data to perform a threshold analysis for cancer instead of the default linear model for genotoxic chemicals such as 1,1-dichloroethane. The SACC stated that we should use all studies qualitatively for weight of scientific evidence. EPA is using the 1,1- and 1,2-dichloroethane (NCI, 1978; NTP, 1978) studies qualitatively and not deriving an oral cancer slope factor. Although, a commenter indicated that similarities in effects via inhalation and oral

exposure to 1,2-dichloroethane could justify a quantitative derivation of the oral slope factor from the Nagano et al. (2006) study, EPA is not pursuing this derivation due for 1,1-dichloroethane due to a lack of an inhalation study that even qualitatively would suggest similar effects by both exposure routes.

Summary: The SACC said that they agree with the Health Effects Division (HED) and ORD statements that the NCI (1978) study is "inadequate to draw any conclusions regarding carcinogenicity and should not be considered in the weight of evidence evaluation of carcinogenicity for [1,1-dichloroethane] due to several study limitations," including decreases in survival of the animals. The SACC stated that they agree with both HED and ORD comments that the National Cancer Institute (NCI) (1978) study is "inadequate to use quantitatively or qualitatively to evaluate the carcinogenicity of [1,1-dichloroethane] due to several study limitations, despite the lack of survival issues observed in rats." The SACC stated that since the NCI (1978) study has been reviewed by multiple groups of scientists over time with multiple recommendations that the limitations and uncertainties are too great to draw conclusions regarding the potential carcinogenicity of 1,1-dichloroethane, either qualitatively or quantitatively, the NTP study should not be relied upon to assess the potential carcinogenicity of 1,1-dichloroethane. The SACC recommended that this study can be used, with some caution, in hazard identification, but should not be used at all for dose-response assessment (citing EPA's guidance on systematic review; *i.e.,* uninformative studies may still be used in hazard identification).

EPA Response: EPA has incorporated the NCI (1978) study for 1,1-dichloroethane as part of the hazard identification but not used the study for dose-response assessment.

Summary: The SACC agreed that the high pneumonia rates in the NTP (1978) 1,2-dichloroethane rat study reduced the ability to infer much from the rat portion of the study because sample sizes were very small. The SACC said that it was impossible to infer what the carcinogenic response would have been if fewer rats had died from pneumonia; however, the surviving animals did continue to suggest a dose-dependent increase in mammary tumors, consistent with other studies. The SACC stated that the NTP (1978) rat study should not have been used for quantitative dose response, however, per EPA's own guidance, it is appropriate to include a discussion of the studies to "qualitatively inform the hazard identification determination and/or weight of the scientific evidence." The SACC said that the current narrative in the draft hazard assessment for 1,2-dichloroethane is too definitive with respect to the evidence that can be gleaned from the NTP (1978) study and should be revised to state that there is some evidence based on the outcomes, but no definitive conclusions can be made due to the confounding by pneumonia and high mortality rates. The SACC said that the results from the NCI (1978) rat study are not suitable for use in dose-response assessment and use in hazard identification is limited, adding that while the results should be discussed, they should be given very little weight in the overall carcinogenic weight of evidence analysis. The SACC said that based on the rating system outlined in EPA's data quality evaluation framework, Metric 22 in the mouse assay should have been given a rating of 3, at a minimum, and per the instructions in the guidance, only the doses unaffected by high mortality from infection could have been used. The SACC said that this scoring would have left only the controls and thus effectively, using this logic, neither study should be used by EPA in the risk evaluation for dose-response assessment.

EPA Response: EPA did not use the 1,1- or 1,2-dichloroethane (NCI, 1978; NTP, 1978) rat studies quantitively in the risk evaluation; however, they were used qualitatively within the hazard identification and overall weight of scientific evidence conclusions. Additionally, SACC using the prior version of guidance for systematic review evaluation (U.S. EPA, 2018) and has since been updated (U.S. EPA, 2021), suggests that the study would have been received a Metric 22 rating of low due to deficiencies or concerns that are likely to have a substantial impact on results. Due to the confounding in the high dose

group of mice due to mortality, this cohort of animals were reevaluated and not used for the cancer slope derivation but was still presented in hazard identification and overall weight of scientific evidence. As a result of the comments received EPA did not include the oral cancer slope factor in the draft RE (calculated from the mouse study based on the NCI (1978) study) in the final RE. As a result, oral/dermal cancer for 1,1-dichloroethane could not be assessed in the final RE.

Updated EPA Response: In agreement with comments from the SACC, EPA revised the application of the information from the 1,1- or 1,2-dichloroethane (NCI, 1978; NTP, 1978) rat and mouse studies and did not use this information quantitively in the risk evaluation; however, conclusions from these studies were used qualitatively within the hazard identification and overall weight of scientific evidence narrative. Specific comments from SACC regarding the systematic review study quality metric were also considered that the study would have received a Metric 22 rating of low due to deficiencies or concerns that are likely to have a substantial impact on results. Due to the confounding across the rat and mouse data in these studies, this cohort of animals were reevaluated and not used for direct cancer slope derivation and a route-to-route extrapolation approach was employed to derive the oral and dermal cancer slope factors from the IUR.

A.5.2 Slope Factor

Summary: A public commenter (0068) stated that in the 1,1-dichloroethane Draft Risk Evaluation and the 1,2-dichloroethane Draft Hazard Assessment, EPA used a slope factor of 6.2×10^{-2}, obtained from the EPA 1987 IRIS assessment of 1,2-dichloroethane using the NTP (1978) mouse study of 1,2-dichloroethane. However, the final slope factor from the EPA 1987 IRIS assessment was 9.1×10^{-2} based on the NCI (1978) rat study, indicating a cancer risk 50%greater than the mouse slope factor. The commenter recommended that EPA use the final slope factor for characterizing risks of 1,1-dichloroethane and 1,2-dichloroethane.

EPA Response: EPA did not use the 9.1×10^{-2} cancer slope factor value as it was based on the rat study from NCI (1978) for 1,2-dichloroethane. This study was confounded by high incidences of pneumonia which systematic review identified the study as not suitable for dose-response and derivation of a cancer slope factor Furthermore, as per SACC recommendation, a cancer slope factor based on the mouse data from the same study was not derived, due to concerns raised to concurrent pneumonia and mortality in the mice administered 1,2-dichloroethane in the high dose group tested. EPA, therefore, is not presenting a quantitative cancer slope factor from this study that could not be utilized to calculate cancer risks.

Updated EPA Response: In accordance with guidance from the SACC, EPA did not use the rat or mouse data quantitatively from the NTP, 1978 study. Increased incidence of pneumonia and mortality within the study animals precluded the use of this study in a manner not consistent with the 1987 EPA IRIS assessment, and data from these animals was only used to bolster the narrative qualitatively. This assessment used the Nagano et al. 2006 inhalation bioassay that was not available when the IRIS assessment was developed. This study was not confounded by pneumonia or increased incidences of mortality. For this reason and a lack of any other available oral exposure cancer data, EPA utilized route-to-route extrapolation from the IUR to develop the CSF. Please see Section 6.2.1 of this document for the specific changes made to the 1,2-dichloroethane cancer assessment following public comment of the draft 1,2-dichloroethane risk evaluation.

Summary: The SACC said that neither study (NCI, 1978; NTP, 1978) (in either species) is an ideal candidate for dose-response assessment and ultimately, the development of oral cancer slope factors. Considering the issues with both studies, it is unclear why the 1,2-dichloroethane mouse study (NTP, 1978) was selected over the 1,1-dichloroethane mouse study (NCI, 1978), given the issues with

pneumonia and mortality were similar and considering that 1,2-dichloroethane is more potent than 1,1-dichloroethane based on metabolism. The SACC said that the NCI (1978) 1,1-dichloroethane studies in both species, while not without limitations, found little evidence of carcinogenicity at low doses. SACC members recommended that it is possible that if carcinogenic, 1,1-dichloroethane is a threshold carcinogen and thus could be assessed with a Reference Dose (RfD) approach that protects against cancer effects based on evaluating doses among non-cancer and cancer studies. The SACC said that the evidence for the carcinogenicity of 1,2-dichloroethane is stronger, but there remain some questions regarding the dose-response curve, and there is some evidence of a threshold response. Given differences in the metabolism of 1,1-dichloroethane and 1,2-dichloroethane and the weaknesses with the NTP studies for both 1,1- and 1,2-dichloroethane, EPA should not use the NTP (1978) 1,2-dichloroethane carcinogenicity to read-across to 1,1-dichloroethane. The SACC said that EPA should consider evaluating an RfD approach for 1,1-dichloroethane or foregoing cancer risk evaluation all together. However, one SACC member noted that the traditional RfD approach does not provide estimates of risk.

EPA Response: EPA did not identify sufficient data to use the RfD approach nor sufficient data to calculate an accurate potency factor. EPA evaluated both 1,1- and 1,2-dichloroethane (NCI, 1978) mouse studies which did not indicate the presence of tumors in the 1,1-dichloroethane mouse study but endometrial polyps, considered pre-cancerous lesions and not suitable for derivation of a slope factor. EPA is using the NCI (1978) and NTP (1978) studies for 1,1- and 1,2-dichloroethane qualitatively and using the Nagano et al. (2006) study for 1,2-dichloroethane quantitatively for inhalation unit risk derivation.

Updated EPA Response: In agreement with comments from the SACC, EPA concluded that the study from (NCI, 1978; NTP, 1978) (in either species) is not an ideal candidate for dose-response assessment and ultimately, the development of oral cancer slope factors. As additional studies directly examining the carcinogenic potential of 1,2-dichloroethane via oral exposure were not identified as sufficient for direct cancer slope factor derivation, a route-to-route approach was employed to derive a cancer slope factor from the IUR. Additionally, a mode of action analysis was undertaken to evaluate the potential for mode of action information to inform the low dose response range or potential for a threshold-based carcinogenic response. To briefly summarize, evidence of genotoxicity, DNA damage and potential mutagenicity were characterized resulting from a variety of reactive metabolites of 1,2-dichloroethane. Importantly, EPA was not able to develop or characterize a complete mode of action for 1,2-dichloroethane-mediated carcinogenesis and used a default approach of low dose linear extrapolation, precluding the use of a "protective" RfD-based approach, a potential alternative approach suggested by the SACC. In total, and in response to SACC comments, the NCI (1978) and NTP (1978) studies for 1,1- and 1,2-dichloroethane were utilized qualitatively to support weight of evidence conclusions, while the Nagano et al. (2006) study for 1,2-dichloroethane was employed quantitatively for inhalation unit risk derivation and subsequent route-to-route extrapolation for development of a cancer slope factor for 1,2-dichloroehtane.

A.5.3 Review of Nagano et al. (2006) and Mode of Action (MOA)

Summary: A public commenter, in multiple submissions to the docket (0066, 0067), expressed several concerns regarding the dose response methods employed by EPA in determining potential potency for 1,2-dichloroethane from Nagano et al. (2006), including: the selection of endpoint for modeling (*e.g.,* combined mammary and subcutaneous tumors); the applicability of the BMD modeling to the selected endpoint; and the use of linear low-dose extrapolation in light of existing *in vivo* evidence on the potential genotoxicity of 1,2-dichloroethane and recent studies investigating potential MOAs for 1,2-dichloroethane. First, the commenter said that EPA determined that the highest inhalation unit risk

estimate for 1,2-dichloroethane was based on the findings in Nagano et al. (2006) of increased incidences of subcutaneous fibromas and mammary gland adenomas, fibroadenomas, and adenocarcinomas in female rats exposed to 1,2-dichloroethane. However, the commenter said that control animals demonstrated mammary gland tumors at incidence rates that either exceeded or did not statistically differ from those reported for 1,2-dichloroethane-exposed animals. This was true for all doses except the highest 1,2-dichloroethane dose tested, according to the commenter. In addition to concerns about the appropriateness of the endpoint upon which EPA based their inhalation unit risk estimate for 1,2-dichloroethane, the commenter said that this endpoint may not be suitable for the BMD modeling EPA used to predict potency. The commenter recommended that EPA provide an expanded rationale for modeling the combination of the mammary gland tumors with the subcutaneous tumors. The commenter said that a review of the Nagano et al. (2006) data and BMD modeling results indicate that modeling the combined mammary gland tumors without the addition of the subcutaneous tumors is a more appropriate approach. Finally, the commenter said that EPA used a linear extrapolation approach to the tumor data from Nagano et al. (2006), which is uncertain, since there is evidence indicating 1,2-dichloroethane may act through a non-mutagenic MOA for carcinogenesis. The commenter suggested using a non-mutagenic threshold instead. Similarly, in evaluating carcinogenicity, a public commenter (0053) recommended that EPA and the SACC consider both 1) other potential MOAs for 1,2-dichloroethane and 2) whether genotoxicity data for 1,1-dichloroethane warrants a linear low dose extrapolation assumption. Similarly, two public commenters (0059, 0078) also suggested that the SACC carefully assess the MOA and its implications for the development of screening values.

EPA Response: EPA used the Multistage/Multi-tumor model as all the tumors were considered adverse and independent of each other. The purpose of Multistage/Multi-tumor Combo model in BMDS is to allow the user to calculate BMDs and BMDLs for a combination of tumors (corresponding to a defined risk of getting one or more of those tumors) when the individual tumor dose-responses have been modeled using a Multistage-Cancer model. Thus, the output of the run will present the results of fitting each individual tumor (including the BMD and BMDL for that tumor) plus the combined log - likelihood, BMD, and BMDL for the combination of specified tumor responses. BMD modeling of the combined tumor incidences in female rats was performed as the incidences of the mammary tumors and subcutaneous fibromas showed a significant positive trend with increased concentration and were significantly different from the control group at 160 ppm (combined mammary tumors were also different from historical controls incidences at 40 ppm). The incidences of mammary tumors in the control group were at incidence rates (16%) that did not exceed the maximum tumor incidences when compared to historical controls (20%) and thus retained in the modeling for comparison to the incidence rates of 16, 22, and 50%in female rats treated with 10, 40, and 160 ppm of 1,2-dichloroethane, respectively. Nagano et al. (2006) also concluded that the highest tested dose did not exceed the maximum tolerated dose thus the top dose is relevant for the analysis. EPA used the linear low dose of the curve to calculate the slope factor. EPA did not identify sufficient data to determine if 1,2-dichloroethane acts through a mutagenic MOA for carcinogenicity.

Updated EPA Response: Please see Section 6.2.1 of this document for any changes made to the 1,2-dichloroethane cancer assessment following public comment of the draft 1,2-dichloroethane risk evaluation.

Summary: The SACC agreed with both HED and ORD that the Nagano et al. (2006) study "is of high quality and that data are sufficient for use in the weight of evidence for evaluating 1,2-dichloroethane carcinogenicity, despite the lack of individual animal data." The SACC said that while the Nagano et al. (2006) study should be of adequate quality to conduct a quantitative assessment to develop an Inhalation Unit Risk (IUR) for 1,2-dichloroethane, there are remaining questions about the dose response

relationships of other tumor types based on visual observations of the tumor counts at each dose and the concerns with Peto's test for both species but particularly for rats given mortality was low. The SACC suggested that EPA should attempt to obtain the raw individual animal data and re-run trend tests via the Poly-3 method or other trend test to confirm dose-response relationships. The SACC stated that two other studies showed no evidence of cancer at the exposures assessed – the inhalation study by Maltoni et al. (1980) was ranked as uninformative in the risk evaluation, but Cheever was ranked as high quality. The SACC said that there is no discussion of Maltoni et al. (1980) outside of the tables in the risk evaluation generally, and it appears the hazard identification weight of evidence evaluation for carcinogenicity is incomplete.

EPA Response: As the SACC suggested, EPA attempted to obtain the raw individual animal data for the Nagano et al. (2006) study from the authors but was unsuccessful and was therefore unable to rerun an analysis to confirm the dose-response relationships. Additionally, EPA has incorporated narrative regarding the Maltoni et al. (1980) and Cheever et al. (1990) studies as part of the weight of scientific evidence regarding cancer via the inhalation route.

Updated EPA Response: In agreement with SACC comments, EPA attempted to obtain the original individual animal data from the Nagano et al. (2006) study from study authors but was unsuccessful. EPA was therefore unable to rerun trend tests (poly-3 or otherwise) to confirm the described trend in the dose-response relationship. EPA agreed with comments from the SACC that the Nagano et al. (2006) study was of high quality and sufficient for deriving an IUR for 1,2-dichloroethane. Furthermore, language regarding the inhalation study by Maltoni et al. (1980) was added to the discussion in addition to language describing the study quality rating as uninformative. The study by Cheever was ranked as high quality and was described in further detail within the narrative. However, this study only investigated a single dose, limiting its use in IUR derivation. In total, discussion of the two additional studies mentioned by the SACC was bolstered, and an IUR was developed from the Nagano et al. (2006) study. Given the lack of identified oral exposure cancer data, a CSF was derived from route-to-route extrapolation from the IUR. Please see Section 6.2.1 of this document for any changes made to the 1,2-dichloroethane cancer assessment following public comment of the draft 1,2-dichloroethane risk evaluation.

Summary: The SACC said that the Nagano et al. (2006) should be of adequate quality to conduct a quantitative assessment to develop an IUR for 1,2-dichloroethane. However, using read-across to extend this to 1,1-dichloroethane is dependent upon addressing the recommendations of the SACC for Charge Question 3 regarding the current read-across approach.

EPA Response: EPA did not identify a cancer study via the inhalation route for 1,1-dichloroethane that was sufficient for dose-response and calculating inhalation unit risk. As per the recommendation by the SACC in using qualitative data in hazard identification. EPA identified similar tumor types in 1,1- and 1,2-dichloroethane based on evaluation of the NCI (1978) and NTP (1978) oral studies for both chemicals, as well as those identified in the Nagano et al. (2006) inhalation study. Thus, these data support the read-across approach and Nagano et al. (2006) is considered protective for 1,1-dichloroethane via the inhalation route.

A.5.4 Age-Dependent Adjustment Factors (ADAFs)

Summary: A public commenter (0068) stated that apply should apply ADAFs when calculating cancer risks to the general population, as required under EPA guidelines, for chemicals that are mutagenic. The commenter said that failure to apply ADAFs will result in underestimation of risks and would be inconsistent with the best available science.

EPA Response: EPA did not identify data to indicate that mutagenic mode of action for 1,1- or 1,2-dichloroethane and thus a derivation of an ADAF for 1,1- or 1,2-dichloroethane was not applied for the risk estimates for the general population.

Updated EPA Response: While EPA evaluated all available information relevant to potential mode(s) of action and characterized evidence of genotoxicity and DNA damage following exposure to 1,2-dichloroethane, evidence of mutagenic activity was suggestive but mixed and a mode of action could not be characterized. Therefore, EPA is using the default approach (default-linear) to inform low dose extrapolation, consistent with EPA guidelines (U.S. EPA, 2005a). Consistent with EPA guidance, in cases where a mode of action cannot be determined and the default linear low dose extrapolation is used, and ADAF is not applied (U.S. EPA, 2005b). Please see Section 6.2.1 of this document for any changes made to the 1,2-dichloroethane cancer assessment following public comment of the draft 1,2-dichloroethane risk evaluation.

A.6 Charge Question 11 – Extended One-generation Reproductive-development Toxicity

The charge question asked for comments on the data quality evaluation of WIL Research (2015).

Summary: Two public commenters (0059, 0067) said that the findings of the extended one-generation reproductive toxicity study call into question the hazards upon which the Agency based PODs for their sub-chronic and chronic toxicity benchmarks for oral and inhalation routes of exposure. A public commenter, in multiple submissions to the docket (0053, 0066, 0067), stated that the extended one-generation reproductive toxicity study for 1,2-dichloroethane exposure in drinking water by WIL Research (2015) does not indicate impairment of reproduction associated with 1,2-dichloroethane exposure. The commenter (0053) stated that EPA's dismissal of this study was inappropriate and requested that the SACC consider the implications of excluding drinking water studies to support prediction of effects of inhalation exposure.

EPA Response: All studies identified by EPA were subjected to the systematic review process and any inadequacies identified that preclude the use of the study for dose response have been acknowledged in the Draft Risk Evaluation and the final Risk Evaluation within the hazard identification. EPA evaluated the use of the WIL Research (2015) study and concluded it was not suitable for quantitative dose response analyses This drinking water study had multiple concerns for dosing accuracy, fundamental to toxicology. There were high rates of chemical evaporation and water spillage was not quantified, making the doses highly uncertain with low confidence in the results. EPA did consider the results of the WIL Research (2015) study qualitatively in the hazard identification and weight of evidence evaluations as recommended by the SACC.

Updated EPA Response: All studies identified by EPA or submitted to the Agency were subjected to the systematic review process and any inadequacies identified that preclude the use of the study for dose-response have been acknowledged in the Draft Risk Evaluation and final Risk Evaluation for 1,2-dichloroethane within the hazard identification. EPA reevaluated the WIL Research (2015) study and updated the systematic review overall quality determination to Low but retained the conclusion that the study was not suitable for quantitative dose response analyses. The rationale for not selecting this study for dose-response is further described in Section 4.2.2.2 of the Human Health Hazard TSD due to concerns pertaining to palatability, dosimetry, and dehydration; however, the results of this study were incorporated into hazard identification qualitatively and integrated into the weight of scientific evidence

for reproductive effects due to oral 1,2-dichloroethane exposure, per SACC and public comment recommendations.

Summary: The SACC agreed that there is concern that the body weight loss from palatability may have affected the study results. One SACC member "noted that the loss of body weight has implications for many other endocrine and reproductive functions. As mentioned in the study report, there were detectable changes in some of the reproductive hormones in treated groups, and there is some uncertainty regarding the cause of these changes. The study report largely concluded that the palatability issues did not affect results," but there was some concern from at least one SACC member that "observed effects were improperly discounted, and thus remaining uncertainty regarding the usefulness of the study for hazard characterization."

Additionally, The SACC said that they were concerned that this study was one of just a few studies evaluating this endpoint. The SACC said that "in contrast to those that were not excluded, it reported no significant treatment-related effects at the ingested doses. Moreover, the goal of this study and the consent order was to gather data for EPA that could be used with pharmacokinetic data to conduct route-to-route extrapolation from the oral to the inhalation route of exposure." The SACC expressed concern that a test requested by and designed for EPA's program was excluded from the risk evaluation, even for hazard identification.

The SACC provided several recommendations:

- "Review Uncited Paper about the WIL Research (2015) study: EPA should review and include the results of the analysis by Sweeney and Gargas (2016), which was not cited in the draft risk evaluation.
- Reassess the uninformative rating: EPA should re-evaluate the WIL Research (2015) study, in light of the SACC's comments and after considering the Sweeney and Gargas (2016) analysis. EPA should consider whether the overall study rating should be changed given the preceding comments on the uninformative rating generally and also explicitly in light of the other strengths of the study.

Provide summary: Even if EPA chooses to keep the uninformative rating for the WIL Research (2015) study, EPA should provide a summary of the findings of this study because it is an important study for evaluating potential reproductive and developmental hazards."

EPA Response: EPA has further evaluated and incorporated the WIL Research (2015) study into the hazard identification and weight of scientific evidence narrative. Additionally, EPA also further outlined the uncertainties and limitation of this study that precluded its use for dose-response. Furthermore, EPA incorporated the considerations regarding the Sweeney and Gargas (2016) analysis for route-to-route extrapolation from the oral to inhalation routes *in lieu* of using inhalation studies that were since identified via systematic review.

Updated EPA Response: EPA has further evaluated and incorporated the WIL Research (2015) study into the hazard identification and weight of scientific evidence narrative. Additionally, EPA also further outlined the uncertainties and limitation of this study that precluded its use for dose-response. Furthermore, EPA incorporated the considerations regarding the Sweeney and Gargas (2016) analysis for route-to-route extrapolation from the oral to inhalation routes *in lieu* of using inhalation studies that were since identified via systematic review. The model was intended to derive equivalent inhalation values based on rat-specific oral studies due to a lack of available route-specific inhalation data at the time the model was developed. EPA has since identified route-specific inhalation studies from rats and

mice for dose-response consideration rather than being restricted in using the model for extrapolating from rat-specific oral studies.

A.7 Charge Question 12 – Systematic Review/Best Available Science

The charge question asked for comments on uninformative ratings and use of these studies in the assessment.

Summary: A public commenter, in multiple submissions to the docket (0059, 0078), stated that the studies deemed "uninformative" by EPA, including Munson et al. (1982) and NTP (1991), may provide important weight of evidence considerations regarding hazard potential for 1,2-dichloroethane, as well as important dose response information that could critically alter conclusions reached by EPA in their hazard assessment for 1,2-dichloroethane. A public commenter (0053) requested that the SACC consider the study quality and applicability of Munson et al. (1982) and consistency of results across treatment regimens, including: the consistency of findings of immunotoxicity across dosing regimens; the relevance of the NOAEL of the drinking water study; and the relevance of the immunotoxic effect observed in the 14-day gavage study.

Two public commenters (0053, 0059) said that ATSDR relied on NTP's drinking water study for derivation of their intermediate minimum risk level. Therefore, one of the commenters (0059) said that the Agency's decision to exclude these studies may not be appropriate and/or justifiable. Another public commenter (0069) discussed the NTP (1991) drinking water study and said that the inclusion of the study would not impact the derivation of oral noncancer short-term and long-term chronic PODs, since the immunosuppressive effects identified in Munson et al. (1982) reflect the more sensitive endpoint. However, the commenter said that the NTP drinking water studies are important for the weight of evidence determination of renal effects from 1,1- and 1,2-dichloroethane exposure. The commenter went on to state that EPA should change its rating of Metric 21 to "Low" based on the reduction in water intake due to palatability issues and the study assessment of which effects were potentially affected by dehydration. A public commenter (0053) requested that the SACC consider the study quality and applicability of NTP (1991) and consistency of results across treatment regimens.
Another public commenter (0068) suggested that EPA should revise its "uninformative" rating for the NCI (1978) rat study.

The SACC stated that it may be appropriate to exclude all uninformative studies from use for quantitative risk assessment, but that these studies should not be wholly excluded from the hazard identification process. Rather, the SACC recommended that "EPA include all studies in the qualitative weight of evidence evaluation for hazard identification." The SACC stated that this is consistent with the 2021 Draft Protocol for Systematic Review in TSCA Risk Evaluations. The SACC said that the draft risk evaluation does not sufficiently describe or justify in cases where the uninformative studies were excluded from hazard identification, that the study deficiencies were serious enough that they were not informative at all to the overall weight of evidence for that endpoint. The SACC also recommended that "at a minimum, EPA provide short summaries of the results of all studies identified for a given endpoint, including the identified methodological flaws, and, where justified, clearly state why the deficiencies in the study limited the study's use in the overall weight of the scientific evidence."

The SACC also expressed concerns regarding the process in which EPA TSCA data quality evaluation yields "uninformative" ratings. The SACC said that rating studies as uninformative based on a single criterion is problematic. Several members of the SACC also expressed concerns that the single-criterion approach may allow unjustified exclusion of studies that were otherwise high quality and demonstrated a lack of toxicity following chemical exposure. The SACC stated that this is readily apparent, for

example, with the WIL Research (2015) one-generation reproductive study, in which nearly all of the 22 data quality metrics were rated as "high" with the exception of one rated critically deficient based solely on reduced water consumption and associated body weight loss.

The SACC provided EPA with several recommendations:

- "Include All Studies in Hazard Identification: Incorporate uninformative studies into the qualitative weight of evidence evaluations to ensure comprehensive hazard identification."
- "Reassess Uninformative Ratings: Revisit the methodology for designating studies as uninformative, potentially eliminating the single-criterion approach in favor of a more holistic evaluation considering cumulative quality."

"Adopt Tiered Evaluation: Consider adopting a tiered study rating system to provide balanced assessments of study quality that also facilitate assigning more weight to the overall rating for the most influential study domains."

EPA Response: Studies identified as uninformative/not suitable for dose response were still evaluated by EPA with regards to qualitative hazard identification as suggested by the SACC, if the study was able to be incorporated in the weight of scientific evidence based on suggestive causality between exposure and health effects identified in the study. If too many uncertainties regarding the methodology of the study were identified or limitations in the data reporting, these studies were described to clarify the rationale for exclusion from evidence integration for the corresponding health effects. Accurate dosing is a fundamental parameter for dose response analysis in toxicology, if there were great concerns in dosing, then a study can obtain an uninformative for dose response systematic review score for quantitative dose response, due to the lack of confidence in this critical parameter.

A.8 Other Comments

Summary: A public commenter (0061) stated that NEI utility members that operate commercial nuclear power reactors use 1,2-dichloroethane as part of a biocide analysis performed for their cooling ponds. The commenter requested that EPA consider including a provision in any risk management rulemaking that will allow continued use of the chemical by commercial nuclear power reactors until an alternative can be identified.

EPA Response: EPA followed up with the commenter (0061) about the use of 1,2-dichloroethane as part of a biocide analysis and confirmed this use, as a laboratory reagent for a biocide analysis, falls under the laboratory condition of use for 1,2-dichloroethane. It is not an active biocide and this use is not covered by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). TSCA section 6(b)(4)(A) and (F) requires that a Risk Evaluation not consider "costs or other nonrisk factors" such as availability of alternatives. During the risk management stage, EPA will consider a variety of relevant factors in choosing one or more of the available TSCA section 6(a) regulatory tools, including the availability of technically and economically feasible alternatives. *See* TSCA section 6(c)(2)(C).