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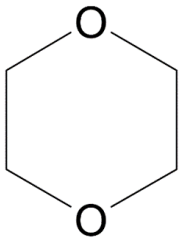
Office of Chemical Safety and
Pollution Prevention

Response to Public Comments: Toxic Substances Control Act (TSCA) Risk Determination for 1,4-Dioxane

CASRN 123-91-1



Docket: EPA–HQ–OPPT–2016–0723

November 2024

Table of Contents

Acronyms and Abbreviations

CFR	Code of Federal Regulations
COU	Condition of use
DTD	Down-the-drain
ECEL	Existing chemical exposure limit
EPA	U.S. Environmental Protection Agency
HBCD	Cyclic aliphatic bromide cluster
LOD	Limit of detection
MOA	Mode of action
NASEM	National Academies of Science, Engineering, and Medicine
NIOSH	U.S. National Institute for Occupational Safety & Health
NYS	New York State
NYS DEC	New York State Department of Environmental Conservation
OEL	Occupational exposure limit
OMB	Office of Management and Budget
ONU	Occupational non-user
OPP	Office of Pesticide Programs
OPPT	Office of Pollution Prevention and Toxics
OSHA	U.S. Occupational Safety & Health Administration
PCE	Perchloroethylene
PEL	Permissible exposure limit
PESS	Potentially exposed or susceptible subpopulations
PET	Polyethylene Terephtalate
PPE	Personal protective equipment
PV 29	Colour index pigment violet 29
SACC	Science Advisory Committee on Chemicals
SDWA	Safe Drinking Water Act
TSCA	Toxic Substances Control Act
U.S.	United States

Introduction

On July 26, 2023, the U.S. Environmental Protection Agency (EPA) published a notice of availability and request for comment for a draft revision to the Toxic Substances Control Act (TSCA) Risk Determination for 1,4-dioxane. In the notice, EPA announced that public comments would be accepted until September 8, 2023.

EPA received a total of 16 posted public comment submissions received in response to the request for comments and determined that 15 are unique and responsive to the request for comments, and 1 is a duplicate. Table 1, Index of Comment Submissions Sorted by Submission Number, identifies the commenter name and the comment number for the 15 unique submissions included in this summary.

The comment summaries and responses that follow are organized into issue topic areas, as indicated in the table of contents.

Table 1: Index of Comment Submissions Sorted by Submission Number

Submission Number	Commenter Name
EPA-HQ-OPPT-2016-0723-0105	American Cleaning Institute
EPA-HQ-OPPT-2016-0723-0106	Energy Workforce & Technology Council
EPA-HQ-OPPT-2016-0723-0107	ISSA
EPA-HQ-OPPT-2016-0723-0108	American Water Works Association (AWWA), et al.
EPA-HQ-OPPT-2016-0723-0109	American Cleaning Institute
EPA-HQ-OPPT-2016-0723-0110	Energy Workforce & Cleaning Institute
EPA-HQ-OPPT-2016-0723-0111	New York State Office of the Attorney General
EPA-HQ-OPPT-2016-0723-0112	Household and Commercial Products Association
EPA-HQ-OPPT-2016-0723-0113	Dow Chemical
EPA-HQ-OPPT-2016-0723-0114	CropLife America (CLA) and Responsible Industry for a Sound Environment (RISE)
EPA-HQ-OPPT-2016-0723-0115	American Chemistry Council
EPA-HQ-OPPT-2016-0723-0116	Environmental Protection Network (EPN)
EPA-HQ-OPPT-2016-0723-0117	Plastics Industry Association (PLASTICS)
EPA-HQ-OPPT-2016-0723-0118	American Coatings Association
EPA-HQ-OPPT-2016-0723-0119	American Cleaning Institute

Section 1 – Requests for an extension of the comment period

Several commenters requested an extension of the comment period. An industry trade organization (0105) requested a 60-day extension, reasoning that the extension is needed because the 2023 Draft Supplement to the Risk Evaluation includes non-peer reviewed methodologies that are the basis for new risk determinations as well as amendments to EPA's 2020 risk determination. Another industry trade organization (0106) agreed, adding that additional time would allow them to facilitate internal collaboration, seek feedback from member company subject matter experts, and undertake an analysis of the proposed exposure scenario. Another industry trade organization (0112) agreed that additional time is needed to review methodologies that have not previously been used or evaluated and stated that additional technical materials were added to the supplemental risk assessment docket as late as August 10, 2023. Another industry trade organization (0117) stated that the only-recent availability of some background documents, a lack of detail as to how the 2023 Draft Supplement was prepared, and EPA

regulations at 40 CFR 702.51 warrant additional public engagement for the 2023 Draft Supplement and the revised risk determination. The industry trade organization (0117) stated that it found significant issues with data relied upon in reaching exposure and risk conclusions and that the combined 60-day comment period for the 2023 Draft Supplement and 45-day period for the revised risk determination should be extended.

EPA RESPONSE: *While EPA's supplemental risk evaluation includes some new methodologies and analyses, EPA disagrees that a 60-day comment period is necessary for the revised risk determination because the policy updates regarding PPE assumptions and the single risk determination approach have already been finalized as part of the rulemaking on the framework for TSCA risk evaluations[1]. With respect to those aspects of the risk determination that touch on the new methodologies and analyses in the supplemental risk evaluation, EPA believes that a 45-day comment period is adequate.*

Section 2 – Legal issues

Section 2.1 – Statutory authority / Strength of the information supporting the risk evaluation

An industry trade organization (0115) stated that EPA's proposed approach does not comply with TSCA's section 26 and section 6 requirements that risk evaluations be consistent with best available science and based on the weight of the scientific evidence. The commenter added that the legislative record for the TSCA amendments also does not support EPA's new policy direction.

Additionally, the industry trade organization (0115) commented that the EPA 2021 Draft Systematic Review protocol significantly updated the TSCA systematic review process and developed a systematic review protocol to address the National Academies of Science, Engineering, and Medicine (NASEM) recommendations to EPA on its systematic review process for risk evaluations. The industry trade organization urged that the revised unreasonable risk determination should be updated to reflect the EPA 2021 Draft Systematic Review protocol in order to meet the requirements under TSCA section 26.

EPA RESPONSE: *The final revised unreasonable risk determination for 1,4-dioxane is based on the peer reviewed risk characterization in the December 2020 1,4-Dioxane Risk Evaluation (2020 Risk Evaluation) and the 2024 1,4-Dioxane Supplemental Risk Assessment (2024 Supplement), which are based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) and (i) to make decisions under TSCA section 6 in a manner consistent with the best available science and based on the weight of scientific evidence. EPA also views the peer reviewed hazard and exposure assessments and associated risk characterizations as robust and upholding the standards of best available science and weight of the scientific evidence per TSCA sections 26(h) and (i). The policy changes described in the Federal Register Notice announcing the availability of the draft revised risk determination for 1,4-dioxane have been finalized as part of the rulemaking on the framework for TSCA risk evaluations*[1]*. The policy changes do not amend or impact the underlying data and analysis presented in the risk characterization of the 2020 Risk Evaluation or the 2024 Supplement, nor do they impact the characterization of risk estimates by condition of use (summarized in Section 4 of the 2020 final risk evaluation and Section 5 of the 2024 supplement to the risk evaluation), or the occupational exposures to workers and occupational non-users (ONUs) (summarized in Section 2.4.1 of the 2020 Risk Evaluation and Section 3.1 of the 2024 Supplement. Further discussion of EPA's consideration of workplace practices is in Section 3.2.4 of this document.*

[1] Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA), 89 FR 37028, May 3, 2024.

EPA disagrees with the commenter's assertion about the legislative record to support EPA's new policy direction. As previously noted, EPA has revised 40 CFR part 702 to reflect this policy direction. More information can be found in the 2024 final rule on the framework for TSCA risk evaluations[1] *and the associated Response to Public Comments document.*

While EPA has undertaken efforts to refine its 2018 approach to systematic review by developing a draft systematic review protocol that has undergone review by NASEM, the draft protocol is not a final document. EPA expects to use chemical-specific protocols in the future that reflect EPA's experience to date, including from the Science Advisory Committee on Chemicals (SACC) peer review process and public comment. EPA does not expect to apply adjustments retroactively; retroactive application would lead to further delays in completing the risk evaluations for the first ten substances contrary to Congressional intent. Thus, EPA maintains that the 2020 Risk Evaluation, as supplemented by the 2024 Supplement, meets TSCA section 26(h) requirements.

Section 2.2 – Process of revising the risk determination

EPA received comments related to the process of revising the risk determination. An industry trade organization (0115) requested that EPA withdraw the draft revision to the risk determination and provide an explanation for the proposed changes and additional public comment opportunity before applying the changes. Furthermore, the commenter stated that the whole chemical approach lacks clarity and would have substantial impacts on future chemical analysis.

EPA RESPONSE:

The revised unreasonable risk determination for 1,4-dioxane is based on the peer reviewed risk characterization of the 2020 Risk Evaluation and the 2024 Supplement, which were developed according to the TSCA section 26(h) requirement to make science-driven decisions, consistent with best available science, and in accordance with the TSCA section 26(i) requirement to make decisions based on the weight of scientific evidence. Changing the risk determination approach to a single risk determination for the chemical does not impact the underlying data and analysis presented in the risk characterization of the risk evaluation.

The draft revised unreasonable risk determination for 1,4-dioxane was published in July 2023 along with the Federal Register Notice explaining the new approach to the risk determination, and why EPA believes that a single risk determination for 1,4-dioxane better aligns with TSCA's objective of protecting health and the environment. The draft revised unreasonable risk determination also explained why EPA believes that not assuming the use of personal protective equipment (PPE) or other mitigating measures better aligns with TSCA. EPA provided notice and an opportunity for public comment on the draft revised risk determination for 1,4-dioxane and the approach described in the Federal Register Notice. In addition, notice and an opportunity for public comment on the policy changes were provided as part of the rulemaking on the framework for TSCA risk evaluations. EPA has inherent authority to reconsider previous decisions and to revise, replace, or repeal a decision to the extent permitted by law and supported by reasoned explanation. FCC v. Fox Television Stations, Inc., 556 U.S. 502, 515 (2009); see also Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co., 463 U.S. 29, 42 (1983). Pursuant to such authority, EPA has reconsidered the risk determinations in the December 2020 1,4-Dioxane Risk Evaluation.

The Revised Risk Determination details how 29 out of the 34 conditions of use EPA evaluated substantially contribute to the unreasonable risk presented by 1,4-dioxane and explains the change in

approach regarding assuming use of PPE by workers. As mentioned, the single risk determination approach does not impact the underlying data and analysis presented in the risk characterization of the 2020 Risk Evaluation and the 2024 Supplement. The 2020 Risk Evaluation already includes exposure analysis with and without PPE (see Tables 4-5, 4-7, and 4-9 in the 2020 Risk Evaluation). EPA has made no changes to this scientific analysis. The Agency believes that the Revised Risk Determination is sufficiently clear that it supersedes any conflicting statements in the 2020 Risk Evaluation. In addition, the Revised Risk Determination is consistent with the requirements in 40 CFR 702.39, which has been revised to incorporate these policy revisions.

Section 2.3 – Other legal issues

Other comments discussing legal issues with the whole chemical approach, including its consistency with TSCA, are discussed below in Section 3.1.

An industry trade organization (0114) requested that EPA consider impacts of regulating 1,4-dioxane related to uses of the chemical regulated by the Office of Pesticide Programs (OPP) and that EPA coordinate with OPP in this effort. The commenter stated that a potential residue limit mandate for 1,4-dioxane could require pesticide reformulation and impact food supply.

EPA RESPONSE: *EPA notes that use of 1,4-dioxane as the commenter describes may not meet the definition of a chemical substance under TSCA, which excludes any pesticide (as defined by the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide; and any food, food additive, drug, cosmetic, or device, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic or device. EPA appreciates the commenter's suggestion to work closely with the Office of Pesticide Programs and intends to do so.*

Section 3 – Revisions to the risk determination

Section 3.1 - Whole chemical approach

Section 3.1.1 – Support for the whole chemical approach

An industry trade organization (0108) and a State elected official (0111) expressed general support for the use of the whole chemical approach in the revised risk determination for 1,4-dioxane.

EPA RESPONSE:

EPA appreciates the comments in support of the single risk determination approach.

Section 3.1.2 – Opposition to whole chemical approach

A chemical manufacturer/importer (0113) and an industry trade organization (0115) expressed general opposition to the whole chemical approach. The chemical manufacturer/importer (0113) stated that there are conditions of use that EPA found posed no unreasonable risk, so it is misleading to the public and consumers if EPA calls the entire chemical an unreasonable risk. The commenter asserted that the decision to use the whole chemical approach is flawed, not rooted in the best available science, and does not align with the intent of the amended TSCA. The industry trade organization (0115) similarly stated that EPA has not supported its claim that its whole chemical approach to risk determinations is science-based and has provided no science-based support for why a majority of conditions of use should trigger

a whole chemical unreasonable risk determination. The commenter discussed substantial unintended consequences of this new approach, including prolonged uncertainty for the regulated community, non-science-based market impacts, continued use of resources to research uses which pose no risk, a negative finding on uses that may not have an unreasonable risk, and regrettable substitutions as manufacturers seek to quickly implement functional alternatives. Both the chemical manufacturer/importer (0113) and the industry trade organization (0115) remarked that the use of the whole chemical approach will confuse the public, as the public will not know which uses are safe and which pose risk.

EPA RESPONSE:

EPA disagrees with these commenters. As explained in the May 2024 final rule "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)"[1]*, the plain language of TSCA requires EPA to determine whether the chemical substance, rather than individual conditions of use, presents an unreasonable risk. The plain language of TSCA instructs EPA to do so "under the conditions of use" (plural), not under each individual condition of use. As such, EPA's determination must be based on analysis of the chemical's conditions of use—rather than on each condition of use "independently." In addition to aligning EPA's process with the statutory text and structure, this approach ensures that the Agency is best positioned to incorporate reasonably available information, and make determinations consistent with the best available science and based on the weight of scientific evidence.*

In response to commenters' assertions that EPA has not supported the claim that the new approach to risk determinations is science-based, EPA emphasizes that the Revised Risk Determination for 1,4-dioxane is based on the peer reviewed risk characterization in the 2020 Risk Evaluation and the 2024 Supplement, based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) and (i) to make decisions under TSCA section 6 in a manner consistent with the best available science and based on the weight of scientific evidence.

Responding to commenters' ideas concerning conditions of use which were identified in the 2020 Risk Evaluation as not presenting unreasonable risk, and what commenters describe as the benefits of a COU-specific approach, in this final revised risk determination, EPA identifies which conditions of use significantly contribute to the unreasonable risk and which conditions of use do not contribute to the unreasonable risk of 1,4-dioxane. Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management actions to the extent necessary so that 1,4-dioxane no longer presents an unreasonable risk. EPA expects to focus its risk management action on the conditions of use that significantly contribute to the unreasonable risk. EPA does not expect that the issuance of a single risk determination for 1,4-dioxane will affect the efficiency of EPA's risk management rulemaking. However, it should be noted that, under TSCA section 6(a), EPA is not limited to regulating the specific activities found to significantly contribute to unreasonable risk and may select from among a suite of risk management requirements in section 6(a) related to manufacture (including import), processing, distribution in commerce, commercial use, and disposal as part of its regulatory options to address the unreasonable risk. As a general example, EPA may regulate upstream activities (e.g., processing, distribution in commerce) in order to address downstream activities (e.g., industrial and commercial uses) driving unreasonable risk even if the upstream activities do not contribute to the unreasonable risk.

EPA appreciates the commenter's concerns (0113 and 0115) regarding which uses do or do not contribute to the unreasonable risk. EPA has provided this information at the beginning of the Revised Risk Determination, and in tables 6-1 and 6-2 of that document.

Section 3.1.3 – Inconsistency with TSCA and Risk Evaluation Rule

One industry trade organization (0115) provided their view that a whole chemical approach is inconsistent with TSCA and its implementing regulations.

Basis for the single risk determination approach

An industry trade organization (0115) stated that by using a whole chemical approach, EPA contradicted TSCA and its implementing regulations, did not use sound reasoning, and lacked science-based justification to be in compliance with TSCA section 26. It cited TSCA section 6(b)(4)(F)(i) and (iv), and stated that EPA must integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance and consider the likely duration, intensity, frequency and number of exposures under the conditions of use.

The industry trade organization (0115) commented that language in the HBCD final risk determination and 1,4-dioxane draft revised risk determination departs from the draft revisions to the risk determinations for HBCD and PV 29. The commenter stated that EPA's use of "substantial amount" of conditions of use to support application of a whole chemical approach is more arbitrary than the "majority" of conditions language used in the earlier draft revisions. The industry trade organization stated its view that this "substantial amount" term is inconsistent with TSCA section 26's requirements that section 6 decisions be grounded in science and thus that EPA's revision lacks a reasoned explanation. Additionally, the commenter stated that EPA changed the phrase "drive the unreasonable risk" to the phrase "contribute to the unreasonable risk" in the current revised risk determination, which allows EPA a degree of flexibility to determine whether there is a contribution from a condition of use. In conclusion, the commenter argued that EPA's shifting articulation of its single whole chemical unreasonable risk determination approach is impermissibly vague.

Inconsistency with TSCA

An industry trade organization (0115) stated that the practical effect of the whole chemical approach is that there are unlikely to be any determinations of no unreasonable risk. The commenter urged that the whole chemical approach thus impermissibly renders parts of the statute – the provisions for a finding of no unreasonable risk – superfluous. The industry trade organization stated that the inclusion in the statute of provisions for a finding of no unreasonable risk, including, for example, TSCA section 18(a)(1)(B)(i), is evidence that Congress must have intended for specific conditions of use to be evaluated by the Agency and risk determinations made for each of those uses.

The industry trade organization (0115) also stated their position that if the individual condition of use approach is no longer employed, then any opportunity for obtaining the Federal preemption of state or local requirements provided for under TSCA section 18(a) for conditions of use that pose no unreasonable risk would either be delayed by years until EPA promulgated a final risk management rule or potentially eliminated depending on the scope of the risk management rule.

EPA RESPONSE:

EPA disagrees with these commenters. As explained in the May 2024 final rule "Procedures for

Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)"[1]*, the plain language of TSCA requires EPA to determine whether the chemical substance, rather than individual conditions of use, presents an unreasonable risk. The plain language of TSCA instructs EPA to do so "under the conditions of use" (plural), not under each individual condition of use. As such, EPA's determination must be based on analysis of the chemical's conditions of use—rather than on each condition of use "independently." In addition to aligning EPA's process with the statutory text and structure, this approach ensures that the Agency is best positioned to incorporate reasonably available information, and make determinations consistent with the best available science and based on the weight of scientific evidence.*

EPA followed the requirements under TSCA section 6(b)(4) in issuing this Revised Risk Determination, including all requirements for a risk evaluation under TSCA section 6(b)(4)(F). Specifically, the Revised Risk Determination describes how EPA integrated and assessed reasonably available information on hazards and exposures for the conditions of use for 1,4-dioxane (considering factors such as environmental releases, aggregate and sentinel exposures, byproducts resulting from manufacturing and processing, environmental monitoring and biomonitoring, inclusion of additional exposure pathways/routes, as well as toxicity testing and physical and chemical properties), to workers, occupational non-users, consumers, and the general population, including modeling.

Regarding the comment that TSCA requires that changes in approach have scientific support, EPA notes that the Revised Risk Determination is based on the peer reviewed risk characterizations from the 2020 Risk Evaluation and the 2024 Supplement, based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) and (i) to make decisions under TSCA section 6 in a manner consistent with the best available science and based on the weight of scientific evidence.

The Revised Risk Determination reflects EPA's objective of conducting a technically sound, manageable evaluation to determine whether the chemical substance—not just individual uses or activities—presents an unreasonable risk. Regarding those commenters who thought that EPA's application of the single risk determination approach had been inconsistent, the revised risk evaluation rule, at 40 CFR 702.39(f), generally requires EPA to make a single determination as to whether the chemical substance presents unreasonable risk.

The Revised Risk Determination does not consider costs or other non-risk factors. In making the unreasonable risk determination, EPA considers relevant risk-related factors, including, but not limited to: the effects of the chemical substance on health and human exposure to such substance under the conditions of use (including cancer and non-cancer risks); the effects of the chemical substance on the environment and environmental exposure under the conditions of use; the population exposed (including any potentially exposed or susceptible subpopulations (PESS)); the severity of hazard (including the nature of the hazard, the irreversibility of the hazard); and uncertainties. EPA takes into consideration the Agency's confidence in the data used in the risk estimate. This includes an evaluation of the strengths, limitations, and uncertainties associated with the information used to inform the risk estimate and the risk characterization. Therefore, the Revised Risk Determination takes in consideration the hazard of 1,4-dioxane and the exposures from all conditions of use of 1,4-dioxane.

TSCA section 18(c)(3) defines the scope of federal preemption with respect to any final rule EPA issues under TSCA section 6(a). That provision provides that federal preemption of "statutes, criminal penalties, and administrative actions" applies to "the hazards, exposures, risks, and uses or conditions

of use of such chemical substances included in any final action the Administrator takes pursuant to [TSCA section 6(a)]." EPA reads this to mean that states are generally preempted from imposing requirements through statutes, criminal penalties, and administrative actions relating to any "hazards, exposures, risks, and uses or conditions of use" evaluated in the final risk evaluation and thus informing the risk determination that EPA addresses in the TSCA section 6(a) rulemaking. For example, unless an exception applies pursuant to TSCA sections 18(d) - (g), federal preemption applies even if EPA does not regulate in that final rule a particular condition of use, as long as that condition of use was evaluated in the final risk evaluation. More information can be found in the 2024 final rule on the framework for TSCA risk evaluations[1] *and the associated Response to Public Comments document.*

As one commenter correctly noted (0115), EPA used the phrase "drive(s) unreasonable risk" in previous iterations of both risk evaluations and proposed rulemakings for many of the chemicals in the First 10. EPA has since revised the regulations at 40 CFR 702.39(f) to state that where EPA makes a determination of unreasonable risk, EPA will identify the conditions of use that significantly contribute to such determination.

Section 3.1.4 – Other comments on the whole chemical approach

<u>Implementation of single risk determination approach for 1,4-dioxane</u>

An advocacy organization (0116) asserted that EPA qualitatively characterized aggregate exposures and risks for 1,4-dioxane, but the aggregate exposures were not quantified. The commenter specifically noted that, for 1,4-dioxane, dermal and oral exposures occur simultaneously for the general population when swimming. However, the commenter asserted that EPA chose not to aggregate the exposures via multiple pathways within a condition of use or swimming. The advocacy organization stated that they had expressed disagreement with the decision not to aggregate exposures in their December 2020 comments on the 2020 Risk Evaluation, and the commenter expressed that they are even more disappointed with the 2023 Draft Supplement to the Risk Evaluation, since it also fails to adequately aggregate exposures and risks. The commenter asserted that the failure to aggregate exposures and risks trivializes the value of EPA having taken the step of conducting assessment and providing risk characterizations for instances in which exposures in ambient air and drinking water are occurring from multiple sources. The advocacy organization stated that steps should be taken to estimate risk more accurately for all the relevant 1,4-dioxane exposure scenarios, and the commenter recommended the Office of Pollution Prevention and Toxics (OPPT) consult with other program offices in the Agency to learn and apply relevant aspects of aggregate exposure and risk assessment tools and practices.

The advocacy organization (0116) stated that the 2023 Draft Supplement does not reevaluate occupational, consumer, or ecological exposure pathways and risks that were assessed in the 2020 Risk Evaluation, but that EPA is requesting feedback on an unreasonable risk determination that requires all elements of risk evaluation to be finalized. The commenter stated that EPA should consider characterization and management of TSCA risks in the aggregate.

EPA RESPONSE:

As explained in the "Response to SACC Recommendations and Public Comments on the Supplement to the Risk Evaluation for 1,4-Dioxane," EPA has expanded on the quantitative analysis of aggregate exposure and risk across routes in the occupational risk calculator. As stated in Section 5.2.2.5 of the 2024 Supplement, "EPA assessed the potential impact of aggregation across routes by summing risks from dermal and exposures for each COU in the occupational risk calculator. Given the uncertainty

around the additive nature of cancer risk across routes, EPA is not relying on these quantitative aggregate risk estimates as the basis for risk conclusions in this assessment. However, the aggregate estimates illustrate the potential magnitude of the impact on risk estimates if risks are assumed to be additive across routes." As noted by some SACC members, it is possible that some combinations of co-exposures may act synergistically. However, EPA does not have data to suggest that aggregate exposure to 1,4-dioxane through multiple routes of exposure results in synergistic, rather than additive, effects.

EPA also notes that aggregate analysis within the air pathway focuses on all facilities in proximity and is not limited to facilities within a single COU. Given the uncertainty around the degree to which individuals may be exposed through multiple scenarios, EPA is not further quantifying aggregate exposure across occupational, consumer and general population exposures. As stated in Section 5.2.2.5 of the 2024 Supplement, "In most potential combinations of exposures scenarios, the exposures and risks from one scenario are much greater than from the other scenarios that may be aggregated with it (e.g., occupational risks for a particular COU may be an order of magnitude greater than risks from 1,4-dioxane in drinking water in the community where the worker lives). When this is the case, aggregate risk would be very similar to risk from the scenario with the highest risk. In more rare cases where risks from a particular combination of exposure scenarios are similar (e.g., occupational risks for a particular COU are equal to risks from drinking water), aggregate risks could theoretically be double the risk from each pathway in isolation."

Impact on Risk Management Rules

An advocacy organization (0116) asserted that a negative unreasonable risk determination made separately for each pathway might flip to a determination of unreasonable risk when judged based upon aggregate exposure and that this would change the dynamics of a risk management decision on prohibition, other mitigation methods, or to leave a condition of use unaffected. The commenter additionally stated that a risk management proposed rule to prohibit a condition of use or modify its retention with mitigation measures will likely prompt the regulated party to develop information that will resolve the uncertainties that currently inhibit EPA's ability to use a fully aggregate approach. Moreover, the advocacy organization expressed that mitigation measures might be available if exposure routes/pathways are judged separately, but not if they are judged in the aggregate.

An industry trade organization (0115) stated that EPA does not discuss how the single whole chemical approach in the revised risk determination will impact subsequent risk management rules. The commenter stated that it submitted comments on the proposed risk management rules for both methylene chloride and perchloroethylene (PCE) that discussed the importance of scoping a TSCA risk evaluation in order to provide stakeholders with sufficient notice, the need for sufficient notice to stakeholders about EPA's potential, the need for sufficient notice to stakeholders about the potential use of an Existing Chemical Exposure Limit (ECEL) in risk management actions, and concerns about duplicative and inconsistent workplace occupational safety risk management measures.

Additionally, the commenter (0115) requested that EPA:

- Review the whole chemical approach in the context of TSCA's risk-based decision-making framework and requirements for risk management rules (0115);
- Explain how the change to a whole chemical approach may affect risk management (0115); and

- Develop principles and criteria that would dictate when and how the whole chemical approach would be applied and when it would not. How will EPA treat the conditions of use that it determines do not present an unreasonable risk in its risk management plan when a whole chemical approach has been taken? (0115).

EPA RESPONSE: *EPA appreciates the commenter's position (0116) and agrees that information developed by regulated entities may provide EPA with additional considerations on the most appropriate assessment approach for future evaluations. However, EPA disagrees that having such information would necessarily inhibit the Agency's use of an aggregate approach. Moreover, EPA intends to consider reasonably available information, such as those provided through comment submissions, to inform individual pathways assessments, probabilistic modeling assessments, and future risk management actions when appropriate. EPA disagrees that measures used to address unreasonable risk in consideration of separate pathways/routes would preclude mitigation of aggregate risks simultaneously.*

EPA appreciates the commenter's (0115) engagement across chemicals and would refer them to EPA's responses to similar inquiries within the respective chemical Response to Comment documents.

With respect to the comments on the new approach to risk determinations, EPA has revised 40 CFR 702.39(f) to state that EPA will make a single determination as to whether the chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use. As explained in the May 2024 final rule "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)"[1]*, the plain language of TSCA requires EPA to determine whether the chemical substance, rather than individual conditions of use, presents an unreasonable risk. The plain language of TSCA instructs EPA to do so "under the conditions of use" (plural), not under each individual condition of use. As such, EPA's determination must be based on analysis of the chemical's conditions of use—rather than on each condition of use "independently." In addition to aligning EPA's process with the statutory text and structure, this approach ensures that the Agency is best positioned to incorporate reasonably available information, and make determinations consistent with the best available science and based on the weight of scientific evidence.*

The Revised Risk Determination is based on the peer reviewed risk characterizations of the 2020 Risk Evaluation and the 2024 Supplement, which are based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) and (i) to make decisions under TSCA section 6 in a manner consistent with the best available science and based on the weight of scientific evidence. Changing to a single risk determination does not impact the underlying data and analysis presented in the risk characterization of the 2020 Risk Evaluation. With respect to the risk management, consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management action to the extent necessary so that 1,4-dioxane no longer presents unreasonable risk. In the final revised risk determination for 1,4-dioxane, EPA has identified the conditions of use that significantly contribute to the unreasonable risk for 1,4-dioxane and will focus its risk management efforts on addressing that unreasonable risk, as required by TSCA. Regarding how EPA may treat the conditions of use that it determines do not contribute to the unreasonable risk, EPA notes that, while risk management is likely to focus on conditions of use that significantly contribute to the unreasonable risk, under TSCA section 6(a), EPA is not limited to regulating the specific activities

found to significantly contribute to the unreasonable risk and may select from among a suite of risk management options related to manufacture, processing, distribution in commerce, commercial use, and disposal in order to address the unreasonable risk. For instance, EPA may regulate upstream activities (e.g., processing, distribution in commerce) in order to address downstream activities that significantly contribute to unreasonable risk (e.g., consumer uses) even if the upstream activities do not significantly contribute to the unreasonable risk. The public will have another opportunity to provide comments during the comment period of the proposed risk management rule.

Section 3.2 - Baseline scenario that assumes no PPE or other mitigation measures in place

Section 3.2.1 - Support for EPA's intention to assume no PPE or other mitigation measures are in place

A State elected official (0111) expressed support for EPA's decision to eliminate the assumption that all workers always appropriately wear PPE. The commenter discussed the reasons that EPA uses to justify their decision to eliminate the assumption that all workers always appropriately wear PPE, and the commenter expressed strong support for this position.

EPA RESPONSE:

EPA appreciates the feedback regarding assumptions on the use of PPE in the 2020 Risk Evaluation, 2023 draft supplement to the risk evaluation, and unreasonable risk determination therein for 1,4-dioxane, general input regarding PPE, the interaction of EPA and OSHA regulation, and worker protection. EPA has amended 40 CFR 702.39 to state at (f)(2) that EPA will not consider exposure reduction based on assumed use of personal protective equipment as part of the risk determination.

Section 3.2.2 - Opposition to EPA's intention to assume no PPE or other mitigation measures are in place

An industry trade organization (0115) expressed opposition to EPA's intention not to assume personal protective equipment is always and properly used when conducting risk determination evaluations. The industry trade organization commented that EPA's decision not to assume the use of PPE is inconsistent with the definition of conditions of use under TSCA and contravenes TSCA's explicit requirement under TSCA section 26(k) to take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator.

The industry trade organization (0115) emphasized that EPA's proposal to determine risk without considering the effects of current occupational safety standards and PPE practices is not supported by the record nor reasonably justified by any of the reasons offered by the Agency. Specifically, the commenter provided its view that EPA cited no data or records to support its belief concerning the insufficiency of PPE at OSHA-regulated facilities. The commenter further stated that EPA has not presented any evidence of widespread refusal to comply with OSHA requirements and urged that OSHA does require the use of appropriate PPE where needed to protect workers from chemical exposures at jobsites.

The industry trade organization (0115) also stated that EPA's proposal is not transparent about its plans for implementation of the proposed change in the risk management rule itself and requested that the Agency develop clear, accurate communication materials to explain EPA's new approach to PPE to the already OSHA-regulated community. The commenter stated that EPA's proposal could inadvertently

create regulatory confusion and potentially subject companies to overlapping workplace protection requirements for workplaces that are already subject to OSHA. The industry trade organization added that such requirements would be costly and either duplicative of or inconsistent with those that OSHA has already imposed on employers and employees in OSHA-regulated businesses. Further, the commenter warned that EPA's rationale for no assumption of PPE in risk evaluations is inconsistent with the statutory and regulatory requirements in the Occupational Safety & Health Act of 1970 (OSH Act) and that EPA must consult with OSHA and NIOSH to understand whether current worker protection from exposure to chemicals is consistent with best available science before making any determinations about the adequacy of OSHA controls.

EPA RESPONSE:

EPA's Revised Risk Determination is explicit insofar as it does not rely on assumptions regarding the use of PPE in making the unreasonable risk determination under TSCA section 6, even though, as mentioned by the commenters, some facilities might be using PPE as one means to reduce worker exposures. Information on the use of PPE as a means of mitigating risk (including public comments received from industry respondents about occupational safety practices in use) will be considered during the risk management phase, as appropriate.

In preparing the 2020 Risk Evaluation and the 2024 Supplement, EPA considered reasonably available information on 1,4-dioxane hazards and exposures under the conditions of use, including information on current industry practices, occupational controls and PPE use at commercial and industrial facilities handling 1,4-dioxane as explained in Sections 1.4.3 and 2.4.1.1 of the 2020 final risk evaluation and Sections 3.1.1.4 and F.3 of the appendix of the 2024 Supplement. This information is also helpful to inform potential risk management actions. However, as noted before, EPA cannot reasonably assume that all facilities will have adopted these practices. Therefore, EPA is making its determination of unreasonable risk from a baseline scenario that does not assume compliance with OSHA standards, including any applicable exposure limits or requirements for use of respiratory protection or other PPE.

The Revised Risk Determination is based on the peer reviewed risk characterizations of the 2020 Risk Evaluation and the 2024 Supplement, which are based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) to make decisions under TSCA section 6 in a manner consistent with the best available science. The policy changes in the Revised Risk Determination do not impact the underlying data and analysis presented in the risk characterization of the 2020 Risk Determination, including how the risk estimates of cancer and non-cancer effects to workers from chronic inhalation exposures at the high-end were calculated and summarized in Table 4-7 and 4-9.

As described in an earlier response, EPA also notes that the assertion that the Agency based its determination on hazard alone is not correct; the 2024 Revised Risk Determination is based on both the hazard of the chemical substance and the exposures or environmental releases, as described in Sections 3 and 2, respectively, of the 2020 Risk Evaluation and in Sections 4, 3, and 2, respectively, of the 2024 Supplement, and further explained in Sections 6.2 and 6.3 of the Revised Risk Determination. The 2020 Risk Evaluation already includes exposure analysis with and without PPE. Tables 4-7 and 4-9 in the 2020 Risk Evaluation present risk estimates for each COU with and without PPE. EPA emphasizes that it has made no changes to this underlying analysis. Therefore, removing the assumption that workers always and appropriately wear PPE when making the unreasonable risk determination does not create a need for new analysis. The Revised Risk Determination and the 2024 revisions to the regulations

regarding TSCA risk evaluations clarify that EPA does not rely on the assumed use of PPE when making the risk determination for the chemical substance.

EPA explicitly stated in the draft Revised Risk Determination and accompanying Federal Register Notice that basing the unreasonable risk determination on the baseline scenario without PPE should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location or that there is widespread non-compliance with applicable OSHA standards. Rather, it reflects EPA's recognition that unreasonable risk may exist for workers (which are included in the risk evaluation as a PESS) that may be highly exposed because they are not covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan, or because their employer is out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970s are described by OSHA as being "outdated and inadequate for ensuring protection of worker health," or because the OSHA PEL alone may be inadequate to protect worker health, or EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements. In some cases, baseline conditions may reflect certain mitigation measures, such as engineering controls, in instances where exposure estimates are based on monitoring data at facilities that have engineering controls in place.

Because the requirements and application of TSCA and OSHA regulatory analyses differ, it is appropriate that EPA conduct risk evaluations and, where it finds unreasonable risk to workers, develop risk management requirements for chemical substances that OSHA also regulates, and it is understood that EPA's findings and requirements may sometimes diverge from OSHA's. However, it is also appropriate that EPA consider the standards that OSHA has already developed, so as to limit the compliance burden to employers by aligning management approaches required by the agencies, where alignment will adequately address unreasonable risk to workers.

As a general matter, when undertaking risk management actions, EPA will consider occupational risk mitigation measures that could address unreasonable risk identified by EPA, and for any such measures included in a proposed or final TSCA risk management rule, EPA intends to strive for compatibility with applicable OSHA requirements and industry best practices, including appropriate application of the hierarchy of controls, to the extent that applying those measures would address the identified unreasonable risk, including unreasonable risk to PESS. When undertaking risk management actions, EPA intends to develop occupational risk mitigation measures to address any unreasonable risks identified by EPA, especially in cases where current OSHA standards may not apply or be sufficient to address the unreasonable risk.

EPA identified the conditions of use that significantly contribute to the unreasonable risk in the risk determination, and options will be developed during the process of the Agency working on the risk management rulemaking to address the unreasonable risk presented by the chemical substance. The risk management rulemaking stage is not when EPA determines which conditions of use significantly contribute to the unreasonable risk.

Under TSCA section 9(a), if EPA determines, in the Administrator's discretion, that an unreasonable risk may be prevented or reduced to a sufficient extent by action taken under a federal law that is not administered by EPA, EPA must submit a report to the agency administering that other authority and undertake a statutorily prescribed referral process. EPA retains the discretion to make this finding in the first instance.

Consistent with TSCA section 9(d), EPA is regularly consulting and coordinating TSCA activities with OSHA and other relevant federal agencies for the purpose of achieving the maximum enforcement of TSCA while avoiding the imposition of duplicative requirements. Consultation with other relevant federal agencies is also required during the risk evaluation process under EPA's implementing regulations at 40 CFR 702.39. Informed by the mitigation scenarios and information gathered during the risk evaluation and risk management process, the Agency might propose rules that require risk management practices that may be already common practice in many or most facilities. Adopting clear, comprehensive regulatory standards will foster compliance across all facilities (ensuring a level playing field) and assure protections for all affected workers, especially in cases where current OSHA standards may not apply or be sufficient to address the unreasonable risk. EPA appreciates the suggestion to formalize a consultation process with OSHA, as well as the request for transparency regarding such consultations. EPA will continue to coordinate with OSHA and other relevant federal agencies during TSCA risk evaluation and risk management activities and expects to refine its consultation process as the Agency conducts additional risk evaluations and risk management rulemakings. The results of any consultation with OSHA, as well as EPA's rationale for proposed risk management requirements, including consideration of the OSHA hierarchy of controls, will be reflected in the proposed rule to address the unreasonable risk presented by 1,4-dioxane.

The public will have an opportunity to comment on the proposed regulatory action, and EPA will consider such public comments and any additional information before finalizing the rulemaking.

Section 3.2.3 – State and other Federal requirements and industry best practices

Section 3.2.3.1 – Permissible exposure limits (PELs)

Section 3.2.3.2 – PPE use

Section 3.2.3.3 – Other comments on State and Federal requirements or best practices

Regulation of 1,4-dioxane

A State elected official (0111) stated that 1,4-dioxane poses serious health risks, including liver and kidney toxicity, adverse effects in the membranes in the nose that affect the sense of smell, and cancer. The commenter remarked that 1,4-dioxane can be released into the air, water, and soil in locations where it is produced or used as a solvent, and the commenter expressed that the physical and chemical properties and behavior of 1,4-dioxane create challenges for its characterization and treatment. The State elected official discussed the fact that 1,4-dioxane has been identified at more than 34 hazardous waste sites on the EPA National Priorities List, and the commenter added that 1,4-dioxane has been found in groundwater at sites throughout the United States. The commenter discussed 1,4-dioxane's potential contamination of drinking water at length, focusing on data from New York water. Finally, the commenter discussed the regulations that States have taken to protect against the dangers of 1,4-dioxane. The State elected official listed many New York regulations, with the most recent regulation being that New York established a maximum allowable concentration of 2 ppm of 1,4-dioxane for household cleansing and personal care products and a maximum concentration level of 10 ppm for cosmetics, as of December 31, 2022.

EPA RESPONSE:

EPA appreciates the commenter's information and agrees that 1,4-dioxane presents an unreasonable risk to health. EPA also understands the challenges with characterization and treatment and continues to coordinate among other EPA program offices and Federal agencies on risk assessment/risk

abatement methods and strategies. EPA appreciates the information provided on New York's regulation on 1,4-dioxane in cleaning products, and notes that the Revised Risk Determination finds that consumer and commercial cleaning product use significantly contributes to the unreasonable risk presented by 1,4-dioxane through drinking water exposures.

Section 3.2.4 - Other comments on the baseline scenario

An industry trade organization (0115) provided several suggestions for how EPA could address the protection of workers as a potentially exposed or susceptible subpopulation including: considering other ways to address concerns about the population of workers not covered by OSHA standards, developing risk evaluations that do not assume that PPE is either always or never used in the workplace, working with OSHA during the scoping phase and discussing improved enforcement of OSHA requirements, considering the European approach to conditions of use for the workplace, and more.

EPA RESPONSE:

For purposes of making the TSCA unreasonable risk determination, it is inappropriate to assume as a general matter that industry best practices are consistently and always properly applied or that all facilities have adopted these practices. Once EPA has determined that a chemical substance presents an unreasonable risk, EPA is required to address the identified unreasonable risk through rulemaking. EPA intends to consider current best workplace practices as it develops TSCA section 6(a) risk management action to address the unreasonable risk identified in the Revised Risk Determination, for instance, to help inform EPA's assessment of the feasibility and efficacy of different risk management options. Information on the best workplace practices could also include information from other countries, such as the European approach.

As a general matter, when undertaking risk management actions, EPA intends to strive for consistency with applicable OSHA requirements and industry best practices, including appropriate application for the hierarchy of controls, to the extent that the requirements, controls, and practices eliminate the identified unreasonable risks. Informed by the mitigation scenarios and information gathered during the risk evaluation and risk management process, the Agency might propose rules requiring risk management practices that may be already common practice in many or most facilities. Adopting clear, comprehensive regulatory standards will foster compliance across all facilities (ensuring a level playing field) and assure protections for all affected workers. EPA will undertake a public notice and comment period as part of the TSCA section 6(a) proposed risk management rulemaking for 1,4-dioxane and will consider public comments and any additional information before finalizing the rulemaking. Consistent with TSCA section 9(d), EPA is consulting and coordinating TSCA activities with OSHA and other relevant federal agencies for the purpose of achieving the maximum enforcement of TSCA while avoiding the imposition of duplicative requirements. Consultation with other relevant federal agencies is also required during the risk evaluation process under EPA's implementing regulations at 40 CFR 702.39.

Section 4 – Unreasonable risk determination

A chemical manufacturer/importer (0113) and an industry trade organization (0119) expressed concerns about the revised draft risk determination. The chemical manufacturer/importer (0113) stated that it disagreed with the revised draft risk determination both in procedure and in substance. More specifically, the commenter remarked that the timing of the process raises serious concerns, as EPA

drew conclusions and proposed to change the risk determination prior to reviewing comments on the 2023 Draft Supplement to the Risk Evaluation and prior to the Science Advisory Committee on Chemicals' peer review of the 2023 Draft Supplement. The commenter asserted that this suggests that EPA had already decided that 1,4-dioxane presents an unreasonable risk prior to having all of the information on which it would make the decision. In addition, the chemical manufacturer/importer (0113) stated that EPA used flawed science and outdated data, and the commenter urged EPA to consider the additional information companies and other commenters are submitting.

EPA RESPONSE:

EPA recognizes the commenter's concern regarding the policy updates and procedures leading to this Revised Risk Determination. EPA disagrees however that conclusions were drawn prematurely because EPA has appropriately made its Revised Risk Determination based on information from the 2020 Risk Evaluation as well as the 2024 Supplement, and in accordance with TSCA sections 26(h), (i), and (k) for the best available science, weight of the scientific evidence, and information that was reasonably available, respectively. As the Agency has expressed in the past, EPA is willing to adopt changes, as necessary, should the Agency receive adequate supporting information during public comment periods to do so.

Mode of action for 1,4-dioxane

Several industry trade organizations (0119, 0117, 0112, 0109) discussed the mode of action (MOA) for 1,4-dioxane and urged EPA to use a threshold mode of action. One industry trade organization (0119) expressed concern about EPA's conclusions with regard to the potential carcinogenic effects of exposures to 1,4-dioxane. The commenter remarked that EPA used a linear approach to assessing risk, despite ample evidence in support of a threshold MOA. The commenter urged EPA to consider recent publications challenging the use of a non-threshold MOA. Another industry trade organization (0117) referenced an opinion from the European Chemicals Agency Committee for Risk Assessment, which found that 1,4-dioxane is a threshold carcinogen. The industry trade organization stated that the World Health Organization, Health Canada, and the Australian National Occupational Health and Safety Commission have all similarly endorsed a threshold MOA. In addition, the commenter asserted that Lafranconi et al. published an integrated assessment of the 1,4-dioxane cancer MOA and threshold response in rodents earlier this year that supported the use of a threshold dose-response model.

An industry trade organization (0117) expressed that EPA rejected a threshold MOA approach and defaulted to a linear low-dose extrapolation approach, because linear extrapolation is the default approach when there is uncertainty about the MOA. The commenter stated that 2005 cancer guidelines do not require scientific certainty to support a threshold MOA, and the commenter added that EPA's cancer guidelines call for "reasoned judgments," not scientific certainty. The commenter remarked that Lafranconi et al.'s findings mean that the conditions in the cancer guidelines for using the linear approach do not exist for 1,4-dioxane. Finally, the industry trade organization asserted that EPA relied on E.O. 13990 rather than the best available science in its decision to reopen the 2020 Risk Evaluation. Another industry trade organization (0107) similarly stated that EPA failed to use the best available science by disregarding information on threshold carcinogenic MOA applications from Health Canada, the European Union and the Commonwealth of Australia. An industry trade organization (0109) agreed that potential risks identified are significantly changed when treated as a threshold carcinogen, as would be the case under international regulations.

An industry trade organization (0112) stated that EPA overly conservatively relies on the incidence of tumors in laboratory animal studies and a linear, non-threshold approach for estimating cancer risk. The commenter argued that a threshold cancer MOA can be established for 1,4-dioxane based on the evidence for liver/nasal hyperplasia and urged EPA to use such an approach.

EPA RESPONSE:

These comments are similar to those provided during the public comment periods on the 2020 Risk Evaluation and the 2024 Supplement. They are addressed in the Response to Comments documents for the 2020 Risk Evaluation[2] *and the 2024 Supplement*[3].

Section 5 - Conditions of use that significantly contribute to the unreasonable risk determination

Section 5.1 – Manufacturing

An industry trade organization (0117) discussed EPA's assessment of releases of 1,4-dioxane from polyethylene terephthalate (PET) manufacturing. The commenter stated that EPA focused on a single value from a single facility in a single year (2019), and the commenter asserted that this release value was an outlier, which was not representative of PET manufacturing facilities. The industry trade organization expressed that the release value is orders of magnitude higher than amounts reported from other PET manufacturing facilities and orders of magnitude higher than amounts reported by the same facility in other years. The commenter added that it is unclear from the text and tables how total releases with or without the 2019 data point were ultimately used, but this data point should not be relied upon.

In addition, the industry trade organization (0117) urged EPA to use more relevant exposure data. The commenter asserted that EPA's assessment of the potential risks from 1,4-dioxane exposure associated with PET manufacturing relied on an extraordinarily small data set of samples from 30 to 40 years ago that were collected entirely from facilities not involved in PET manufacturing. The commenter remarked that EPA's discussion of the data confirms that EPA does not know whether PET was handled at all at the facilities in the data set, and the commenter stated that EPA has no basis to conclude that exposure conditions at those facilities would bear any relation to the exposure scenarios EPA had identified for PET manufacturing. The commenter added that, even if the data were from the right industry, there is no basis to conclude that this small sample set is representative of exposures. The commenter expressed that the obsolete and non-representative data on PET manufacturing that EPA relied upon cannot be reconciled with EPA's conclusion that the weight of the scientific evidence for the assessment is moderate and provides a plausible estimate of exposures. Finally, the commenter stated that EPA is required to employ methods of data analysis consistent with the best science, and EPA had and still has the opportunity to request needed exposure data from PET manufacturers.

EPA RESPONSE:

Responses to these comments on the 2023 draft Supplement can be found in the "Response to SACC Recommendations and Public Comments on the Supplement to the Risk Evaluation for 1,4-Dioxane." For example, as stated therein, inhalation monitoring data for the PET manufacturing occupational

[2] EPA. Summary of External Peer Review and Public Comments and Disposition for 1,4-Dioxane: Response to Support Risk Evaluation of 1,4-Dioxane. December 2020., available at https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0238-0093.

[3] 1 4 Dioxane - Response to SACC and Public Comments on the Supplement to the Risk Evaluation - November 2024.

exposure scenario (Appendix F.4.9 to the 2024 Supplement) was incorporated from a public comment received.

Section 5.2 – Processing

An industry trade organization (0119) commented that ethoxylated surfactants have highly valuable uses that are beneficial for society as a whole, but these surfactant products may contain trace levels of 1,4-dioxane. The commenter remarked that there have been many substantial investments to reduce the 1,4-dioxane impurity content in products, and the development of new technologies is ongoing. In addition, the industry trade organization asserted that EPA has limited data regarding 1,4-dioxane formation during ethoxylation, sulfonation, sulfation, phosphation, and esterification processes, and the commenter urged EPA to seek out additional information.

Two industry trade organizations (0119, 0112) specifically discussed the fact that EPA's worker exposure models for ethoxylation byproduct relied on a monitoring study from a single U.S. production site in 2000. One industry trade organization (0112) stated that the data in the study consisted of a single value from one person during one shift at one site. The commenter asserted that EPA cannot determine the statistical representativeness of the one data point from 2000 towards potential exposures. The other industry trade organization (0119) expressed that their internal monitoring measurements indicate that the exposure value from 2000 is higher than would be expected of typical production sites, and the risk derived likely overestimates risk. Both industry trade organizations (0112, 0119) added that the current methodology for monitoring in manufacturing and processing plants cannot measure to the low detection limits expressed by EPA's ECEL, and the commenters urged EPA to collaborate with and request information from industry stakeholders. One of the industry trade organizations (0112) stated that the ECEL for 1,4-dioxane is 0.055 ppm and thus lower than existing occupational exposure limits (OELs) used by labs, providing examples and stating that non-detect results above this ECEL make identifying a statistical approach to translating these results to an ECEL or ECEL Action Level is difficult.

EPA RESPONSE:

EPA appreciates the information provided by the first commenter (0119) and assures them that EPA is aware that there are methods for reducing the presence of 1,4-dioxane as a byproduct during the production of certain surfactants. In addition, as part of risk management, EPA will continue conducting outreach to relevant stakeholders to further understand how the risks from various chemical processes that produce 1,4-dioxane as a byproduct may be addressed.

With regard to the representativeness of the available data, EPA uses and considers reasonably available information in accordance with TSCA section 6(b)(4)(G) and supplements information gathering through outreach with stakeholders to make a determination. In the absence of reasonably available information, EPA may use modeling approaches to estimate risks which may include conservative assumptions. As such, EPA maintains that the Revised Risk Determination is based on the best available science and the weight of the scientific evidence under TSCA section 26(h) and (i), respectively. EPA also maintains that EPA's analysis is sufficient to decide whether a particular condition of use or exposure pathway significantly contributes to the unreasonable risk presented by 1,4-dioxane. Responses to similar comments on the 2023 draft Supplement can be found in the "Response to SACC Recommendations and Public Comments on the Supplement to the Risk Evaluation for 1,4-Dioxane." For example, as stated therein, monitoring data, process descriptions, and product

concentrations for the ethoxylation occupational exposure scenario (Appendix F.4.10) were incorporated from a public comment received.

As noted by these commenters, EPA is aware that a risk-based ECEL may be challenging to implement due to detection limits of existing methods and feasibility. In addressing the unreasonable risk presented by 1,4-dioxane, EPA will consider a range of risk management options, including consideration of ECEL implementation and timeframes. This may include a revised ECEL that takes into account feasibility and detectability.

Section 5.3 - Industrial and commercial use

Dish soap and dishwashing detergent

Several industry trade organizations (0109, 0112, 0119) discussed EPA's occupational and down-the-drain (DTD) assessments for dish soap and dishwashing detergent, and the commenters asserted that EPA's assessment is not accurate. One industry trade organization (0109) stated that EPA used data from a formulating and packaging plant, rather than a worker washing dishes. In addition, a few industry trade organizations (0109, 0112, 0119) asserted that EPA used old data, which is no longer applicable. More specifically, the commenters urged EPA to remove the Belanger 1980 study from the risk assessment. The industry trade organizations stated that the Belanger 1980 study used decades old data, in which some of the products have 1,4-dioxane levels in excess of 0.4%. The commenters asserted that this is out of date with current industry standards and is not observed in modern products.

One industry trade organization (0112) added that NYS law prohibits products from containing 1,4-dioxane concentrations that exceed 2 ppm, and this limit will go down to 1 ppm on December 31, 2023. The commenter remarked that NYS law is the de facto national upper limit, as most companies manufacture and distribute dish soap and detergent on a national basis. The industry trade organization noted that EPA acknowledged the significant uncertainty involved in using data from the Belanger 1980 study, and the commenter stated that EPA should not utilize information from a study with a high degree of uncertainty. Two industry trade organizations (0109, 0119) added that EPA derived a Limit of Detection (LOD) from the data in the Belanger 1980 study, and this carries significant uncertainty. One industry trade organization (0119) asserted that, under TSCA section 26, EPA must represent the best information reasonably available, and it has not done so.

A few industry trade organizations (0109, 0112, 0119) discussed the availability of data from the New York State Department of Environmental Conservation (NYS DEC) and urged EPA to utilize the data in its occupational and DTD assessments for dish soap and dishwashing detergent. The commenters stated that NYS DEC's data includes an approved waivers spreadsheet of the dish products with 1,4-dioxane levels that do not meet New York's limit of 2 ppm and have received waivers. In addition, the commenters expressed that the approved waivers spreadsheet indicates that the concentration range of 1,4-dioxane in dish products that do not meet the limit is 2.01 to 15 ppm, which is far below the concentrations in the Belanger 1980 study used by EPA to assess the occupational exposures for dish soap and dishwashing detergent. The industry trade organizations added that these numbers are conservative, because they do not include products that meet the established maximum allowable concentration. The industry trade organizations recommended EPA utilize the New York State (NYS) 1,4-dioxane limits and waiver data, as they accurately represent products that are currently on the market. Finally, one industry trade organization (0112) suggested that EPA work with industry stakeholders to generate new data for the dish soap and dishwashing detergent conditions of use.

One industry trade organization (0112) discussed the differences in worker exposure scenarios for back-of-house restaurant and commercial dishwashing workers. The commenter expressed disagreement with

EPA's assertion that commercial exposure is two to four orders of magnitude greater than the 2020 Risk Evaluation consumer exposure inhalation estimate. The industry trade organization remarked that industry has taken steps to ensure the safety of workers and dispensing methods that reduce worker exposure have been widely adopted. The commenter stated that the dermal exposure model used by EPA does not factor in typical use parameters and practices.

EPA RESPONSE:

Many of these comments were also provided during the public comment period on the 2023 draft Supplement and responses to those comments can be found in the "Response to SACC Recommendations and Public Comments on the Supplement to the Risk Evaluation for 1,4-Dioxane". For example, information from the New York State waiver database was incorporated into the 2024 Supplement as suggested by the SACC and several commenters. EPA is aware of New York's regulation for 1,4-dioxane in certain products and will take this into consideration during the risk management phase. Though the commenter may find it reasonable to assume that New York's regulation is a de facto national limit, EPA does not believe that this is an appropriate assumption on which to base an unreasonable risk determination. In response to another commenter (0119) that asserted the EPA did not use reasonably available information in accordance with TSCA section 26(k), EPA disagrees and has stated such in the executive summary of both the 2020 Risk Evaluation and the 2024 Supplement. Moreover, where EPA may have had less certainty in its assessment, the Agency presented this information clearly and, in some cases, requested for public comment where supplemental information could be considered to possibly inform or revise the evaluation. Where no additional data were provided, TSCA requires that EPA discharge its obligations using information that is reasonably available which may be further supplemented using conservative assumptions or through modeling efforts.

EPA appreciates the commenter's (0112) suggestion to meet with industry stakeholders. EPA has already conducted outreach to several key industry users and documented these meetings in the docket for public transparency. EPA assures the commenter that more outreach will be facilitated and emphasizes that there will also be additional opportunities for public comments. The Agency highly encourages that stakeholders take an active engagement approach with EPA and utilizes public comment opportunities.

EPA does not doubt the strides that the commenter (0112) suggests have taken place towards worker safety and is willing to conduct outreach with the commenter during the risk management phase to discuss the widely-adopted dispensing methods described by the commenter to reduce worker exposures.

<u>Hydraulic fracturing</u>

An industry trade organization (0110) wrote about the hydraulic fracturing condition of use extensively. The commenter asserted that EPA provided insufficient notice that hydraulic fracturing was considered as a condition of use, and the commenter specifically stated that the first notice they received that EPA was considering hydraulic fracturing in the risk evaluation of 1,4-dioxane was on July 10, 2023. The commenter stated that they would have commented earlier if they had had more notice.

In addition, the industry trade organization (0110) asserted that EPA mischaracterized the activities and exposure conditions for hydraulic fracturing workers, and this led to overstated exposures and risks. The commenter expressed that the manner in which EPA assumed that workers unload containers was incorrect, and the commenter added that unloading occurs with little or no direct contact between products and air or the worker's skin. Moreover, the industry trade organization remarked that neither container cleaning nor tank/equipment cleaning is undertaken by hydraulic fracturing workers, but EPA assumed that it was. The commenter stated that all product transfers occur through hoses with little or no

contact between products and a worker's skin or breathing-zone air, and workers who are doing the hose connections/disconnections must wear chemically resistant gloves and other PPE. The commenter expressed that EPA should reduce calculated risks by a factor of 20 to account for the use of gloves. The commenter further urged EPA to accept actual data on the hydraulic fracturing condition of use and then complete its risk evaluation based on that information.

In addition, the industry trade organization (0110) remarked that their review of the dockets identified no industry submissions explaining how 1,4-dioxane comes to be present in hydraulic fracturing, and the 2023 Draft Supplement to the Risk Evaluation provides no exposure monitoring data. In addition, the commenter expressed that the "generic scenarios and emission scenario documents" that EPA based its hydraulic fracturing modeling on are not publicly available. The commenter asserted that explaining one's methods in a manner that allows others to evaluate and reproduce the results is part of TSCA's requirement to rely on the best available science in section 26(h). The industry trade organization stated that EPA has not provided sufficient information to explain its methodology or to allow others to evaluate its model inputs and assumptions for hydraulic fracturing. The commenter also said that the 2023 Draft Supplement to the Risk Evaluation is deficient under TSCA section 26(k) because of a failure to use "reasonably available" use and exposure information for the hydraulic fracturing condition of use.

Finally, the industry trade organization (0110) expressed that EPA needs to clearly define the term "facilities" and needs to explain its methodology for selecting the hydraulic fracturing "facilities" included in the analysis. In particular, the commenter asserted that EPA needs to identify the timeframe over which it determined that there were 411 hydraulic fracturing "facilities" at which 1,4-dioxane was present. The industry trade organization stated that, assuming that EPA intended to define a "facility" as a hydraulic fracturing stimulation at a certain well, EPA incorrectly assumed that a hydraulic fracturing worker would be exposed to 1,4-dioxane every year. The commenter remarked that, from 2012 to 2023, an average of 2% of wells in the FracFocus database reported the presence of 1,4-dioxane. The commenter urged EPA to factor the likelihood of exposure into its analysis, and the commenter asserted that doing so would change the chronic risk estimates by a factor of 50.

EPA RESPONSE:

EPA appreciates the commenter (0110) highlighting notification of actions being taken under TSCA for 1,4-dioxane. To increase awareness of EPA activities that may affect their businesses, EPA conducts outreach with industry stakeholders including but not limited to industry consortiums, trade organizations, manufacturers, importers, processors, users, and distributors. EPA also encourages stakeholders to take an active engagement approach with EPA and to take advantage of available public comment opportunities. EPA disagrees with the commenter that there was no indication that hydraulic fracturing as a condition of use would be evaluated because EPA received public comments regarding the presence of 1,4-dioxane in hydraulic fracturing fluids and this consideration was recorded in the Summary of External Peer Review document.[2] *In this document, EPA stated the following: "While EPA has addressed some conditions of use related to 1,4-dioxane as a byproduct in this [draft] risk evaluation, EPA expects that 1,4-dioxane exposures associated with the use of ethoxylated alcohols used in hydraulic fracturing fluids would be considered in the scope of a risk evaluation for ethoxylated alcohols".* **Error! Bookmark not defined.** *As the commenter noted, subsequent to this, EPA announced its Path Forward for TSCA Chemical Risk Evaluations in June 2021, where EPA intended to "re-open and update the 1,4-dioxane risk evaluation to consider whether to include additional exposure pathways, like drinking water and ambient air, and conditions of use where 1,4-dioxane is generated as a byproduct that were excluded from the supplemental and final risk evaluations."*

In response to the commenter's questions regarding the presence of 1,4-dioxane in hydraulic fracturing fluids and the assessment of releases and exposures, more information is provided in the "Response to SACC Recommendations and Public Comments on the Supplement to the Risk Evaluation for 1,4-Dioxane".

Section 5.4 – Disposal

A couple of industry trade organizations (0109, 0108) and a State elected official (0111) discussed EPA's risk determination for exposures related to the disposal of 1,4-dioxane. The State elected official (0111) expressed agreement with EPA that exposure to drinking water sourced from water that is contaminated by 1,4-dioxane released from industrial facilities contributes to the unreasonable risk from 1,4-dioxane. The State elected official added that they believe that other exposures to drinking water contaminated with 1,4-dioxane may also contribute to the unreasonable risk of 1,4-dioxane. The commenter expressed that wastewater can also serve as a source of 1,4-dioxane contamination to both surface and groundwater used for drinking water, and wastewater is also increasingly being used as drinking water itself. The commenter particularly asserted that personal care and cleaning products containing 1,4-dioxane can contaminate drinking water, and the commenter remarked that these products generate at least two 1,4-dioxane-containing waste streams. The commenter noted that bottles with product residues are sent to landfills, which can ultimately contaminate groundwater, and wastewater containing 1,4-dioxane may be sent down the drain and enter treatment plants. The State elected official expressed that consumer products represent a constant source of 1,4-dioxane to wastewater, and this is particularly concerning because most wastewater treatment plants do not remove 1,4-dioxane. Finally, the State elected official stated that EPA is not limited to regulating the specific activities found to contribute to the unreasonable risk and EPA has broad discretion in how the Agency applies TSCA's risk management tools to eliminate risk.

The industry trade organization (0109) asserted that it is unclear how EPA derived an unreasonable risk determination for circumstances described but not evaluated in the 2020 Risk Evaluation or the 2023 Draft Supplement to the Risk Evaluation, and the commenter provided the example of when 1,4-dioxane is generated as a byproduct during sulfonation, sulfation, and esterification processes. The commenter urged EPA and the surfactant industry to collaborate to generate studies to support an evaluation of worker risk and environmental exposure due to disposal from surfactant manufacturing facilities. In addition, the industry trade organization expressed agreement with EPA's finding that there is no unreasonable risk to the general population from exposures to drinking water contaminated with 1,4-dioxane from down-the-drain releases of consumer and commercial products that contain 1,4-dioxane as a byproduct.

Another industry trade organization (0108) stated that EPA's 2020 Risk Evaluation for 1,4-dioxane failed to consider drinking water contamination as a potential route of exposure subject to TSCA. The commenter argued that EPA cannot rely on Safe Drinking Water Act (SDWA) to control this risk because doing so would shift the burden of risk management away from manufacturers and users to drinking water systems. The commenter expressed support for the framework in the 2023 Draft Supplement, stating that it can be leveraged as a screening tool for both existing and new chemicals with, or without, monitoring data. The commenter also stated that EPA's framework correctly assumed that drinking water treatment will not remove 1,4- dioxane, writing that communities likely to be exposed to 1,4-dioxane releases are likely to lack treatment options for this chemical.

EPA RESPONSE:

EPA appreciates the supportive response from the commenter (0111) and general responses from others (0109, 0108). EPA agrees that TSCA grants broad authority to manage downstream risks through upstream uses when necessary. EPA notes that the final Revised Risk Determination finds that ingestion of drinking water sourced from surface water contaminated with industrial discharges or down-the-drain discharges of 1,4-dioxane significantly contributes to the unreasonable risk. EPA also acknowledges the concerns of the commenter (0108) on where the burden of risk management may fall when considering different regulatory statutes such as the SDWA. As discussed in the Revised Risk Determination, TSCA section 9(b) requires EPA to coordinate TSCA actions with actions taken under other Agency authorities. In so doing, EPA has decided that regulatory actions under both TSCA and the Safe Drinking Water Act (SDWA) may be appropriate. Under TSCA, EPA expects to apply section 6(a) requirements to the extent necessary on the manufacture, processing, commercial use, distribution in commerce, and disposal of 1,4-dioxane. These requirements may result in reduced concentrations of 1,4-dioxane in surface water. While reasonably available information indicated that drinking water treatment may not readily remove 1,4-dioxane, EPA is aware of general industry practices that are capable of reducing the formation of 1,4-dioxane as a byproduct and/or removing byproduct 1,4-dioxane from formulations, and EPA will consider this information during risk management.

To address another commenter (0109), EPA has and intends to continue collaborating with stakeholders including those in the surfactant manufacturing sector. As stated in the revised risk determination, because EPA found that all of the processing conditions of use quantitatively evaluated in the 2020 Risk Evaluation and the 2024 Supplement significantly contribute to unreasonable risk, EPA has determined that all processing of 1,4-dioxane significantly contributes to the unreasonable risk. EPA further notes that esterification was evaluated in the 2024 Supplement as part of the evaluation of the PET manufacturing condition of use.

Section 6 - Other comments related to the draft revision of the risk determination

Section 6.1 – Comments discussing the scientific analysis

An industry trade organization (0108) expressed approval for assessing multiple types of common 1,4-dioxane uses and releases with both a facility-specific and probabilistic methodology. The commenter stated that such an approach would benefit from greater transparency and EPA providing additional explanation of how release scenarios are structured, data-driven assumptions that are made, and of flow paths for the calculation of release estimates.

An industry trade organization (0112) recommended that EPA use Monte-Carlo modelling methodology generated using generic data and, when EPA identifies unreasonable risk with low tier exposure modeling, refine the model with a higher tier exposure model before making a final risk determination. The commenter stated that investing in Monte-Carlo modelling technology will improve risk management where reliable data is scarce. However, the commenter stated that the Monte-Carlo and SHEDS-HT models are not intuitive for new users and requested that EPA reinstate and incentivize use of the Sustainable Futures program to provide training for stakeholders on these models.

An advocacy organization (0116) wrote that the Monte-Carlo model relies on good data to produce accurate information, stating that the Monte-Carlo model can provide a defensible approach for predicting distributions of concentrations of 1,4-dioxane but would benefit from better data.

The advocacy organization (0116) also provided comments on EPA's Surface Water Exposure Assessment, stating that the assessment provided good agreement between model prediction and monitoring data and providing a detailed description of the modeling relied upon by the assessment. The commenter stated that the assessment has uncertainty in the lack of a watershed-based analysis regarding co-location of various conditions of use among watersheds and stated that the assessment relied on a beta version of a model.

EPA RESPONSE:

EPA appreciates these comments on the assessments in the 2023 draft Supplement. Responses to these comments can be found in the "Response to SACC Recommendations and Public Comments on the Supplement to the Risk Evaluation for 1,4-Dioxane".

Section 6.2 – Comments on EPA's decision not to conduct a peer review

Two industry trade organizations (0107, 0117) commented generally that EPA's new methods and novel applications of existing methods have not been peer reviewed or subject to public comment thus that they should not be relied upon in reevaluating 1,4-dioxane. One of the commenters (0107) stated that EPA generally seeks comments on new methodologies before using them in a regulatory action and that conformity with 40 CFR 702.41 requires assurance that "all supporting analyses and components of the risk evaluation are suitable for their intended purpose." The commenter urged EPA to withdraw the risk determination because of this issue. Another industry trade organization (0109) stated that use of untested methodologies for risk evaluation is inappropriate, and agreed that, per 40 CFR 702.41, risk determination should be postponed until new methodologies could be reviewed. The commenter and another industry trade organization (0109) stated that, in particular, the Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0 was reviewed by SACC. The commenter stated that SACC reported reproduction difficulties for the approach and recommended improvements. Another industry trade organization (0119) requested that EPA postpone risk determination pending SACC review. The commenter stated that 40 CFR 702.45 requires peer review consistent with EPA's Peer Review Handbook, and OMB's Final Information Quality Bulletin for Peer Review.

A chemical manufacturer/importer (0113) stated that risk determination should be postponed to ensure that EPA reviews comments from SACC and stakeholders on the 2023 Draft Supplement to the Risk Evaluation.

Another industry trade organization (0115) encouraged the American Chemistry Council to provide meaningful recommendations to EPA to improve its risk evaluation process and revise the 2023 Draft Supplement.

EPA RESPONSE:

EPA agrees that some of the methods employed in the 2023 draft Supplement are novel and, for this reason, has completed a peer review by the SACC as well as taken public comment. EPA, in consideration of the comments received, the SACC suggestions, and through additional outreach, has revised the 2023 draft to account for the new information. Therefore, the Revised Risk Determination reflects the most current information and considerations, and is in keeping with TSCA sections 26(h), (i), and (k); the best available science, the weight of the scientific evidence, and reasonably available information. In January 2022, EPA released the TSCA Screening Level Approach for Assessing Ambient

Air and Water Exposures to Fenceline Communities for public comment and peer review; in March 2022, EPA held a public virtual meeting of the Science Advisory Committee on Chemicals (SACC) to peer review the approach. EPA presented Version 1.0 of a screening level methodology for assessing potential air and water pathway chemical exposures to fenceline communities. Along with presenting this methodology, EPA also presented results of applying the screening methodology (case studies) to 1-brompropane (air pathway), n-methylpyrrolidone (water pathway), and methylene chloride (air and water pathways). The proposed screening level methodology went through a public comment period and peer review (by the SACC) for comments on the proposed methodology as well as recommended revisions or improvements to the methodology. The SACC delivered its report in May 2022. The 2023 draft Supplement was based on this screening methodology, taking into account the suggestions from the SACC and the public comments on the methodology, and including improvements as warranted. EPA disagrees with the commenter's (0119) suggestion to postpone the risk determination until after the SACC review because the Revised Risk Determination is based on the feedback received on the 2023 draft Supplement and both TSCA and the regulations governing TSCA risk evaluations envision the risk determination as part of the risk evaluation and not a subsequent step.

Section 7 – Out of scope

An advocacy organization (0116) stated that EPA's Office of Water should prioritize the development of a drinking water standard for 1,4-dioxane.

EPA RESPONSE:

As discussed in the Revised Risk Determination, EPA has decided that regulatory actions under both TSCA and the Safe Drinking Water Act (SDWA) may be appropriate. Under TSCA, EPA expects to apply section 6(a) requirements to the extent necessary on the manufacture, processing, commercial use, distribution in commerce, and disposal of 1,4-dioxane. These requirements may result in reduced concentrations of 1,4-dioxane in surface water. EPA recognizes that actions under TSCA may not fully eliminate releases of 1,4-dioxane to surface water, and that other sources contribute to the presence of 1,4-dioxane in surface water. These other sources may include both uses subject to regulation under TSCA and uses that are expressly excluded from regulation under TSCA due to exclusions from the definition of "chemical substance." As such, EPA will review any remaining risks following the promulgation and implementation of TSCA regulations, to determine whether additional action should be taken under SDWA.