ENVIRO

[EPA-HQ-OPPT-2016-0723; FRL-7918-02-OCSPP]

1,4-Dioxane; Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of and requesting public comment on a draft revision to the risk determination for 1,4-dioxane following a risk evaluation issued under TSCA. EPA published a risk evaluation for 1,4-dioxane in December 2020 and a draft supplement to the risk evaluation in July 2023. This draft revision to the 1,4-dioxane risk determination reflects policy changes announced in June 2021, to ensure the public is protected from unreasonable risks from chemicals in a way that is supported by science and the law, as well as information from the 2023 Draft Supplement to the risk evaluation. In this draft revision to the risk determination EPA has preliminarily determined that 1,4-dioxane, as a whole chemical substance, presents an unreasonable risk of injury to health when evaluated under its conditions of use. This draft risk determination considers the occupational and consumer exposures from the December 2020 Risk Evaluation, as well as the occupational, general population, and fenceline community exposures in the draft supplement to the risk evaluation, including exposures that result from conditions of use where 1,4-dioxane is present due to production as a byproduct and the risks from general population and fenceline communities' exposures to 1,4-dioxane released under the conditions of use to drinking water sourced from surface and ground water and ambient air. In addition, this revised risk determination does not reflect an assumption that all workers always appropriately wear personal protective equipment (PPE). EPA understands that there could be adequate occupational safety protections in place at certain workplace locations; however, not assuming use of PPE reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be

highly exposed because they are not covered by Occupational Safety and Health Administration (OSHA) standards, or their employers are out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being "outdated and inadequate for ensuring protection of worker health," or because EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements. This revision, when final, would supersede the condition of use-specific no unreasonable risk determinations in the December 2020 1,4-dioxane risk evaluation (and withdraw the associated order) and would make a revised determination of unreasonable risk for 1,4-dioxane as a whole chemical substance.

DATES: Comments must be received on or before September 8, 2023.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-EPA-HQ-OPPT-2016-0723, through *https://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Cindy Wheeler, Office of Pollution Prevention and Toxics (7404M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 566-0484; email address: *dioxane.TSCA@EPA.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of interest to those involved in the manufacture, processing, distribution, use, disposal, and/or the assessment of risks involving chemical substances and mixtures. You may be potentially affected by this action if you manufacture (defined under TSCA to include import), process (including recycling), distribute in commerce, use, or dispose of 1,4-dioxane, including 1,4-dioxane in products and including processes that produce 1,4-dioxane as a byproduct. Since other entities may also be interested in this draft revision to the risk determination, EPA has not attempted to describe all the specific entities that may be affected by this action.

B. What is EPA's authority for taking this action?

TSCA section 6, 15 U.S.C. 2605, requires EPA to conduct risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation (PESS) identified as relevant to the risk evaluation by the Administrator, under the conditions of use. 15 U.S.C. 2605(b)(4)(A). TSCA sections 6(b)(4)(A) through (H) enumerate the deadlines and minimum requirements applicable to this process, including provisions that provide instruction on chemical substances that must undergo evaluation, the minimum components of a TSCA risk evaluation, and the timelines for public comment and completion of the risk evaluation. TSCA also requires that EPA operate in a manner that is consistent with the best available science, make decisions based on the weight of the scientific evidence, and consider reasonably available information. 15 U.S.C. 2625(h), (i), and (k).

The statute identifies the minimum components for all chemical substance risk evaluations. For each risk evaluation, EPA must publish a document that outlines the scope of the risk evaluation to be conducted, which includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expects to consider. 15 U.S.C. 2605(b)(4)(D). The statute further provides that each risk evaluation must also: (1)

integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on relevant potentially exposed or susceptible subpopulations; (2) describe whether aggregate or sentinel exposures were considered and the basis for that consideration; (3) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use; and (4) describe the weight of the scientific evidence for the identified hazards and exposures. 15 U.S.C. 2605(b)(4)(F)(i) through (ii) and (iv) through (v). Each risk evaluation must not consider costs or other non-risk factors. 15 U.S.C. 2605(b)(4)(F)(iii).

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 is reconsidering the risk determinations in the December 2020 1,4-Dioxane Risk Evaluation and issuing a 2023 draft risk determination that encompasses the information in the 2023 Draft Supplement to the risk evaluation.

C. What action is EPA taking?

EPA is announcing the availability of and seeking public comment on a 2023 draft revision to the risk determination for the 2020 1,4-Dioxane Risk Evaluation under TSCA (Ref. 1). This includes revision to the risk determination initially published in December 2020 (Ref. 2) and addition of information from the 2023 Draft Supplement to the risk evaluation (Ref. 3), which includes evaluation of additional conditions of use of 1,4-dioxane and critical exposure pathways not included in the 2020 1,4-Dioxane Risk Evaluation. EPA has announced the availability of the 2023 Draft Supplement to the risk evaluation in a separate **Federal Register** notice, which also describes the requests for public comment and the peer review process for the 2023 Draft Supplement (88 FR 43562, July 10, 2023) (FRL-10798-02-OCSPP).

EPA is seeking public comment on the draft revision to the risk determination for the risk evaluation where the agency preliminarily intends to determine that 1,4-dioxane, as a whole chemical, presents an unreasonable risk of injury to health when evaluated under its conditions of use. The Agency has preliminarily determined that the risk determination for 1,4-dioxane is better characterized as a whole chemical risk determination rather than condition-of-use-specific risk determinations. Accordingly, EPA would revise and replace section 5 of the 2020 Risk Evaluation for 1,4-dioxane where the findings of unreasonable risk to health were previously made for the individual conditions of use evaluated. EPA would also withdraw the order issued previously for two conditions of use previously determined not to present unreasonable risk. However, before finalization of the risk determination, EPA is specifically seeking public comment on several aspects of the 2023 draft unreasonable risk determination, including EPA's finding that general population and fenceline community exposure to 1,4-dioxane in drinking water contributes to the determination that 1,4-dioxane presents an unreasonable risk and whether the risks to the general population and fenceline communities from drinking water exposure can be attributed to specific conditions of use of 1,4-dioxane. A more robust description of the request for comment is in Unit II.D.

This proposed revision to the 2020 unreasonable risk determination would be consistent with EPA's plans to revise specific aspects of the first ten TSCA chemical risk evaluations in order to ensure that the risk evaluations better align with TSCA's objective of protecting health and the environment. EPA proposes that the 2023 draft revision would include several changes. First, EPA would make an unreasonable risk determination for 1,4-dioxane as a whole chemical substance, rather than making unreasonable risk determinations separately on each individual condition of use evaluated in the risk evaluation. EPA proposes that this is the most appropriate approach to 1,4-dioxane under the statute and implementing regulations, with more explanation provided in Unit II.C.1. Second, EPA would remove the assumption that workers always and appropriately wear PPE (see Unit II.C.) in making the whole chemical risk determination for 1,4-

dioxane. The impacts of this change are described in detail in Unit II.C.2. Third, based on the 2023 Draft Supplement to the risk evaluation, several additional conditions of use would also contribute to the unreasonable risk determination due to worker inhalation and dermal risks; these are described in more detail in Unit II.C.3. Fourth, EPA proposes to include risks to the general population and fenceline communities from drinking water sourced from surface water contaminated with 1,4-dioxane that is discharged from industrial facilities (including where it is produced as a byproduct) as contributing to the unreasonable risk from 1,4-dioxane and is seeking public comment on several issues. These risks are described in more detail in Unit II.C.4 and a description of the request for comment is in Unit II.D. The list of the conditions of use evaluated for the 1,4-dioxane TSCA risk evaluation is in Table 6-1 of the draft revised unreasonable risk determination (Ref. 1) and in Table D-1 of the 2023 Draft Supplement to the Risk Evaluation for 1,4-Dioxane (Ref. 3)).

D. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html*.

II. Background

A. What is 1,4-dioxane and what did EPA evaluate in 2020?

1,4-Dioxane is primarily used as a solvent in commercial and industrial applications. It

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

1,4-Dioxane is one of the first 10 chemical substances undergoing the TSCA risk evaluation process under TSCA section 6(b). In 2019, EPA released the draft 1,4-dioxane risk evaluation, which assessed risk from occupational exposures and surface water exposures to environmental organisms. This assessment, which included the physical and chemical properties, lifecycle information, environmental fate and transport information, and hazard identification and dose-response analysis received public comment, was reviewed by the Science Advisory Committee on Chemicals (SACC). The Agency considered the SACC feedback and is not seeking additional review of that information at this time as this information has not changed.

A 2020 supplement to the draft 1,4-dioxane risk evaluation assessed an additional eight additional conditions of use of 1,4-dioxane present in consumer products and general population exposure to 1,4-dioxane from incidental contact with surface water. Both assessments were incorporated into the 2020 Risk Evaluation, which was released in December 2020.

The December 2020 Risk Evaluation assessed a total of 24 conditions of use. In December 2020, EPA determined that 13 conditions of use presented unreasonable risks due to exposure to workers or occupational non-users, and that 11 conditions of use did not present an unreasonable risk (of those 11, 3 were industrial/commercial uses, and 8 were consumer uses).

EPA found that none of the conditions of use present an unreasonable risk to the environment.

B. Why is EPA re-issuing the risk determination for the 2023 1,4-dioxane risk evaluation conducted under TSCA?

In 2016, as directed by TSCA section 6(b)(2)(A), EPA chose the first ten chemical substances to undergo risk evaluations under the amended TSCA. These chemical substances are asbestos, 1-bromopropane, carbon tetrachloride, C.I. Pigment Violet (PV 29), cyclic aliphatic bromide cluster (HBCD), 1,4-dioxane, methylene chloride, n-methylpyrrolidone (NMP), perchloroethylene (PCE), and trichloroethylene (TCE).

From June 2020 to January 2021, EPA published risk evaluations on the first ten chemical substances, including for 1,4-dioxane in December 2020. The risk evaluations included individual unreasonable risk determinations for each condition of use evaluated. EPA issued determinations that particular conditions of use did not present an unreasonable risk by order under TSCA section 6(i)(1).

In accordance with Executive Order 13990 (Ref. 4) and other Administration priorities (Refs. 5, 6, and 7), EPA reviewed the risk evaluations for the first ten chemical substances, including 1,4-dioxane, to ensure that they meet the requirements of TSCA, including conducting decision making in a manner that is consistent with the best available science.

As a result of this review, EPA announced plans to revise specific aspects of the first ten risk evaluations in order to ensure that the risk evaluations appropriately identify unreasonable risks and thereby help ensure the protection of human health and the environment (Ref. 8). EPA also announced plans, in response to public comments and peer review, to supplement the 2020 Risk Evaluation for 1,4-Dioxane to assess critical human exposure pathways not previously considered in the 2020 Risk Evaluation, and to consider occupational exposures to conditions of use where 1,4-dioxane is present due to production as a byproduct. EPA has now developed the 2023 Draft Supplement to the risk evaluation and has announced its availability and request for public comment in a separate **Federal Register** notice, which also describes the peer review

process (88 FR 43562, July 10, 2023) (FRL-10798-02-OCSPP). In the 2023 Draft Supplement, EPA assessed the risks from 8 industrial/commercial uses of 1,4-dioxane as a byproduct, from processing 1,4-dioxane as a byproduct, and from the general population exposures to 1,4-dioxane in ambient air and drinking water. This 2023 draft revised risk determination is for 1,4-dioxane as a whole chemical – and thus includes not only information from the 2023 Draft Supplement to the 1,4-dioxane risk evaluation but also proposes revisions to the 2020 risk determination based on the 2020 Risk Evaluation. EPA is releasing this 2023 draft revised unreasonable risk determination separately from the draft supplement to the risk evaluation but is aligning the comment period for the two documents so that the final unreasonable risk determination can be released concurrently with the final supplemental risk evaluation.

This action pertains only to the risk determination for 1,4-dioxane. While EPA has taken additional similar actions on other of the first ten chemicals, EPA is taking a chemical-specific approach to reviewing the risk evaluations and is incorporating new policy direction in a surgical manner, while being mindful of the Congressional direction on the need to complete risk evaluations and move toward any associated risk management activities in accordance with statutory deadlines.

C. What are EPA's considerations in the Draft Revised Unreasonable Risk Determination for 1,4-Dioxane?

In this draft revised unreasonable risk determination for 1,4-dioxane, EPA is reconsidering two key aspects of the risk determinations for 1,4-dioxane published in December 2020, proposing several additional changes and updates, and highlighting specific requests for comment.

First, following a review of specific aspects of the December 2020 1,4-dioxane risk evaluation, EPA proposes that making an unreasonable risk determination for 1,4-dioxane as a whole chemical substance, rather than making unreasonable risk determinations separately on each individual condition of use evaluated in the risk evaluation, is the most appropriate

approach to 1,4-dioxane under the statute and implementing regulations. Second, EPA proposes that the risk determination should be explicit that it does not rely on assumptions regarding the use of personal protective equipment (PPE) in making the unreasonable risk determination under TSCA section 6, even though some facilities might be using PPE as one means to reduce workers' exposures; rather, the use of PPE as a means of addressing unreasonable risk will be considered during risk management, as appropriate. As a result, EPA preliminarily identifies two additional conditions of use from the 2020 Risk Evaluation as contributing to the determination that 1,4-dioxane presents unreasonable risk. Additionally, for some of the conditions of use in the 2020 Risk Evaluation that were identified as "presenting" an unreasonable risk to workers due to cancer, eliminating the PPE assumption means that acute and chronic non-cancer effects from inhalation exposure now also contribute to the unreasonable risk. Third, based on the 2023 supplement to the risk evaluation, EPA proposes to identify several additional conditions of use as contributing to the unreasonable risk determination due to worker inhalation and dermal risks. Fourth, EPA proposes that the risks to the general population and fenceline communities from exposures to 1,4-dioxane in drinking water sourced from surface water contaminated with industrial discharges of 1,4-dioxane (including when it is generated as a byproduct) contributes to the determination that 1,4-dioxane presents an unreasonable risk, and is seeking public comment on several issues related to this proposed determination, as described in Unit II.D.

1. *What is a whole chemical view of the unreasonable risk determination for the 1,4-dioxane risk evaluation?*

TSCA section 6 repeatedly refers to determining whether a chemical *substance* presents unreasonable risk under its conditions of use. Stakeholders have disagreed over whether a chemical substance should receive: A single determination that is comprehensive for the chemical substance after considering the conditions of use, referred to as a whole-chemical determination; or multiple determinations, each of which is specific to a condition of use, referred to as condition-of-use-specific determinations.

The proposed risk evaluation procedural rule was premised on the whole chemical approach to making an unreasonable risk determination (Ref. 9). In that proposed rule, EPA acknowledged a lack of specificity in statutory text that might lead to different views about whether the statute compelled EPA's risk evaluations to address all conditions of use of a chemical substance or whether EPA had discretion to evaluate some subset of conditions of use (i.e., to scope out some manufacturing, processing, distribution in commerce, use, or disposal activities), but also stated that "EPA believes the word 'the' [in TSCA section 6(b)(4)(A)] is best interpreted as calling for evaluation that considers all conditions of use." (Ref. 9).

The proposed rule, however, was unambiguous on the point that an unreasonable risk determination would be for the chemical substance as a whole, even if based on a subset of uses. (See Ref. 9 at pgs. 7565-66: "TSCA section 6(b)(4)(A) specifies that a risk evaluation must determine whether 'a chemical substance' presents an unreasonable risk of injury to health or the environment 'under the conditions of use.' The evaluation is on the chemical substance—not individual conditions of use—and it must be based on 'the conditions of use.' In this context, EPA believes the word 'the' is best interpreted as calling for evaluation that considers all conditions of use."). In the proposed regulatory text, EPA proposed to determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use (Ref. 9 at pg. 7480).

The final risk evaluation procedural rule stated (82 FR 33726, July 20, 2017) (FRL-9964–38) (Ref. 10): "As part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of uses [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents." (See also 40 CFR 702.47). For the unreasonable risk determinations in the first ten risk evaluations, EPA applied this provision by making individual risk determinations for each condition of use evaluated in each risk evaluation (i.e., the condition-of-use-specific approach to risk determinations). That approach was based on one

particular passage in the preamble to the final risk evaluation procedural rule, which stated that EPA will make individual risk determinations for all conditions of use identified in the scope. (Ref. 10 at pg. 33744).

In contrast to this portion of the preamble of the final risk evaluation procedural rule, the regulatory text itself and other statements in the preamble reference a risk determination *for the chemical substance* under its conditions of use, rather than separate risk determinations for each of the conditions of use of a chemical substance. In the key regulatory provision excerpted earlier from 40 CFR 702.47, the text explains that "[a]s part of the risk evaluation, EPA will determine whether *the chemical substance* presents an unreasonable risk of injury to health or the environment under each condition of uses [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents" (Ref. 10, emphasis added). Other language reiterates this perspective. For example, 40 CFR 702.31(a) states that the purpose of the rule is to establish the EPA process for conducting a risk evaluation to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment as required under TSCA section 6(b)(4)(B). Likewise, there are recurring references to whether the chemical substance presents an unreasonable risk in 40 CFR 702.41(a). See, for example, 40 CFR 702.41(a)(6), which explains that the extent to which EPA will refine its evaluations for one or more condition of use in any risk evaluation will vary as necessary to determine whether a chemical substance presents an unreasonable risk. Notwithstanding the one preambular statement about condition-of-use-specific risk determinations, the preamble to the final rule also contains support for a risk determination on the chemical substance as a whole. In discussing the identification of the conditions of use of a chemical substance, the preamble notes that this task inevitably involves the exercise of discretion on EPA's part, and "as EPA interprets the statute, the Agency is to exercise that discretion consistent with the objective of conducting a technically sound, manageable evaluation to determine whether a chemical substance—not just individual uses or activities—presents an unreasonable risk." (Ref. 9 at pg. 33729).

Therefore, notwithstanding EPA's choice to issue condition-of-use-specific risk determinations to date, EPA interprets its risk evaluation regulation to also allow the Agency to issue whole-chemical risk determinations. Either approach is permissible under the regulation. A panel of the Ninth Circuit Court of Appeals also recognized the ambiguity of the regulation on this point. *Safer Chemicals v. EPA, 943 F.3d 397, 413* (9th Cir. 2019) (holding a challenge about "use-by-use risk evaluations [was] not justiciable because it is not clear, due to the ambiguous text of the Risk Evaluation Rule, whether the Agency will actually conduct risk evaluations in the manner Petitioners fear").

EPA plans to consider the appropriate approach for each chemical substance risk evaluation on a case-by-case basis, taking into account considerations relevant to the specific chemical substance in light of the Agency's obligations under TSCA. The Agency expects that this case-by-case approach will provide greater flexibility in the Agency's ability to evaluate and manage unreasonable risk from individual chemical substances. EPA believes this is a reasonable approach under TSCA and the Agency's implementing regulations.

With regard to the specific circumstances of 1,4-dioxane, as further explained in this notice, EPA proposes that a whole chemical approach is appropriate for 1,4-dioxane in order to protect health and the environment. The whole chemical approach is appropriate for 1,4-dioxane because there are benchmark exceedances for multiple conditions of use (spanning across most aspects of the chemical lifecycle–from manufacturing (including import), processing, industrial and commercial use, and disposal) for health of workers, occupational non-users, and fenceline communities and the general population, and the understanding that the health effects (specifically liver toxicity, olfactory epithelium effects, and cancer) associated with 1,4-dioxane exposures are irreversible. Because these chemical-specific properties cut across the conditions of use within the scope of the risk evaluation, it is appropriate for the Agency to make a determination for 1,4-dioxane that the whole chemical presents an unreasonable risk.

As explained later in this document, the revisions to the unreasonable risk determination

(section 5 of the 2020 Risk Evaluation) would be based on the existing risk characterization section of the 2020 Risk Evaluation (section 4 of the 2020 Risk Evaluation) and the 2023 Draft Supplement to the Risk Evaluation for 1,4-Dioxane. The discussion of the issues presented in this ***Federal Register*** notice and in the accompanying draft revision to the risk determination would supersede any conflicting statements in the prior 2020 1,4-dioxane risk evaluation and the response to comments document (Ref. 11). With respect to the 1,4-dioxane risk evaluation, while EPA intends to change the risk determination to a whole chemical approach without considering the use of PPE, EPA is basing the 2023 draft unreasonable risk determination on the underlying scientific analysis from the 2020 Risk Evaluation and 2023 Draft Supplement to the Risk Evaluation. EPA does not intend to amend, nor does a whole chemical approach require amending, the underlying scientific analysis of the risk evaluation in the risk characterization section of the 2020 Risk Evaluation. EPA also notes the Correction of Dermal Acute and Chronic Non-Cancer Hazard Values Used to Evaluate Risks from Occupational Exposures that explained, while the corrections slightly alter occupational dermal risk estimates, they do not appreciably impact the overall risk conclusions (Ref. 12). Because updates are not necessary for the 2020 publication, EPA views the peer reviewed hazard and exposure assessments and associated risk characterization as robust and upholding the standards of best available science and weight of the scientific evidence per TSCA sections 26(h) and (i).

EPA is announcing the availability of and seeking public comment on the 2023 draft unreasonable risk determination for 1,4-dioxane, including a description of the risks contributing to the unreasonable risk determination under the conditions of use for the chemical substance as a whole. For purposes of TSCA section 6(i), EPA is making a draft risk determination on 1,4-dioxane as a whole chemical. Under the proposed revised approach, the "whole chemical" risk determination for 1,4-dioxane would supersede the no unreasonable risk determinations (and withdraw the associated order) for 1,4-dioxane that were premised on a condition-of-use-specific approach to determining unreasonable risk. When finalized, EPA's revised unreasonable risk

determination would also contain an order withdrawing the TSCA section 6(i)(1) order in section 5.4.1 of the December 2020 1,4-Dioxane Risk Evaluation.

2. *What revision does EPA propose about the use of PPE for the 1,4-dioxane risk evaluation?*

In the risk evaluations for the first ten chemical substances, as part of the unreasonable risk determination, EPA assumed for several conditions of use that workers were provided and always used PPE in a manner that achieves the stated assigned protection factor (APF) for respiratory protection, or used impervious gloves for dermal protection. In support of this assumption, EPA used reasonably available information such as public comments indicating that some employers, particularly in the industrial setting, provide PPE to their employees and follow established worker protection standards (e.g., Occupational Safety and Health Administration (OSHA) requirements for protection of workers).

For the December 2020 1,4-Dioxane Risk Evaluation, EPA assumed, based on reasonably available information, that workers use PPE – specifically respirators with an APF ranging from 10 to 50 and gloves with PF 10 or 20 – for 15 occupational conditions of use. However, in the December 2020 Risk Evaluation, EPA determined that there is unreasonable risk for 13 of those 15 occupational conditions of use even with assumed PPE.

EPA is revising the assumption for 1,4-dioxane that workers always or properly use PPE. However, this does not mean that EPA questions the veracity of public comments which describe occupational safety practices often followed by industry. EPA believes it is appropriate when conducting risk evaluations under TSCA to evaluate the levels of risk present in baseline scenarios where PPE is not assumed to be used by workers. This approach of not assuming PPE use by workers considers the risk to potentially exposed or susceptible subpopulations (workers and occupational non-users) who may not be covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan. It should be noted that, in some cases, baseline conditions may reflect certain mitigation measures, such as

engineering controls, in instances where exposure estimates are based on monitoring data at facilities that have engineering controls in place.

In addition, EPA believes it is appropriate to evaluate the levels of risk present in scenarios considering applicable OSHA requirements (e.g., chemical-specific permissible exposure limits (PELs) and/or chemical-specific PELs with additional substance-specific standards) as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the Agency. Consistent with this approach, the December 2020 1,4-dioxane risk evaluation (Ref. 2) characterized risk to workers both with and without the use of PPE. By characterizing risks using scenarios that reflect different levels of mitigation, EPA risk evaluations can help inform potential risk management actions by providing information that could be used during risk management to tailor risk mitigation appropriately to address any unreasonable risk identified, or to ensure that applicable OSHA requirements or industry or sector best practices that address the unreasonable risk are required for all potentially exposed or susceptible subpopulations (including self-employed individuals and public sector workers who are not covered by an OSHA State Plan). Similarly, for the occupational exposures assessed as part of the added conditions of use in the 2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation, EPA characterizes risks to workers with and without the use of PPE (Complete risk calculations and results for occupational conditions of use from the 2020 Risk Evaluation and the 2023 Draft Supplement are in the Draft Supplement to the Risk Evaluation for 1,4-Dioxane – Supplemental Information File: Occupational Exposure and Risk Estimates (Ref. 13)).

When undertaking unreasonable risk determinations as part of TSCA risk evaluations, however, EPA does not believe it is appropriate to assume as a general matter that an applicable OSHA requirement or industry practices related to PPE use is consistently and always properly applied. Mitigation scenarios included in the EPA risk evaluation (e.g., scenarios considering use of various PPE) likely represent what is happening already in some facilities. However, the Agency cannot assume that all facilities have adopted these practices for the purposes of making

the TSCA risk determination (Ref. 14).

Therefore, EPA proposes to make a determination of unreasonable risk for 1,4-dioxane 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. Making unreasonable risk determinations based on the baseline scenario should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location, or that there is widespread non-compliance with applicable OSHA standards. Rather, it reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan, or because their employer is out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being "outdated and inadequate for ensuring protection of worker health," (Ref. 15) or because EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements.

In accordance with this approach, EPA is proposing the draft revision to the 1,4-dioxane risk determination without relying on assumptions regarding the occupational use of PPE in making the unreasonable risk determination under TSCA section 6; rather, information on the use of PPE as a means of mitigating risk (including information received from industry respondents about occupational safety practices in use) would be considered during the risk management phase as appropriate. This would represent a change from the approach taken in the 2020 Risk Evaluation for 1,4-dioxane and EPA invites comments on this 2023 draft change to the 1,4-dioxane risk determination. 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 of the hierarchy of controls, when those measures would address an identified unreasonable risk, including unreasonable risk to potentially exposed or susceptible subpopulations. Consistent with TSCA section 9(d), EPA will

consult and coordinate TSCA activities with OSHA and other relevant Federal agencies for the purpose of achieving the maximum applicability of TSCA while avoiding the imposition of duplicative requirements. 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.

Removing the assumption that workers always and appropriately wear PPE in making the whole chemical risk determination for 1,4-dioxane would mean that for the conditions of use evaluated in the 2020 Risk Evaluation, two conditions of use in addition to the original 13 conditions of use would contribute to the unreasonable risk determination for 1,4-dioxane; an additional route of exposure (i.e., inhalation) would also be identified as contributing to the unreasonable risk to workers in five of those 13 conditions of use; and additional risks for acute and chronic non-cancer effects from inhalation exposures would also contribute to the unreasonable risk determination from seven of those 13 conditions of use (where previously those conditions of use were identified as presenting unreasonable risk from inhalation exposures only from cancer). The draft revision to the risk determination would clarify that EPA does not rely on the assumed use of PPE when making the risk determination for the whole substance. EPA is requesting comment on this potential change.

3. *What conditions of use is EPA adding to the 2023 draft revised unreasonable risk determination?*

1,4-Dioxane produced as a byproduct of manufacturing processes can result in occupational exposures in industrial settings and may be present in consumer and commercial products. It also may be released to the environment through direct and indirect industrial and commercial releases. While the 2020 Risk Evaluation considered risks to consumers and

bystanders from 1,4-dioxane present in consumer products due to its production as a byproduct, it did not evaluate other exposures to 1,4-dioxane produced as a byproduct. The 2023 Draft Supplement to the risk evaluation considers occupational, fenceline community, and general population exposures that result from conditions of use where 1,4-dioxane is present, including as a result of production as a byproduct. These exposures include 1,4-dioxane present in drinking water sourced from surface water as a result of direct and indirect industrial releases and down-the-drain releases of consumer and commercial products; 1,4-dioxane present in drinking water sourced from groundwater contaminated as a result of disposals; and 1,4-dioxane released to air from industrial and commercial sources.

The following conditions of use are added to the 2023 Draft Supplement:

• Processing as a byproduct (including polyethylene terephthalate (PET) byproduct and ethoxylation process byproduct);

• Industrial/commercial use: Other uses: Hydraulic fracturing;

• Industrial/commercial use: Arts, crafts, and hobby materials: Textile dye;

• Industrial/commercial use: Automotive care products: Antifreeze;

• Industrial/commercial use: Cleaning and furniture care products: Surface cleaner;

• Industrial/commercial use: Laundry and dishwashing products: Dish soap;

• Industrial/commercial use: Laundry and dishwashing products: Dishwasher detergent;

• Industrial/commercial use: Laundry and dishwashing products: Laundry detergent; and

• Industrial/commercial use: Paints and coatings: Paint and floor lacquer;

For each of these conditions of use, EPA evaluated risks of non-cancer and cancer effects due to acute or chronic inhalation or dermal exposure. For the 2023 draft supplement, EPA relied on the physical and chemical properties information, as well as lifecycle information, environmental fate and transport information, and hazard identification and dose-response analyses presented in the 2020 Risk Evaluation (Ref. 2).

4. *Which exposure pathways are being added to EPA's 2023 revised unreasonable risk*

determination?

The 2020-2021 risk evaluations for several of the first 10 chemicals, including 1,4-dioxane, excluded exposure pathways that were or could be regulated under another EPA-administered statute. For 1,4-dioxane, the air and drinking water exposure pathways were excluded from the 2020 Risk Evaluation and were not assessed. The 2023 Draft Supplement evaluates risks from general population and fenceline community exposures to 1,4-dioxane released to surface and groundwater, air, and land. The risks EPA evaluated to fenceline communities and the general population (using reasonably available monitoring and modeling data for inhalation, dermal, and ingestion exposures) include risks from the conditions of use assessed in the 2020 Risk Evaluation as well as the conditions of use assessed in the 2023 Draft Supplement, including conditions of use where 1,4-dioxane is manufactured, or where it is present due to production as a byproduct. These exposures to 1,4-dioxane include releases to air and water from polyethylene terephthalate (PET) plastic manufacturing, ethoxylation processes, hydraulic fracturing operations, and use of a range of consumer and commercial products.

D. What conclusions is EPA proposing to reach in the 2023 draft revised unreasonable risk determination and on what is EPA seeking public comment?

In the 2020 Risk Evaluation, EPA determined that 1,4-dioxane presents an unreasonable risk to health under the following 13 conditions of use, based on risks to workers:

- Manufacturing (domestic manufacture);
- Manufacturing (import/repackaging);
- Processing: Repackaging;
- Processing: Recycling;
- Processing: Non-incorporative;
- Processing: Processing as a reactant;
- Industrial/commercial use: Intermediate;
- Industrial/commercial use: Processing aid;

• Industrial/commercial use: Laboratory chemicals;

• Industrial/commercial use: Adhesives and sealants;

• Industrial/commercial use: Printing and printing compositions;

• Industrial/commercial use: Dry film lubricant; and

• Disposal.

Under the proposed whole chemical approach to the 1,4-dioxane risk determination, those same conditions of use would continue to contribute to the unreasonable risk from 1,4-dioxane. In addition, by removing the assumption of PPE use in making the whole chemical risk determination for 1,4-dioxane, two conditions of use (in addition to the original 13 conditions of use in the 2020 Risk Evaluation found to contribute to the unreasonable risk) would contribute to the unreasonable risk:

• Industrial/commercial use: Functional fluids (open and closed system): Metalworking fluid, cutting and tapping fluid, polyalkylene glycol fluid; and

• Industrial/commercial use: Other uses: Spray polyurethane foam.

Of the conditions of use that have been added in the 2023 Draft Supplement, EPA has preliminarily determined that the following would contribute to the unreasonable risk determination, based on risks to workers:

• Processing as a byproduct (including polyethylene terephthalate (PET) byproduct and ethoxylation process byproduct);

• Industrial/commercial use: Other uses: Hydraulic fracturing;

• Industrial/commercial use: Arts, crafts, and hobby materials: Textile dye;

• Industrial/commercial use: Laundry and dishwashing products: Dish soap;

• Industrial/commercial use: Laundry and dishwashing products: Dishwasher detergent; and

• Industrial/commercial use: Paints and coatings: Paint and floor lacquer;

Based on the occupational risk estimates and EPA's confidence in them, EPA finds that

the worker exposure to 1,4-dioxane from all but four occupational conditions of use (Ref. 1) contributes to the unreasonable risk from 1,4-dioxane.

In the 2020 Risk Evaluation, EPA evaluated risks to consumers from eight conditions of use and found that they did not present an unreasonable risk to consumers or bystanders. In the 2023 draft revised unreasonable risk determination, EPA does not propose to identify the consumer conditions of use as contributing to the unreasonable risk determination from 1,4-dioxane. However, EPA notes that the generation of 1,4-dioxane as an ethoxylation process byproduct – i.e., the upstream processing of many of these the consumer products - does contribute to the unreasonable risk determination, due to worker risks of cancer and non-cancer effects from inhalation and dermal exposures during those processes and risk to the general population and fenceline communities from exposures to drinking water sourced from surface water contaminated with 1,4-dioxane discharged from industrial facilities.

Regarding ambient air exposures, EPA estimated risks from fenceline community exposures to 1,4-dioxane released to air. Risks were evaluated for air releases from industrial conditions of use, hydraulic fracturing operations, and industrial and institutional laundry facilities. EPA's modeling methodologies, risk estimates, and confidence in those estimates is described in Section 5 of the draft supplemental risk evaluation (Ref. 3). Standard cancer benchmarks used by EPA and other regulatory agencies are an increased cancer risk above benchmarks ranging from 1 in 1,000,000 to 1 in 10,000 (i.e., $1x10^{-6}$ to $1x10^{-4}$) depending on the subpopulation exposed. Based on the risk estimates for cancer, non-cancer acute effects, and non-cancer chronic effects, the fact that the risk estimates are within the applicable benchmark range, and EPA's confidence in the risk estimates, EPA preliminarily finds that fenceline community exposure to 1,4-dioxane in ambient air from releases from industrial conditions of use, including hydraulic fracturing, industrial laundry facilities, and institutional laundry facilities does not contribute to EPA's unreasonable risk determination. More details on EPA's preliminary determination regarding fenceline communities' exposure to 1,4-dioxane in ambient

air is in the 2023 draft revised risk determination (Ref. 1).

Regarding drinking water exposures, in the 2023 Draft Supplement, EPA evaluated oral exposures via ingestion of drinking water sourced from surface water or groundwater contaminated with 1,4-dioxane from facility-specific releases, down-the-drain releases of consumer and commercial products that contain 1,4-dioxane as a byproduct, hydraulic fracturing releases, and leaching from landfills. 1,4-Dioxane is not readily removed through typical wastewater or drinking water treatment processes. Sources of 1,4-dioxane in surface water include direct and indirect industrial releases from COUs where 1,4-dioxane is manufactured, processed, or used, industrial COUs where 1,4-dioxane is present due to production as a byproduct (including PET manufacturing, ethoxylation processes, and hydraulic fracturing operations), and down-the-drain releases of 1,4-dioxane present in consumer and commercial products. EPA considered risks from these sources individually and in aggregate. The relative contribution from different sources varies under different conditions and is likely to be driven by site-specific factors including the amounts released from each source, flow rates of receiving water bodies, and proximity of releases to drinking water intakes. Drinking water exposure and risk estimates for surface water are highly dependent on the amount of 1,4-dioxane released and the flow of the receiving water body. Exposure and risk estimates are also influenced by whether there is a drinking water intake downstream of a release and the degree of dilution that occurs between the point of release and the drinking water intake. Available surface water monitoring datasets are not designed to reflect source water impacts of direct and indirect releases into water bodies. Therefore, EPA estimated concentrations using modeling for a range of specific release scenarios. Similarly, for groundwater, EPA estimated cancer and non-cancer risks for a range of general population and fenceline community exposures to groundwater used as drinking water; sources of 1,4-dioxane in groundwater may include leachate from landfills and disposal of hydraulic fracturing waste.

Based on information in the 2023 Draft Supplement to the risk evaluation, several

conditions of use of 1,4-dioxane could result in exposures to the general population and fenceline communities from 1,4-dioxane in drinking water after it is discharged from facilities engaging in one of several conditions of use. EPA also notes that many of the conditions of use assessed in the 2023 Draft Supplement contribute to more than one exposure pathway. For example, 1,4-dioxane present as a byproduct of PET manufacturing may contribute to occupational exposures during manufacturing as well as exposures to the general population and fenceline communities through releases to water. In addition, for many of the exposure pathways assessed, multiple conditions of use contribute to 1,4-dioxane exposure. For example, many conditions of use can contribute to general population and fenceline communities' exposures to 1,4-dioxane in surface water, including industrial releases from a range of conditions of use and down-the-drain releases of consumer and commercial products.

EPA proposes to include the risks to the general population and fenceline communities from drinking water sourced from surface water contaminated with 1,4-dioxane that is discharged from industrial facilities (including where it is produced as a byproduct) as contributing to the unreasonable risk determination. However, due to the uncertainties described in this Unit, in more detail in section 6.2.4 of the 2023 draft revised unreasonable risk determination, and throughout the 2023 Draft Supplement, EPA has outlined several specific requests for comment regarding this draft risk determination, in this Unit.

As described in the 2023 draft revised unreasonable risk determination, EPA's proposed unreasonable risk determination for 1,4-dioxane as a whole chemical is based on cancer and non-cancer risks to workers from inhalation and dermal exposures, and cancer risks to the general population and fenceline communities from exposures to 1,4-dioxane in drinking water sourced from surface water contaminated by industrial discharges of 1,4-dioxane (including when it is generated as a byproduct). EPA proposes to identify the following conditions of use, from both the 2020 Risk Evaluation and the 2023 Draft Supplement, as contributing to the unreasonable risk from 1,4-dioxane:

• Manufacture (including domestic manufacture and import);

• Processing (including repackaging, recycling, non-incorporative, as a reactant, and as a byproduct);

• Industrial/commercial use: Functional fluids (open and closed system): Metalworking fluid, cutting and tapping fluid, polyalkylene glycol fluid, hydraulic fluid;

• Industrial/commercial use: Intermediate;

• Industrial/commercial use: Processing aid;

• Industrial/commercial use: Laboratory chemicals;

• Industrial/commercial use: Adhesives and sealants;

• Industrial/commercial use: Other uses: Printing and printing compositions;

• Industrial/commercial use: Other uses: Dry film lubricant;

• Industrial/commercial use: Other uses: Spray polyurethane foam;

• Industrial/commercial use: Other uses: Hydraulic fracturing;

• Industrial/commercial use: Arts, crafts, and hobby materials: Textile dye;

• Industrial/commercial use: Laundry and dishwashing products: Dish soap;

• Industrial/commercial use: Laundry and dishwashing products: Dishwasher detergent;

• Industrial/commercial use: Paints and coatings: Paint and floor lacquer; and

• Disposal.

Because the risk estimates for all processing COUs identified and evaluated in the 2020 Risk Evaluation and the 2023 Draft Supplement (including those where 1,4-dioxane is processed as a byproduct) contribute to the unreasonable risk, EPA believes that it is appropriate to conclude that any processing of 1,4-dioxane contributes to the unreasonable risk. This would include circumstances described but not necessarily individually quantified in the 2020 Risk Evaluation or the 2023 Draft Supplement, such as when 1,4-dioxane is generated as a byproduct during sulfonation, sulfation, and esterification processes. EPA also emphasizes that this determination identifies any manufacturing, processing, or disposal of 1,4-dioxane – including as

a byproduct – as contributing to the unreasonable risk if the 1,4-dioxane contaminates surface water that is the source of drinking water.

EPA is seeking public comment for certain considerations for determining unreasonable risk to the general population or fenceline communities from 1,4-dioxane in drinking water. EPA notes that the agency has preliminarily determined that the worker risks identified provide sufficient basis for the determination that 1,4-dioxane as a whole chemical presents unreasonable risk. Nonetheless, for the purposes of transparency, clear public communication on unreasonable risk, and to inform future risk management activities, EPA is seeking comment on the following:

• *Industrial discharges of 1,4-dioxane to surface water.* EPA is able to provide risk estimates for drinking water contaminated with 1,4-dioxane from surface water discharges from some facility-specific releases of 1,4-dioxane, including from some facilities that manufacture, process, or use 1,4-dioxane (including as a byproduct). Several high-end risk estimates exceed the range of applicable benchmarks for increased cancer risk (i.e., $1x10^{-4}$ to $1x10^{-6}$), and EPA has higher confidence in the facility-specific risk estimates for discharges to surface water compared to other drinking water risk estimates (i.e., groundwater, down-the-drain releases from commercial and consumer products). In general, the aggregate analysis for drinking water sourced from surface water indicates that the high-end risk analysis may be driven primarily by high-end industrial releases, under certain conditions. EPA has preliminarily determined that exposures to surface water containing 1,4-dioxane from industrial discharges contribute to the unreasonable risk.

EPA seeks comment on whether EPA's evaluation of facilities that discharge 1,4-dioxane in processes that manufacture 1,4-dioxane or generate 1,4-dioxane as a byproduct (e.g., PET manufacturing, and ethoxylation processes), can reasonably be assumed to represent the spectrum of facilities or sectors producing 1,4-dioxane as a byproduct for the purposes of risk determination and, if necessary, any risk management action.

Because multiple sources may contribute to 1,4-dioxane concentrations in drinking water

sourced from surface water in a single location, EPA estimated aggregate general population exposures and risks that could occur from combined contributions from multiple sources. EPA seeks comment on whether an unreasonable risk determination is supported in instances where EPA is unable to attribute exposures to specific COUs as specific sources of risk, but rather is able to attribute exposures to sources of the chemical covering many COUs as an aggregate contributor to unreasonable risk.

• *Down-the-drain releases of 1,4-dioxane from consumer and commercial products.* EPA evaluated the potential contribution of down-the-drain releases of consumer and commercial products that contain 1,4-dioxane as a byproduct to drinking water exposure and risk. EPA's drinking water exposure estimates correspond to surface water concentrations estimated by probabilistic modeling of down-the-drain releases under varying population sizes and stream flows. With some combinations of factors, exposures to down-the-drain releases of 1,4-dioxane in drinking water alone result in increased cancer risks within EPA's benchmark range of $1x10^{-6}$ to $1x10^{-4}$ in some instances. Assuming no dilution between the point of release and the drinking water intake, the estimated risks range from 2.04×10^{-11} to 6.11×10^{-5} with the risks increasing as population increases and stream flow decreases. Based on the conservative analysis of no assumed dilution, confidence in risk estimates, and consideration of uncertainties, EPA has preliminarily determined that down-the-drain releases of 1,4-dioxane do not contribute to the unreasonable risk determination.

EPA seeks comment regarding to what extent factors such as stream flow and population size should be factored into the unreasonable risk determination, or whether consideration of those factors is more appropriate for the risk management stage.

EPA seeks comment on its draft determination that down-the-drain releases of 1,4-dioxane do not contribute to the unreasonable risk determination due to the uncertainties identified in the risk characterization regarding consumer and commercial products that contain 1,4-dioxane as a byproduct (i.e., soaps, dishwashing detergents, and laundry detergent).

• *Groundwater and potential 1,4-dioxane exposure in drinking water.* EPA estimated risks from exposures that could occur if groundwater containing 1,4-dioxane is used as a source of drinking water. These risk estimates are not tied to known releases at specific locations. Rather, the analysis defines the conditions under which 1,4-dioxane disposal to landfills or from hydraulic fracturing operations could result in varying levels of risk from groundwater concentrations of 1,4-dioxane. EPA's drinking water exposure scenario relies on the assumption that modeled groundwater concentrations reflect the actual groundwater concentrations that occur at well locations. While the modeling methodology is robust and the release information relied on as model input data is supported by moderate evidence, no monitoring data are available to confirm detection of 1,4-dioxane in groundwater, specifically near hydraulic fracturing operations. EPA has preliminarily determined that groundwater containing 1,4-dioxane does not contribute to the unreasonable risk determination. EPA seeks comment on its draft determination that groundwater exposures from 1,4-dioxane do not contribute to the unreasonable risk determination due to the uncertainties identified in the risk characterization regarding releases of 1,4-dioxane from landfill leachate and hydraulic fracturing operations.

• *Determination of general population and fenceline community risks.* As described in the 2023 Draft Supplement (Ref. 3), fenceline communities are members of the general population that are in proximity to air-emitting facilities or a receiving waterbody, and who therefore may be disproportionately exposed to a chemical undergoing risk evaluation under TSCA section 6. For the air pathway, proximity goes out to 10,000 meters from an air emitting source. For the water pathway, proximity does not refer to a specific distance measured from a receiving waterbody, but rather to those members of the general population that may interact with the receiving waterbody and thus may be exposed. EPA seeks comment, for the purposes of drinking water, on what parameters EPA should consider in identifying whether exposures to the general populations contribute to an unreasonable risk determination. Specifically, EPA seeks comment on whether and how to incorporate exposures to the general population from multiple sources

that cannot be attributed to COUs, is dependent on site-specific circumstances, variable across the country, or dependent on stream flow, population size, or population density. EPA also seeks comment on whether other parameters should be considered, and, if so, how they should be incorporated.

As noted in Unit II.C.1., EPA is also seeking comment on the draft superseding unreasonable risk determination for 1,4-dioxane, including a description of the risks that contribute to the unreasonable risk determination under the conditions of use for the chemical substance as a whole. Additionally, as noted in Unit II.C.2, EPA is also seeking comment on EPA's 2023 draft revision to the 1,4-dioxane risk determination without relying on assumptions regarding the occupational use of PPE in making the unreasonable risk determination under TSCA section 6.

III. Revision of the December 2020 Risk Evaluation

A. Why is EPA proposing to revise the risk determination for the 1,4-dioxane risk evaluation?

EPA is proposing to revise the risk determination for the 1,4-dioxane risk evaluation pursuant to TSCA section 6(b) and consistent with Executive Order 13990, ("Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis") and other Administration priorities (Refs. 4, 5, and 7). EPA is revising specific aspects of the first ten TSCA existing chemical risk evaluations in order to ensure that the risk evaluations better align with TSCA's objective of protecting health and the environment.

For the 1,4-dioxane risk evaluation, this includes the draft revisions: (1) making the risk determination in this instance based on the whole chemical substance instead of by individual conditions of use, (2) emphasizing that EPA does not rely on the assumed use of PPE when making the risk determination and identifying which conditions of use in the 2020 Risk Evaluation would contribute to the unreasonable risk determination based on worker exposure without assuming use of PPE, (3) identifying which of the additional conditions evaluated in the 2023 Draft Supplement contribute to the unreasonable risk determination based on worker

exposure, and (4) proposing that the risks to fenceline communities from exposure to 1,4-dioxane in drinking water sourced from surface water contaminated by industrial discharges of 1,4-dioxane (including when it is generated as a byproduct) and (5) seeking public comment on several issues, as listed in Unit II.D.

B. What are the draft revisions?

EPA is releasing a draft revision of the risk determination for the 1,4-dioxane risk evaluation pursuant to TSCA section 6(b). Under the revised determination, EPA proposes to conclude that 1,4-dioxane, as evaluated in the risk evaluation as a whole, presents an unreasonable risk of injury to health under its conditions of use. This revision would replace the previous unreasonable risk determinations made for 1,4-dioxane by individual conditions of use, supersede the determinations (and withdraw the associated order) of no unreasonable risk for the conditions of use identified in the TSCA section 6(i)(1) no unreasonable risk order, clarify the lack of reliance on assumed use of PPE as part of the risk determination, and incorporate information (including the addition of conditions of use and exposure pathways) assessed in the 2023 Draft Supplement to the Risk Evaluation for 1,4-Dioxane.

These draft revisions do not alter any of the underlying technical or scientific information that informs the risk characterization in the 2020 Risk Evaluation, and as such the hazard, exposure, and risk characterization sections in the 2020 Risk Evaluation are not changed except to the extent that statements about PPE assumptions in the executive summary and including sections 4.2.2.6 (Occupational Risk Estimation for Cancer Effects), 4.6.2.1 (Summary of Risk for Workers and ONUs), and section 5.1.1.3 (Determining Unreasonable Risk of Injury to Health) of the 1,4-dioxane risk evaluation would be superseded and the 2023 draft risk determination also reflects the 2023 supplemental risk evaluation. The discussion of the issues in this notice and in the accompanying draft revision to the risk determination would supersede any conflicting statements in the prior executive summary, including sections 4.2.2.6, 4.6.2.1, and section 5.1.1.3 from the 1,4-dioxane risk evaluation and the response to comments document

(Refs. 2 and 11).

C. Will the draft revised risk determination be peer reviewed?

The risk determination (section 5 in the December 2020 Risk Evaluation) was not part of the scope of the peer review of the 1,4-dioxane risk evaluation by the SACC. Thus, consistent with that approach, EPA is not seeking peer review of the 2023 draft revised unreasonable risk determination for the 1,4-dioxane risk evaluation. EPA is, however, seeking peer review as well as public comment on the 2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation, as described in a separate ***Federal Register*** notice (88 FR 43562, July 10, 2023) (FRL-10798-02-OCSPP). EPA will consider changes made to the risk evaluation in response to peer review and public comment on that supplement when developing the final risk determination.

D. What are the next steps for finalizing revisions to the risk determination?

EPA will review and consider public comment received on the draft revised risk determination for the 1,4-dioxane risk evaluation and will review and consider public comment and peer review on the 2023 Draft Supplement to the 1,4-Dioxane Risk Evaluation. After considering those public comments, EPA will issue the revised final 1,4-dioxane risk determination. If finalized as drafted, EPA would also issue a new order to withdraw the TSCA section 6(i)(1) no unreasonable risk order issued in Section 5.4.1 of the 2020 1,4-dioxane risk evaluation. This final revised risk determination would supersede the December 2020 risk determinations of no unreasonable risk. Consistent with the statutory requirements of TSCA, EPA would initiate risk management for 1,4-dioxane either by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that 1,4-dioxane no longer presents an unreasonable risk or determining pursuant to TSCA sections 9(a) and/or 9(b) that other Federal laws can eliminate or reduce to a sufficient extent the unreasonable risk.

IV. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA,

including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

1. EPA Draft Revised Unreasonable Risk Determination for 1,4-Dioxane, July 2023.

2. EPA. Risk Evaluation for 1,4-Dioxane. December 2020. EPA Document #EPA-740-R1-8007. *https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0238-0092.*

3. EPA. Draft Supplemental Risk Evaluation for 1,4-Dioxane. July 2023. EPA Document #EPA-740-D-23-001. *https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0905-0027.*

4. Executive Order 13990. Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. *Federal Register.* 86 FR 7037, January 25, 2021.

5. Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. *Federal Register.* 86 FR 7009, January 25, 2021.

6. Executive Order 14008. Tackling the Climate Crisis at Home and Abroad. *Federal Register.* 86 FR 7619, February 1, 2021.

7. Presidential Memorandum. Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking. *Federal Register.* 86 FR 8845, February 10, 2021.

8. EPA Press Release. EPA Announces Path Forward for TSCA Chemical Risk Evaluations. June 2021. *https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations*.

9. EPA. Proposed Rule; Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act. *Federal Register.* 82 FR 7562, January 19, 2017 (FRL-9957-75).

10. EPA. Final Rule; Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act. *Federal Register.* 82 FR 33726, July 20, 2017 (FRL-9964-38).

11. EPA. Summary of External Peer Review and Public Comments and Disposition for 1,4-Dioxane. December 2020. *https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0238-0093.*

12. EPA. Correction of Dermal Acute and Chronic Non-Cancer Hazard Values Used to Evaluate Risks from Occupational Exposures in the Final Risk Evaluation for 1,4-dioxane. June 26, 2023.

13. EPA. Draft Supplement to the Risk Evaluation for 1,4-Dioxane – Supplemental Information File: Occupational Exposure and Risk Estimates. July 2023.

14. Occupational Safety and Health Administration (OSHA). Top 10 Most Frequently Cited Standards for Fiscal Year 2021 (Oct. 1, 2020, to Sept. 30, 2021). Accessed October 13, 2022. *https://www.osha.gov/top10citedstandards*.

15. Occupational Safety and Health Administration. Permissible Exposure Limits – Annotated Tables. Accessed June 13, 2022. *https://www.osha.gov/annotated-pels*.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: July 21, 2023.

Michal Freedhoff,

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