WASHINGTON, D.C. 20460

November 5, 2024

MEMORANDUM

SUBJECT: Coordinated Risk Management Action on 1,4-Dioxane under Section 9(b) of the *Toxic Substances Control Act*

FROM: Michal I. Freedhoff, Assistant Administrator
Office of Chemical Safety and Pollution Prevention

MICHAL FREEDHOFF Digitally signed by MICHAL FREEDHOFF Date: 2024.11.06 16:22:40 -05'00'

Bruno Pigott, Principal Deputy Assistant Administrator
Office of Water

Bruno Pigott Digitally signed by Bruno Pigott Date: 2024.11.06 16:06:57 -05'00'

TO: Michael S. Regan
Administrator

PURPOSE

The purpose of this memorandum is to document coordinated action within the U.S. Environmental Protection Agency to address unreasonable risk associated with 1,4-dioxane pursuant to Section 9(b) of the *Toxic Substances Control Act*, and to document agreement between the Office of Chemical Safety and Pollution Prevention and the Office of Water on next steps to ensure sufficient protection against such risks.

OCSPP conducted a risk evaluation for 1,4-dioxane under TSCA and determined that the chemical substance presents an unreasonable risk to human health under the conditions of use.[1] Among other exposures and risks, OCSPP found that 1,4-dioxane presents risk to the general population via drinking water sourced from surface water contaminated with 1,4-dioxane. TSCA section 6(a) requires the EPA to impose one or more of its risk management requirements, to the extent necessary, so this chemical no longer presents an unreasonable risk. TSCA section 9(b) requires the EPA to coordinate TSCA actions with actions taken under other agency authorities. In coordinating regulatory action under TSCA with other offices at the EPA, the agency considered the authorities of the *Safe Drinking Water Act* and has determined that, in addition to TSCA, certain regulatory actions under the SDWA may be appropriate for 1,4-dioxane. Therefore, as described in more detail below and consistent with TSCA Section 9(b)(1), OCSPP and OW are memorializing this agreement for coordinated action on risks from 1,4-dioxane contamination in drinking water through actions under both OCSPP TSCA Section 6(a) and OW consideration of remaining risks and appropriate action under SDWA.

[1] Includes conclusions from the 2020 Risk Evaluation and the 2024 Supplement to the 2020 Risk Evaluation for 1,4-Dioxane.

COORDINATED ACTION ON UNREASONABLE RISK

The EPA determined in its risk evaluation, that 1,4-dioxane presents unreasonable risk based on cancer and non-cancer risks to workers from inhalation and dermal exposures, and cancer risks to fenceline communities and the general population from exposures to drinking water contaminated with 1,4-dioxane.

As part of this determination, OCSPP also determined that manufacturing, processing, commercial use, and disposal of 1,4-dioxane (including as a byproduct) significantly contribute to the unreasonable risk, namely to workers. Additionally, OCSPP found that the risk to the general population, including fenceline communities, significantly contributed to the determination of unreasonable risk of 1,4-dioxane. This risk to the general population comes from exposure to drinking water sourced from surface water contaminated both by industrial discharges of 1,4-dioxane and down-the-drain releases of products that contain 1,4-dioxane (generated as an unintentional byproduct). As required under TSCA, OCSPP must apply requirements of TSCA Section 6(a) in a rule to address the unreasonable risk posed by 1,4-dioxane.

Occupational Risks

OCSPP and OW agree that TSCA is the most appropriate regulatory authority to prevent or reduce risks of 1,4-dioxane to a sufficient extent to protect workers from 1,4-dioxane exposure. TSCA explicitly requires OCSPP to assess the risk to potentially exposed or susceptible subpopulations, and the law lists workers as an example that the EPA might identify as potentially exposed or susceptible subpopulations in a particular action. Since the EPA determined for 1,4-dioxane that the risk to workers contributes to the unreasonable risk finding, TSCA requires regulatory protections to address the unreasonable risk to this potentially exposed or susceptible subpopulations. OCSPP expects to apply requirements under TSCA Section 6(a) to the extent necessary to address the unreasonable risk to workers within industrial and commercial facilities that manufacture, process, use, and/or dispose of 1,4-dioxane. Requirements designed to protect workers may have the incidental benefit of limiting environmental releases, and as discussed in this memo, would thus also protect the general population.

General Population Risks

Relevant to general population risks associated with 1,4-dioxane in drinking water, OCSPP and OW have determined that the risk to human health associated with 1,4-dioxane exposure via drinking water sourced from surface water contaminated with industrial discharges and down-the-drain releases of products containing 1,4-dioxane are best managed by coordinating actions under both TSCA and SDWA.

Under TSCA, OCSPP 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. Under TSCA Section 6(a) these restrictions may include one or a combination of the following:

- Prohibit or otherwise restrict, or limit the manufacture, processing or distribution in commerce of the substance or mixture;

- Prohibit or otherwise restrict, or limit the manufacture, processing, or distribution in commerce of the substance or mixture for a particular use or above a set concentration for a particular use;
- Require adequate minimum warnings and instructions with respect to its use, distribution in commerce, or disposal;
- Require recordkeeping, monitoring, or testing by manufacturers and processors;
- Prohibit or regulate manner or method of commercial use;
- Prohibit or regulate manner or method of disposal; and/or
- Direct manufacturers/processors to give notice of the determination of risk to distributors and users and replace or repurchase.

The EPA expects that these TSCA requirements will significantly reduce the discharge and release of 1,4-dioxane to surface water, thereby reducing potential risks for the general population from exposure from drinking water. However, OCSPP recognizes that any actions taken under TSCA may not fully eliminate industrial discharges or down-the-drain releases of 1,4-dioxane to surface water, and that other non-industrial 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 the exclusions from the definition of "chemical substance."

As such, OW has committed that any remaining risks following the promulgation and implementation of TSCA regulations will be reviewed by OW under SDWA authorities. These actions may include, but are not limited to: collecting occurrence information under the Unregulated Contaminant Monitoring Rule program, keeping 1,4-dioxane on future Contaminant Candidate Lists, and considering it for future regulatory determinations. Specifically, OW may undertake a review of including 1,4-dioxane as a contaminant for monitoring in the Unregulated Contaminant Monitoring Rule cycle that follows full implementation of the TSCA regulations. As part of the SDWA regulatory development process, the results of Unregulated Contaminant Monitoring Rule monitoring data, along with other data and information, are used in regulatory determination under SDWA to determine whether there would be meaningful opportunity for health risk reduction for persons served by public water systems by regulating the contaminant in drinking water.

CONSIDERATIONS FOR A REGULATORY APPROACH

TSCA Section 9(b) directs the EPA to coordinate actions to manage chemical risks under TSCA with actions taken under other federal laws administered in whole or in part by the EPA. In considering this coordinated response to address the unreasonable risk from 1,4-dioxane to the general population via drinking water, OCSPP and OW examined the authorities afforded to the agency under TSCA and SDWA, including efficiencies of different regulatory approaches.

1. Timing Associated with Regulatory Approaches: Following a finding of unreasonable risk from a TSCA risk evaluation, OCSPP must within one year propose, and one additional year finalize, risk management actions that eliminate the unreasonable risk using the TSCA Section 6(a) authorities. The compliance date of any regulation must be as soon as practicable but generally not later than

five years after the date of promulgation of the rule. Subsequent implementation of TSCA regulatory provisions could take additional time.

Under Section 1412(b)(1)(A) of SDWA, the EPA must regulate a contaminant in drinking water if the Administrator determines that: (i) the contaminant may have an adverse effect on the health of persons; (ii) the contaminant is known to occur or there is substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and (iii) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

SDWA Section 1412(b)(1)(B)(ii)(II) requires that the EPA include consideration of the data collected by the Unregulated Contaminant Monitoring Rule program in making regulatory determinations. The EPA then bases the regulatory determination for a contaminant, in part, on the Unregulated Contaminant Monitoring Rule monitoring data indicating whether the contaminant is occurring at levels of public health concern. The Unregulated Contaminant Monitoring Rule sampling is limited by statute to no more than 30 contaminants every five years (SDWA Section 1445(a)(2)).

If the EPA determines that all three of the statutory criteria for regulatory determination are met and makes a final determination to regulate a contaminant (i.e., a positive determination), the agency must publish a proposed Maximum Contaminant Level Goal[2] and National Primary Drinking Water Regulation[3] within 24 months. (SDWA Section 1412(b)(1)(E)). After a proposal, the agency must publish a final Maximum Contaminant Level Goal and promulgate a final National Primary Drinking Water Regulation within 18 months.[4] (SDWA Section 1412(b)(1)(E)). The Administrator, by notice in the *Federal Register*, may extend the timeframe for such final rule promulgation by up to nine months. The EPA may also develop regulatory determinations and associated rulemakings outside of this process.

Under TSCA, OCSPP would expect to promulgate a final rule to address the unreasonable risk of 1,4-dioxane in 2026, with an effective date as soon as practicable following promulgation, and implementation to occur shortly thereafter.

2. Regulated Entity: TSCA's authority allows the agency to impose restrictions on industrial releases to water, requiring chemical manufacturers, processors, and/or commercial users to comply with specific standards. In the TSCA risk evaluation, the EPA has identified the conditions of use and associated industries that significantly contribute to the unreasonable risk determination. Imposing a TSCA requirement to reduce the risk from industrial sources is expected to ultimately

[2] A Maximum Contaminant Level Goal is the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, and which allows an adequate margin of safety. Maximum Contaminant Level Goals are non-enforceable health goals. (40 C.F.R. 141.2; 42 U.S.C. 300g-1).

[3] A National Primary Drinking Water Regulation is a legally enforceable standard that applies to public water systems. A National Primary Drinking Water Regulation sets a legal limit (called a maximum contaminant level) or specifies a certain treatment technique for public water systems for a specific contaminant or group of contaminants. The maximum contaminant level is the highest level of a contaminant that is allowed in drinking water and is set as close to the Maximum Contaminant Level Goal as feasible using the best available treatment technology and taking cost into consideration.

[4] SDWA authorizes a nine-month extension of this promulgation date.

reduce the concentration of 1,4-dioxane in surface water prior to this water source being treated at drinking water facilities.

Under SDWA, the EPA sets standards for drinking water quality nationwide through regulations, National Primary Drinking Water Regulations, that apply to "public water systems."[5] These standards are enforced by the EPA and states that are approved by the EPA to implement the federal program. Following the final promulgation of National Primary Drinking Water Regulations, public water systems must generally comply with the requirements of the rule and implement solutions to reduce the contaminant levels to below the drinking water standard within three years (subject to the possibility of a two-year extension if additional time is deemed necessary for capital improvements).

Using TSCA authorities to reduce the chemical's concentration from the source is expected to be a timelier and more efficient mitigation of risk for the general population than actions by drinking water authorities and associated municipalities. Additionally, under TSCA, the EPA can focus any risk management efforts on those chemical industries where risks have specifically been identified.

3. Federal Implementation and Enforcement: Restrictions imposed under TSCA are federally implemented and enforced. Once any restrictions on industrial releases of 1,4-dioxane under TSCA are promulgated, TSCA Section 18's preemption provisions apply. The restrictions and TSCA preemption can ensure nationwide predictability and consistency for the regulated community and thus prevent a patchwork of differing state laws and regulations on 1,4-dioxane, though some exceptions to TSCA preemption may apply (i.e., TSCA Sections 18(d), (e), (f)).

   Several states have already begun reviewing possible risk management options to protect the general public from drinking water risks of 1,4-dioxane. For example: New York state has implemented restrictions related to the concentration of 1,4-dioxane in household cleaning and personal care products,[6] established a drinking water standard, and provided water quality guidance value for surface water. North Carolina passed legislation in 2023 that required the state's Department of Environmental Quality to conduct a risk assessment and prepare a review of treatment technologies, and there are efforts toward implementing industrial discharge reductions for 1,4-dioxane.[7] California is investigating approaches to 1,4-dioxane concentrations in products as well as drinking water notification levels.[8] Additionally, there are a number of other states that have set or in the process of setting drinking water guidelines, action levels, or clean up levels for 1,4-dioxane. In establishing risk management options under TSCA, the EPA will review and consider existing and anticipated state efforts, as appropriate.

[5] A public water system provides water for human consumption through pipes or other constructed conveyances to at least 15 service connections or serves an average of at least 25 people for at least 60 days a year. A public water system may be publicly or privately owned.

[6] The New York State Legislature amendments to Environmental Conservation Law Article 35 and Article 37.

[7] General Assembly of North Carolina, Session 2023. Session Law 2023-137. House Bill 600. An Act to Provide Further Regulatory Relief to Citizens of North Carolina.

[8] The state of California has an established a drinking water notification level, as well as certain requirements and recommendations applicable to drinking water notification levels.

SDWA established a federal-state arrangement in which states may be approved to be the primary authority for implementation and enforcement (i.e., primacy) for the drinking water program. SDWA requires the EPA to establish and enforce standards that "public water systems" must follow, including maximum contaminant levels or treatment techniques and monitoring and reporting requirements. The EPA approves states and Indian Tribes to be the primary implementation authority for these standards under state law if they meet certain requirements. Any future National Primary Drinking Water Regulation would require states and Tribes to apply to obtain primacy implementation and enforcement authority within two years of the promulgation of the regulation. To obtain primacy states must adopt regulations that are no less stringent than the National Primary Drinking Water Regulation. In the case of 1,4-dioxane, there is no current National Primary Drinking Water Regulation, therefore states may determine whether to regulate this contaminant in drinking water independently. If there is a National Primary Drinking Water Regulation promulgated for a contaminant under the SDWA, public water systems must generally comply with the requirements of the rule and implement solutions to reduce the contaminant levels to below the drinking water standard within three years.

Restrictions imposed under TSCA are federally implemented and enforced and would bring regulatory certainty and nation-wide protection.

4. Remaining Risk: Regulatory options available under TSCA can require the regulated entity (manufacturers and processors) to conduct recordkeeping, monitoring, or testing. This information may be used to show compliance and inform any enforcement action(s). However, the EPA is not required under TSCA to re-assess risks following implementation of regulatory restrictions under TSCA Section 6(a), or to conduct any type of review to confirm the effectiveness of its regulatory approach.

   Using SDWA authorities, OW collected occurrence information under Unregulated Contaminant Monitoring Rule 3 (sampling between 2013 and 2015) for 1,4-dioxane and may conduct additional monitoring of finished drinking water in the future under the Unregulated Contaminant Monitoring Rule following implementation of the TSCA risk mitigation requirements. As such, OW is uniquely positioned to assess the effectiveness of regulatory restrictions on industrial releases in reducing the overall presence of 1,4-dioxane by comparing 1,4-dioxane occurrence in drinking water before and after the TSCA risk mitigation requirements are in place. This information is expected to inform future Contaminant Candidate Lists, regulatory determinations, and development of drinking water regulations, if appropriate.

   The EPA will consider any information collected under TSCA authorities as part of Section 6(a) regulatory action and any additional data, including from subsequent Unregulated Contaminant Monitoring Rule' collection activities, to assess any remaining risk from 1,4-dioxane exposure via drinking water. OW expects to undertake a review of appropriate next steps as part of the Unregulated Contaminant Monitoring Rule cycle that follows full implementation of the TSCA regulations.

5. Additional Regulatory Protections: TSCA authority is limited to address a "chemical substance," as defined in the law to specifically exclude certain types of chemicals (e.g., when manufactured, processed, or distributed for use as a pesticide, food, drug, etc.). OCSPP lacks authority to directly

address risks from uses of a chemical falling outside of TSCA's jurisdiction (e.g., use of 1,4-dioxane in personal care products regulated under the *Federal Food, Drug, and Cosmetic Act*). As such, regulatory actions under TSCA to limit down-the-drain releases or discharges would not be applicable to these particular sources. The information collected under SDWA through the future Unregulated Contaminant Monitoring Rule, for example, would measure the concentration of 1,4-dioxane in finished drinking water, effectively capturing all sources of contaminants post treatment at the public water system. If determined to be necessary following implementation of TSCA regulations, any future regulatory determination and potential National Primary Drinking Water Regulation would be developed in accordance with SDWA to address any remaining 1,4-dioxane risk irrespective of the source.

OCSPP and OW conclude that SDWA is the most appropriate regulatory authority able to monitor 1,4-dioxane concentrations in finished drinking water following implementation of TSCA requirements, and if 1,4-dioxane is, at that time, occurring at frequency and levels of public health concern and meets all three of the SDWA criteria for regulatory determination, including that regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems, in the sole judgement of the Administrator, the EPA could make a positive determination and initiate a rulemaking to impose restrictions to further reduce exposure that would not otherwise be addressed under TSCA authorities.

CONCLUSION

In the risk evaluation for 1,4-dioxane, the EPA determined that the chemical substance presents unreasonable risk based on cancer and non-cancer risks (from liver toxicity and effects in the olfactory epithelium) to workers from inhalation and dermal exposures, and cancer risks to fenceline communities and the general population from exposures to 1,4-dioxane from drinking water. OCSPP found risk to the general population from exposure to drinking water sourced from surface water contaminated with industrial discharges of 1,4-dioxane and down-the-drain releases of products that contain 1,4-dioxane that is generated as an unintentional byproduct.

TSCA requires regulatory protections to address this risk and requires coordination with the EPA's other federally administered authorities. OCSPP and OW agree that TSCA is the appropriate regulatory authority to address the risk to human health associated with 1,4-dioxane to workers and the general population exposure via drinking water sourced from surface water contaminated with industrial discharges and down-the-drain releases of products containing 1,4-dioxane.OCSPP and OW further concluded that any remaining risk after the implementation of the TSCA regulatory protections would be best managed by SDWA.