

EPA RISK EVALUATION FOR 1,4-DIOXANE

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On November 14, 2024, the U.S. Environmental Protection Agency (“EPA”) determined that 1,4-dioxane presents an unreasonable risk of injury to human health under its conditions of use. This determination now requires that EPA to propose risk management regulations under section 6(a) of the Toxic Substances Control Act (“TSCA”) to eliminate the unreasonable risk.

This risk determination applies to many entities, including those that manufacture, import, process, distribute, use, and dispose of 1,4-dioxane particularly for use as a solvent or chemical stabilizer.

This unreasonable risk determination is expected to lead to restrictions, which could include regulation of the manufacturing, processing, distribution, or disposal of 1,4-dioxane, and could lead to additional notification or recordkeeping requirements. The unreasonable risk determination may also affect the implementation of remedy selection decisions at sites contaminated with 1,4-dioxane.

WHAT IS 1,4-DIOXANE?

1,4-Dioxane is used as a solvent in many commercial and industrial applications, such as in the manufacture of chemicals, as a processing aid, or as a laboratory chemical. 1,4-Dioxane can also be used in adhesives, sealants, spray polyurethane foam, and printing inks.

Products containing 1,4-dioxane can contaminate surface water when disposed using the storm or drainage system. Additionally, 1,4-dioxane is produced as a byproduct through several manufacturing processes. 1,4-Dioxane can be found in certain dish soaps, cleaning products, paints, and laundry detergents. Although there are no direct consumer uses of 1,4-dioxane, it is present as a contaminant in commercial and consumer products.

HISTORY OF 1,4-DIOXANE ACTIONS

Below is a summary of the actions that EPA has taken prior to 2024 with respect to 1,4-Dioxane, primarily under TSCA.

- 2016. Designated 1,4-Dioxane for a risk evaluation along with nine other chemical substances.

- [2020](#). Published a supplemental analysis to the draft TSCA Risk Evaluation for 1,4-Dioxane.
- [2021](#). Investigated new pathway exposures, such as drinking water or ambient air.
- [2023](#). Published a draft revision to the TSCA Risk Evaluation for 1,4-Dioxane.

The [2024 final unreasonable risk determination](#) supersedes the risk conclusions expressed previously in these documents.

COMPONENTS OF THE 1,4-DIOXANE UNREASONABLE RISK DETERMINATION

EPA states that its [final risk determination](#) is based on cancer and non-cancer risks to workers and occupational non-users, including liver toxicity, inhalation, dermal (skin) exposure, and drinking water contaminated from surface water sources. According to [EPA](#), the future rulemaking to address these risks “may regulate upstream activities (e.g., processing, distribution in commerce) to address downstream activities (e.g., consumer uses) contributing significantly to unreasonable risk, even if the upstream activities do not contribute significantly to the unreasonable risk.” Moreover, [EPA asserts](#) that “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) and down-the-drain disposals of commercial and consumer products that are contaminated with 1,4-dioxane significantly contribute to the unreasonable risk from 1,4-dioxane.”

[EPA determined](#) that 22 industrial and commercial conditions of use “significantly contribute to the unreasonable risk to workers,” including:

- Manufacturing (including domestic manufacture and import);
- Processing (such as repackaging and recycling, both as a byproduct and reactant);
- Commercial and consumer applications in processing aids, metalworking fluids, adhesives, sealants, paints and coatings, and cleaning products; and
- Laboratory use as a solvent.

By contrast, [EPA determined](#) that distribution in commerce and consumer use of certain products containing 1,4-dioxane did not contribute to the unreasonable risk determination.

For additional information, EPA created a website entitled “[Risk Management for 1,4-Dioxane](#).”

POTENTIAL CONSEQUENCES

At present, EPA is required to proceed with developing regulations to eliminate the unreasonable risks that EPA has determined to be presented by 1,4-dioxane. Industry has been quick to react, with

trade groups such as the [American Cleaning Institute](#) objecting to this evaluation, stating on behalf of its members that, among other things, the EPA determination “does not fully reflect the best available science.” Industry influence may help to shape the forthcoming regulations, and further public comment will be required in conjunction with EPA’s risk management rulemaking.

As noted above, EPA’s anticipated rules following an unreasonable risk determination under TSCA will be “upstream” to restrict manufacturing, processing, distribution, or disposal activities or otherwise impose notification or recordkeeping requirements. Further, EPA’s unreasonable risk determination may cause renewed focus within investigation and remediation activities pursuant to other federal or state environmental laws, such as CERCLA or drinking water standards. BCLP further expects that the incoming federal administration may scrutinize this risk assessment prior to issuing any proposed risk management rules, anticipated in the fall of 2025 subject to any change as a result of the incoming change in administration.

CONCLUSION

Additional information with respect to the forthcoming regulations concerning 1,4-dioxane is expected in 2025. BCLP is monitoring these changes.

If you have any questions regarding 1,4-Dioxane or the 2024 final risk evaluation or other applicable regulations, please contact [Phil Karmel](#), [Erin Brooks](#), or [John Kindschuh](#).

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