

Background on Risk Evaluation Under the Toxic Substances Control Act (TSCA): 1,4-Dioxane

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In 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA; [P.L. 114-182](#)) amended Title I of the Toxic Substances Control Act (TSCA; [15 U.S.C. §2601 et seq.](#)) to direct the U.S. Environmental Protection Agency (EPA) to systematically prioritize chemicals for risk evaluation. (For more information, see CRS Report R45149, [Title I of the Toxic Substances Control Act \(TSCA\): A Summary of the Statute.](#)) The purpose of the risk evaluations is to determine whether particular chemicals warrant regulation in terms of the risks associated with their manufacture, processing, distribution, use, or disposal. If EPA identifies “unreasonable” risk to human health or the environment associated with one or more of the elements of a chemical’s lifecycle, TSCA Section 6 directs EPA to promulgate a rule to mitigate those risks. TSCA Section 9 limits EPA’s authority to regulate a chemical under TSCA if another law may be used to regulate a chemical for the unreasonable risk identified by the agency.

As amended, TSCA Section 6 directed EPA to select 10 chemicals for risk evaluation from [a list of 90 chemicals that the agency identified in 2014](#) as warranting risk assessment. EPA based this list on a screening of 345 chemicals for potential hazard and exposure, and persistence and bioaccumulation characteristics. With more than 86,000 chemicals on the [TSCA Inventory](#), EPA’s screening approach was intended to focus the agency’s resources and attention on a select group of chemicals for which sufficient scientific and technical information is available to suggest greater concern to human health or the environment. Pursuant to TSCA Section 6, EPA selected the initial 10 chemicals for risk evaluation, including 1,4-dioxane, in 2016 ([81 Federal Register 91927-91929, December 19, 2016](#)).

Each chemical substance that EPA evaluates has unique properties, uses, and risks, which may warrant different risk management approaches. The process of conducting risk evaluations and assessing risk management options involves judgments about the reliability of available scientific and technical information. Aspects of this process and what information EPA identifies as the basis for justifying certain regulatory action can generate disagreement between the agency and stakeholders (e.g., industry, environmental and public health organizations). As EPA continues to implement TSCA, the agency’s risk evaluations and related actions are likely to receive scrutiny among stakeholders. Congress may consider assessing EPA’s implementation of TSCA, as amended by the LCSA, and the resulting outcomes from the

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agency's actions and decisions. The next section discusses EPA's risk evaluation for 1,4-dioxane and potential next steps toward addressing the unreasonable risks that the agency identified.

1,4-Dioxane

In 2016, EPA selected 1,4-dioxane (CAS Number 123-91-1) as one of the initial 10 chemicals for which a risk evaluation would be conducted. According to EPA, 1,4-dioxane is predominantly used as a processing aid to manufacture a variety of other chemicals, and approximately 1.1 million pounds of the chemical are manufactured in, or imported to, the United States annually. For many years, 1,4-dioxane was used as a stabilizer for chlorinated solvents, such as 1,1,1-trichloroethane (also known as methyl chloroform). However, in 1995, the [Montreal Protocol on Substances That Deplete the Ozone Layer](#) as amended and Title VI of the Clean Air Act ([42 U.S.C. 7671 et seq.](#)) established a process to phase out 1,1,1-trichloroethane production in the United States for non-essential uses. The manufacture and use of 1,4-dioxane decreased with the phaseout of 1,1,1-trichloroethane.

In December 2020, EPA finalized its [risk evaluation for 1,4-dioxane](#), identifying unreasonable risks to the health of workers and occupational non-users from 13 conditions of use out of 24 evaluated. EPA did not identify unreasonable risks to consumers, bystanders, the general population, or the environment for any of the conditions of use that the agency evaluated. EPA based its determinations on a comparison of various sources of scientific information. The agency considered the predicted exposure to 1,4-dioxane from various exposure scenarios (e.g., workers involved in handling the chemical with or without the use of a respirator) and an estimated level of exposure expected not to result in the development of adverse health effects while taking into account a *margin of exposure*. EPA's risk determinations regarding potential environmental effects are based on the predicted exposure to 1,4-dioxane for various species compared to the estimated level of exposure expected not to result in the development of adverse effects in species at the population level.

EPA determined that certain hepatic (i.e., liver) effects are associated with acute exposure to 1,4-dioxane through inhalation or skin contact and certain respiratory effects are associated with chronic exposure to 1,4-dioxane through inhalation and skin contact. EPA also determined that chronic exposure to 1,4-dioxane is associated with an increase in the risk of developing liver cancer. These determinations are largely based on findings from rodent studies.

Given that EPA identified unreasonable risks associated with 1,4-dioxane, the agency is developing a rule under TSCA Section 6 to address such risks. Section 6(a) identifies seven risk management options that EPA may use alone or in combination to address the risks of 1,4-dioxane, including prohibiting the manufacture of the chemical and requiring manufacturers of the chemical to communicate the chemical's risks to allow downstream processors, users, and distributors the opportunity to take applicable protective measures. In developing the rule, EPA is required pursuant to Section 6 to identify various risk management options that would adequately address the identified unreasonable risk and determine the associated costs for each proposed risk management option.

In its risk evaluation, EPA acknowledged multiple existing regulations (e.g., occupational standards, stationary source emissions standards, drinking water standards) that apply to 1,4-dioxane, which were promulgated under various statutes that EPA and other agencies administer. Any risk management option that EPA considers and promulgates to address identified unreasonable risk could supplement existing regulations. Congress may conduct oversight or consider legislation with regard to EPA's efforts to manage risks associated with 1,4-dioxane and whether such efforts are aligned with the intent of the TSCA amendments.

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