



Background on Risk Evaluation Under the Toxic Substances Control Act (TSCA): Carbon Tetrachloride

September 12, 2022

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 carbon tetrachloride, 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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IN12011

agency's actions and decisions. The next section discusses EPA's risk evaluation for carbon tetrachloride and potential next steps toward addressing the unreasonable risks that the agency identified.

Carbon Tetrachloride

In 2016, EPA selected carbon tetrachloride (CAS Number 56-23-5) as one of the initial 10 chemicals for which a risk evaluation would be conducted. For many decades, carbon tetrachloride was used as a solvent. Because carbon tetrachloride was found to contribute to stratospheric ozone depletion, 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 carbon tetrachloride production in the United States for most nonfeedstock domestic uses by 1996. For the past few years, carbon tetrachloride has been used predominantly to manufacture other chemicals, such as hydrochlorofluorocarbons (HCFCs), hydrofluorocarbons (HFCs), and hydrofluoroolefins (HFOs). According to EPA, approximately 130 million pounds of carbon tetrachloride are manufactured in, or imported to, the United States annually.

In November 2020, EPA finalized its risk evaluation for carbon tetrachloride, identifying unreasonable risks to the health of workers and occupational non-users from 13 conditions of use out of 15 evaluated. EPA did not identify unreasonable risks to consumers, bystanders, the general population, or the environment from any of the conditions of use evaluated by the agency. EPA based its determinations on a comparison of various sources of scientific information. The agency considered the predicted exposure to carbon tetrachloride 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 to limit the increase in risk of developing liver cancer to certain guideline ranges. EPA primarily relied on rodent studies to ascertain the carcinogenicity of carbon tetrachloride from inhalation and dermal exposures. EPA's risk determinations regarding potential environmental effects are based on the predicted exposure to carbon tetrachloride 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.

In June 2021, EPA announced its intention to approach the TSCA unreasonable risk determinations by making one determination for a chemical substance rather than multiple determinations for each condition of use. In August 2022, EPA released a draft revised risk determination for carbon tetrachloride, which indicates that the chemical presents unreasonable risks to human health. This revised risk determination would supersede the November 2020 risk determinations in the risk evaluation.

EPA is developing a rule under TSCA Section 6 to address unreasonable risks identified by the agency and anticipates proposing this rule in October 2022. Section 6(a) identifies seven risk management options that EPA may use alone or in combination to address the risks of carbon tetrachloride, including prohibiting the manufacture of the chemical and requiring manufacturers of the chemical to communicate the chemicals' 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, drinking water standards, consumer product regulations) that apply to carbon tetrachloride, which were promulgated under various statutes that EPA and other agencies administer. A risk management rule could supplement these existing regulations. Congress may consider conducting oversight or consider legislation with regard to EPA's efforts to manage risks associated with carbon tetrachloride and whether such effects are aligned with the intent of the TSCA amendments.

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