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Background on Risk Evaluation Under the Toxic Substances Control Act (TSCA): Methylene Chloride

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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 methylene chloride, 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 methylene chloride and potential next steps toward addressing the unreasonable risks that the agency identified.

Methylene Chloride

In 2016, EPA selected methylene chloride (CAS Number 75-09-2; also known as dichloromethane) as one of the initial 10 chemicals for a risk evaluation. Methylene chloride is predominantly used as a solvent. According to EPA, approximately 260 million pounds of methylene chloride are manufactured in, or imported to, the United States annually.

In June 2020, EPA finalized its risk evaluation for methylene chloride, identifying unreasonable risks to the health of workers, occupational non-users, consumers, and bystanders from 47 out of 53 conditions of use that the agency evaluated. EPA did not identify unreasonable risks to the environment from 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 methylene chloride 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 methylene chloride 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's June 2020 risk evaluation was challenged in court. In July 2021, the Ninth Circuit Court of Appeals granted EPA's motion to remand the risk evaluation to the agency "for the limited purpose of permitting the agency to reconsider the challenged no-unreasonable risk determinations." In June 2022, EPA released a draft revised risk determination for methylene chloride, proposing that methylene chloride as a "whole substance" presents unreasonable risks to human health. The draft revised risk determination, if finalized, would supersede the risk determinations in the June 2020 risk evaluation.

Given that EPA identified unreasonable risks associated with methylene chloride, 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 methylene chloride, 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, consumer product regulations) that apply to methylene chloride, which were promulgated under various statutes that EPA and other agencies administer. In 2019, EPA promulgated a rule under TSCA to prohibit the manufacture, processing, and distribution of methylene chloride in all paint removers for consumer use. See 84 *Federal Register* 11420-11436, March 27, 2019, and 40 C.F.R. Part 751, Subpart B. A rule to address unreasonable risk that methylene chloride poses could build upon EPA's 2019 rule and other existing regulations.

Since methylene chloride is manufactured at relatively high volumes, EPA's forthcoming risk management rule and underlying risk evaluation will likely be scrutinized by stakeholders. Congress may conduct oversight or consider legislation with regard to EPA's efforts to manage risks associated with methylene chloride and whether such efforts are aligned with the intent of the TSCA amendments.

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