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

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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-bromopropane (1-BP), 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-BP and potential next steps toward addressing the unreasonable risks that the agency identified.

1-Bromopropane (1-BP)

In 2016, EPA selected 1-BP (CAS Number 106-94-5) as one of the initial 10 chemicals for which a risk evaluation would be conducted. 1-BP is predominantly used as a solvent for a variety of industrial and commercial applications. According to EPA, approximately 26 million pounds of 1-BP are manufactured in, or imported to, the United States annually.

In August 2020, EPA finalized its risk evaluation for 1-BP, identifying unreasonable risks to the health of workers, occupational non-users, consumers, and bystanders from 16 out of 25 conditions of use described and evaluated by the agency. EPA did not identify unreasonable risks to the general population and environment from the evaluated conditions of uses. EPA based its risk determinations on a comparison of various sources of scientific information. The agency considered the predicted exposure to 1-BP 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 adverse health effects while taking into account a *margin of exposure*. Additionally, EPA compared predicted exposure to 1-BP with an estimated level of exposure associated with certain guideline limits to the risk of developing lung cancer. EPA primarily relied on findings from rodent studies to inform its evaluation. EPA's risk determinations regarding potential environmental effects are based on the predicted exposure to 1-BP 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 July 2022, EPA released a draft revised risk determination for 1-BP, which indicates that the chemical presents unreasonable risks to human health. This revised risk determination would supersede the August 2020 risk determinations in the risk evaluation.

Given that EPA identified unreasonable risks associated with 1-BP, the agency is developing a rule under TSCA Section 6 to address such risks 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 1-BP, 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. The forthcoming risk management rule could supplement existing regulations that apply to 1-BP.

Relatedly, in February 2022, EPA added 1-BP to the list of hazardous air pollutants subject to stationary source emissions standards promulgated under Section 112 of the Clean Air Act (42 U.S.C. §7412). See 87 *Federal Register* 393-396, January 5, 2022. The extent to which EPA addresses risks to human health and the environment associated with 1-BP using TSCA or other statutes the agency administers may be an issue that Congress considers in evaluating whether implementation of TSCA is aligned with the intent of the TSCA amendments.

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