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Background on Risk Evaluation Under the Toxic Substances Control Act (TSCA): Cyclic Aliphatic Bromide Cluster

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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 the cyclic aliphatic bromide cluster, 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

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assessing EPA's implementation of TSCA, as amended by the LCSA, and the resulting outcomes from the agency's actions and decisions. The next section discusses EPA's risk evaluation for the cyclic aliphatic bromide cluster and potential next steps toward addressing the unreasonable risks that the agency identified.

Cyclic Aliphatic Bromide Cluster

In 2016, EPA selected the cyclic aliphatic bromide cluster (CAS Numbers 25637-99-4, 3194-55-6, 3194-57-8) as one of the initial 10 chemicals for risk evaluation. The chemicals considered as part of the cyclic aliphatic bromide cluster (e.g., hexabromocyclododecane or HBCD) are predominantly used as flame retardants in certain polystyrene products after their use in consumer textiles was largely phased out. In 2015, due to concerns regarding potential human health and environmental effects from exposure to such chemicals, EPA promulgated a rule that required notification to the agency for reintroducing these chemicals into consumer textiles. See 80 *Federal Register* 57293-57302, September 23, 2015, and 40 C.F.R. §721.10281. According to EPA, less than 100,000 pounds of cyclic aliphatic bromide cluster chemicals are manufactured in, or imported to, the United States annually.

In September 2020, EPA finalized its risk evaluation for the cyclic aliphatic bromide cluster, identifying unreasonable risks to the environment for 6 out of 12 conditions of use evaluated by the agency. Additionally, EPA identified unreasonable risks to the health of workers and occupational non-users from the use and disposal of such chemicals in building and construction materials. EPA did not identify unreasonable risks to the general population or consumers 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 the cyclic aliphatic bromide cluster chemicals 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 effects while taking into account a *margin of exposure*. EPA also determined that releases of HBCD into surface water and sediment may be of concern to aquatic organisms (e.g., fish and algae).

In June 2021, EPA announced its intention to approach the TSCA unreasonable risk determinations for the cyclic aliphatic bromide cluster by making one determination for the chemical substances rather than multiple determinations for each condition of use. In June 2022, EPA released a final revised risk determination for the cyclic aliphatic bromide cluster, which indicated that HBCD presents unreasonable risks to human health and the environment. This revised risk determination supersedes the September 2020 risk determinations in the risk evaluation.

Given that EPA identified unreasonable risks associated with the cyclic aliphatic bromide cluster, the agency is developing a rule under TSCA Section 6 to address such risks and anticipates proposing this rule in September 2022. Section 6(a) identifies seven risk management options that EPA may use alone or in combination to address the risks of the cyclic aliphatic bromide cluster, 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. Since most uses of chemicals considered part of the cyclic aliphatic bromide cluster have already been phased out, EPA's forthcoming risk management rule is expected to affect a narrower segment of industry that still uses these chemicals.

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