Congressional Research Service
Informing the legislative debate since 1914

INSIGHT

Background on Risk Evaluation Under the Toxic Substances Control Act (TSCA): N-Methylpyrrolidone

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 N-methylpyrrolidone (NMP), 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

Congressional Research Service
https://crsreports.congress.gov
IN12015

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

N-Methylpyrrolidone (NMP)

In 2016, EPA selected NMP (CAS Number 872-50-4) as one of the initial 10 chemicals for which a risk evaluation would be conducted. According to EPA, approximately 160 million pounds of NMP are manufactured in, or imported to, the United States annually. NMP is predominantly used as a solvent in the manufacture of a variety of industrial and consumer products, including electronics, petroleum products, pharmaceuticals, polymers, and other specialty chemicals.

In December 2020, EPA finalized its risk evaluation for NMP, identifying unreasonable risks to the health of workers and consumers from 26 of 37 conditions of use evaluated. EPA did not identify unreasonable risks to occupational non-users, bystanders, the general population, or 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 NMP 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 NMP 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 developmental effects are associated with acute exposure to NMP through ingestion and certain reproductive effects are associated with chronic exposure to NMP through ingestion. Both determinations were largely based on rodent studies.

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 NMP, which indicates that the chemical presents unreasonable risks to human health. This revised risk determination would supersede the December 2020 risk determinations in the risk evaluation.

Given that EPA identified unreasonable risks associated with NMP, the agency is in the process of 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 NMP, 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 NMP is manufactured at relatively high volumes, those who manufacture and use NMP are likely to scrutinize the forthcoming risk management rule and underlying risk evaluation. Congress may conduct oversight or consider legislation with regard to EPA's efforts to manage the risks associated with NMP and whether such efforts are aligned with the intent of the TSCA amendments.

Author Information

Jerry H. Yen
Analyst in Environmental Policy

Disclaimer