NMP
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NMP News Brief
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Proposed Risk Management for NMP; Schedule for EPA Actions and Expectations for Risk Management

The U.S. Environmental Protection Agency (EPA) announced on June 14, 2024, the availability of a proposed rule for the risk management of N-methylpyrrolidone (NMP) and provided a 45-day public comment period. In the proposed rule, EPA proposed to:

- Prohibit the manufacture (including import), processing, distribution, and use of NMP in certain occupational conditions of use (COU);
- Require worker protections through an NMP workplace chemical protection program (WCPP) or prescriptive controls (including concentration limits) for most of the occupational COUs;
- Require concentration limits on a consumer product;
- Regulate certain consumer products to prevent commercial use; and
- Establish recordkeeping, labeling, and downstream notification requirements.

Several organizations commented on the proposed risk management rule, both supporting and criticizing EPA's approach to managing the COUs that EPA determined present an unreasonable risk of injury to health.

Addressing Data Quality Concerns with the Risk Evaluation

The N-Methylpyrrolidone Producers Group, Inc. (NMP Producers Group) continues to take steps to strengthen the science regarding the risk evaluation of NMP.

- In February 2023, the manuscript "An evaluation of reproductive toxicity studies and data interpretation of N-methylpyrrolidone for risk assessment: An expert panel review" was published in the peer-reviewed journal *Regulatory Toxicology and Pharmacology*. The panelists concluded that the key study selected by EPA for the risk evaluation of NMP was not a high-quality study due to several design flaws, and the panel recommended that the study should not be considered for quantitative risk assessment of NMP; rather, two other high-quality studies should be used. Exclusion of the results of the one study from the risk evaluation would result in a change in the identification of the most sensitive endpoint for

NMP, based on consideration of the best available science and weight of scientific evidence supported by the available toxicity data for NMP.

- The NMP Producers Group submitted to EPA in April 2023 a Request for Correction (RFC) of information under the Information Quality Act for the NMP risk evaluation and included the peer-reviewed publication that concluded the key study selected by EPA is not a high-quality study and therefore should not be considered the best available science. EPA responded in August 2023 to the RFC, stating that the issues raised in the RFC were appropriately addressed in the Toxic Substances Control Act (TSCA) Existing Chemical Risk Evaluation public comment period for NMP even though the manuscript was not available during the risk evaluation period.

- The NMP Producers Group submitted in July 2024 comments on the proposed risk management rule, highlighting that EPA's risk evaluation is flawed, and as a result, the proposed risk management rule is not based on the best available science and weight of scientific evidence.

Next Steps in the TSCA Risk Evaluation and Risk Management Process

Final Risk Management Rule -- May 2025

EPA must publish a final risk management rule no later than two years after the publication in final of the risk evaluation. For NMP, the revised risk determination, and therefore the risk evaluation, was published in final in December 2022. Although the statute does allow for extension of the proposed and final risk management rules up to two years under certain conditions, NMP is on the 2014 TSCA Work Plan for Chemical Assessments list, and this option does not apply to those listed substances. EPA's Spring 2024 Regulatory Agenda indicates that EPA's timeline for publishing the final rule is **May 2025**.

The final risk management rule is the only step in the process of prioritization and risk evaluation of existing chemicals that may be challenged legally for any COUs that EPA intends to regulate. Depending on how EPA responds to the public comments received on the proposed risk management rule, it is possible NMP stakeholders could decide to file petitions for judicial review of EPA's risk management rule and the science that supports it. The first two of EPA's final risk management rules for substances within the group of the "first 10" risk evaluations have been legally challenged thus far. Legal arguments and the court's decisions regarding those petitions are ongoing.

Potential Stakeholder Impacts

The NMP Producers Group strongly encourages all NMP stakeholders to continue to remain engaged, with particular focus on the risk management measures proposed by EPA for their applications of interest. This will also ensure a record of concerns is established should stakeholders wish later to request judicial review of EPA's actions.

In the proposed risk management rule, EPA identified the dermal route of exposure as the primary exposure of concern for NMP. EPA has therefore not proposed an existing chemical exposure limit (ECEL) for NMP. Many industry stakeholder groups already use the appropriate engineering controls and personal protective equipment (PPE) measures to protect workers. Thus, if EPA proceeds with issuing a final risk management regulation requiring certain gloves and/or other PPE, it is not expected to have a substantial impact on those operations that have already implemented these controls. There will be increased recordkeeping and worker notification requirements.

Other regulatory requirements in the draft risk management rule include documentation requirements and changes to hazard communication; additionally, the *proposed* Section 6 risk management rule triggers lower reporting thresholds for TSCA Section 8(a) Chemical Data Reporting (CDR) and annual export notification requirements under TSCA Section 12(b). Daily operations related to worker protection for most user groups, however, are not expected to be impacted significantly, unless the use is a COU that is prohibited going forward.