NMP
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NMP News Brief
November 2023

Revised Risk Determination for NMP; Schedule for EPA Actions and Expectations for Risk Management

The U.S. Environmental Protection Agency (EPA) announced on July 1, 2022, the availability of a draft revised risk determination for N-methylpyrrolidone (NMP) and provided a 30-day public comment period. The draft revision of the NMP risk determination reflected EPA's announced policy changes to make a "whole chemical" risk determination and to eliminate the assumption that personal protective equipment (PPE) provided to and used by workers reduces the risk of chemical exposures. As a result of applying these policy changes, EPA revised the risk determination for NMP as follows:

- Three conditions of use (COU) determined previously to present "no unreasonable risk" were revised to present "unreasonable risk."
  - Industrial and commercial use in ink, toner, and colorant products (printer ink; inks in writing equipment);
  - Industrial and commercial use in other uses in soldering materials; and
  - Industrial and commercial use in other uses in fertilizer and other agricultural chemical manufacturing (processing aids and solvents).
- The number of COUs determined to present unreasonable risk increased from 26 to 29 of 37 COUs evaluated for NMP.
- EPA determined that the 29 COUs determined to present unreasonable risk drive a whole chemical unreasonable risk determination for NMP.

A number of organizations commented on the draft revised risk determination both supporting and criticizing EPA's approach to revising the risk determination. Many of the criticisms were consistent with comments made on other of the "first 10" high-priority risk evaluations for which EPA has taken similar action. EPA published on December 19, 2022, its response to comments and the final revised risk determination for NMP. Under Section 6 of the Toxic Substances Control Act (TSCA), EPA must develop risk management actions to address the COUs that are determined to present unreasonable risk.

Addressing Data Quality Concerns with the Risk Evaluation

The NMP Producers Group, Inc. (NMP Producers Group) has taken 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*. An expert panel evaluated the reproductive toxicology study data for NMP and their application to the health risk assessment. 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. Exclusion of the results of this study from the risk evaluation results 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 TSCA Existing Chemical Evaluation public comment period for NMP.

Next Steps in the TSCA Risk Evaluation and Risk Management Process

Proposed Risk Management -- December 2023

EPA must propose risk management actions within one year of 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. EPA's Spring 2023 Regulatory Agenda indicates that EPA's timeline for a notice of proposed rulemaking (NPRM) for the risk management of NMP is October 2023; EPA did not issue the NPRM in October 2023 but is expected to publish it by the **end of 2023**. It is not clear to Bergeson & Campbell, P.C. (B&C®) whether EPA will seek to ban those uses of NMP that it found to present unreasonable risk. EPA has many options available to mitigate unreasonable risk under TSCA Section 6 and is required to do so to the "extent necessary." EPA has in its first four risk management rule proposals proposed phaseouts/bans, even though EPA also concluded that a Workplace Chemical Protection Plan (WCPP), including an existing chemical exposure limit (ECEL), would be

protective. EPA's determinations of unreasonable risk for certain NMP applications are based on high-end exposure scenarios that assume a lack of proper use of PPE. It is more likely that the risk management measures that might arise from unreasonable risk determinations will focus on an ECEL, ensuring proper use of PPE, especially dermal PPE that is demonstrated to be impervious to NMP, and other measures to prevent human exposure. EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) Assistant Administrator Michal Freedhoff has stated publicly, however, that if EPA has no exposure data for a COU to indicate that the ECEL established during the risk evaluation can be met, then EPA will assume the ECEL cannot be met and will propose a ban for that COU.

Final Risk Management -- December 2024

EPA is required to issue the final risk management rule no later than two years after the date of the final risk evaluation for NMP. Although the statute does allow for extension of the proposed and final risk management rules for 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. If EPA releases a proposed risk management rule by **December 2023**, a final risk management rule could be issued by **December 2024**.

Potential Stakeholder Impacts

EPA's issuance of the revised risk determination is not considered a final agency action and therefore not subject to legal challenge. The next opportunity that stakeholders may have to challenge legally EPA's approach to and actions taken regarding the risk evaluation for NMP will likely follow the publication in final of the risk management rule for NMP. The NMP Producers Group strongly encourages all NMP stakeholders 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.

EPA has stated that it intends to use information on the use of PPE as a means of mitigating risk (including public comments received from industry respondents about occupational safety practices in use) during the risk management phase as appropriate. Many industry stakeholder groups already use the appropriate engineering controls and PPE measures to protect workers. Thus, if EPA proceeds with issuing a final regulation requiring certain gloves and/or other PPE, it is not expected to have a material impact on those operations that have already implemented these controls. The development of exposure monitoring data will enable stakeholders to ensure current data are available to either avoid the possibility of risk management for their COUs of interest or to evaluate their ability to meet an ECEL when it is

established. Stakeholders that do not have exposure monitoring data for their COUs should consider developing exposure monitoring data and submitting it to EPA before it issues the proposed risk management rule or during the public comment period to demonstrate that the ECEL for NMP can be met for your COU, including exposure to workers and occupational non-users (ONU), and avoid a ban. The exposure data will also ensure that stakeholders can demonstrate that their engineering controls and PPE measures are protective of workers.

Other regulatory requirements expected from a TSCA Section 6 risk management rule include documentation requirements and changes to hazard communication; additionally, a *proposed* Section 6 risk management rule will trigger lower reporting thresholds for TSCA Section 8(a) Chemical Data Reporting (CDR) and 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.