NMP
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NMP News Brief
September 2022

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 protection 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 in 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's responses to similar comments on revised risk determinations released in final for other substances suggest that it is unlikely EPA will change its position on its approach to revising its previous risk determinations, including 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.

Next Steps in the TSCA Risk Evaluation and Risk Management Process

Proposed Risk Management -- May 2023

EPA must propose risk management actions within one year of the publication in final of the risk evaluation. For NMP, the risk evaluation is expected to be published in final by the **end of 2022**. EPA's Spring 2022 Regulatory Agenda indicates that EPA's timeline for a notice of proposed rulemaking for the risk management of NMP is **May 2023**; neither EPA, nor the NMP Producers Group expects EPA to meet the deadline for proposing risk management actions. EPA is not expected 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'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 existing chemical exposure limit (ECEL), ensuring proper use of PPE, especially dermal PPE that is demonstrated to be impervious to NMP, and other measures to prevent human exposure.

Final Risk Management -- August 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 **June 2023**, a risk management rule could be published in final by **June 2024**.

Potential Stakeholder Impacts

EPA's issuance in final of a revised risk determination that includes no order reflecting a determination that the substance does not present an unreasonable risk 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 to later 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. When EPA publishes in final the revised risk determination, it is expected that EPA will also withdraw the order it issued in 2021 for the 11 COUs previously determined to present unreasonable risk. This will have the effect of suspending the preemption of regulation under TSCA Section 18 of the same COUs of use for NMP at the state level until risk management actions are published in final by EPA.

Many industry stakeholder groups already use the appropriate engineering controls and PPE measures to protect workers. Thus, even 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.

Other regulatory requirements expected from a TSCA Section 6 risk management action 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 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.