



NMP News Brief

January 9, 2017

March 2015 NMP Risk Evaluation under TSCA Work Plan Chemicals Program

In March 2015, the [U.S. Environmental Protection Agency \(EPA\)](#) issued a [final risk assessment report for N-Methylpyrrolidone \(NMP\)](#) under the Toxic Substances Control Act (TSCA) Work Plan Chemicals Program. The scope of the NMP risk assessment focused on paint stripping applications and included acute and chronic occupational scenarios and acute consumer scenarios. The scope did not include chronic exposures to consumers. EPA calculated a margin of exposure (MOE) for acute exposure consumer scenarios. The presence of risk was defined as an MOE less than the benchmark of 30. All assessed consumer scenarios except one had MOEs greater than 30. The one consumer exposure scenario, designed as upper bound exposure, yielded an MOE of 29.5. EPA states, however, that the 29.5 MOE is considered equivalent to 30. Therefore, in its March 2015 risk assessment report, EPA found all consumer applications to be low or no risk (*i.e.*, at or above the MOE of 30 threshold for risk).

Proposed Section 6 Rulemaking on NMP; Meeting with OMB

EPA has prepared a proposed Section 6 risk management rulemaking for NMP. Despite the clear findings stated in the report, EPA has developed the Section 6 rulemaking to address potential risks to consumers. On December 5, 2016, representatives of the NMP Producers Group met with the Office of Management and Budget (OMB) to express concerns with the proposed Section 6 rulemaking on NMP. The key point made was that the anticipated Section 6 rulemaking does not comport with the scope or the findings of the March 2015 risk evaluation, which is in violation of Section 26(l)(4) under amended TSCA, which states:

With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments *for which the Administrator has published a completed risk assessment prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act*, the Administrator may publish *proposed and final rules under section 6(a) that are consistent with the scope of the completed risk assessment* for the chemical substance and consistent with other applicable requirements of section 6 (emphasis added).

At the meeting, the NMP Producers Group urged OMB to direct EPA to:

- Withdraw the current Section 6 proposal if it includes risk management actions associated with consumer risk;

NMP Producers Group News Brief
January 9, 2017
Page 2

- Complete the risk evaluation for all conditions of use under amended TSCA (*see* “Announcement of NMP Risk Evaluation Work under Amended TSCA” below);
- Publish the full risk evaluation, including the supplemental risk evaluation conducted as part of the TSCA Work Plan Chemicals Program that was never issued, for public review and comment; and
- If necessary, reissue the Section 6 rulemaking.

The NMP Producers Group also noted that it was inappropriate for EPA to continue to link NMP and methylene chloride in its review processes and proposal. They noted that both the peer review and the small business consultations covered both chemicals, and the proposed rulemaking likewise lists both chemicals. Any final action on NMP should be issued separate from methylene chloride.

The proposed Section 6 rulemaking was sent to OMB on October 24, 2016. As of December 29, 2016, the proposed rulemaking remains at OMB.

Announcement of NMP Risk Evaluation Work under Amended TSCA

On November 29, 2016, [EPA announced that NMP would be among the first ten chemicals to be evaluated under amended TSCA](#). It is expected that the risk evaluation under amended TSCA will cover all intended conditions of use, and not just paint stripper applications. EPA will need to prepare a scoping document for the assessment and presumably would offer an opportunity for stakeholders to submit information relevant to the risk evaluation.

EPA is expected to propose its Section 6 risk evaluation process rulemaking before **January 20, 2017**, which should provide insight as to how EPA intends to proceed with the NMP risk evaluation.

Information on exposure levels associated with conditions of use will be critical for the EPA NMP risk evaluation under amended TSCA.

EPA EDSP Group 2 Test Orders

NMP is included in the Group 2 list of chemicals subject to test orders under the EPA Endocrine Disruptor Screening Program (EDSP). Test orders on Group 2 chemicals could be issued in **2017**. EPA is reportedly re-reviewing the Tier 1 studies, including consideration as to how high throughput screening and other modeling could be used. It is expected that EPA will make changes in the

NMP Producers Group News Brief
January 9, 2017
Page 3

required testing for Tier 1, but no specific information on what those changes will be has been shared.

The NMP Producers Group is actively engaged in reviewing available literature to identify potential opportunities for test waiver requests.

Workplace Environmental Exposure Limit (WEEL)

The NMP Producers Group has been actively engaged in dialogue with the WEEL Committee as it considers an update to the NMP WEEL value. The draft WEEL value is expected to be available for public review in **late February or early March 2017**.