



NMP News Brief

November 2019

Draft EPA TSCA Section 6 Risk Evaluation for NMP

The U.S. Environmental Protection Agency (EPA) [notice on the N-Methylpyrrolidone \(NMP\) Draft Toxic Substances Control Act \(TSCA\) Risk Evaluation and TSCA Science Advisory Committee on Chemicals \(SACC\) Meeting](#) was published in the November 7, 2019, *Federal Register*. The SACC will review the draft risk evaluation at a two-day meeting in Washington, DC, on **December 5 and 6, 2019**. Public comments on the draft risk evaluation are due on **January 6, 2020**.

It is important to note that the recently issued document is a DRAFT risk evaluation. Those uses that EPA preliminarily concluded as unreasonable risk are not final. EPA has clearly stated that the initial determinations on unreasonable risk are based on its evaluation of available information and are not EPA's final determinations. Furthermore, even if the EPA conclusions are later made final, it does not mean that those uses will automatically be prohibited or banned. There are many options available to EPA to mitigate unreasonable risk. Any EPA actions related to restrictions on NMP use would not be proposed until **2021** at the earliest. See "Next Steps in TSCA Risk Evaluation and Risk Management Process" section for further information on EPA's Section 6 timeline.

Initial Findings on Unreasonable Risk

In the [posted draft risk assessment](#), EPA concluded no unreasonable risks to the environment, bystanders, or occupational non-users from NMP for all the conditions of use included in the draft risk evaluation. EPA also concluded that the following conditions of use of NMP did not present an unreasonable risk:

- Domestic manufacture;
- Import (including repackaging and loading/unloading);
- Processing as a reactant or intermediate in several manufacturing processes, including plastic material and resin manufacturing and in pharmaceutical and medicine manufacturing;
- Processing as a reactant or intermediate, other;
- Processing for incorporation into articles in other sectors, including in plastic product manufacturing;

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- Repackaging for wholesale and retail trade;
- Processing -- recycling;
- Distribution in commerce;
- Industrial and commercial use in ink, toner, and colorant products, including printer ink and inks in writing equipment;
- Industrial and commercial use in processing aids, specific to petroleum production in petrochemical manufacturing, and other uses in oil and gas drilling and pharmaceutical and medicine manufacturing;
- Industrial and commercial use in other uses in soldering materials;
- Industrial and commercial use, Other Uses, Fertilizer, and Other agricultural chemical manufacturing -- processing aids and solvents;
- Industrial and commercial use in other uses, wood preservatives;
- Consumer use in paints and coatings, adhesive removers;
- Consumer use in paints and coatings, lacquers, stains, varnishes, primers, and floor finishes;
- Consumer use in paint additives and coating additives not described by other codes, paints and arts and crafts paints;
- Consumer use in adhesives and sealants single-component glues and adhesives, including lubricant adhesives and two-component glues and adhesives including some resins;
- Consumer use in other uses in automotive care products;
- Consumer use in other uses lubricant and lubricant additives, including hydrophilic coatings; and

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- Disposal including industrial pre-treatment, industrial wastewater treatment publicly owned treatment works (POTW), underground injection, landfill (municipal, hazardous or other land disposal), and emissions to air, incinerators (municipal and hazardous waste).

The draft risk assessment includes a number of use applications for which EPA has preliminarily concluded as unreasonable risk, which are noted below:

Processing Uses	<ul style="list-style-type: none">• Incorporation into a formulation, mixture, or reaction product in several industrial sectors• Incorporation into articles as lubricants and lubricant additives in machinery manufacturing• Incorporation into articles as paint additives and coating additives not described by other codes in transportation equipment manufacturing• Incorporation into articles as a solvent (which becomes part of product formulation or mixture), including in textiles, apparel, and leather manufacturing
Industrial and Commercial Uses	<ul style="list-style-type: none">• For paint and coating removers and in adhesive removers• For paint and coatings (lacquers, stains, varnishes, primers and floor finishes, and powder coatings, surface preparation), in paint additives and coating additives not described by other codes in several manufacturing sectors, and in adhesives and sealants, several types• As a solvent (for cleaning or degreasing) used in electrical equipment, appliance and component manufacturing, and for other uses in manufacturing lithium ion batteries• As other uses in anti-freeze and de-icing products, automotive care products, and lubricants and greases• As other uses in metal products not covered elsewhere and lubricant and lubricant additives including hydrophilic coatings• As other uses in laboratory chemicals



	<ul style="list-style-type: none"> As other uses, cleaning and furniture care products, including wood cleaners and gasket removers
Consumer Uses	<ul style="list-style-type: none"> For paints and coatings, paint and coating removers As other uses, cleaning and furniture care products, including wood cleaners and gasket removers.

Next Steps in TSCA Risk Evaluation and Risk Management Process

1. Deadline for Public Review and Comment -- **January 6, 2020**

The recently issued document is a DRAFT risk evaluation. EPA will use input received during the public comment period and peer review processes to inform its final risk determinations for NMP.

Stakeholders within the use applications that have been tentatively identified as having unreasonable risk should review carefully the information assessed by EPA for that sector to determine if its assumptions and considerations of workplace practices are accurate. As noted, EPA is accepting public comments until **January 6, 2020**.

2. Final Risk Evaluation -- no later than **June 2020**

Under amended TSCA, EPA is anticipated to issue a final risk evaluation on a subject chemical no later than three years after initiation. There is, however, an option for a six-month extension, which EPA will need to use for the NMP risk evaluation. As one of the first ten chemicals to be evaluated under amended TSCA, the NMP risk evaluation started in December 2016. The three-year timeline for a risk evaluation would be **December 2019**. Given the issuance date of the draft risk assessment and peer review schedule, it is not feasible for EPA to complete the final risk evaluation by the **December 2019** deadline, which means EPA must use the six-month extension option -- putting the date for a final risk evaluation as **June 2020**. At this time, EPA will make a final decision as to which use applications are considered as unreasonable risk and require risk management measures.

3. Proposed Risk Management -- **June 2021**

If EPA issues a final decision that one or more NMP applications present an unreasonable risk, it has one year to issue proposed actions to manage those risks, which, based on the anticipated date of **June 2020** for a final risk evaluation, would be **June 2021**.

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While prohibition of the identified use is an option for risk management, the statute requires EPA to pursue actions that manage the risk *to the extent necessary* (emphasis added). There are many risk management options available to EPA, including limitation of the amount or concentration of NMP within a particular use, warning and instruction requirements, recordkeeping provisions, and air monitoring.

4. Final Risk Management -- **June 2022**

EPA is required to issue the final risk management rule no later than two years after the date of the final risk evaluation. Again, based on the anticipated final risk evaluation date of **June 2020** and assuming that final determination concludes one or more applications as having unreasonable risk, the final risk management rule would be issued by **June 2022**.

Although the statute does allow for extension of the proposed and final risk management rules for up to two years, this option does not apply to NMP as it is a chemical drawn from the 2014 TSCA Work Plan for Chemical Assessments, and this option does not apply to those listed chemicals.

Stakeholder Engagement

The NMP Producers Group strongly encourages all NMP stakeholders to submit comments on the draft risk evaluation document, with particular focus on the exposure factors used by EPA for their applications of interest. In many cases, EPA assumes that users, including workers in occupational settings, may not be wearing proper gloves or other protection equipment, which increases the likelihood that calculated risk will exceed the unreasonable risk threshold. It is absolutely imperative that NMP user groups correct EPA on any misperceptions related to user protections within the industrial and commercial settings.