



Environmental Justice Consultation on Forthcoming Proposed Rulemakings under TSCA Section 6(a)

n-Methylpyrrolidone (NMP)

July 7 and July 13, 2021

Office of Pollution Prevention and Toxics

U.S. Environmental Protection Agency





Opening Remarks and Consultation Overview



Today's Consultation

- Welcome
- Purpose of today's consultation
- Risk management under TSCA section 6(a)
- Proposed rulemaking for n-methylpyrrolidone (NMP)
 - Questions and discussion
- Next Steps



E.O. 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

- The purpose of E.O. 12898 is to focus federal attention on the environmental and human health effects of federal actions on minority and low-income populations with the goal of achieving environmental protection for all communities
- Under E.O. 12898, EPA is seeking input from stakeholders interested in environmental justice issues during this consultation and encourages participation and comments to inform EPA's upcoming proposed regulation



Impact of Biden-Harris Executive Order on Protecting Public Health and the Environment

- As the Biden-Harris Administration works to advance EPA's mission of protecting human health and the environment, the agency is committed to ensuring the safety of chemicals used by all Americans
- To that end, EPA will follow the science and law, while reviewing TSCA implementation and take any needed steps to ensure that actions protect human health and the environment
- This review is being done in accordance with the Administration's Executive Orders and other directives, including those on environmental justice, scientific integrity, and regulatory review
- The Agency will keep stakeholders updated as decisions are made, and next steps are determined



Risk Management under TSCA Section 6(a)



Risk Management Requirements

- Under TSCA, EPA is required to take action to address chemicals that pose unreasonable risks to human health or the environment
- Following a determination of unreasonable risk, EPA must issue a TSCA section 6(a) rule so that the chemical no longer presents an unreasonable risk, within two years:
 - Proposed rule one year after risk evaluation
 - Final rule two years after risk evaluation
- Specific requirements regarding consideration of alternatives depending on the options selected, and a statement of effects for each risk management rule
- Input from stakeholders is critical to the process



TSCA Section 6(a) Regulatory Options

- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce
- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce for particular use or for use above a set concentration
- Require minimum warnings and instructions with respect to use, distribution, and/or disposal
- Require recordkeeping, monitoring or testing
- Prohibit or regulate manner or method of commercial use
- Prohibit or regulate manner or method of disposal by certain persons
- Direct manufacturers/processors to give notice of the unreasonable risk determination to distributors, users, and the public and replace or repurchase



TSCA Section 6(a)

- TSCA provides EPA with authority to address unreasonable risks in occupational settings, and to regulate entities including:
 - Manufacturers and processors (e.g., formulators)
 - Distributors
 - Commercial users (workplaces and workers)
 - Entities disposing of chemicals for commercial purposes
- TSCA also requires EPA to address unreasonable risks to consumers
 - Under TSCA, EPA has authority to regulate at the manufacturing, processing or distribution levels in the supply chain to eliminate or restrict the availability of chemicals and chemical-containing products for consumer use
 - These authorities allow the EPA to regulate at key points in the supply chain to effectively address unreasonable risks to consumers



Principles for Transparency During Risk Management

- Transparent, proactive, and meaningful engagement
- One-on-one meetings, public webinars, and required consultations with state and local governments, tribes, environmental justice communities, and small businesses
- Extensive dialogue about the findings in the risk evaluations, the risk management process required by TSCA, and the options available for managing unreasonable risks
- Seeking input from stakeholders on potential risk management approaches, their effectiveness, and impacts those approaches might have on businesses, workers, and consumers
- Input can help the agency develop regulations that are practical and protective



Types of Information to Inform Risk Management

- Suggestions on effective methods EPA can use to address the unreasonable risks
- Input on protective regulatory approaches
- Information related to controlling exposures, including current work practices, engineering and administrative controls
- Information on essential uses, and the impacts if the chemical were not available
- Identification of uses that have been phased out, or can be phased out, and thus are no longer needed
- Any information on substitute chemicals that are safe and effective alternatives
- Suggestions on how EPA can further improve its regulatory processes or be more transparent



Your Comments

- Please provide specific comments on:
 - Do you have any concerns related to environmental justice and NMP?
 - How do you anticipate this rulemaking would have an environmental justice impact?
 - Other thoughts on the rulemaking?



Your Advice for EPA

- Please provide specific examples of:
 - Any experience with NMP
 - Any experience with regulation of NMP
 - Any risk management experience with specific conditions of use of NMP



Potential Regulatory Options

- Prohibition
- Existing Chemical Exposure Limit (ECEL)
 - A risk management option similar to a PEL, for industrial and most commercial conditions of use
 - Establishes a performance-based inhalation limit and is non-prescriptive, thus enabling users to determine how to most effectively meet the ECEL based on what works best for their workplace
 - Industries are already familiar with PELs, and methods of compliance
- Prescriptive controls
 - Includes prescriptive controls for personal protective equipment (PPE), engineering changes, or administrative practices
 - Potential alternatives to an ECEL, though they may limit flexibility for the regulated entity



Potential Regulatory Options

- Concentration Limit
 - Restrictions on the concentration or weight fraction within the formulation such that the risk is mitigated
- Regulatory options applied broadly with other restrictions
 - Recordkeeping and downstream notification
 - Monitoring and labeling
 - Training, certification, and limited access program



n-Methylpyrrolidone (NMP)

- Background on risk evaluation and findings for NMP
- Focused discussion on specific conditions of use
- Consultation comments
- Your advice for EPA



Overview of Risk Evaluation for NMP

- Final risk evaluation published December 30, 2020
 - 37 conditions of use were evaluated
 - Final risk evaluation follows a series of risk evaluation activities
 - NMP draft risk evaluation: November 2019; NMP problem formulation: June 2018; NMP scope document: June 2017
- Public comments and external scientific peer review informed the final risk evaluation
 - 35 public comments received on the draft risk evaluation (comment period closed January 21, 2020)
 - Peer review: EPA's Science Advisory Committee on Chemicals (SACC) met to review the draft evaluation (December 2019)
- The final risk evaluation and supplemental materials are in docket [EPA-HQ-OPPT-2019-0236](#) with additional materials supporting the risk evaluation process in docket [EPA-HQ-OPPT-2016-0743](#) on www.regulations.gov



Unreasonable Risk Determinations

- EPA determined that 26 of the 37 conditions of use of NMP present an unreasonable risk of injury to health
- EPA's determinations are based on unreasonable risks of injury to:
 - Workers during occupational exposures
 - Consumers during exposures to one consumer use
- EPA's risk evaluation identified unreasonable risks for non-cancer developmental effects from acute inhalation and dermal exposures and reproductive effects from chronic inhalation and dermal exposures to NMP



NMP Manufacturing and Processing Uses that Present an Unreasonable Risk

- Manufacturing (domestic manufacturing)
- Manufacturing (import)
- Processing: As a reactant/intermediate in plastic material and resin manufacturing and other non-incorporative processing
- Processing: Incorporation into formulation, mixture or reaction product in multiple industrial sectors
- Processing: Incorporation into articles in lubricants and lubricant additives in machinery manufacturing
- Processing: Incorporation into articles in paint additives and coating additives not described by other codes in transportation equipment manufacturing
- Processing: Incorporation into articles as a solvent (which becomes part of a product formulation or mixture) including in textiles, apparel and leather manufacturing
- Processing: Incorporation into articles in other sectors, including in plastic product manufacturing
- Processing: Repackaging in wholesale and retail trade
- Processing: Recycling



NMP Industrial and Commercial Uses that Present an Unreasonable Risk

- Industrial and commercial use in paints, coatings and adhesive removers
- Industrial and commercial use in paints and coatings in lacquers, stains, varnishes, primers and floor finishes and powder coatings in surface preparation
- Industrial and commercial use in paint additives and coating additives not described by other codes in computer and electronic product manufacturing in electronic parts manufacturing
- Industrial and commercial use in paint additives and coating additives not described by other codes in computer and electronic product manufacturing for use in semiconductor manufacturing
- Industrial and commercial use in in paint additives and coating additives not described by other codes in multiple manufacturing sectors
- Industrial and commercial use as a solvent (for cleaning or degreasing) in electrical equipment, appliance and component manufacturing
- Industrial and commercial use as a solvent (for cleaning or degreasing) in electrical equipment, appliance and component manufacturing for use in semiconductor manufacturing



NMP Industrial and Commercial Uses and Disposal that Present an Unreasonable Risk

- Industrial and commercial use in processing aids, specific to petroleum production in petrochemical manufacturing, in other uses in oil and gas drilling, extraction and support activities, and in functional fluids (closed systems)
- Industrial and commercial use in adhesives and sealants including binding agents, single component glues and adhesives, including lubricant adhesives, and two-component glues and adhesives including some resins
- Industrial and commercial use in other uses in anti-freeze and de-icing products, automotive care products, and lubricants and greases
- Industrial and commercial use in other uses in metal products not covered elsewhere, and lubricant and lubricant additives including hydrophilic coatings
- Industrial and commercial use in other uses in laboratory chemicals
- Industrial and commercial uses in other uses in lithium ion battery manufacturing
- Industrial and commercial use in other uses in cleaning and furniture care products, including wood cleaners and gasket removers
- Disposal



NMP Consumer Use that Presents Unreasonable Risk

- Consumer use in adhesives and sealants in glues and adhesives, including lubricant adhesives and sealants



In-Depth Discussion on NMP

1. Manufacturers, import, repackaging, recycling and disposal
2. Processing into Formulation, Mixtures and Reaction Products and into Articles in various sectors
3. Industrial and commercial uses in paints/coatings, paint/coating removers, adhesives, sealants, lubricants, automotive care, laboratories, cleaning and furniture care
4. Industrial and commercial uses as paint/coating additives and as solvents in electronic parts manufacturing, semiconductor manufacturing and in other uses in lithium ion battery manufacturing
5. Consumer uses in adhesives and sealants including lubricant adhesives and sealants.



Group 1: Manufacturers, importers, repackaging, recycling and disposal

- Relevant conditions of use:
 - Manufacturing (domestic manufacturing)
 - Manufacturing (import)
 - Processing: repackaging
 - Processing: recycling
 - Disposal
- What is NMP used for? How is it applied?
 - NMP is domestically manufactured, imported, and repackaged from bulk containers to smaller containers; NMP is loaded and unloaded into different containers
 - NMP waste streams are collected and transported to third-party sites for disposal, treatment, or recycling



Potential Regulatory Options (Group 1)

Any regulatory option could be used alone or in combination so that NMP no longer presents an unreasonable risk under any condition of use:

- Prohibition
- Existing Chemical Exposure Limit (ECEL)
- Prescriptive controls (PPE, engineering and administrative controls)
- Regulatory options applied broadly with other restrictions
 - Recordkeeping and downstream notification
 - Monitoring and labeling
 - Training, certification, and limited access program



Group 2: Processing as a Reactant or Intermediate or Incorporation into Formulation, Mixture or Reaction Products and into Articles

- Relevant Conditions of Use
 - Processing as an intermediate in Plastic Material and Resin Manufacturing
 - Processing, Incorporation in Formula, Mixture or Reaction Products in various uses including adhesives and sealant chemicals, anti-adhesive agents, process aids, solvents for various sectors
 - Processing, Incorporation into articles in lubricants, lubricant additives, paint additives and coating additives, solvents and in plastic product manufacturing
- What is NMP used for? How is NMP applied?
 - NMP is commonly used as a feedstock in the production of other chemicals products and may be incorporated into various products and formulations at varying concentrations for further distribution
 - These uses entail use of NMP as an intermediate, as a media for synthesis, processing, and purification
 - NMP may be used for maintenance, bottling, shipping, sampling and loading into or unloading from containers



Potential Regulatory Options (Group 2)

Any regulatory option could be used alone or in combination so that NMP no longer presents an unreasonable risk under any condition of use:

- Prohibition
- Existing Chemical Exposure Limit (ECEL)
- Prescriptive controls (PPE, engineering and administrative controls)
- Concentration limit
- Regulatory options applied broadly with other restrictions
 - Recordkeeping and downstream notification
 - Monitoring and labeling
 - Training, certification, and limited access program



Group 3: Industrial and Commercial Paint and Coating and Solvent Uses

- Relevant conditions of use
 - Industrial and commercial use in paints, coatings, paint/coating/adhesive removers, in paints and coatings in lacquers, stains, primers and floor finishes and powder coatings in surface preparation
 - Industrial and commercial use in paint additives and coating additives
 - Industrial and commercial use as a solvent for cleaning and degreasing
 - Industrial and commercial use for ink, toner and colorant products
 - Industrial and commercial use in processing aids for petrochemical manufacturing, in other uses in oil and gas drilling, extraction and support activities, in functional fluids in closed systems in petrochemical manufacturing and oil and gas drilling
 - Industrial and commercial use in adhesives and sealants and soldering materials
 - Industrial and commercial use in anti-freeze and de-icing, automotive care, lubricants and greases, metal products, lubricant and lubricant additives, laboratories, and cleaning/furniture care



Group 3: Industrial and Commercial Paint and Coating and Solvent Uses

- What is NMP used for? How is it applied?
 - NMP is used in paints and coatings, in paint/coating additives and as a solvent for cleaning and degreasing to remove a variety of contaminants and materials in a variety of businesses
 - NMP is used in processing aids in petroleum production in petrochemical manufacturing, in other uses in oil and gas drilling, extraction and support activities and in functional fluids in a closed system
 - NMP is also used in adhesives and sealants and in various automotive care products including anti-freeze, de-icing products and lubricants and greases
 - NMP is also used in metal products
 - Activities include loading/unloading, analytical and maintenance activities



Potential Regulatory Options (Group 3)

Any regulatory option could be used alone or in combination so that NMP no longer presents an unreasonable risk under any condition of use:

- Prohibition
- Existing Chemical Exposure Limit (ECEL)
- Prescriptive controls (PPE, engineering and administrative controls)
- Concentration limit
- Regulatory options applied broadly with other restrictions
 - Recordkeeping and downstream notification
 - Monitoring and labeling
 - Training, certification, and limited access program



Group 4: Industrial and Commercial Uses in Manufacturing of Electronic Parts, Semiconductors, and Lithium Ion Batteries

- Relevant conditions of use:
 - Industrial and commercial use in paint additives and coating additives and solvents in:
 - Electronic Parts Manufacturing
 - Semiconductor Manufacturing
 - Lithium Ion Battery Manufacturing
- What is NMP used for? How is it applied?
 - NMP is used as a paint additive and coating additive and as a solvent in cleaning and degreasing in manufacturing of electronic parts and semiconductors
 - NMP is used in lithium ion battery manufacturing in cathode coating, cathode mixing, and other activities



Potential Regulatory Options (Group 4)

Any regulatory option could be used alone or in combination so that NMP no longer presents an unreasonable risk under any condition of use:

- Prohibition
- Existing Chemical Exposure Limit (ECEL)
- Prescriptive controls (PPE, engineering and administrative controls)
- Concentration limit
- Regulatory options applied broadly with other restrictions
 - Recordkeeping and downstream notification
 - Monitoring and labeling
 - Training, certification, and limited access program



Group 5: Consumer Use

- Consumer use in adhesives and sealants in glues and adhesives, including lubricant adhesives and sealants



Potential Regulatory Options (Group 5)

Any regulatory option could be used alone or in combination so that NMP no longer presents an unreasonable risk under any condition of use:

- Prohibition of manufacturing, processing or distribution of products for consumer use
- Concentration limit
- Regulatory options applied broadly with other restrictions
 - Recordkeeping and downstream notification
 - Monitoring and labeling
 - Training, certification, and limited access program



Your Comments

- Please provide specific examples of:
 - Any experience with use of NMP
 - Any experience with regulation of NMP
 - Any risk management experience with specific conditions of use of NMP
- Please provide specific comments:
 - Do you have any concerns related to environmental justice and NMP?
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Additional Information

- General TSCA: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>
- Current Chemical Risk Management Activities: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-management-activities>
- NMP Risk Management: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-n-methylpyrrolidone-nmp>
- NMP: Sheehan.Eileen@epa.gov, 415-972-3287, Hull.Clara@epa.gov, 202-564-3954, Shuman.Amy@epa.gov, 202-564-2978
- General risk management outreach: Douglas Parsons Parsons.Douglas@epa.gov, 202-564-0341



Next Steps

- Please send written comments by August 27, 2021, to Amanda Hauff at Hauff.Amanda@epa.gov with a cc: to Sheehan.Eileen@epa.gov for NMP