Appendices to Final Report of the Small Business Advocacy Review Panel on Toxic Substances Control Act (TSCA) Section 6(a) Rulemaking for N-Methylpyrrolidone (NMP)

Appendix A1: Materials Shared with Small Entity Representatives for the Pre-Panel Outreach Meeting, March 28, 2023

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Agenda

EPA's SBAR Pre-Panel Outreach Meeting with Small Entity Representatives on the Proposed Rulemaking for n-Methylpyrrolidone (NMP) under TSCA Section 6(a)

March 28, 2023, 1:00pm-4:00pm, Eastern time zone

Agenda

1:00 Welcome and Opening Remarks

- Bill Nickerson (EPA Small Business Advocacy Chair / Office of Policy)
- Brian Symmes (Acting Director, Existing Chemicals Risk Management Division, EPA Office of Chemical Safety and Pollution Prevention)
- Tayyaba Zeb (Small Business Administration, Office of Advocacy)
- Austin Mudd (Office of Management and Budget, Office of Information and Regulatory Affairs)

1:15 SER Introductions

1:25 Presentation on Panel process (Bill Nickerson, EPA SBAC)

1:35 Presentation on proposed rulemaking for NMP under TSCA section 6(a) (Office of Chemical Safety and Pollution Prevention)

- Consultations with Small Entity Representatives (SERs)
- Overview of the unreasonable risk determinations in the risk evaluation and the risk management requirements under TSCA
- Overview of conditions of use in the rulemaking and basis for unreasonable risk determination
- Section 6 risk management overview: EPA's authority to regulate occupational and consumer risks, key "tools in the toolbox" for managing unreasonable risks
- Potential regulatory options

2:05 Discussion on conditions of use (COU) with unreasonable risk determinations. (*See list at end for all conditions of use by group*).

- Detailed description of NMP use
- Your experience with exposure control and risk reduction
- Possible risk management actions
- Cost associated with implementations
- Available alternatives
- Other implementation considerations

NMP COU Group 1: Manufacturers, Repackaging/Recycling, and Disposal
NMP COU Group 2: Commercial Processing and Formulation Uses

2:50 Break

3:00 Discussion (continued)

NMP COU Group 3: Industrial and Commercial Paint, Coating, and Solvent Uses
NMP COU Group 4: Industrial and Commercial Uses in Manufacturing of Electronic Parts, Semiconductors, and Lithium Ion Batteries
NMP COU Group 5: Consumer Uses

3:45 Closing session

- Closing remarks from EPA, SBA, and OMB
- Wrap up and next steps (what to expect next)

4:00 Adjourn

Condition of Use Discussion Groups

Group 1: Manufacturing, Repackaging/Recycling, and Disposal

– Includes the following conditions of use:
  - Manufacturing (domestic manufacture)
  - Manufacturing (import)
  - Processing: repackaging in wholesale and retail trade
  - Processing: recycling
  - Disposal

Group 2: Commercial Processing and Formulation Uses

– Includes the following conditions of use:
  - Processing – as a reactant or intermediate in plastic material and resin manufacturing and other non-incorporative processing
  - Processing – Incorporation into a 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 as a solvent (which becomes part of a product formulation or mixture) including in textiles, apparel and leather manufacturing
  - Processing – Incorporation into articles in paint additives and coating additives not described by other codes in transportation equipment manufacturing
  - Processing – Incorporation into articles in other sectors, including in plastic product manufacturing

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

– Includes the following conditions of use:
  - 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 in paint additives and coating additives not described by other codes in multiple manufacturing sectors
  - Industrial and commercial use in ink, toner and colorant products in printer ink and inks in writing equipment
  - 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 soldering materials

- 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 use in other uses in cleaning and furniture care products, including wood cleaners and gasket removers
- Industrial and commercial use in other uses in fertilizer and other agricultural chemical manufacturing, processing aids and solvents

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

– Includes the following condition of use:
  - 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 paint additives and coating additives not described by other codes in computer and electronic product manufacturing in electronic parts manufacturing
  - 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
  - Industrial and commercial uses in other uses in lithium ion battery manufacturing

Group 5: Consumer Use

– Includes the following condition of use:
  - Consumer use in adhesives and sealants in glues and adhesives, including lubricant adhesives and sealants

Panel Process Presentation

An Overview of the Small Business Advocacy Review (SBAR) Panel Process

March 2023

Bill Nickerson, EPA's Small Business Advocacy Chair
Office of Regulatory Policy and Management
Office of Policy

Why does EPA convene an SBAR Panel?

The Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), requires agencies to:

"assure that small entities have been given an **opportunity to participate** in the rulemaking process" for any rule "which will have a **significant economic impact** on a substantial number of small entities."

What is an SBAR Panel?

An EPA Small Business Advocacy Review (SBAR) Panel is made up of **four** managers from **three** federal agencies:

- EPA's Small Business Advocacy **Chair** (EPA's SBAC is from OP)
- A **manager** from the EPA program responsible for writing the rule

- The Small Business Administration's **Chief Counsel** for Advocacy

- The **Administrator** of the Office of Management and Budget's (OMB's) Office of Information and Regulatory Affairs (OIRA)

What does an SBAR Panel do?

The RFA tasks the Panel with **reviewing the material** the Agency has available concerning the rulemaking, and **collecting advice and recommendations** from small entity representatives (SERs) on issues related to the following **four** elements:

- Who are the small entities to which the proposed rule will apply?
- What are the anticipated compliance requirements of the upcoming proposed rule?
- Are there any existing federal rules that may overlap or conflict with the regulation?
- Are there any significant regulatory alternatives that could minimize the impact on small entities?

SERs Participation in the Pre-panel and Panel process

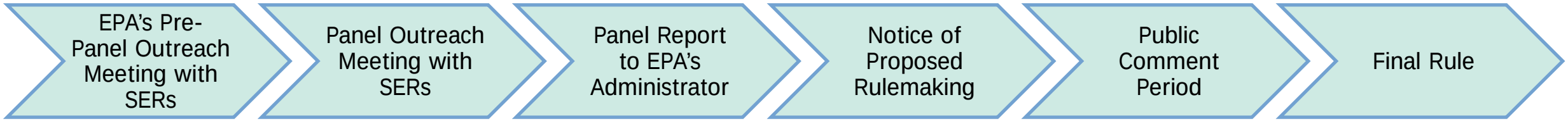
SERs are invited to 2 meetings: Pre-panel Outreach meeting and Panel Outreach meeting

- At each meeting, SERs participate in the discussion about how the rule might impact them and provide suggestions about how to minimize that impact.
- Panel Outreach meeting will focus on further refining SER advice and recommendations from the Pre-panel Outreach

SERs are invited to supplement the verbal meeting discussions with **written comments** (due 2 weeks after each meeting)

SER FAQ webpage https://www.epa.gov/reg-flex/frequent-questions-small-entities.

Where does the Panel process fit within the rulemaking process?



It is EPA's goal to host SBAR Panels well **before a proposed rule** is written so there is adequate time to incorporate Panel recommendations into senior management decision-making about the proposed rule

SER participation in the Pre-panel and Panel Outreach meetings **does not preclude** or take the place of participation in the normal public comment period at the time the rule is proposed

What does the Panel do with the information, advice, and recommendations from SERs?

The Panel prepares a Panel Report

- SER comments are **summarized**, and written comments are included as an appendix
- SER information, advice, and recommendations are **synthesized** into a set of Panel recommendations
- **Submitted** to the EPA Administrator
- Considered during senior-management decision-making **prior** to the issuance of the proposed rule
- Placed in the **rule's docket** when the proposed rule is published

Thank You

We realize that small entities make significant sacrifices to participate in this process

Thank you for taking time and effort away from your business or organization to assist the Panel in this important work

Contact Information for SBAC Staff

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Pre-Panel Rulemaking Presentation

N-Methylpyrrolidone (NMP)
Small Entity Consultation
on Proposed Rulemaking under TSCA Section 6

Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

Pre-Panel Outreach Meeting with Small Entity Representatives
March 28, 2023

Overview

- SERs and the regulatory process
- Findings from the risk evaluation for NMP
- Overview of conditions of use (COU) in the rulemaking
- Basis for unreasonable risk determination
- Risk management requirements under TSCA
- EPA’s authority and “tools in the toolbox”
- Potential regulatory options
- Additional discussion with Small Entity Representatives
- Closing remarks

Consultation with Small Entity Representatives

- EPA is interested in not only information, but also advice and recommendations from the small entity representatives (SERs)

- EPA will use this information to inform the agency's decision on potential regulatory options and to develop a regulatory flexibility analysis, which becomes part of the record for the potential regulation

Consultation with Small Entity Representatives

- Key elements in this regulatory flexibility analysis:
  - Number of small entities to which the potential rule would apply
  - Projected compliance requirements of the potential rule
  - Identification of all relevant Federal rules which may duplicate, overlap or conflict with the potential rule
  - Any significant alternatives to the potential rule which accomplish the stated objectives, and which minimize significant economic impact of the potential rule on small entities

Potentially Affected Entities

- The potentially affected industries/sectors for this proposed rule are identified by NAICS code, SBA thresholds and U.S. Census Bureau Statistics of U.S. Business datasets, published annually
- 244 industries/sectors and their associated NAICS code have been identified although not all of the small firms indicated in the attachment are necessarily expected to be impacted by the proposed rule
- SBA size standards vary greatly by NAICS code and range from $8 - $47 million and 100-1,500 employees
- The attachment “Industry Sectors with Small Entities Potentially Affected by the Rulemaking” provides small firm statistics (size standard or number of smalls) for each industry/sector or use category
- EPA estimates 95% of firms are small entities that may be impacted by the proposed rule
- As more specific information about each entity is identified, it is possible that some entities could be dropped from the list

SERs and the Regulatory Process

- We are seeking information on how the options presented might impact your business or organization
  - Provide specific examples of impacts
  - Provide cost data, if available
  - Please see detailed questions in a separate handout

SERs and the Regulatory Process

- We are also seeking alternative methods of regulating unreasonable risks identified for NMP
  - Suggest other relevant options, including data costs and information on how to ensure compliance
  - Suggest ways that small businesses could benefit from flexibilities, such as different compliance timetables, simplified reporting requirements, and exemptions
- We would like to minimize duplication
  - Provide information on any duplicative or contradictory federal, state, county, or city regulations you are aware of
  - For a list of existing regulations, please see summary of related regulations

Overview of the Risk Evaluation for NMP

- Risk evaluation published December 30, 2020:
  - 37 conditions of use were evaluated
  - Risk evaluation follows a series of opportunities for public input into EPA's NMP risk evaluation activities
  - NMP draft risk evaluation: December 2019; NMP problem formulation: June 2018; NMP scope document: June 2017

Overview of the Risk Evaluation for NMP

- 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 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

Determination of Unreasonable Risk

- In the December 2020 risk evaluation, EPA determined that NMP presented unreasonable risk to health and the environment. In that risk evaluation, EPA determined that 26 of the 37 conditions of use (COU) of NMP presented unreasonable risk
- With EPA's policy change to a whole chemical approach, EPA has issued a revised whole chemical unreasonable risk determination without presuming use of PPE. The changes from that revised determination are included in this presentation and available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/final-risk-evaluation-n-methylpyrrolidone-nmp
- There may be some conditions of use that EPA has determined do not drive the unreasonable risk but may still be subject to regulation due to uses elsewhere in the supply chain that drive the unreasonable risk

Recent Changes to the Risk Determination

- EPA released for public comment a draft revision to the unreasonable risk determination for NMP on July 1, 2022
- EPA published the final revised risk determination on December 19, 2022
- Incorporates policy changes announced in June 2021
- Specifically, EPA has determined that:
  - Making an unreasonable risk determination for NMP as a whole chemical substance, rather than unreasonable risk determinations separately on each individual condition of use in the risk evaluation, is the most appropriate approach to NMP under the statute and implementing regulations
  - The risk determination does not rely on assumptions regarding the use of personal protective equipment (PPE) in making the unreasonable risk determination under TSCA section 6, even though some facilities might be using PPE as one means to reduce workers' exposures; rather, the use of PPE would be considered during risk management as appropriate

Recent Changes to the Risk Determination

- Removing the assumption that workers always and appropriately wear PPE in making the whole chemical risk determination for NMP result in:

  - Three additional conditions of use that drive the unreasonable risk determination for NMP:
    - Industrial and commercial use in ink, toner, and colorant products;
    - Industrial and commercial use in other uses soldering materials;
    - Industrial and commercial use in other uses in fertilizer and other agricultural chemical manufacturing—processing aids and solvents

Recent Changes to the Risk Determination Cont.

- Additionally, removing the assumption that workers always and appropriately wear PPE in making the whole chemical risk determination for NMP result in risks for acute non-cancer effects from inhalation and dermal exposures also driving the unreasonable risk in five conditions of use (where previously those conditions of use were identified as presenting unreasonable risk from chronic non-cancer effects):
  - Processing for incorporation into articles in paint additives and coating additives not described by other codes in transportation equipment manufacturing;
  - 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, powder coatings (surface preparation);
  - Industrial and commercial use paint additives and coating additives in multiple manufacturing sectors; and
  - Industrial and commercial use in adhesives and sealants including binding agents, single component glues and adhesives, including lubricant additives, two-component glues, and adhesives including some resins.

Recent Changes to the Risk Determination Cont.

- Overall, 29 conditions of use out of 37 EPA evaluated drive the NMP whole chemical unreasonable risk determination
- EPA has not conducted new scientific analysis on NMP; the risk evaluation continues to characterize risks associated with individual conditions of use
- The final risk determination is in docket EPA-HQ-OPPT-2016-0743 at regulations.gov

Recent Changes to the Risk Determination

- Separately, EPA is conducting a screening approach to assess potential risks from the air and water pathways for several of the first 10 chemicals, including NMP
  - This screening analysis was presented to the SACC in March and EPA is currently incorporating comments from the SACC and public commenters on revisions to the analysis
- Exposure pathways that were or could be regulated under another EPA-administered statute were excluded from the 2020 NMP risk evaluation, resulting in certain air and water pathways not being fully assessed
- EPA's screening approach will identify if there are risks that were unaccounted for in the risk evaluation for NMP
- If the results suggest there is additional risk, EPA will determine if the risk management approach being contemplated for NMP will protect against these risks or if the risk evaluation will need to be formally supplemented or revised

NMP Manufacturing and Processing Uses that Drive the 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 Drive the 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

NMP Industrial and Commercial Uses that Drive the Unreasonable Risk

- Industrial and commercial use as a solvent (for cleaning or degreasing) in electrical equipment, appliance and component manufacturing for use in semiconductor manufacturing
- Industrial and commercial use in ink, toner and colorant products in printer ink and inks in writing equipment
- 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 soldering materials

NMP Industrial and Commercial Uses and Disposal that Drive the Unreasonable Risk

- 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 battery manufacturing
- Industrial and commercial use in other uses in cleaning lithium-ion and furniture care products, including wood cleaners and gasket removers
- Industrial and commercial use in other uses in fertilizer and other agricultural chemical manufacturing, processing aids and solvents
- Disposal

NMP Consumer Uses that Drive the Unreasonable Risk

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

Basis for Unreasonable Risk Determination: Workers

- The unreasonable risk determination for workers is based on the following health hazards during occupational exposures to NMP:
  - Developmental effects from acute inhalation and dermal exposures
  - Reproductive effects from chronic inhalation and dermal exposures
- Consideration of Personal Protective Equipment (PPE):
  - EPA does not assume that workers are always provided or appropriately wear PPE, for the purposes of unreasonable risk determination
  - EPA does not assume that it is a standard industry practice that workers in some small commercial facilities (e.g., those performing cleaning or degreasing, using automotive care products, soldering materials, or commercial printing and copying) have a respiratory protection program or regularly employ dermal protection; therefore, the use of respirators and gloves is assumed to be unlikely for workers in these facilities
  - When no PPE is assumed to be in place, 29 of the 37 COUs drive the unreasonable risk
  - As previously noted, this assumption results in three additional COUs driving the unreasonable risk determination, and five conditions of use with acute effects in addition to chronic affects driving the unreasonable risk determination

Basis for Unreasonable Risk Determination: Consumers

- The unreasonable risk determinations for consumers is based on the following health hazards during consumer exposures to NMP:
  - Developmental toxicity from acute inhalation and dermal exposure

- The unreasonable risk determinations were based on the high intensity risk estimates for consumers

- EPA did not evaluate chronic exposures to NMP for consumer users because EPA considered the frequency of consumer product use to be too low to create chronic risk concerns

Related Regulations and TSCA Section 6 Authority

- NMP is subject to several federal laws and regulations in the United States and is also subject to regulatory actions by states
  - See separate document “Related Regulations (EPA, other Federal, State, and International)” for more information on the regulatory history of NMP
- EPA determined that NMP presents an unreasonable risk to workers and consumers in the TSCA risk evaluation
- Therefore, EPA is required to develop risk management actions under TSCA to address the unreasonable risk
- TSCA Section 9 allows EPA to use statutory authorities to a sufficient extent by action taken under a Federal law not administrated by the Administrator to reduce or eliminate identified risk to health or the environment

Risk Management Requirements

- Under TSCA, EPA is required to take action, to the extent necessary, to address chemicals that pose unreasonable risks to human health or the environment
- EPA must issue a TSCA section 6(a) rule following risk evaluation to address all identified unreasonable risks within two years:
  - Proposed rule one year after risk evaluation
  - Final rule two years after risk evaluation
- Specific requirements on consideration of alternatives, selecting among options and statement of effects apply to risk management rules
- Input from stakeholders is critical to the process and EPA is seeking stakeholder input now during the SBAR process and during the public comment period following the proposed rule

TSCA 6a Rule Requirements (15 U.S.C 2605(c)(2)):

- (A) Statement of effects
  - In proposing and promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to—
  - (i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture;
  - (ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture;
  - (iii) the benefits of the chemical substance or mixture for various uses; and
  - (iv) the reasonably ascertainable economic consequences of the rule, including consideration of—
    - (I) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;
    - (II) the costs and benefits of the proposed and final regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator; and
    - (III) the cost effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

- (B) Selecting requirements
  - In selecting among prohibitions and other restrictions, the Administrator shall factor in, to the extent practicable, the considerations under subparagraph (A) in accordance with subsection (a).

TSCA Section 6(a)

- TSCA provides EPA with authority to address unreasonable risks, and to regulate entities including:
  - Manufacturers (including importers and importers of articles) ~~and~~
  - Processors (e.g., formulators)
  - Distributors
  - Commercial users (workplaces and workers)
  - Entities disposing of chemicals for commercial purposes
- Cannot directly regulate consumer users
  - Under TSCA, EPA has authority to regulate at the manufacturing, processing and distribution levels in the supply chain to eliminate or restrict the availability of chemicals and chemical-containing products for consumer use
  - These authorities allow EPA to regulate at key points in the supply chain to effectively address unreasonable risks to consumers

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

Availability of Alternatives: TSCA Section 6(c)(2)(C)

- TSCA section 6(c)(2)(C) requires EPA "…in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action…to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect"
  - Substitute products and methods vary by condition of use
  - For example, alternatives to NMP in paint and coating removal include solvent-based alternatives like n-ethylpyrrolidone (NEP), benzyl alcohol, and other methyl acetate-based stripping formulations, or process-based alternatives like heat and sanding (https://dtsc.ca.gov/wp-content/uploads/sites/31/2019/09/Final-NMP-Paint-Stripper-Graffiti-Remover_Profile.pdf)

Effective Dates: TSCA Section 6(d)

- TSCA section 6(d) describes effective dates and compliance dates for TSCA section 6(a) rules
- In these rules, EPA must specify an effective date, which must be as soon as practicable
- Except for uses exempted under TSCA section 6(g), EPA must:
  - Specify mandatory compliance dates for all rule requirements, no later than five years after promulgation of the rule, or, in the case of a ban or phase-out:
    - Specify mandatory compliance dates for the start of a ban or phase-out requirements, which shall be as soon as practicable and no later than five years after promulgation of the rule, and
    - Specify mandatory compliance dates for full implementation of a ban or phase-out requirements, which shall be as soon as practicable
- EPA must also provide for a reasonable transition period

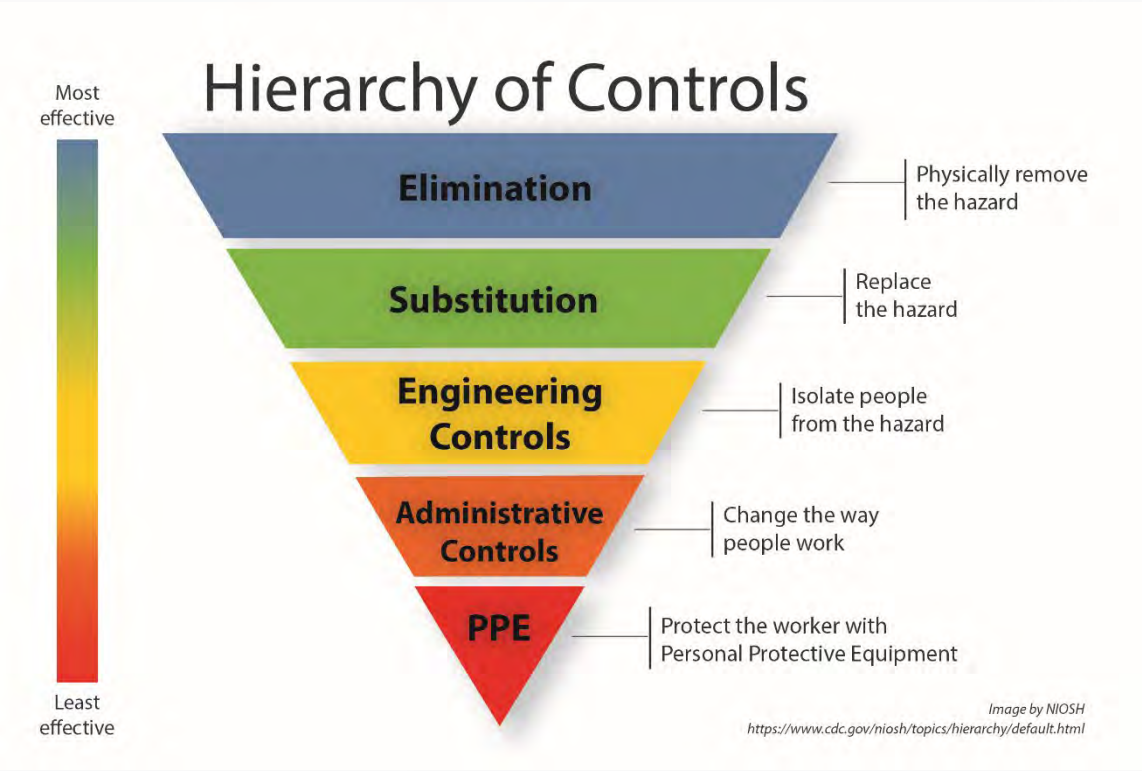
Critical or Essential Uses: TSCA Section 6(g)

TSCA Section 6(g) allows EPA to grant, by rule, a time-limited exemption from a section 6(a) rule for a specific condition of use

- EPA can provide an exemption under three conditions:
  - The specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available;
  - Compliance with the rule would significantly disrupt the national economy, national security, or critical infrastructure; or
  - The specific condition of use, as compared to alternatives, provides a substantial benefit to health, the environment, or public safety
- In granting an exemption, EPA must:
  - Provide a time limit for the exemption
  - Analyze the need for the exemption and make the analysis public
  - Include conditions, such as recordkeeping, monitoring, and reporting requirements, to the extent EPA determines they are necessary to protect health and the environment while achieving the purposes of the exemption
- EPA appreciates any information to inform whether it would be appropriate to propose an exemption under section 6(g), such as:
  - How the exemption request for a COU would meet one or more of the criteria under section 6(g) and information on specific impacts if the chemical were not available
  - Whether the chemical is used to meet requirements or specifications from other regulations, describe the process, timeline, and challenges for obtaining industry/government approval for use of an alternative substance or method
  - Description of how long a potential section 6(g) exemption would be needed and why

Hierarchy of Controls

- EPA is considering the NIOSH/OSHA hierarchy of controls when developing risk management actions
  - As described by NIOSH (https://www.cdc.gov/niosh/topics/hierarchy/default.html), the hierarchy of controls can be used to implement feasible and effective controls to protect workers
  - It typically includes elimination, substitution, engineering controls, administrative controls, and PPE on a scale of most to least protective
- Any regulatory requirement can be used alone or in combination to the extent necessary so that NMP no longer presents an unreasonable risk under its conditions of use



Potential Regulatory Options

- EPA has considered several regulatory options under TSCA section 6(a), and a wide range of risk reduction practices and options
- Through Agency review and stakeholder input, the following potential options have been identified as reducing exposures, so NMP no longer presents an unreasonable risk of injury to health
- These options are currently being considered and evaluated by EPA, and are not final at this time. EPA has not made a decision at this point about what regulatory options to propose
- Regulatory requirements could be used alone or in combination to the extent necessary so that NMP no longer presents an unreasonable risk under its conditions of use
  - Additionally, under TSCA section 6(g), EPA may propose a time-limited exemption for a specific condition of use under three circumstances, as discussed previously on slide 30

Potential Regulatory Options

- Prohibit use above a set concentration (concentration limits)
- Prescriptive PPE controls
- Prescriptive administrative controls
- Prescriptive engineering controls
- Combination of controls (non-prescriptive)
- Prohibit or restrict manufacturing, processing, and distribution
- Prohibit or restrict manufacturing, processing, and distribution for a particular use
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Training, certification, and limited access program

Potential Regulatory Options, cont.

- EPA has not decided on the primary regulatory options to propose in the rule.
- Nonetheless, EPA's primary performance metric for eliminating the unreasonable risk of injury to human health is to eliminate or reduce significantly direct dermal contact with NMP. EPA is considering the following regulatory options and seeking feedback on the impacts of applying one or more of the following regulatory options to address the unreasonable risk from NMP.
- Unlike some of the other chemicals currently undergoing risk management under TSCA section 6, EPA is not considering an airborne concentration limit for NMP and is focusing on dermal protection measures. The 2020 risk evaluation for NMP and revised unreasonable risk determination found that the unreasonable risk of injury to human health is driven by direct dermal contact with liquid NMP.

Potential Regulatory Options, cont.

- For processing, industrial, and commercial uses (occupational exposures) EPA is considering the following regulatory options to address the unreasonable risk:
  - Concentration Limit
    - A risk management option that would restrict the concentration or weight fraction within the formulation.
    - For example, if scientific analysis supported it, EPA could limit the percentage amount of the chemical in the formulation if that percentage addressed the unreasonable risk and the formulation was still efficacious.
    - In the 2020 Risk Evaluation for NMP, EPA identified the expected weight fraction of NMP in liquid products based on publicly available information, public comments, and available products on the market. If ranges of NMP in formulations were identified, EPA generally assessed the lower bound of the range as the central tendency and the upper bound of the range as the high end.
      - Example: EPA identified and assessed the commercial use of NMP in paints, coatings, adhesives and sealants based on products with 2-53% NMP. At the high-end concentration, in the expected occupational exposure scenarios, these conditions of use drive the unreasonable risk.
      - Example: EPA identified and assessed the commercial use of NMP in metal finishing products with 60-90% NMP. At these concentrations, in the expected occupational exposure scenarios, this condition of use drives the unreasonable risk.
    - There is uncertainty if lowering the concentration limit may impact efficacy of the products. For a concentration or weight fraction limit to address the unreasonable risk, it would need to be lower than those that drove the unreasonable risk in the risk evaluation.

Potential Regulatory Options, cont.

- Prescriptive Engineering Controls
  - Would reduce worker exposure by requiring specific physical changes to the workplace to eliminate or reduce direct dermal contact
  - Examples: installing additional or different equipment, such as enclosed transfer liquid lines, closed loop container systems or a laboratory type fume hood, to reduce the exposure to the chemical
- Prescriptive Administrative Controls
  - Would reduce worker exposure by requiring processes or procedures in the workplace to eliminate or reduce direct dermal contact
  - Examples: Limit access to work areas (restricted areas) or confining operations (enclosed areas)
  - EPA's confidence that the unreasonable risk from NMP can be addressed is highest for highly standardized and industrialized settings, such as where NMP is used in a closed-loop system

Potential Regulatory Options, cont.

- Prescriptive PPE Controls
  - A risk management option that would require the use of specific PPE to minimize exposure. This may limit flexibility for the regulated entity
    - Some examples of potential PPE that could contribute to reducing the unreasonable risk are listed separately in Appendix F of the 2020 final risk evaluation, as well as the Potential Costs of Regulatory Options table later in this presentation
  - Requiring the use of dermal and inhalation PPE that provides an impervious barrier in combination with a set concentration limit of NMP would allow more flexibility for regulated entities to mitigate unreasonable risk
  - EPA anticipates that PPE would need to be combined with training and other controls in order to address the unreasonable risk from NMP
- Combination of Controls (non-prescriptive)
  - A combination of risk management approaches for conditions of use where strict industrial practices may already exist. Enables users to determine how to most effectively separate, distance, physically remove, or isolate workers from direct handling of NMP or from contact with equipment/materials for which NMP may exist based on what works best for their workplace and the ability to combine prescriptive controls
  - Would eliminate direct dermal contact in accordance with the Pollution Prevention Act and NIOSH hierarchy of controls
  - Could include engineering or administrative controls to reduce or eliminate exposure
  - If direct dermal contact could not be eliminated using elimination, substitution, engineering controls, or administrative controls, could require personal protective equipment that provides an impervious barrier
  - Examples: Automation, barriers, or design of tools

Potential Regulatory Options, cont.

- Prohibition
  - EPA could include prohibition on manufacturing, processing, distribution, use, or disposal for specific conditions of use or the chemical as a whole
  - EPA requests data and feedback about availability and viability of NMP alternatives, testing and analysis that SERs have completed of potential alternatives, the cost impacts of SERs switching to alternatives, and the overall impacts to SERs' businesses if NMP is prohibited.

Potential Regulatory Options, cont.

- For consumer uses, EPA is considering the following regulatory options to address the unreasonable risk:
  - Regulation at key points in the supply chain (manufacturing, processing, and/or distribution) to address unreasonable risks to consumers
    - Example: March 2019 rule to address unreasonable risks to consumers from methylene chloride in paint and coating removal prohibited manufacture (including import), processing, and distribution in commerce of methylene chloride for this use (including distribution to and by retailers)
  - Potential regulatory options:
    - Prohibition
    - Concentration Limits
    - Container size

Potential Regulatory Options, cont.

- Regulatory options applied broadly with other restrictions
  - Recordkeeping – example: ordinary business records to demonstrate compliance (for example not selling products to consumers)
  - Downstream notification – example: modify the SDS to indicate that the product should not be used in consumer products or indicate other regulatory requirements
  - Monitoring – example: monitor for compliance or concentration limits
  - Labeling – example: labeling products to indicate that they should not be used by consumers or to describe other regulatory requirements
  - Container size – example: a minimum or maximum container size (e.g., 32 ounce container, 55 gallon drum) to reduce likelihood of purchase by certain types of users (consumers or commercial users)
  - Limited access program – example: access only to users with certain equipment or types of facilities

Cost of Regulatory Options

Option/Type of Cost	Estimated Compliance Cost	Notes
Prohibition of manufacturing, processing, and distribution	Varies with condition of use	Cost will vary by condition of use. Potential activities could include changes in process and equipment, costs of alternatives, reformulation (see below), and more. Requires input from potentially regulated entities.
Prohibition of Use	Varies with condition of use	Cost will vary by condition of use. Potential activities could include changes in process and equipment, costs of alternatives, reformulation (see below), and more. Requires input from potentially regulated entities.
Reformulation of product to reduce NMP concentration	$17,000 per product	Costs reflect dilution reformulation approach.
Reformulation of product to eliminate NMP concentration	$60,000-$102,000 per product	Costs will vary by condition of use and will be dependent on reformulation approach. Requires input from potentially regulated entities.

Cost of Regulatory Options, cont.

Option/Type of Cost	Estimated Compliance Cost	Notes
Engineering/ Administrative Controls	Varies by control type and needs of user	Requires input from potentially regulated entities
Personal Protective Equipment (PPE) – (e.g., respirators)	APF 10: $1,800 APF 25: $1,300 APF 50: $1,700 APF 1000: $1,100 APF 10000: $2,000	Annualized costs are per person and include purchase of equipment (including filters), training, fit-testing, and medical clearance. The unit costs include a written respiratory program and equipment cleaning. Does not include existing PPE use nor PPE replacement due to employee turn-over. Includes both purified and supplied air respirators.
Personal Protective Equipment (PPE) (dermal)	Reusable gloves: $6-$55 Disposable gloves: $0.50 Reusable apron:$25-$34 Disposable apron: $4	Reusable glove costs are per pair of butyl, laminated polyethylene, neoprene, and natural rubber/latex gloves. Disposable glove costs are per pair of nitrile gloves. Disposable nitrile gloves are not used alone, but in combination with the reusable gloves. Reusable apron costs are per nitrile and neoprene apron. Disposable apron costs are per polyethylene apron.

Cost of Regulatory Options, cont.

Option/Type of Cost	Estimated Compliance Cost	Notes
Combination of controls (non-prescriptive)	Annualized costs of Exposure control plan: $560-$630 per facility costs $35 per worker costs One-time costs of Exposure control plan: - 40 hours one time cost to develop plan: $3,730 per facility - 4 hours annual cost for regular inspections: $370 per facility per year - 0.43 hours annual recordkeeping: $40 per facility per year Costs of engineering controls, monitoring, or PPE varies by control type and needs of user See PPE costs for glove and apron costs	Non-prescriptive approach would likely include development of an exposure control plan. Costs include costs for conducting regular inspections, PPE program plan documentation, records of plan implementation, and records of dermal exposure. Includes both per-facility and per-worker costs. Costs will depend on baseline PPE and dermal exposure control plan activities.

Cost of Regulatory Options, cont.

Option/Type of Cost	Estimated Compliance Cost	Notes
Product Label or Warnings	$830- $8,900 per product, one time cost	Costs will vary by condition of use. Potential activities may include graphic design changes, plate changes, discarded inventory, and labor.
Container Sizes	$9,500-$47,500 per product, one time cost	A change in container size would lead to costs at the lower end while a packaging material change would likely result in costs at the higher end.
Substitute Products (average per ounce)	Varies with condition of use	Would vary by price of NMP per ounce vs. substitutes, as well as the differences in efficacy of the substitute products.
Substitute Methods	Varies by job labor rate	This will primarily be labor cost and cost of alternative equipment.

Cost of Regulatory Options, cont.

Option/Type of Cost	Estimated Compliance Cost	Notes
Recordkeeping	$218-$340 per firm	Ongoing annual labor and material costs associated with documentation of ordinary business records.
Downstream Notification	$121-$138 per product, one time cost	Costs are per product and include labor and material costs to update a product's safety data sheet (SDS).
Limited Access Program	Varies with condition of use and type of distributor	Would vary by type of requirements for certification and any distribution processes or restrictions already in place.

In-Depth Discussion on Conditions of Use for NMP

1. Manufacturing, repackaging/recycling, and disposal
2. Commercial processing and formulation uses
3. Industrial and commercial paint, coating, and solvent uses
4. Industrial and commercial uses in manufacturing of electronic parts, semiconductors, and lithium-ion batteries
5. Consumer uses

NMP Group 1: Manufacturers, Repackaging/Recycling, and Disposal

- Relevant conditions of use:
  - Manufacturing (domestic manufacture)
  - Manufacturing (import)
  - Processing: repackaging in wholesale and retail trade
  - 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 for NMP Group 1: Manufacturing, Repackaging/Recycling, and Disposal

As noted previously EPA is considering the following regulatory options and is seeking your feedback. Any regulatory requirement could be used alone or in combination to the extent necessary so that NMP no longer presents an unreasonable risk under its conditions of use:

- Prescriptive Controls (Engineering, Administrative, PPE)
- Combination of Controls (Non-Prescriptive)
- Prohibition
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling

Discussion with Small Entity Representatives

Please provide your comments or questions regarding:

- Number and types of small entities affected
- Potential reporting, recordkeeping and compliance requirements
- Related Federal rules
- Regulatory flexibility alternatives

Discussion – Your Business and NMP

- How does your organization use NMP?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of NMP use in your organization?
- How important to your business is the function that NMP provides?
- Are there potential critical or essential uses?
- Are there uses for which there are no available technically or economically feasible alternatives?

Discussion – Workplace Exposure

- What is your experience with exposure control and risk reduction?
- How many employees are exposed to NMP, and for how long (days/years and hours/day)?
- What is the concentration of NMP in the product you use?
- What routine worker activities result in worker exposure to NMP and what type of exposure?
- What engineering controls are used to minimize exposure to NMP? Are additional controls feasible?
- What administrative controls and training do you use to minimize exposure to NMP?
- What respiratory and dermal PPE is regularly worn by workers to minimize exposure to NMP?

Discussion – Regulatory Options

- What regulatory approach should EPA take?
- Are there concerns about the ability to comply with any of the potential regulatory options?
- What advice do you have for reducing impacts on small businesses?
- What timeframe would your business need to comply with potential new regulations or restrictions?

NMP Group 2: Processors

- Relevant conditions of use
  - Processing – as a reactant or intermediate in plastic material and resin manufacturing and other non-incorporative processing
  - Processing – Incorporation into a 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 as a solvent (which becomes part of a product formulation or mixture) including in textiles, apparel and leather manufacturing
  - Processing – Incorporation into articles in paint additives and coating additives not described by other codes in transportation equipment manufacturing
  - Processing – Incorporation into articles in other sectors, including in plastic product manufacturing

- What is NMP used for? How is it 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 for NMP Group 2: Processors

As noted previously EPA is considering the following regulatory options and is seeking your feedback. Any regulatory requirement could be used alone or in combination to the extent necessary so that NMP no longer presents an unreasonable risk under its conditions of use:

- Concentration Limit
- Prescriptive Controls (Engineering, Administrative, PPE)
- Combination of Controls (Non-Prescriptive)
- Prohibition
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling

Discussion with Small Entity Representatives

Please provide your comments or questions regarding:

- Number and types of small entities affected
- Potential reporting, recordkeeping and compliance requirements
- Related Federal rules
- Regulatory flexibility alternatives

Discussion – Your Business and NMP

- How does your organization use NMP?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of NMP use in your organization?
- How important to your business is the function that NMP provides?
- Are there potential critical or essential uses?
- Are there uses for which there are no available technically or economically feasible alternatives?

Discussion – Workplace Exposure

- What is your experience with exposure control and risk reduction?
- How many employees are exposed to NMP, and for how long (days/years and hours/day)?
- What is the concentration of NMP in the product you use?
- What routine worker activities result in worker exposure to NMP and what type of exposure?
- What engineering controls are used to minimize exposure to NMP? Are additional controls feasible?
- What administrative controls and training do you use to minimize exposure to NMP?
- What respiratory and dermal PPE is regularly worn by workers to minimize exposure to NMP?

Discussion – Formulators of Products Containing NMP

- Product reformulation
  - How often do you reformulate your products?
  - What is the typical cost of reformulating your products?
  - What might reformulation costs be if you needed to reformulate your products without NMP? (For example, costs might include R&D, testing, capital costs of production changes, packaging, labeling)
- Product relabeling
  - How often do you relabel your products?
  - What is the typical cost of relabeling?

Discussion – Formulators of Products Containing NMP (Cont.)

- Alternatives
  - Do you sell another product that does not contain NMP that is designed for the same use or application as the NMP product?
    - If yes, what solvent replaces NMP in the alternative product? How does the alternative product compare in terms of safety, efficacy, and cost?
    - If no, if you needed to reformulate this product with a lower concentration of NMP, what would the implications be for the product in terms of cost and efficacy? What solvent would replace NMP? How do you think the alternative would compare in terms of efficacy and cost?
  - Are there any restrictions or other limitations that prescribe the use of NMP to perform your services (e.g., for aerospace or DOD customers)?
  - Is there a subset of uses for your product where using a product formulated without NMP would be problematic?

Discussion – Regulatory Options

- What regulatory approach should EPA take?
- Are there concerns about the ability to comply with any of the potential regulatory options?
- What advice do you have for reducing impacts on small businesses?
- What timeframe would your business need to comply with potential new regulations or restrictions?

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

- Relevant conditions of use:
  - Industrial and commercial use in paints, coatings, and adhesive removers
  - Industrial and commercial use 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 not described by other codes in multiple manufacturing sectors
  - Industrial and commercial use in ink, toner and colorant products in printer ink and inks in writing equipment
  - 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 soldering materials
  - Industrial and commercial use in anti-freeze and de-icing, automotive care products, and lubricants and greases
  - Industrial and commercial use metal products, lubricant and lubricant additives including hydrophilic coatings
  - Industrial and commercial use in laboratory chemicals
  - Industrial and commercial use in cleaning and furniture care products, including wood cleaners and gasket removers
  - Industrial and commercial use in fertilizer and other agricultural chemical manufacturing, processing aids, and solvents

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

As noted previously EPA is considering the following regulatory options and is seeking your feedback. Any regulatory requirement could be used alone or in combination to the extent necessary so that NMP no longer presents an unreasonable risk under its conditions of use:

- Concentration Limit
- Prescriptive Controls (Engineering, Administrative, PPE)
- Combination of Controls (Non-Prescriptive)
- Prohibition
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Container size

Discussion with Small Entity Representatives

Please provide your comments or questions regarding:

- Number and types of small entities affected
- Potential reporting, recordkeeping and compliance requirements
- Related Federal rules
- Regulatory flexibility alternatives

Discussion – Your Business and NMP

- How does your organization use NMP?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of NMP use in your organization?
- How important to your business is the function that NMP provides?
- Are there potential critical or essential uses?
- Are there uses for which there are no available technically or economically feasible alternatives?

Discussion – Workplace Exposure

- What is your experience with exposure control and risk reduction?
- How many employees are exposed to NMP, and for how long (days/years and hours/day)?
- What is the concentration of NMP in the product you use?
- What routine worker activities result in worker exposure to NMP and what type of exposure?
- What engineering controls are used to minimize exposure to NMP? Are additional controls feasible?
- What administrative controls and training do you use to minimize exposure to NMP?
- What respiratory and dermal PPE is regularly worn by workers to minimize exposure to NMP?

Discussion – Users of Products Containing NMP

- What chemicals or processes have you considered as an alternative to using NMP or a product containing NMP?
- Do you currently use any alternatives to NMP or products containing NMP?
- Did you try to switch to another chemical, process, or product, only to switch back? If so, what did you switch to, why did you switch back, and what made you switch in the first place?
- Are there any restrictions or other limitations that prescribe the use of NMP to perform your services (e.g., for aerospace or DOD customers)?
- What are the relative advantages and disadvantages of different substitutes and/or processes that you have considered, including in terms of exposure, cost, and hazard?

Discussion – Regulatory Options

- What regulatory approach should EPA take?
- Are there concerns about the ability to comply with any of the potential regulatory options?
- What advice do you have for reducing impacts on small businesses?
- What timeframe would your business need to comply with potential new regulations or restrictions?

NMP 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 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 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
  - Industrial and commercial uses in other uses in 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 for NMP Group 4: Industrial and Commercial Uses in Manufacturing of Electronic Parts, Semiconductors, and Lithium-Ion Batteries

As noted previously EPA is considering the following regulatory options and is seeking your feedback. Any regulatory requirement could be used alone or in combination to the extent necessary so that NMP no longer presents an unreasonable risk under its conditions of use:

- Prescriptive Controls (Engineering, Administrative, PPE)
- Combination of Controls (Non-Prescriptive)
- Prohibition
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling

Discussion with Small Entity Representatives

Please provide your comments or questions regarding:

- Number and types of small entities affected
- Potential reporting, recordkeeping and compliance requirements
- Related Federal rules
- Regulatory flexibility alternatives

Discussion – Your Business and NMP

- How does your organization use NMP?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of NMP use in your organization?
- How important to your business is the function that NMP provides?
- Are there potential critical or essential uses?
- Are there uses for which there are no available technically or economically feasible alternatives?

Discussion – Workplace Exposure

- What is your experience with exposure control and risk reduction?
- How many employees are exposed to NMP, and for how long (days/years and hours/day)?
- What is the concentration of NMP in the product you use?
- What routine worker activities result in worker exposure to NMP and what type of exposure?
- What engineering controls are used to minimize exposure to NMP? Are additional controls feasible?
- What administrative controls and training do you use to minimize exposure to NMP?
- What respiratory and dermal PPE is regularly worn by workers to minimize exposure to NMP?

Discussion – Users of Products Containing NMP

- What chemicals or processes have you considered as an alternative to using NMP or a product containing NMP?
- Do you currently use any alternatives to NMP or products containing NMP?
- Did you try to switch to another chemical, process, or product, only to switch back? If so, what did you switch to, why did you switch back, and what made you switch in the first place?
- Are there any restrictions or other limitations that prescribe the use of NMP to perform your services (e.g., for aerospace or DOD customers)?
- What are the relative advantages and disadvantages of different substitutes and/or processes that you have considered, including in terms of exposure, cost, and hazard?

Discussion – Regulatory Options

- What regulatory approach should EPA take?
- Are there concerns about the ability to comply with any of the potential regulatory options?
- What advice do you have for reducing impacts on small businesses?
- What timeframe would your business need to comply with potential new regulations or restrictions?

NMP Group 5: Consumer Uses

- Relevant condition of use:
  - Consumer use in adhesives and sealants in glues and adhesives, including lubricant adhesives and sealants

Potential Regulatory Options for NMP Group 5: Consumer Uses

As noted previously EPA is considering the following regulatory options and is seeking your feedback. Any regulatory requirement could be used alone or in combination to the extent necessary so that NMP no longer presents an unreasonable risk under its conditions 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
  - Container size

Discussion with Small Entity Representatives

Please provide your comments or questions regarding:

- Number and types of small entities affected
- Potential reporting, recordkeeping and compliance requirements
- Related Federal rules
- Regulatory flexibility alternatives

Discussion – Your Business and NMP

- How does your organization use NMP?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of NMP use in your organization?
- How important to your business is the function that NMP provides?
- Are there potential critical or essential uses?
- Are there uses for which there are no available technically or economically feasible alternatives?

Discussion – Distributors and Retailers

- What is your experience with exposure control and risk reduction?
- If you could no longer sell products containing NMP, how would this impact your business?
- Are there particular challenges to small business doing distribution of products containing NMP that are different from large distributors?
- What is your preferred method of downstream notification?
- If you were required to limit sales of NMP containing products to only persons who were certified to purchase it, what activities and costs would be involved? What guidance would be helpful from the Agency?

Discussion – Regulatory Options

- What regulatory approach should EPA take?
- Are there concerns about the ability to comply with any of the potential regulatory options?
- What advice do you have for reducing impacts on small businesses?
- What timeframe would your business need to comply with potential new regulations or restrictions?

Closing Session

- Closing remarks from EPA, SBA, and OMB
- Next steps
  - Written comments by April 11, 2023
  - The risk evaluation and supplemental materials are in docket EPA-HQ-OPPT-2019-0236, with additional materials supporting the risk evaluation process and the revised unreasonable risk determination in docket EPA-HQ-OPPT-2016-0743, on www.regulations.gov

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
- June 2021 Policy Changes: https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations
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- OMB OIRA: Austin Mudd (Austin.B.Mudd@omb.eop.gov)

Appendix

- Pre-Panel Outreach SER Questions for Discussion (separate document)
- Related Regulations (EPA, other Federal, state, and international) (separate document)
- Industry Sectors with Small Entities Potentially Affected by the Rulemaking (separate document)
- Personal Protective Equipment Respirator System Per Worker Unit Cost Breakdown (separate document)
- Example: OSHA Respiratory Protection Table (Slide 86)
- Dermal Personal Protective Equipment Unit Cost (Slide 87)

Example: OSHA Respiratory Protection Table

Minimum Requirements for Respiratory Protection for Airborne Methylene Chloride	
Methylene Chloride Airborne Concentration (ppm) or Condition of Use	Minimum Respirator Required
Up to 625 ppm (25 X PEL)	Continuous flow supplied-air respirator, hood, or helmet
Up to 1,250 ppm (50 X PEL)	(1) Full facepiece supplied-air respirator operated in negative-pressure (demand) mode (2) Full facepiece self-contained breathing apparatus (SCBA) operated in negative-pressure (demand) mode
Up to 5,000 ppm (200 X PEL)	(1) Continuous flow supplied-air respirator, full facepiece (2) Pressure demand supplied-air respirator, full facepiece (3) Positive-pressure full facepiece SCBA
Unknown concentration, or above 5,000 ppm (Greater than 200 X PEL)	(1) Positive-pressure full facepiece SCBA (2) Full facepiece pressure (demand) supplied-air respirator with an auxiliary self-contained air supply
Firefighting	Positive-pressure full facepiece SCBA
Emergency Escape	(1) Any continuous flow or pressure-demand SCBA (2) Gas mask with organic vapor canister

https://www.osha.gov/sites/default/files/publications/osha3144.pdf

Dermal Personal Protective Equipment Unit Cost

Glove Material	Type	Average Price Per Pair (2021$)	Useful Life (pairs per year)
Butyl	Reusable	$54.53	4
Natural Rubber/Latex	Reusable	$6.16	4
Neoprene	Reusable	$11.25	4
Laminated Polyethylene	Reusable	$7.48	4
Nitrile	Disposable	$0.56	260

Apron Material	Type	Average Price per Apron (2021$)	Useful Life (per year)
Polyethylene	Disposable	$3.64	260
Neoprene	Reusable	$33.87	4
Nitrile	Reusable	$25.13	4

Industry Sectors with Small Entities Potentially Affected by the Rule

EPA's SBAR Pre-Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-Methylpyrrolidone (NMP) under TSCA Section 6(a)

Industry Sectors with Small Entities Potentially Affected by the Rulemaking

Entities potentially regulated by this rulemaking to address the unreasonable risks from NMP include those entities relevant to the conditions of use of NMP that EPA evaluated, including domestic manufacturing, import, processing uses of NMP, repackaging and recycling, industrial and commercial uses of NMP (such as solvents for cleaning or degreasing, adhesives and sealants, lubricants and greases, paints and coatings, and in a variety of cleaning products), consumer uses (including adhesives and sealants), and disposal. Entities may include manufacturers (including importers), processors, formulators, industrial and commercial users, or distributors (such as retailers) of NMP or products containing NMP within the scope of this rulemaking.

Potentially affected entities will include both employer and non-employer firms and establishments identified within these sectors by the U.S. Census for each applicable North American Industry Classification System (NAICS) code. Since the Small Business Administration (SBA) size standard varies by NAICS code, they are also included in the table below. NAICS codes of potentially affected entities may include but are not limited to those in Table 1 below. Table 2 shows the estimated number of small firms by condition of use (COU).

Table 1: Potentially Affected Entities

NAICS	NAICS Description	SBA Size Standard
236115	New Single-family Housing Construction (Except For-Sale Builders)	$45.0 million
236116	New Multifamily Housing Construction (except For-Sale Builders)	$45.0 million
236117	New Housing For-Sale Builders	$45.0 million
236118	Residential Remodelers	$45.0 million
236210	Industrial Building Construction	$45.0 million
236220	Commercial and Institutional Building Construction	$45.0 million
237110	Water and Sewer Line and Related Structures Construction	$45.0 million
237120	Oil and Gas Pipeline and Related Structures Construction	$45.0 million
237130	Power and Communication Line and Related Structures Construction	$45.0 million
237310	Highway, Street, and Bridge Construction	$45.0 million
237990	Other Heavy and Civil Engineering Construction	$45.0 million
238110	Poured Concrete Foundation and Structure Contractors	$19.0 million
238120	Structural Steel and Precast Concrete Contractors	$19.0 million
238130	Framing Contractors	$19.0 million
238190	Other Foundation, Structure, and Building Exterior Contractors	$19.0 million
238210	Electrical Contractors and Other Wiring Installation Contractors	$19.0 million
238220	Plumbing, Heating, and Air-Conditioning Contractors	$19.0 million
238290	Other Building Equipment Contractors	$22.0 million
238310	Drywall and Insulation Contractors	$19.0 million
238320	Painting and Wall Covering Contractors	$19.0 million
238330	Flooring Contractors	$19.0 million
238910	Site Preparation Contractors	$19.0 million
238990	All Other Specialty Trade Contractors	$19.0 million
313210	Broadwoven Fabric Mills	1,000 employees

EPA's SBAR Pre-Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-Methylpyrrolidone (NMP) under TSCA Section 6(a)

NAICS	NAICS Description	SBA Size Standard
313320	Fabric Coating Mills	1,000 employees
316110	Leather and Hide Tanning and Finishing	500 employees
316210	Footwear Manufacturing	1,000 employees
321912	Cut Stock, Resawing Lumber, and Planing	500 employees
322220	Paper Bag and Coated and Treated Paper Manufacturing	750 employees
323111	Commercial Printing (except Screen and Books)	500 employees
323113	Commercial Screen Printing	500 employees
323117	Books Printing	1,250 employees
323120	Support Activities for Printing	500 employees
324110	Petroleum Refineries	1,500 employees
324191	Petroleum Lubricating Oil and Grease Manufacturing	750 employees
325110	Petrochemical Manufacturing	1,000 employees
325120	Industrial Gas Manufacturing	1,000 employees
325180	Other Basic Inorganic Chemical Manufacturing	1,000 employees
325199	All Other Basic Organic Chemical Manufacturing	1,250 employees
325199	All Other Basic Organic Chemical Manufacturing	1,250 employees
325211	Plastics Material And Resin Manufacturing	1,250 employees
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	1,000 employees
325320	Pesticide and Other Agricultural Chemical Manufacturing	1,000 employees
325412	Pharmaceutical Preparation Manufacturing	1,250 employees
325510	Paint And Coating Manufacturing	1,000 employees
325520	Adhesive Manufacturing	500 employees
325611	Soap And Other Detergent Manufacturing	1,000 employees
325612	Polish and Other Sanitation Good Manufacturing	750 employees
325612	Polish and Other Sanitation Good Manufacturing	750 employees
325998	All Other Miscellaneous Chemical Product And Preparation Manufacturing	500 employees
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	750 employees
326199	All Other Plastics Product Manufacturing	750 employees
327390	Other Concrete Product Manufacturing	500 employees
327910	Abrasive Product Manufacturing	750 employees
331110	Iron and Steel Mills and Ferroalloy Manufacturing	1,500 employees
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	1,000 employees
331221	Rolled Steel Shape Manufacturing	1,000 employees
331222	Steel Wire Drawing	1,000 employees
331313	Alumina Refining and Primary Aluminum Production	1,000 employees
331314	Secondary Smelting and Alloying of Aluminum	750 employees
331315	Aluminum Sheet, Plate, and Foil Manufacturing	1,250 employees
331318	Other Aluminum Rolling, Drawing, and Extruding	750 employees
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	1,000 employees
331420	Copper Rolling, Drawing, Extruding, and Alloying	1,000 employees
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	750 employees

EPA's SBAR Pre-Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-Methylpyrrolidone (NMP) under TSCA Section 6(a)

NAICS	NAICS Description	SBA Size Standard
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	750 employees
331511	Iron Foundries	1,000 employees
331512	Steel Investment Foundries	1,000 employees
331513	Steel Foundries (except Investment)	500 employees
331523	Nonferrous Metal Die-Casting Foundries	500 employees
331524	Aluminum Foundries (except Die-Casting)	500 employees
331529	Other Nonferrous Metal Foundries (except Die-Casting)	500 employees
332111	Iron and Steel Forging	750 employees
332112	Nonferrous Forging	750 employees
332114	Custom Roll Forming	500 employees
332117	Powder Metallurgy Part Manufacturing	500 employees
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	500 employees
332215	Metal Kitchen Cookware, Utensil, Cutlery, and Flatware (except Precious) Manufacturing	750 employees
332216	Saw Blade and Handtool Manufacturing	750 employees
332311	Prefabricated Metal Building and Component Manufacturing	750 employees
332312	Fabricated Structural Metal Manufacturing	500 employees
332313	Plate Work Manufacturing	750 employees
332321	Metal Window and Door Manufacturing	750 employees
332322	Sheet Metal Work Manufacturing	500 employees
332323	Ornamental and Architectural Metal Work Manufacturing	500 employees
332410	Power Boiler and Heat Exchanger Manufacturing	750 employees
332420	Metal Tank (Heavy Gauge) Manufacturing	750 employees
332431	Metal Can Manufacturing	1,500 employees
332439	Other Metal Container Manufacturing	500 employees
332510	Hardware Manufacturing	750 employees
332613	Spring Manufacturing	500 employees
332618	Other Fabricated Wire Product Manufacturing	500 employees
332710	Machine Shops	500 employees
332721	Precision Turned Product Manufacturing	500 employees
332722	Bolt, Nut, Screw, Rivet, and Washer Manufacturing	500 employees
332811	Metal Heat Treating	750 employees
332812	Metal Coating, Engraving (except Jewelry and Silverware), and Allied Services to Manufacturers	500 employees
332813	Electroplating, Plating, Polishing, Anodizing, and Coloring	500 employees
332911	Industrial Valve Manufacturing	750 employees
332912	Fluid Power Valve and Hose Fitting Manufacturing	1,000 employees
332913	Plumbing Fixture Fitting and Trim Manufacturing	1,000 employees
332919	Other Metal Valve and Pipe Fitting Manufacturing	750 employees
332991	Ball and Roller Bearing Manufacturing	1,250 employees
332992	Small Arms Ammunition Manufacturing	1,250 employees
332993	Ammunition (except Small Arms) Manufacturing	1,500 employees

EPA's SBAR Pre-Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-Methylpyrrolidone (NMP) under TSCA Section 6(a)

NAICS	NAICS Description	SBA Size Standard
332994	Small Arms, Ordnance, and Ordnance Accessories Manufacturing	1,000 employees
332996	Fabricated Pipe and Pipe Fitting Manufacturing	500 employees
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	750 employees
333111	Farm Machinery and Equipment Manufacturing	1,250 employees
333112	Lawn and Garden Tractor and Home Lawn and Garden Equipment Manufacturing	1,500 employees
333120	Construction Machinery Manufacturing	1,250 employees
333131	Mining Machinery and Equipment Manufacturing	500 employees
333132	Oil and Gas Field Machinery and Equipment Manufacturing	1,250 employees
333241	Food Product Machinery Manufacturing	500 employees
333242	Semiconductor Machinery Manufacturing	1,500 employees
333243	Sawmill, Woodworking, and Paper Machinery Manufacturing	500 employees
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	500 employees
333414	Heating Equipment (except Warm Air Furnaces) Manufacturing	500 employees
333415	Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing	1,250 employees
333511	Industrial Mold Manufacturing	500 employees
333514	Special Die and Tool, Die Set, Jig, and Fixture Manufacturing	500 employees
333515	Cutting Tool and Machine Tool Accessory Manufacturing	500 employees
333517	Machine Tool Manufacturing	500 employees
333519	Rolling Mill and Other Metalworking Machinery Manufacturing	500 employees
333611	Turbine and Turbine Generator Set Units Manufacturing	1,500 employees
333612	Speed Changer, Industrial High-Speed Drive, and Gear Manufacturing	750 employees
333613	Mechanical Power Transmission Equipment Manufacturing	750 employees
333618	Other Engine Equipment Manufacturing	1,500 employees
333912	Air and Gas Compressor Manufacturing	1,000 employees
333914	Measuring, Dispensing, and Other Pumping Equipment Manufacturing	750 employees
333921	Elevator and Moving Stairway Manufacturing	1,000 employees
333922	Conveyor and Conveying Equipment Manufacturing	500 employees
333923	Overhead Traveling Crane, Hoist, and Monorail System Manufacturing	1,250 employees
333924	Industrial Truck, Tractor, Trailer, and Stacker Machinery Manufacturing	750 employees
333991	Power-Driven Handtool Manufacturing	500 employees
333992	Welding and Soldering Equipment Manufacturing	1,250 employees
333993	Packaging Machinery Manufacturing	500 employees
333994	Industrial Process Furnace and Oven Manufacturing	500 employees
333995	Fluid Power Cylinder and Actuator Manufacturing	750 employees
333996	Fluid Power Pump and Motor Manufacturing	1,250 employees
334111	Electronic Computer Manufacturing	1,250 employees
334112	Computer Storage Device Manufacturing	1,250 employees
334118	Computer Terminal and Other Computer Peripheral Equipment Manufacturing	1,000 employees
334210	Telephone Apparatus Manufacturing	1,250 employees

EPA's SBAR Pre-Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-Methylpyrrolidone (NMP) under TSCA Section 6(a)

NAICS	NAICS Description	SBA Size Standard
334220	Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing	1,250 employees
334290	Other Communications Equipment Manufacturing	750 employees
334310	Audio and Video Equipment Manufacturing	750 employees
334413	Semiconductor And Related Device Manufacturing	1,250 employees
334510	Electromedical and Electrotherapeutic Apparatus Manufacturing	1,250 employees
334511	Search, Detection, Navigation, Guidance, Aeronautical, and Nautical System and Instrument Manufacturing	1,250 employees
334512	Automatic Environmental Control Manufacturing for Residential, Commercial, and Appliance Use	500 employees
334513	Instruments and Related Products Manufacturing for Measuring, Displaying, and Controlling Industrial Process Variables	750 employees
334514	Totalizing Fluid Meter and Counting Device Manufacturing	750 employees
334515	Instrument Manufacturing for Measuring and Testing Electricity and Electrical Signals	750 employees
334516	Analytical Laboratory Instrument Manufacturing	1,000 employees
334517	Irradiation Apparatus Manufacturing	1,000 employees
334519	Other Measuring and Controlling Device Manufacturing	500 employees
335210	Small Electrical Appliance Manufacturing	1,500 employees
335220	Major Household Appliance Manufacturing	1,500 employees
335311	Power, Distribution, and Specialty Transformer Manufacturing	750 employees
335312	Motor and Generator Manufacturing	1,250 employees
335313	Switchgear and Switchboard Apparatus Manufacturing	1,250 employees
335314	Relay and Industrial Control Manufacturing	750 employees
335921	Fiber Optic Cable Manufacturing	1,000 employees
335929	Other Communication and Energy Wire Manufacturing	1,000 employees
335931	Current-Carrying Wiring Device Manufacturing	500 employees
335932	Noncurrent-Carrying Wiring Device Manufacturing	1,000 employees
335991	Carbon and Graphite Product Manufacturing	750 employees
335999	All Other Miscellaneous Electrical Equipment and Component Manufacturing	500 employees
336120	Heavy Duty Truck Manufacturing	1,500 employees
336211	Motor Vehicle Body Manufacturing	1,000 employees
336212	Truck Trailer Manufacturing	1,000 employees
336213	Motor Home Manufacturing	1,250 employees
336214	Travel Trailer and Camper Manufacturing	1,000 employees
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	1,000 employees
336320	Motor Vehicle Electrical and Electronic Equipment Manufacturing	1,000 employees
336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	1,000 employees
336340	Motor Vehicle Brake System Manufacturing	1,250 employees
336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	1,500 employees
336360	Motor Vehicle Seating and Interior Trim Manufacturing	1,500 employees

EPA's SBAR Pre-Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-Methylpyrrolidone (NMP) under TSCA Section 6(a)

NAICS	NAICS Description	SBA Size Standard
336370	Motor Vehicle Metal Stamping	1,000 employees
336390	Other Motor Vehicle Parts Manufacturing	1,000 employees
336411	Aircraft Manufacturing	1,500 employees
336412	Aircraft Engine and Engine Parts Manufacturing	1,500 employees
336413	Other Aircraft Parts and Auxiliary Equipment Manufacturing	1,250 employees
336413	Other Aircraft Part and Auxiliary Equipment Manufacturing7	1,250 employees
336414	Guided Missile and Space Vehicle Manufacturing	1,250 employees
336415	Guided Missile and Space Vehicle Propulsion Unit and Propulsion Unit Parts Manufacturing	1,250 employees
336419	Other Guided Missile and Space Vehicle Parts and Auxiliary Equipment Manufacturing	1,000 employees
336510	Railroad Rolling Stock Manufacturing	1,500 employees
337110	Wood Kitchen Cabinet and Counter Top Manufacturing	750 employees
337122	Nonupholstered Wood Household Furniture Manufacturing	750 employees
339112	Surgical and Medical Instrument Manufacturing	1,000 employees
339113	Surgical Appliance and Supplies Manufacturing	750 employees
339114	Dental Equipment and Supplies Manufacturing	750 employees
339115	Ophthalmic Goods Manufacturing	1,000 employees
339116	Dental Laboratories	500 employees
339950	Sign Manufacturing	500 employees
339999	All Other Miscellaneous Manufacturing	500 employees
423120	Motor Vehicle Supplies and New Parts Merchange Wholesalers	200 employees
423220	Home Furnishing Merchant Wholesalers	100 employees
423330	Roofing, Siding, and Insulation Material Merchant Wholesalers	225 employees
423390	Other Construction Material Merchant Wholesalers	100 employees
423490	Other Professional Equipment and Supplies Merchant Wholesalers	150 employees
423610	Electrical Apparatus and Equipment, Wiring Supplies, and Related Equipment Merchant Wholesalers	200 employees
423620	Electrical And Electronic Appliance, Television, And Radio Set Merchant Wholesalers	225 employees
423840	Industrial Supplies Merchant Wholesalers	125 employees
423850	Service Establishment Equipment and Supplies Merchant Wholesalers	125 employees
424690	Other Chemical And Allied Products Merchant Wholesalers	175 employees
424710	Petroleum Bulk Stations and Terminals	225 employees
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	200 employees
441110	Automobile Dealers	200 employees
441110	New Car Dealers	200 employees
441120	Used Car Dealers	$30.5 million
488410	Motor Vehicle Towing	$9.0 million
531190	Lessors of Other Real Estate Property9	$34.0 million
541330	Engineering Services	$25.5 million
541380	Testing Laboratories	$19.0 million

EPA's SBAR Pre-Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-Methylpyrrolidone (NMP) under TSCA Section 6(a)

NAICS	NAICS Description	SBA Size Standard
561110	Office Administrative Services	$12.5 million
561210	Facilities Support Services	$47.0 million
561720	Janitorial Services	$22.0 million
561740	Carpet and Upholstery Cleaning Services	$8.5 million
562211	Hazardous Waste Treatment and Disposal	$47.0 million
562212	Solid Waste Landfill	$47.0 million
562213	Solid Waste Combustors and Incinerators	$47.0 million
562219	Other Nonhazardous Waste Treatment and Disposal	$47.0 million
562920	Materials Recovery Facilities	$25.0 million
711510	Independent Artists, Writers, and Performers	$9.0 million
712110	Museums	$34.0 million
811111	General Automotive Repair	$9.0 million
811121	Automotive Body, Paint, and Interior Repair and Maintenance	$9.0 million
811121	Automotive Body, Paint and Interior Repair and Maintenance	$9.0 million
811122	Automotive Glass Replacement Shops	$17.5 million
811191	Automotive Oil Change and Lubrication Shops	$11.0 million
811192	Car Washes	$9.0 million
811198	All Other Automotive Repair and Maintenance	$10.0 million
811412	Appliance Repair and Maintenance	$19.0 million
811420	Reupholstery and Furniture Repair	$9.0 million
811430	Footwear and Leather Goods Repair	$9.0 million
811490	Other Personal and Household Goods Repair and Maintenance	$9.0 million
812310	Coin-Operated Laundries and Drycleaners	$13.0 million
812320	Drycleaning and Laundry Services (except Coin-Operated)	$8.0 million
812331	Linen Supply	$40.0 million
812332	Industrial Launderers	$47.0 million
Source: U.S. Small Business Administration Table of Small Business Size Standards Available at: https://www.sba.gov/document/support--table-size-standards		

Table 2: Small Entities Potentially Affected

Use Category	Estimated Number of Firms Using NMP	Percent of Firms That Are Small	Estimated Number of Small Firms Using NMP
Manufacture/Import	49	24%	12
Repackaging	32	95%	30
Processing: incorporation into a formulation, mixture or reaction product	66	62%	41
Lithium ion battery manufacturing	55	87%	48
Waste handling, disposal, treatment, and recycling	1,787	91%	1,624
Plastic and resin product manufacturing	983	94%	922
Textiles, leather, and apparel manufacturing	33	95%	31
Processing aids in petrochemical manufacturing, oil and gas activities, and functional fluids (closed systems)	479	89%	428
Laboratory use	56	93%	51
Paints and coatings	13,574	97%	13,202
Paint, coating, and adhesive removers	4,296	91%	3,903
Electronic product and semiconductor manufacturing	3,473	94%	3,279
Adhesives and sealants	7,012	97%	6,816
Cleaning and furniture care products	2,702	99%	2,667
Ink, toner, and colorant products	114	99%	113
Soldering	2,768	98%	2,715
Fertilizer and other agricultural chemical manufacturing	9	90%	8
Lubricants and lubricant additives	-	-	-
Anti-freeze and de-icing	-	-	-
Total	**37,488**	**96%**	**35,892**

Related Regulations (EPA, Federal, State, and International)

EPA's SBAR Pre-Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-methylpyrrolidone (NMP) under TSCA Section 6(a)

Related Regulations (EPA, Federal, State, and International)

Table 1 – EPA Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
EPA Statutes/Regulations		
Toxic Substances Control Act (TSCA) – Section 6(a)	Provides EPA with the authority to prohibit or limit the manufacture (including import), processing, distribution in commerce, use or disposal of a chemical if EPA evaluates the risk and concludes that the chemical presents an unreasonable risk to human health or the environment.	Proposed rule under section 6 of TSCA to address the unreasonable risk presented by NMP in paint and coating removal (82 FR 7464, January 19, 2017) The NMP portion of the proposed rule was withdrawn in 2021 (86 FR 3932, January 15, 2021).
Toxic Substances Control Act (TSCA) – Section 6(b)	Directs EPA to promulgate regulations to establish processes for prioritizing chemical substances and conducting risk evaluations on priority chemical substances. In the meantime, EPA was required to identify and begin risk evaluations on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments.	NMP is on the initial list of 10 chemical substances to be evaluated for unreasonable risk of injury to health or the environment (81 FR 91927, December 19, 2016)
Toxic Substances Control Act (TSCA) – Section8(a)	The TSCA Section 8(a) Chemical Data Reporting (CDR) Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the US.	NMP manufacturing, importing, processing and use information is reported under the CDR rule (76 FR 50816, August 16, 2011).
Toxic Substances Control Act (TSCA) – Section8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured, processed, or imported in the United States.	NMP was on the initial TSCA Inventory and therefore was not subject to EPA's new chemicals review process (60 FR 16309, March 29, 1995).

EPA's SBAR Pre-Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-methylpyrrolidone (NMP) under TSCA Section 6(a)

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Toxic Substances Control Act (TSCA) – Section 8(e)	Manufacturers (including importers), processors and distributors must immediately notify EPA if they obtain information that supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.	Seven notifications of substantial risk (Section 8(e)) received (2007 – 2010) (US EPA, ChemView. Accessed April 13, 2017).
Toxic Substances Control Act (TSCA) – Section 4	Provides EPA with authority to issue rules and orders requiring manufacturers (including importers) and processors to test chemical substances and mixtures.	Six submissions from a test rule (Section 4) received in the mid-1990s. (US EPA, ChemView. Accessed April 13, 2017).
Emergency Planning and Community Right-To-Know Act (EPCRA) – Section 313	Requires annual reporting from facilities in specific industry sectors that employ 10 or more full time equivalent employees and that manufacture, process, or otherwise use a TRI-listed chemical in quantities above threshold levels. A facility that meets reporting requirements must submit a reporting form for each chemical for which it triggered reporting, providing data across a variety of categories, including activities and uses of the chemical, releases and other waste management (*e.g.*, quantities recycled, treated, combusted) and pollution prevention activities (under Section 6607 of the Pollution Prevention Act). This data includes on-site and off-site data as well as multimedia data (*i.e.*, air, land and water).	NMP is a listed substance subject to reporting requirements under 40 CFR 372.65 effective as of January 1, 1995.
Federal Food, Drug and Cosmetic Act (FFDCA) – Section 408	FFDCA governs the allowable residues of pesticides in food. Section 408 of the FFDCA provides EPA with the authority to set tolerances (rules that establish	NMP is currently approved for use as a solvent and co-solvent inert ingredient in pesticide formulations for both food and non-food uses and is exempt from the requirements of a

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	maximum allowable residue limits), or exemptions from the requirement of a tolerance, for all residues of a pesticide (including both active and inert ingredients) that are in or on food. Prior to issuing a tolerance or exemption from tolerance, EPA must determine that the tolerance or exemption is "safe." Sections 408(b) and (c) of the FFDCA define "safe" to mean the Agency has a reasonable certainty that no harm will result from aggregate exposures to the pesticide residue, including all dietary exposure and all other exposure (*e.g.*, non-occupational exposures) for which there is reliable information. Pesticide tolerances or exemptions from tolerance that do not meet the FFDCA safety standard are subject to revocation. In the absence of a tolerance or an exemption from tolerance, a food containing a pesticide residue is considered adulterated and may not be distributed in interstate commerce.	tolerance limit (40 CFR Part 180.920).
Clean Air Act (CAA) – Section 111 (b)	Requires EPA to establish new source performance standards (NSPS) for any category of new or modified stationary sources that EPA determines causes, or contributes significantly to, air pollution which may reasonably be anticipated to endanger public health or welfare. The standards are based on the degree of emission limitation achievable through the application of the best system of emission reduction which (considering the cost of achieving reductions and non-air	NMP is subject to CAA Section 111 Standards of Performance for New Stationary Sources of Air Pollutants for volatile organic compound (VOC) emissions from synthetic organic chemical manufacturing industry distillation operations (40 CFR Part 60, subpart NNN) and reactor processes (40 CFR Part 60, Subpart RRR). This rule applies only to sources constructed after 1983 and includes the production of NMP. EPA expects that facilities included in the risk evaluation already meet this standard.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	quality health and environmental impacts and energy requirements) EPA determines has been adequately demonstrated.	
Clean Air Act (CAA) – Section 183(e)	Section 183(e) requires EPA to list the categories of consumer and commercial products that account for at least 80 percent of all VOC emissions in areas that violate the National Ambient Air Quality Standards for ozone and to issue standards for these categories that require "best available controls." In lieu of regulations, EPA may issue control techniques guidelines if the guidelines are determined to be substantially as effective as regulations.	NMP is listed under the National Volatile Organic Compound Emission Standards for Aerosol Coatings (40 CFR part 59, subpart E). This is a content-based limit confined to manufacturers of aerosol coating products.
Clean Air Act (CAA) – Section 612	Under Section 612 of the CAA, EPA's Significant New Alternatives Policy (SNAP) program reviews substitutes for ozone depleting substances within a comparative risk framework. EPA publishes lists of acceptable and unacceptable alternatives. A determination that an alternative is unacceptable, or acceptable only with conditions, is made through rulemaking.	Under EPA's SNAP program, EPA listed NMP as an acceptable substitute for "straight organic solvent cleaning (with terpenes, C620 petroleum hydrocarbons, oxygenated organic solvents such as ketones, esters, alcohols, etc.)" for metals, electronics and precision cleaning and "Oxygenated organic solvents (esters, ethers, alcohols, ketones)" for aerosol solvents (59 FR, March 18, 1994).
Safe Drinking Water Act (SDWA) – Section 1412 (b)	Every 5 years, EPA must publish a list of contaminants (1) that are currently unregulated, (2) that are known or anticipated to occur in public water systems, and (3) which might require regulations under SDWA. EPA must also determine whether to regulate at least five contaminants from the list every 5 years.	NMP was identified on both the Third (2009) and Fourth (2016) Contaminant Candidate Lists (74 FR 51850, October 8, 2009) (81 FR 81099 November 17, 2016).

EPA's SBAR Pre-Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-methylpyrrolidone (NMP) under TSCA Section 6(a)

Table 2 – Other Federal Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Other Federal Statutes/Regulations		
Occupational Safety and Health Act (OSHA)	Requires employers to provide their workers with a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress, or unsanitary conditions. Under the Act, OSHA can issue occupational safety and health standards including such provisions as Permissible Exposure Limits (PELs), exposure monitoring, engineering and administrative control measures and respiratory protection.	OSHA has not established a PEL for NMP.
Federal Food, Drug and Cosmetic Act (FFDCA)	Provides the U.S Food and Drug Administration (FDA) with authority to oversee the safety of food, drugs and cosmetics.	Food and Drug Administration identifies NMP as an "Indirect Additive Used in Food Contact Substances" specifically as: 1) an adjuvant substance in the preparation of slimicides (21 CFR 176.300), 2) an adjuvant substance in the production of polysulfone resin authorized for use as articles intended for use in contact with food (21 CFR 177.1655) and 3) a residual solvent in polyetherone sulfone resins authorized as articles for repeated use in contact with food (21 CFR 177.2440). FDA also identifies NMP as a Class 2 solvent, namely a solvent that "should be limited in pharmaceutical products because of their inherent toxicity."

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		FDA established a Permissible Daily Exposure (PDE) for NMP of 5.3 mg/day with a concentration limit of 530 ppm. FDA's Center for Veterinary Medicine developed a method in 2011 for detection of the residues of NMP in edible tissues of cattle (21 CFR 500.1410)
Federal Hazardous Material Transportation Act	Section 5103 of the Act directs the Secretary of Transportation to: Designate material (including an explosive, radioactive material, infectious substance, flammable or combustible liquid, solid or gas, toxic, oxidizing or corrosive material and compressed gas) as hazardous when the Secretary determines that transporting the material in commerce may pose an unreasonable risk to health and safety or property. Issue regulations for the safe transportation, including security of hazardous material in intrastate, interstate and foreign commerce.	The Department of Transportation (DOT) has designated NMP as a hazardous material, and there are special requirements for marking, labeling and transporting it (49 CFR Part 171, 49 CFR 172, 40 CFR § 173.202 and 40 CFR § 173.242.

Table 3 – State Laws and Regulations

State Actions	Description of Action
State Air Regulations	New Hampshire (Env-A 1400: Regulated Toxic Air Pollutants) lists NMP as a regulated toxic air pollutant. Vermont (Vermont Air Pollution Control Regulations, 5261) lists NMP as a hazardous air contaminant.
Chemicals of Concern to Children	Several states have adopted reporting laws for chemicals in children's products that include NMP including Oregon (OAR 333-016-2000), Vermont (18 V.S.A. Sections 1771 to 1779) and Washington state (WAC 173-334-130). Minnesota has listed NMP as a chemical of concern to children (Minnesota Statutes 116.9401 to 116.9407).

State Actions	Description of Action
State Permissible Exposure Limits	California PEL is 1 ppm as an 8hr TWA, along with a skin notation (Cal Code Regs, title 8, Section 5155).
State Right-to-Know Acts	Massachusetts (454 CMR 21.00), New Jersey (42 N.J.R. 1709(a)) and Pennsylvania (Chapter 323. Hazardous Substance List).
Other	In California, NMP is listed on Proposition 65 (Cal. Code Regs. Title 27, Section 27001) due to reproductive toxicity. California OEHHA lists a Maximum Allowable Dose Level (MADL) for inhalation exposure = 3,200 µg/day MADL for dermal exposure = 17,000 µg/day. The California Department of Toxic Substances Control (DTSC) Safer Consumer Products Program lists NMP as a Candidate Chemical for development toxicity and reproductive toxicity. In addition, DTSC is moving to address paint strippers containing NMP and specifically cautioned against replacing methylene chloride with NMP. In August 2018 the California DTSC Safer Consumer Products program proposed to list Paint and Varnish Strippers and Graffiti Removers Containing NMP as a priority product citing (1) potential for human and other organism exposure to NMP in paint and varnish strippers and graffiti removers; and (2) the exposure has the potential to contribute to or cause significant or widespread adverse impacts. DTSC published a Product-Chemical Profile for Paint and Varnish Strippers and Graffiti Removers Containing NMP to support the listing. California Department of Public Health's Hazard Evaluation System and Information Service (HESIS) issued a Health Hazard Advisory on NMP in 2006 and updated the Advisory in June 2014. The Advisory is aimed at workers and employers at sites where NMP is used.

Table 4 – International Laws and Regulations

Country/Organization	Requirements and Restrictions
European Union	In 2011, NMP was listed on the Candidate list as a Substance of Very High Concern (SVHC) under regulation (EC) No 1907/2006 – REACH. In March 2017, NMP was included in the public consultation of chemicals recommended for inclusion in Annex XIV of the ECHA under Annex (Authorisation list) of regulation (EC) No 1907/2006 – REACH. In 2013, the Netherlands submitted a proposal under REACH to restrict manufacturing and all industrial and professional uses of NMP where workers' exposure exceeds a level specified in the restriction ECHA database. Accessed November 4, 2022).

EPA's SBAR Pre-Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-methylpyrrolidone (NMP) under TSCA Section 6(a)

Country/Organization	Requirements and Restrictions
	On April 18, 2018, the European Union added NMP to REACH Annex XVII, the restricted substances list. The action specifies three conditions of restriction. The conditions are: 1) NMP shall not be placed on the market as a substance on its own or in mixtures in concentrations greater than 0.3% after May 9, 2020, unless manufacturers, importers and downstream users have included chemical safety reports and SDSs with Derived No-Effect Levels (DNELs) relating to workers' exposures of 14,4 mg/m^3 for exposure by inhalation and 4,8 mg/kg/day for dermal exposure; 2) NMP shall not be manufactured, or used, as a substance on its own or in mixtures in a concentration equal to or greater than 0.3% after May 9, 2020 unless manufacturers and downstream users take the appropriate risk management measures and provide the appropriate operational conditions to ensure that exposure of workers is below the DNELs specified above: and 3) the restrictions above shall apply from May 9, 2024 to placing on the market for use, or use, as a solvent or reactant in the process of coating wires.
Australia	NMP was assessed under Human Health Tier III of the Inventory Multi-tiered Assessment and Prioritisation (IMAP) (National Industrial Chemicals Notification and Assessment Scheme, NICNAS, 2017, Human Health Tier III assessment for 2-Pyrrolidinone, 1methyl-. Accessed April,18 2017).
Japan	NMP is regulated in Japan under the following legislation: • Act on the Evaluation of Chemical Substances and Regulation of their Manufacture, etc. (Chemical Substances Control Law) • Industrial Safety and Health Act (National Institute of Technology and Evaluation (NITE) Chemical Risk Information Platform (CHIRP). Accessed April 18, 2017).
European Union and Australia, Austria, Belgium, Canada (Ontario), Denmark, Finland, France, Germany, Ireland, Italy, Latvia, New Zealand, Poland, Spain, Sweden, Switzerland, The Netherlands, Turkey and the United Kingdom.	Occupational exposure limits (OELs) for NMP can be found by searching for CAS No. 872-50-4, or N-Methyl-2-pyrrolidon, at GESTIS International limit values for chemical agents (OELs) database. Accessed April 18, 2017.

SER Questions for Discussion

EPA's SBAR Pre-Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-Methylpyrrolidone (NMP) under TSCA Section 6(a)

Pre-Panel Outreach Small Entity Representative (SER) Questions for Discussion on NMP

For rules that may have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act (RFA) requires agencies to evaluate regulatory alternatives that may minimize the burden on small entities expected to be regulated. The RFA notes that the regulatory alternatives must be consistent with the stated objectives of applicable statutes (i.e., TSCA), and suggests significant alternatives such as:

- the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;
- the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;
- the use of performance rather than design standards; and
- an exemption from coverage of the rule, or any part thereof, for such small entities.

To that end, these informal questions on your work practices and your experiences with n-methylpyrrolidone (NMP) are aimed at guiding our discussion today, and your later written feedback, towards ideas for minimizing the economic impact on your business while remaining within the constraints of TSCA. We are not seeking a structured response on each question; rather, we are interested in any feedback or details you can provide, and hope that these questions let you know what type of information would be most useful as we consider advice from the small entity representatives concerning TSCA regulation of NMP.

If you are interested in providing this or other information in writing, please see the contact information below.

We ask that you refrain from providing Confidential Business information (CBI) during the discussion or in email to EPA. If you choose to provide CBI, we will provide special instructions.

Contact Information:

Lanelle Wiggins
Office of Regulatory Policy and Management
Office of Policy
Phone: (202) 566-2372
E-mail: wiggins.lanelle@epa.gov

1) **Your business *(All SERs)***
   a. How does your organization use NMP? How much NMP does your organization use?
   b. Does your organization still use NMP? What is the trend of use? For example, has your organization increased use of NMP? Has use remained constant? Is use decreasing? Is your organization phasing out the use of NMP?
   c. Can you describe the specific use, as well as the workplace and workplace setting where NMP is used?
   d. Why does your organization use NMP? What function does NMP provide?

e. Where is your organization in the supply chain? (e.g., are you a processor – formulating another product with NMP, a distributor, or final user of NMP in an application?) Do you provide finished product to another small entity or to a large entity?
f. For what industries or applications do you provide products or services for? (e.g., aerospace, electronics, military, automotive, optics, museums/art restorations, academic, commercial laboratory, consumers, other) Can you provide NAICs code(s) for the products/services you provide?
g. For what process are you using NMP? (can be more than one, such as cleaning, drying, inspection, etc.)
h. If NMP were not available, how would you adjust and what would the impacts be on your business? What specific barriers would your business face in switching to an alternative?
i. What are the benefits to your business of NMP? Are there specific benefits for small businesses using NMP as compared to benefits for larger businesses?
j. If the concentration of NMP in a product was limited, would this impact the efficacy of the product and/or increase the duration of use or exposure? For which particular uses?

2) Workplace exposure *(All SERs)*

a. How many employees, and what fraction of your employees, are exposed to NMP, and for how long (days/year and hours/day)?
b. If you use a product containing NMP, what product do you use and what is the concentration of NMP in the product?
c. What work activities result in worker exposure to NMP? And what type of exposure (dermal, inhalation)?
d. For each activity, in what physical state and concentration is NMP?
e. Have you taken industrial hygiene monitoring data? If so, what was typical and high-end exposure to NMP?
f. How do you measure whether and how much dermal exposure workers experience?
    i. How are workers informed about potential dermal or inhalation exposure to NMP
    ii. If workers experience an accidental exposure what procedures are followed?
g. What engineering controls are used to minimize exposure to NMP? How effective are those controls?
    i. Would it be feasible to use additional engineering controls to minimize exposure to NMP? If so, what might those engineering controls be?
    ii. What is your experience with equipment changes to reduce exposure or cross-examination?
h. What administrative controls and training do you use to minimize exposure to NMP? Do you use training to minimize exposure to NMP?
i. Is personal protective equipment (PPE) is regularly worn by workers to minimize exposure to NMP?
    i. If yes, could you provide more information regarding the type of PPE that is used? And would it be feasible to use PPE that provided a level of protection beyond what

you are already using? Do you have experience with air supplied respirators? Do you have experience with other respirators, or glove PPE?

ii. If no, would it be feasible to have workers wear PPE to minimize their exposure to NMP? And what PPE would be feasible for workers to wear? Are there workers or processes where the use of PPE would be impractical?

j. How many employees are located in the same room where the work activities related to NMP are taking place but not necessarily handling NMP or NMP-containing products?

k. If applicable, what do you do to comply with Cal/OSHA standards for NMP?

l. If outside of California, what measures or specifications do you measure to for workplace safety?

3) Regulatory options *(All SERs)*

a. Which of the regulatory options presented today would you recommend?

b. Cost estimates: In your experience, are the cost estimates reasonably representative? Do you have additional information to improve the cost estimates?

c. What indirect costs to your organization do you estimate would occur as a result of this regulation?

d. Recognizing that the cost estimates are only partial unit costs, can you provide any additional information on potential costs or cost considerations the Agency should consider when evaluating the costs of complying with potential regulatory options?

e. Can you think of ways to add flexibility to this rulemaking for your small businesses?

f. Are there other alternative regulatory options that the agency should consider to manage the unreasonable risk identified for NMP?

g. How do you learn about EPA regulations and what you should do to comply?

h. What kind of additional information or resources would help you understand the regulations and steps necessary to comply?

i. What is the best way to reach out to members of your industry?

j. Is there additional information on potential costs or cost considerations the Agency should consider when evaluating the costs of complying with potential regulatory options?

4) Additional questions for formulators of products containing NMP: substitutes and alternatives

a. Product reformulation:

i. How often do you reformulate your products?

ii. What is the typical cost of reformulating your products?

iii. What might reformulation costs be if you needed to reformulate your products without NMP? (e.g., costs associated with research and development, testing, capital costs of production changes, packaging, labeling)

b. Product relabeling:

i. How often do you relabel your products?

ii. What is the typical cost of relabeling?

c. Alternatives:

i. Do you sell another product that does not contain NMP that is designed for the same use or application as the NMP product?
   - If yes:
     - What solvent replaces NMP in the alternative product?
     - How does the alternative product compare in terms of safety, efficacy, and cost?
   - If no:
     - If you need to reformulate this product with a lower concentration of NMP, what would be the implications for the product in terms of cost and efficacy?
     - If you need to reformulate this product without NMP, what solvent would replace NMP in the alternative product? How do you think the alternative product would compare in terms of efficacy and cost?

ii. Is there a subset of uses for your product where using a product formulated without NMP would be problematic?

iii. Are there differences between products intended for consumer or commercial use (such as formulation, labeling, container size)?

5) Additional questions for NMP in commercial and consumer formulations:

a. What type of formulations do you use with NMP? In soldering, paints and coatings, inks, paint and coating removers, or other formulations?

b. Current work practices:
   i. Is this NMP formulation applied through a system (closed pipe or transfer lines, heated recapture systems) or handheld applications (as an aerosol, brush, or dip application)?
   ii. What type of items do you apply the NMP formulation too?
   iii. Is there a difference in commercial versus consumer grade product?

c. Current work practices:
   i. How significant is this NMP formulation to your business overall? Does this use seem representative of most small businesses?
   ii. When do you use NMP in the process flow in your facility, are you using other processes as well? For example, do you do aqueous cleaning in addition to cleaning with NMP? Does aqueous cleaning happen before or after NMP formulations are used?

d. How significant is this NMP formulation to your business overall? Does this use seem representative of most small businesses?

6) Additional questions for users of products containing NMP: substitutes and alternatives

a. What chemicals or processes have you considered as an alternative to using NMP or a product containing NMP? Why? How do these chemicals or processes compare to current uses containing NMP? More specifically:
   i. Do you currently use any alternatives to NMP (or product)?

ii. Did you try to switch to another chemical, product, or process only to switch back? What were the results? If so, what did you switch to, why did you switch back, and what made you switch in the first place?
iii. If you have tried or switched to alternative chemicals or methods, how did they do? how long did that process take? Did it require equipment modifications or new equipment purchases?
iv. Is there any difference in terms of operation time for alternative products or processes to you NMP formulation? For example, between a graffiti remover containing NMP versus a cold cleaning process.
v. What are the relative advantages and disadvantages of different substitutes and/or processes that you have considered, including in terms of exposure, cost, and hazard?
vi. Provide specific information related to each substitute chemical, product, or process related to the use of alternative chemicals/products and compare to NMP:
    - Identification of alternative chemical/product/process
    - How much of the alternative product/chemical would be needed to perform same activity?
    - Capital costs including new equipment, retrofitting of old equipment, etc. of using the alternative chemical/process, loss of use of existing equipment
    - Number of workers required, amount of worker time required
    - Number of workers exposed
    - Costs associated with transitioning to the alternative chemical (e.g., identifying and testing the alternative chemical/process, certifying or otherwise ensuring customer or other required production standards are met, production downtime during the transition, lost productivity while learning how to use the alternative efficiently)
    - Process changes required (e.g., additional time to complete task, additional steps, etc.)
    - Energy and other resource (e.g., water) usage
    - Other operation and maintenance costs (e.g., filters, tank cleanings, etc.)
    - Changes in production or output of operation
    - Releases of alternative chemicals/products
    - Waste and disposal costs associated with alternative chemical/process
    - Changes in your product/service quality
    - Training, medical surveillance, or other employee-related costs
    - Recordkeeping burden/costs
    - Monitoring and testing costs
    - Potential barriers/concerns with switching to alternatives
vii. Have you considered similar solvents like 1-ethyl-2-pyrrolidone (NEP), or other non-halogenated solvents or aqueous processes?
viii. Are you using NMP on some but not all products? If you use NMP or a substitute, how did you decide which to use?

- If you have tried or switched to alternative chemicals or methods, how did they do? how long did that process take? Did it require equipment modifications or new equipment purchases?
- Is there any difference in terms of operation time for alternative products or processes to you NMP formulation? For example, between a graffiti remover containing NMP versus a cold cleaning process.

ix. If NMP formulations could no longer be used for your use, or required to be used at a lower concentration:
- At what concentration of NMP is your formulation no longer effective?
- Would the mix of alternative chemicals/methods be different for you as a small businesses compared to larger businesses? For example, are there particular alternatives that are more suitable for small businesses?

x. If you had to change your cleaning process to another somewhat similar solvent like a NEP blend, can you give an estimate of costs?
- Use equipment
- Process development
- Process verification and validation (including lab testing and/or third-party verification), i.e., proving to yourself that the process works
- Customer certification
- Training
- Insurance
- Permitting
- Facilities changes
- Documentation
- PPE requirements

xi. What if you needed to move your use to a different process like aqueous or another non-similar solvent (modified alcohols, hydrocarbons, alcohols, other blends)? Can you give an estimate of costs?
- Use equipment
- Process development
- Process verification and validation (including lab testing and/or third-party verification) (i.e., proving to yourself that the process works))
- Customer certification
- Training
- Insurance
- Permitting
- Facilities changes
- Documentation
- PPE requirements

xii. If there is no technically and economically feasible alternative for NMP available for your use, what are some consequences/impacts that your business may experience?

xiii. What would be the cost to your business if your use of NMP was prohibited?

7) **Additional questions for electronics manufacturing, including capacitor, resistor, coil, transformer, and other inductor manufacturing; semiconductor manufacturing; lithium-ion cell manufacturing:**

a. Facility information:
   i. How long have you owned or worked at the electronics manufacturing facility?
   ii. What is the status of your business (i.e., independently owned, family operation, chain operation, or franchise)?
   iii. What's the facility size in square feet and height? Who are your nearest neighbors (e.g., residence, business, school, hospital, other)? Is your facility co-residential or co-commercial?
   iv. Do you have an industrial hygiene system in the electronics manufacturing facility? If so, what type of exposure controls are implemented (e.g., restricted access, pneumatic tools, enclosed machines, wall fan, powered exhaust ceiling fan, non-powered exhaust ceiling fan, open door, open window, vapor barrier room around the machine, or local ventilation system such as a fume hood or shroud over machine)?

b. Work practices related to electronics manufacturing operations:
   i. How many employees work at your electronics manufacturing operation full time? Part time?
   ii. How many days a week/year are you open? What are your operating hours?
   iii. What is the location of your equipment (i.e., is it in a separate room, close to the finishing equipment, etc.)?

b. Machine information:
   i. Do you have a special model of machine? How many machines do you have?
   ii. How much NMP do you purchase per month in gallons?
   iii. How old is the equipment? When did you last update your system and what was the nature of the update (e.g., new system/machinery, installation of emissions devices, etc.)? What prompted this update?
   iv. How often do you inspect the machine? What type of leak detector test do you use?

c. Operating information:
   i. From whom do you purchase your solvent or product containing NMP? How much does it cost?
   ii. How do you dispose of your waste (e.g., still bottoms, filter)?

d. Alternatives:
   i. Why do you use NMP rather than other alternatives?
   ii. Do you also use alternatives in addition to NMP? If so, what alternative do you use?
   iii. Are you using NMP on some but not all items? Are there items that you prefer to use NMP on? If so, what items and why is NMP preferred?
   iv. How did you decide which solvent to use?

e. If NMP could no longer be used for electronics manufacturing, would the mix of alternative cleaning methods be different for you as a small business compared to larger

businesses? For example, are there particular alternatives that are more suitable for small businesses?

f. Questions regarding electronics manufacturing as an industry:
    i. How many electronic manufacturers in the U.S. use NMP? What percentage of these manufacturers using NMP are small businesses?
    ii. How much NMP is used in the U.S. for electronic manufacturing every year?

8) Additional questions for distributors and retailers (for consumer uses)

a. How much of your business is supplying products containing NMP to consumers? How much of your business is supplying products containing NMP to commercial or industrial users?
b. If you could no longer sell products containing NMP, how would this impact your business?
c. Do you also sell products designed for the same application or use that do not contain NMP?
    i. If yes, what is the relative share of sales for the product(s) containing NMP compared to the products that do not contain NMP?
d. Are there particular challenges to small business doing distribution of products containing NMP that are different from large distributors? Please describe.
e. What is your preferred method of downstream notification?
f. If you were required to limit sales of NMP-containing products to only persons who were certified to purchase it, what activities and costs would be involved? What guidance would be helpful from the Agency? Please identify any challenges you see with such a limitation.
g. If restrictions (e.g., prohibition or limit to concentration of NMP in products or articles) were placed on NMP in products or articles, how long would you need to notify downstream users? How long would it take to clear channels or trade?
h. If restriction (e.g., restricted container size for NMP-containing products) were placed on NMP in products, what activities and costs would be involved in repackaging activities? How long would it take to implement and to clear channels or trade?

Personal Protective Equipment Respirator System Per Worker Unit Cost Breakdown

EPA's SBAR Pre-Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-Methylpyrrolidone (NMP) under TSCA Section 6(a)

Personal Protective Equipment Respirator System Per Worker Unit Cost Breakdown

OSHA's Respiratory Protection Standard (29 CFR 1910.134)[1] identifies several types of respirators and their Assigned Protection Factors (APFs). The APF denotes the level of respiratory protection that a given respirator is expected to provide employees. Table 1 presents example annualized unit costs estimates for respirators, respirator system components, training, fit testing, and medical clearance. Written respirator program and cleaning costs are not present in this table. Actual costs will vary for each rule depending on the affected industry and the analytical timeframe. Useful lives define the schedule used to discount each cost component before the estimates are annualized.

Respirators are organized by their corresponding APF. Unit cost estimates for individual respirator system components and kits are based on price data collected from retailer websites. Price data are averaged for component and kit unit cost estimates that incorporate the price of more than one product brand.

Table 1: Example Annualized PPE Unit Costs per Worker, by Respirator System in 2021$

Respirator System	Component	Unit Cost	Useful Life	Annualized Unit Costs[1]	
				3%	7%
APF Factor 10					
APR, Half Mask	Half Mask, (APR)	$21.53	2	$11	$11
	Cartridge Filters (APR)	$19.48	0.01	$1,825	$1,780
	Training	$123.00	1	$115	$112
	Qualitative Fit-Testing	$62.00	1	$58	$57
	Medical Clearance	$104.00	21	$6	$8
			Total	**$2,016**	**$1,968**
APF Factor 25					
PAPR, Loose-Fitting Facepiece	Loose-Fitting Facepiece (PAPR)	$56.60	3	$20	$20
	Cartridge Filters (PAPR)	$12.37	0.02	$580	$565
	PAPR System	$1,126.63	3	$398	$404
	Breathing Tube	$57.93	3	$20	$21
	Training	$245.00	1	$230	$224
	Medical Clearance	$104.00	21	$6	$8
			Total	**$1,254**	**$1,242**
	Loose-Fitting Facepiece (PAPR)	$56.60	3	$20	$20

[1] The Respiratory Protection Standard (29 CFR 1910.134), promulgated by OSHA, contains requirements for program administration, procedures for respirator selection, employee training, fit testing, medical evaluation, respirator use, APFs and Maximum Use Concentrations (MUCs), as well as other provisions.

Respirator System	Component	Unit Cost	Useful Life	Annualized Unit Costs[1]	
				3%	7%
SAR, Continuous Flow Mode, Loose-Fitting Facepiece	Breathing Tube	$157.55	3	$56	$56
	Pump	$976.52	7	$182	$195
	Pump Installation	$53.45	7	$10	$11
	Pump Inlet Filter	$8.33	0.48	$16	$16
	Pump Outlet Filter	$14.07	0.19	$69	$68
	Training	$245.00	1	$230	$224
	Medical Clearance	$104.00	21	$6	$8
			Total	**$589**	**$598**
APF Factor 50					
APR, Full Facepiece	Full Facepiece (APR)	$236.14	2	$118	$117
	Cartridge Filters (APR)	$19.48	0.01	$1,825	$1,780
	Training	$123.00	1	$115	$112
	Qualitative Fit-Testing	$62.00	1	$58	$57
	Medical Clearance	$104.00	21	$6	$8
			Total	**$2,123**	**$2,075**
PAPR, Half Mask	Half Mask	$21.53	3	$8	$8
	Cartridge Filters (PAPR)	$12.37	0.02	$580	$565
	PAPR System Components Kit	$1,126.63	3	$398	$404
	Breathing Tube and Airline Hose	$57.93	3	$20	$21
	Training	$245.00	1	$230	$224
	Quantitative Fit-Testing	$144.00	1	$135	$132
	Medical Clearance	$104.00	21	$6	$8
			Total	**$1,376**	**$1,361**
SAR, Continuous Flow Mode, Half Mask	Half Mask	$21.53	3	$8	$8
	Breathing Tube	$157.55	3	$56	$56
	Pump	$976.52	7	$182	$195
	Pump Installation	$53.45	7	$10	$11
	Pump Inlet Filter	$8.33	0.48	$16	$16

Respirator System	Component	Unit Cost	Useful Life	Annualized Unit Costs[1]	
				3%	7%
	Pump Outlet Filter	$14.07	0.19	$69	$68
	Training	$245.00	1	$230	$224
	Quantitative Fit-Testing	$144.00	1	$135	$132
	Medical Clearance	$104.00	21	$6	$8
			Total	**$712**	**$717**
APF Factor 1000					
PAPR, Full Facepiece	Full Facepiece	$194.14	3	$69	$70
	PAPR System	$1,126.63	3	$398	$404
	Breathing Tube	$57.93	3	$20	$21
	Cartridge Filters (PAPR)	$12.37	0.02	$580	$565
	Training	$245.00	1	$230	$224
	Quantitative Fit-Testing	$144.00	1	$135	$132
	Medical Clearance	$104.00	21	$6	$8
			Total	**$1,437**	**$1,423**
PAPR, Helmet/Hood	Hood	$96.02	3	$34	$34
	PAPR System Components Kit	$1,126.63	3	$398	$404
	Breathing Tube	$57.93	3	$20	$21
	Cartridge Filters (PAPR)	$12.37	0.02	$580	$565
	Training	$245.00	1	$230	$224
	Quantitative Fit-Testing	$144.00	1	$135	$132
	Medical Clearance	$104.00	21	$6	$8
			Total	**$1,403**	**$1,388**
SAR, Continuous Flow Mode, Full Facepiece	Full Facepiece	$194.14	3	$69	$70
	Pump (1/4 HP)	$976.52	7	$182	$195
	Breathing Tube and Airline Hose	$157.55	3	$56	$56
	Pump Installation	$53.45	7	$10	$11
	Pump Inlet Filter	$8.33	0.48	$16	$16
	Pump Outlet Filter	$14.07	0.19	$69	$68

Respirator System	Component	Unit Cost	Useful Life	Annualized Unit Costs[1]	
				3%	7%
	Training	$245.00	1	$230	$224
	Quantitative Fit-Testing	$144.00	1	$135	$132
	Medical Clearance	$104.00	21	$6	$8
			Total	**$773**	**$779**
SAR, Continuous Flow Mode, Helmet/Hood	Hood	$96.02	3	$34	$34
	Pump (3/4 HP)	$1,055.77	7	$197	$211
	Breathing Tube and Airline Hose	$157.55	3	$56	$56
	Pump Installation	$53.45	7	$10	$11
	Pump Inlet Filter	$12.53	0.48	$24	$24
	Pump Outlet Filter	$14.07	0.19	$69	$68
	Training	$245.00	1	$230	$224
	Quantitative Fit-Testing	$144.00	1	$135	$132
	Medical Clearance	$104.00	21	$6	$8
			Total	**$761**	**$768**
APF Factor 10000					
SCBA, Positive-pressure Mode, Full Facepiece	Positive-pressure SCBA System (includes full facepiece):	$2,431.38	3	$859	$871
	Air Compressor	$5,776.86	16	$669	$766
	Training	$490.00		$459	$448
	Quantitative Fit-Testing	$144.00		$135	$132
	Medical Clearance	$104.00		$6	$8
			Total	**$2,128**	**$2,225**
SCBA, Positive-pressure Mode, Helmet/Hood	Positive-pressure SCBA system (includes hood)	$2,660.77	3	$940	$953
	Air Compressor	$5,776.86	16	$669	$766
	Training	$490.00	1	$459	$448
	Quantitative Fit-Testing	$144.00	1	$135	$132
	Medical Clearance	$104.00	21	$6	$8
			Total	**$2,209**	**$2,308**

Respirator System	Component	Unit Cost	Useful Life	Annualized Unit Costs[1]	
				3%	7%
[1] Costs are annualized over a 20-year time period					

Acronyms

- APF: Assigned Protection Factors
- APR: Air-Purifying Respirator
- OSHA: Occupational Safety and Health Administration
- PARP: Powered Air-Purifying Respirator
- PPE: Personal Protective Equipment
- SAR: Supplied-Air Respirator (SAR) or Airline Respirator
- SCBA: Self-Contained Breathing Apparatus

Potential Regulatory Options and Estimated Costs

EPA's SBAR Pre-Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-Methylpyrrolidone (NMP) under TSCA Section 6(a)

Potential Regulatory Options and Estimated Costs

Any regulatory requirement could be used alone or in combination to the extent necessary so that NMP no longer presents an unreasonable risk under its condition of use. Additionally, under TSCA section 6(g), EPA may propose a time-limited exemption for specific conditions of use provided certain criteria are met.[1]

When considering practicability and a reasonable transition period, EPA works to account for various factors such as supply chains, availability of alternatives, and time needed for recertification, testing, and retrofitting. Any information on historical timelines from industry on replacing chemicals in the past are especially helpful in determining a reasonable transition period, along with the information mentioned in the previous sentence.

Unlike some of the other chemicals currently undergoing risk management under TSCA section 6, EPA is not considering an airborne concentration limit for NMP and is focusing on dermal protection measures. The 2020 risk evaluation for NMP and revised unreasonable risk determination found that the unreasonable risk of injury to human health is driven by direct dermal contact with liquid NMP.

EPA has not made a decision at this point about what regulatory options to propose. Nonetheless, EPA's primary performance metric for eliminating the unreasonable risk of injury to human health is to eliminate or reduce significantly direct dermal contact with NMP. EPA is considering the following regulatory options and seeking feedback on the impacts of applying one or more of the following regulatory options to address the unreasonable risk from NMP.

Concentration Limit

- A risk management option that would restrict the concentration or weight fraction within the formulation.
    - For example, if scientific analysis supported it, EPA could limit the percentage amount of the chemical in the formulation if that percentage addressed the unreasonable risk and the formulation was still efficacious.
    - In the 2020 Risk Evaluation for NMP, EPA identified the expected weight fraction of NMP in liquid products based on publicly available information, public comments, and available products on the market. If ranges of NMP in formulations were identified, EPA generally assessed the lower bound of the range as the central tendency and the upper bound of the range as the high end.
        - Example: EPA identified and assessed the commercial use of NMP in paints, coatings, adhesives and sealants based on products with 2-53%

[1] In order to propose an exemption under TSCA section 6(g), EPA must find that the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available; compliance with the rule would significantly disrupt the national economy, national security, or critical infrastructure; or the specific condition of use, as compared to alternatives, provides a substantial benefit to health, the environment, or public safety. In proposing the exemption, EPA must provide a time limit for the exemption; analyze the need for the exemption and make the analysis public; and include interim conditions to protect health and the environment.

NMP. At the high-end concentrations, in the expected occupational exposure scenarios, this condition of use drives the unreasonable risk.
    - Example: EPA identified and assessed the commercial use of NMP in metal finishing products with 60-90% NMP. At these concentrations, in the expected occupational exposure scenarios, this condition of use drives the unreasonable risk.
- There is uncertainty if lowering the concentration limit may impact efficacy of the products. For a concentration or weight fraction limit to address the unreasonable risk, it would need to be lower than those that drove the unreasonable risk in the risk evaluation.

Prescriptive Engineering Controls

- A risk management option that would reduce worker exposure by requiring specific physical changes to the workplace to eliminate or reduce direct dermal contact.
    - Examples: installing additional or different equipment, such as enclosed transfer liquid lines, closed loop container systems or a laboratory type fume hood, to reduce the exposure to the chemical.
- EPA's confidence that the unreasonable risk from NMP can be addressed is highest for highly standardized and industrialized settings, such as where NMP is used in a closed-loop system.

Prescriptive Administrative Controls

- A risk management option that would reduce worker exposure by requiring processes or procedures in the workplace to eliminate or reduce direct dermal contact.
    - Examples: Limit access to work areas (restricted areas) or confining operations (enclosed areas)

Prescriptive PPE Controls

- A risk management option that would require the use of specific PPE to minimize exposure. This may limit flexibility for the regulated entity.
    - Some examples of potential PPE that could contribute to reducing the unreasonable risk are listed separately in in Appendix F of the 2020 final risk evaluation, as well as the Potential Costs of Regulatory Options table later in this document.
- Requiring the use of dermal and inhalation PPE that provides an impervious barrier in combination with a set concentration limit of NMP would allow more flexibility for regulated entities to mitigate unreasonable risk.
- EPA anticipates that PPE would need to be combined with training and other controls in order to address the unreasonable risk from NMP.

Combination of Controls (non-prescriptive)

- A combination of risk management approaches for conditions of use where strict industrial practices may already exist. Enables users to determine how to most effectively separate, distance, physically remove, or isolate workers from direct handling of NMP or from contact with equipment/materials for which NMP may exist based on what works best for their workplace and the ability to combine prescriptive controls
- This approach would eliminate direct dermal contact in accordance with the Pollution Prevention Act and NIOSH hierarchy of controls.
- This approach could also include engineering and administrative controls to reduce exposure.
- If direct dermal contact could not be eliminated using elimination, substitution, engineering controls, or administrative controls, EPA could require personal protective equipment that provides an impervious barrier.
- Examples: Automation, barriers, or design of tools

Prohibition

- EPA could include prohibition on manufacturing, processing, distribution, use, or disposal for specific conditions of use or the chemical as a whole.
    - For example, alternatives to NMP in paint and coating removal include solvent-based alternatives like n-ethylpyrrolidone (NEP), benzyl alcohol, and other methyl acetate-based formulations, or process-based alternatives like heat and sanding.
        - https://dtsc.ca.gov/wp-content/uploads/sites/31/2019/09/Final-NMP-Paint-Stripper-Graffiti-Remover_Profile.pdf
- EPA requests data and feedback about availability and viability of NMP alternatives, testing and analysis that SERs have completed of potential alternatives, the cost impacts of SERs switching to alternatives, and the overall impacts to SERs' businesses if NMP is prohibited.

Regulate the Manufacturing, Processing, and/or Distribution

- A risk management option for industrial, commercial, and consumer conditions of use. These authorities allow EPA to regulate at key points, including the manufacturing, processing, and distribution in commerce of a chemical or product in the supply chain.

Regulatory options applied broadly with other restrictions

- Recordkeeping and downstream notification
    - For example, EPA could require manufacturers, processors, and distributors to provide downstream notification to help ensure regulatory information (*i.e.*, prohibition) reaches all users in the supply chain.
    - Additionally, as an example, EPA could require manufacturers, processors, and distributors to maintain ordinary business records and an exposure control plan.

- Monitoring, labeling, and container sizes –
    - For monitoring, EPA could require initial or periodic monitoring of occupational exposure or for concentration limits.
    - For labeling, EPA could require that a prominent label be securely attached to each container with specific directions, limitation, and precautions, or that describes the health endpoints. EPA could also require labeling products to indicate that they should not be used by consumers or to describe other regulatory requirements.
    - For container sizes, EPA could require a minimum or maximum container size (e.g., 32 ounce container, 55 gallon drum) to reduce likelihood of purchase by certain types of users (consumers or commercial users)
- Limited access program
    - For example, restrict distribution of a chemical or product only to certain users, under a limited access program that could require training and certification, or restrict distribution only to users with certain equipment or type of facilities.

Potential Costs of Regulatory Options

Type of Cost	Estimated Compliance Cost	Notes
Prohibition of manufacturing, processing, and distribution	Varies with condition of use	Cost will vary by condition of use. Potential activities could include changes in process and equipment, costs of alternatives[2], reformulation (see below), and more. Requires input from potentially regulated entities.
Prohibition of Use	Varies with condition of use	Cost will vary by condition of use. Potential activities could include changes in process and equipment, costs of alternatives, reformulation (see below), and more. Requires input from potentially regulated entities.
Reformulation of product to reduce NMP concentration	$17,000 per product	Costs reflect dilution reformulation approach.
Reformulation of product to eliminate NMP concentration	$60,000-$102,000 per product	Costs will vary by condition of use and will be dependent on reformulation approach. Requires input from potentially regulated entities.
Engineering/Administrative Controls	Varies by control type and needs of user	Requires input from potentially regulated entities
Personal Protective Equipment (PPE) for NMP (respirators)	APF 10: $1,800 APF 25: $1,300 APF 50: $1,700 APF 1000: $1,100 APF 10000: $2,000	Annualized costs are per person and include purchase of equipment (including filters), training, fit-testing, and medical clearance. The unit costs include a written respiratory program and equipment cleaning. Does not include existing PPE use nor PPE replacement due to employee turn-over. Includes both purified and supplied air respirators.
Personal Protective Equipment (PPE) for NMP (dermal)	Reusable gloves: $6-$55 Disposable gloves: $0.50 Reusable apron: $25-$34 Disposable apron: $4	Reusable glove costs are per pair of butyl, laminated polyethylene, neoprene, and natural rubber/latex gloves. Disposable glove costs are per pair of nitrile gloves. Disposable nitrile gloves are not used alone, but in combination with the reusable gloves. Reusable apron costs are per nitrile and neoprene apron. Disposable apron costs are per polyethylene apron.

[2] TSCA section 6(c)(2)(C) requires EPA "…in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action…to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect."

Type of Cost	Estimated Compliance Cost	Notes
Combination of controls (non-prescriptive)	Annualized costs of Exposure control plan: $560-$630 per facility costs $35 per worker costs One-time costs of Exposure control plan: 40 hours one time cost to develop plan: $3,730 per facility 4 hours annual cost for regular inspections: $370 per facility per year 0.43 hours annual recordkeeping: $40 per facility per year Costs of engineering controls, monitoring, or PPE varies by control type and needs of user See PPE costs for glove and apron costs	Non-prescriptive approach would likely include development of an exposure control plan. Costs include costs for conducting regular inspections, PPE program plan documentation, records of plan implementation, and records of dermal exposure. Includes both per-facility and per-worker costs. Costs would depend on baseline PPE and dermal exposure control plan activities.
Product Label or Warnings	$830- $8,900 per product, one time cost	Costs will vary by condition of use. Potential activities may include graphic design changes, plate changes, discarded inventory, and labor.
Container Sizes	$9,500-$47,500 per product, one time cost	A change in container size would lead to costs at the lower end while a packaging material change would likely result in costs at the higher end.
Substitute Products (average per ounce)	Varies with condition of use	Would vary by price of NMP per ounce vs. substitutes, as well as the differences in efficacy of the substitute products.
Substitute Methods	Varies by job labor rate	This will primarily be labor cost and cost of alternative equipment.
Recordkeeping	$218-$340 per firm	Ongoing annual labor and material costs associated with documentation of ordinary business records.
Downstream Notification	$121-$138 per product, one time cost	Costs are per product and include labor and material costs to update a product's safety data sheet (SDS).
Limited Access Program	Varies with condition of use and type of distributor	Would vary by type of requirements for certification and any distribution processes or restrictions already in place.

Information on Weight Fractions of NMP Evaluated in the 2020 Risk Evaluation

EPA's SBAR Pre-Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-methylpyrrolidone (NMP) under TSCA Section 6(a)

Information on Weight Fractions of NMP Evaluated in the 2020 Risk Evaluation

EPA's 2020 Risk Evaluation for NMP is available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/final-risk-evaluation-n-methylpyrrolidone-nmp. The table below provides a summary of weight fractions (concentrations) of NMP evaluated for each condition of use (COU) and location of that information in the risk evaluation (the Occupational Exposure Scenario (OES) number is also the relevant section of the Risk Evaluation).

To support the Risk Evaluation, EPA determined the weight fraction of NMP in various products through information provided in the reasonably available literature, previous risk assessments, and the 2017 NMP Market Profile (ABT, 2017). This Market Profile was prepared in part by searching Safety Data Sheets (SDSs) of products that contain NMP and compiling the associated name, use, vendor and NMP concentration associated with each of these products. Where multiple data points for a given type of product (*e.g.*, paints and coatings) were available, EPA estimated exposures using the central tendency (50th percentile, or CT) and high-end (95th percentile, or HE) NMP concentrations.

Condition of Use (COU)*	**Occupational Exposure Scenario (OES)**	**Weight Fraction Evaluated (CT and HE)**	**Notes**
Domestic manufacture	2.4.1.2.1	100%	Evaluated pure NMP. This COU drives the unreasonable risk (acute and chronic worker exposure).
Manufacture: import	2.4.1.2.2	100%	Evaluated pure NMP. This COU drives the unreasonable risk (acute and chronic worker exposure).
Processing: as a reactant or intermediate in plastic material and resin manufacturing and other non-incorporative processing	2.4.1.2.3	100%	Evaluated pure NMP. This COU drives the unreasonable risk (acute and chronic worker exposure).
Processing: incorporation into a formulation, mixture or reaction product in multiple industrial sectors	2.4.1.2.4	100%	Evaluated pure NMP. This COU drives the unreasonable risk (acute and chronic worker exposure).
Processing: incorporation into articles in lubricants and lubricant additives in machinery manufacturing	2.4.1.2.5	60-90%	Evaluated a range of NMP weight fractions. This COU drives the unreasonable risk (acute worker exposure at the high end and chronic worker exposure at the central tendency and high end).

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Condition of Use (COU)*	Occupational Exposure Scenario (OES)	Weight Fraction Evaluated (CT and HE)	Notes
Processing: incorporation into articles in paint additives and coating additives not described by other codes in transportation equipment manufacturing	2.4.1.2.6	2-53%	Evaluated a range of NMP weight fractions. This COU drives the unreasonable risk (acute and chronic worker exposure at the high end).EPA used data from public comments, literature, and the *Use and Market Profile for n-Methylpyrrolidone* to determine the NMP weight fraction.
Processing: incorporation into articles as a solvent (which becomes part of product formulation or mixture), including in textiles, apparel and leather manufacturing	2.4.1.2.4	100%	Evaluated pure NMP. This COU drives the unreasonable risk (acute and chronic worker exposure).
Processing: incorporation into articles in other sectors, including in plastic product manufacturing	2.4.1.2.3	100%	Evaluated pure NMP. This COU drives the unreasonable risk (acute and chronic worker exposure).
Processing: repackaging in wholesale and retail trade	2.4.1.2.2	100%	Evaluated pure NMP. This COU drives the unreasonable risk (acute and chronic worker exposure).
Processing: recycling	2.4.1.2.7	92-100%	Evaluated a range of NMP weight fractions. This COU drives the unreasonable risk (acute and chronic worker exposure).
Industrial and commercial use in paints, coatings, and, adhesive removers	2.4.1.2.8	31-70%	Evaluated a range of NMP weight fractions. This COU drives the unreasonable risk (acute worker exposure at the high end, and chronic worker exposure at the central tendency and high end). EPA used data from public comments, literature sources, and the *Use and Market Profile for n-Methylpyrrolidone* to determine the NMP weight fraction.

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Condition of Use (COU)*	Occupational Exposure Scenario (OES)	Weight Fraction Evaluated (CT and HE)	Notes
Industrial and commercial use in paints and coatings in lacquers, stains, varnishes, primers and floor finishes, and powder coatings, surface preparation	2.4.1.2.6	2-53%	Evaluated a range of NMP weight fractions. This COU drives the unreasonable risk (acute worker exposure at the high end, and chronic worker exposure at the central tendency and high end). EPA used data from public comments, literature, and the *Use and Market Profile for n-Methylpyrrolidone* to determine the NMP weight fraction.
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	2.4.1.2.9	60-100%	Evaluated a range of NMP weight fractions. This COU drives the unreasonable risk (acute and chronic worker exposure at the central tendency and high end). EPA used data from public comments, literature, and the *Use and Market Profile for n-Methylpyrrolidone* to determine the NMP weight fraction.
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	2.4.1.2.10	Container handling, small containers 60-75% Container handling, drums 50-75% Fab worker 2.5-5% Maintenance 50-100% Waste truck loading 92%	Evaluated a range of NMP weight fractions. This COU drives the unreasonable risk (acute worker exposure at the high end in most tasks, and chronic worker exposure at the central tendency and high end). EPA used data from public comments, literature, and the *Use and Market Profile for n-Methylpyrrolidone* to determine the NMP weight fraction.
Industrial and commercial use in in paint additives and coating additives not described by other codes in several manufacturing sectors	2.4.1.2.6	2-53%	Evaluated a range of NMP weight fractions. This COU drives the unreasonable risk (acute and chronic worker exposure at the high end). EPA used data from public comments, literature, and the *Use and Market Profile for n-Methylpyrrolidone* to determine the NMP weight fraction.

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Condition of Use (COU)*	Occupational Exposure Scenario (OES)	Weight Fraction Evaluated (CT and HE)	Notes
Industrial and commercial use as a solvent (for cleaning or degreasing) use in electrical equipment, appliance and component manufacturing	2.4.1.2.9	60-100%	Evaluated a range of NMP weight fractions. This COU drives the unreasonable risk (acute worker exposure at the high end, and chronic worker exposure at the central tendency and high end). EPA used data from public comments, literature, and the *Use and Market Profile for n-Methylpyrrolidone* to determine the NMP weight fraction.
Industrial and commercial use as a solvent (for cleaning or degreasing) in electrical equipment, appliance and component manufacturing for use in semiconductor manufacturing	2.4.1.2.10	Container handling, small containers 60-75% Container handling, drums 50-75% Fab worker 2.5-5% Maintenance 50-100% Virgin NMP truck loading 100% Waste truck loading 92%	Evaluated a range of NMP weight fractions. This COU drives the unreasonable risk (acute worker exposure at the high end in most tasks, and chronic worker exposure at the central tendency and high end). EPA used data from public comments, literature, and the *Use and Market Profile for n-Methylpyrrolidone* to determine the NMP weight fraction.
Industrial and commercial use in ink, toner, and colorant products in printer ink and inks in writing equipment	2.4.1.2.11	Printing 5-7% Writing 10-20%	Evaluated a range of NMP weight fractions. This COU drives the unreasonable risk (chronic worker exposure at the high end). EPA used data from public comments and the *Use and Market Profile for n-Methylpyrrolidone* to determine the NMP weight fraction.

EPA's SBAR Pre-Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-methylpyrrolidone (NMP) under TSCA Section 6(a)

Condition of Use (COU)*	Occupational Exposure Scenario (OES)	Weight Fraction Evaluated (CT and HE)	Notes
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)	2.4.1.2.3	100%	Evaluated pure NMP. This COU drives the unreasonable risk (acute and chronic worker exposure).
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	2.4.1.2.6	2-53%	Evaluated a range of NMP weight fractions. This COU drives the unreasonable risk (acute and chronic worker exposure at the high end). EPA used data from public comments, literature, and the *Use and Market Profile for n-Methylpyrrolidone* to determine the NMP weight fraction.
Industrial and commercial use in other uses in soldering materials	2.4.1.2.12	1-2.5%	Evaluated a range of NMP weight fractions. This COU drives the unreasonable risk (chronic worker exposure at the high end). EPA used data from public comments, literature, and the *Use and Market Profile for n-Methylpyrrolidone* to determine the NMP weight fraction.
Industrial and commercial use in other uses in anti-freeze and de-icing products, automotive care products, and lubricants and greases	2.4.1.2.13	2.5-33%	Evaluated a range of NMP weight fractions. This COU drives the unreasonable risk (acute and chronic worker exposure at the high end). EPA used data from public comments, literature, and the *Use and Market Profile for n-Methylpyrrolidone* to determine the NMP weight fraction.
Industrial and commercial use in other uses in metal products not covered elsewhere, and lubricant and lubricant additives including hydrophilic coatings	2.4.1.2.5	60-90%	Evaluated a range of NMP weight fractions. This COU drives the unreasonable risk (acute and chronic worker exposure at the central tendency and high end).

EPA's SBAR Pre-Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-methylpyrrolidone (NMP) under TSCA Section 6(a)

Condition of Use (COU)*	Occupational Exposure Scenario (OES)	Weight Fraction Evaluated (CT and HE)	Notes
Industrial and commercial use in other uses in laboratory chemicals	2.4.1.2.14	100%	Evaluated pure NMP. This COU drives the unreasonable risk (acute and chronic worker exposure).
Industrial and commercial uses in other uses in lithium ion battery manufacturing	2.4.1.2.15	Container handling, small containers 99-100%	Evaluated a range of NMP weight fractions. This COU drives the unreasonable risk (acute worker exposure at the high end in most tasks, and chronic worker exposure at the central tendency and high end). EPA used data from public comments, literature, and the *Use and Market Profile for n-Methylpyrrolidone* to determine the NMP weight fraction.
		Container handling, drums 60-100%	
		Cathode coating 60%	
		Cathode mixing 60%	
		Research and development 60-100%	
		Miscellaneous additional activities 60-100%	
Industrial and commercial use in other uses in cleaning and furniture care products, including wood cleaners and gasket removers	2.4.1.2.16	Dip cleaning 85-100%	Evaluated a range of NMP weight fractions. This COU drives the unreasonable risk (acute and chronic worker exposure at the central tendency and high end). EPA used data from public comments, literature sources, and the *Use and Market Profile for n-Methylpyrrolidone* to determine the NMP weight fraction.
		Spray/wipe cleaning 31-99%	
Industrial and commercial use in other uses in fertilizer and other agricultural chemical manufacturing, processing aids and solvents	2.4.1.2.17	0.1-7%	Evaluated a range of NMP weight fractions. This COU drives the unreasonable risk (chronic worker exposure at the high end). EPA used data from public comments, literature sources, and the *Use and Market Profile for n-Methylpyrrolidone* to determine the NMP weight fraction.

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Condition of Use (COU)*	Occupational Exposure Scenario (OES)	Weight Fraction Evaluated (CT and HE)	Notes
Consumer use in adhesives and sealants in glues and adhesives, including lubricant adhesives and sealants	2.4.2.5 Adhesives and Sealants	0.77-85%	Evaluated a range of NMP weight fractions. This COU drives the unreasonable risk (consumer exposure (acute only) at the high intensity).
Disposal	2.4.1.2.7	92-100%	Evaluated a range of NMP weight fractions. This COU drives the unreasonable risk (acute and chronic worker exposure).
* This table includes only conditions of use identified as driving the unreasonable risk for NMP. As a result, several consumer conditions of use and distribution in commerce are not listed in this table, but risk estimates are provided in the Risk Evaluation.			

Reference

ABT. (2017). Use and Market Profile for N-methylpyrrolidone (NMP). (EPA-HQ-OPPT-2016-0743-0060). Prepared for: Economic and Policy Analysis Branch Chemistry, Economics, and Sustainable Strategies Division, Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency. https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0743-0060.

Appendix A2: Materials Shared with Small Entity Representatives for the Panel Outreach Meeting, May 24, 2023

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Agenda

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-Methylpyrrolidone (NMP) under TSCA Section 6(a)

May 24, 2023, 12:30pm-3:00pm, Eastern time zone

Agenda

12:30 Welcome and Opening Remarks

- Bill Nickerson (EPA Small Business Advocacy Chair / Office of Policy)
- Eileen Murphy (Division Director, Existing Chemicals Risk Management Division, EPA Office of Chemical Safety and Pollution Prevention)
- Tayyaba Zeb (Small Business Administration, Office of Advocacy)
- Mike Ciccarone (Office of Management and Budget, Office of Information and Regulatory Affairs)

12:45 SER Introductions

12:55 Presentation on Panel process (Bill Nickerson, EPA SBAC)

1:05 Presentation on proposed rulemaking for NMP under TSCA section 6(a) (Office of Chemical Safety and Pollution Prevention)

- Consultations with Small Entity Representatives (SERs)
- Key takeaways from the Pre-panel outreach meeting
- Overview of the unreasonable risk determinations in the risk evaluation and the risk management requirements under TSCA
- Overview of conditions of use in the rulemaking and basis for unreasonable risk determination
- Section 6 risk management overview: EPA's authority to regulate occupational and consumer risks, key "tools in the toolbox" for managing unreasonable risks
- Potential regulatory options

1:25 Discussion on conditions of use (COU) with unreasonable risk determinations. (*See list at end for all conditions of use by group*).

- Detailed description of NMP use
- Your experience with exposure control and risk reduction
- Possible risk management actions
- Cost associated with implementations
- Available alternatives
- Other implementation considerations

NMP COU Group 1: Manufacturers, Repackaging/Recycling, and Disposal
NMP COU Group 2: Commercial Processing and Formulation Uses

2:10 Break

2:20 Discussion (continued)

NMP COU Group 3: Industrial and Commercial Paint, Coating, and Solvent Uses
NMP COU Group 4: Industrial and Commercial Uses in Manufacturing of Electronic Parts, Semiconductors, and Lithium Ion Batteries
NMP COU Group 5: Consumer Uses

2:45 Closing session

- Closing remarks from EPA, SBA, and OMB
- Wrap up and next steps (what to expect next)

3:00 Adjourn

Condition of Use Discussion Groups

Group 1: Manufacturing, Repackaging/Recycling, and Disposal

– Includes the following conditions of use:
  - Manufacturing (domestic manufacture)
  - Manufacturing (import)
  - Processing: repackaging in wholesale and retail trade
  - Processing: recycling
  - Disposal

Group 2: Commercial Processing and Formulation Uses

– Includes the following conditions of use:
  - Processing – as a reactant or intermediate in plastic material and resin manufacturing and other non-incorporative processing
  - Processing – Incorporation into a 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 as a solvent (which becomes part of a product formulation or mixture) including in textiles, apparel and leather manufacturing
  - Processing – Incorporation into articles in paint additives and coating additives not described by other codes in transportation equipment manufacturing
  - Processing – Incorporation into articles in other sectors, including in plastic product manufacturing

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

– Includes the following conditions of use:
  - 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 in paint additives and coating additives not described by other codes in multiple manufacturing sectors
  - Industrial and commercial use in ink, toner and colorant products in printer ink and inks in writing equipment
  - 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 soldering materials

- 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 use in other uses in cleaning and furniture care products, including wood cleaners and gasket removers
- Industrial and commercial use in other uses in fertilizer and other agricultural chemical manufacturing, processing aids and solvents

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

– Includes the following condition of use:
- 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 paint additives and coating additives not described by other codes in computer and electronic product manufacturing in electronic parts manufacturing
- 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
- Industrial and commercial uses in other uses in lithium ion battery manufacturing

Group 5: Consumer Use

– Includes the following condition of use:
- Consumer use in adhesives and sealants in glues and adhesives, including lubricant adhesives and sealants

Rulemaking Presentation (updated from Pre-Panel version)

N-Methylpyrrolidone (NMP)
Small Entity Consultation
on Proposed Rulemaking under TSCA Section 6

Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

Small Business Representative Panel Outreach Meeting
May 24, 2023

Overview

- SERs and the regulatory process
- Key Takeaways from Pre-Panel Outreach Meeting
- Findings from the risk evaluation for NMP
- Overview of conditions of use (COU) in the rulemaking
- Basis for unreasonable risk determination
- Risk management requirements under TSCA
- EPA’s authority and “tools in the toolbox”
- Potential regulatory options
- Additional discussion with Small Entity Representatives
- Closing remarks

Consultation with Small Entity Representatives

- EPA is interested in not only information, but also advice and recommendations from the small entity representatives (SERs)

- EPA will use this information to inform the agency's decision on potential regulatory options and to develop a regulatory flexibility analysis, which becomes part of the record for the potential regulation

Consultation with Small Entity Representatives

- Key elements in this regulatory flexibility analysis:
  - Number of small entities to which the potential rule would apply
  - Projected compliance requirements of the potential rule
  - Identification of all relevant Federal rules which may duplicate, overlap or conflict with the potential rule
  - Any significant alternatives to the potential rule which accomplish the stated objectives, and which minimize significant economic impact of the potential rule on small entities

Potentially Affected Entities

- The potential affected industries/sectors for this proposed rule are identified by its NAICS code, SBA thresholds and U.S. Census Bureau Statistics of U.S. Business datasets, published annually
- 302 industries/sectors and their associated NAICS code have been identified although not all of the small firms indicated in the attachment are necessarily expected to be impacted by the proposed rule
- SBA size standards vary greatly by NAICS code and range from $8 - $47 million and 100-1,500 employees
- The attachment “Industry Sectors with Small Entities Potentially Affected by the Rulemaking” provides small firm statistics (number of and employee size) for each industry/sector
- EPA estimates 97% of firms are small entities may be impacted by the proposed rule
- As more specific information about each entity is identified, it is possible that some entities could be dropped from the list

SERs and the Regulatory Process

- We are seeking information on how the options presented might impact your business or organization
  - Provide specific examples of impacts
  - Provide cost data, if available
  - Please see detailed questions in a separate handout

SERs and the Regulatory Process

- We are also seeking alternative methods of regulating unreasonable risks identified for NMP
  - Suggest other relevant options, including data costs and information on how to ensure compliance
  - Suggest ways that small businesses could benefit from flexibilities, such as different compliance timetables, simplified reporting requirements, and exemptions
- We would like to minimize duplication
  - Provide information on any duplicative or contradictory federal, state, county, or city regulations you are aware of
  - For a list of existing regulations, please see summary of Federal regulations

Key Takeaways from Pre-Panel Outreach Meeting

- Participants: 9 SERs participated and one SER submitted written comments
- SERs discussed: Number and types of small entities affected
  - Included how their products are used and identified uses of NMP
  - Specifically, SERs described processing incorporation into formulation (in lawn care and agricultural fertilizer, in pesticides, herbicides, and fungicides, in industrial cleaners), and as an extraction solvent in re-refining used motor oil. SERs included descriptions of the concentrations of NMP in the final product in industrial cleaners (1.5% to 15%) and in some pesticide products (10% by weight or less)
  - A processor SER explained that NMP is used as an extraction solvent in order to yield a higher purity of re-refined oil, and their need NMP for its selectivity for polars and aromatics and low flammability and volatility
  - In written comments, a processor SER described their business as a “cleantech” company advancing stability, and they described their expected benefits from their technology to re-refine used motor oil based on reduction in carbon dioxide emissions from used motor oil currently being disposed of improperly or burned as fuel

Key Takeaways from Pre-Panel Outreach Meeting

- SERs discussed: potential reporting, recordkeeping and compliance requirements
  - SERs discussed their experience with:
    - Engineering controls (Enclosed pipes and mixing vessels, vacuum suction pumps, ventilation systems, carbon scrubbing systems, infrared product formulation verification, fume hoods)
    - Personal protective equipment (PPE): Chemically-resistant gloves (standard and elbow-length), lab coats, glasses/goggles, face shields, boots
    - Other exposure controls (e.g., administrative controls and hazard communication): SDS sheets, good laboratory practices, signs, specialized training
    - Substitute chemicals, and their challenges using those substitutes, such as increased degredation, safety concerns with use (flammable/explosive), less effective than NMP, or regulatory concerns (are currently subject a TSCA section 5 Significant New Use Rule)

Key Takeaways from Pre-Panel Outreach Meeting

- SERs discussed: potential reporting, recordkeeping and compliance requirements
  - SERs discussed their perspective on potential prohibitions:
    - In pesticides, herbicides, and fungicides, and industrial cleaners, SERs described how prohibition on NMP could lead to significant costs for switching to alternatives, especially if pesticide registrations were needed. SERs described increased costs (material degredation, internal document revisions, and EPA FIFRA registration delays) associated with use of alternatives, especially in the case of modified 1-butyl-2-pyrrolidone or dimethyl sulfoxide
    - In solvent extraction operations, a SER described their perspective that alternatives are not as efficacious as NMP and how identifying those alternatives would lead to significant time delays for research and development
    - In the written comment the processor SER stated that as an extraction solvent NMP could potentially be replaced by furfural or phenol (hydroxy benzene) but the SER describes these chemicals as less effective than NMP at extracting polar and aromatic compounds, as well as how, compared to those chemicals, NMP has a lower flammability, lower volatility, and greater thermal stability
    - SERs also discussed the challenges of identifying feasible alternatives and concern that they had transitioned back to NMP after using known alternatives

Key Takeaways from Pre-Panel Outreach Meeting

- SERs discussed: Related Federal rules
  - Two SERs mentioned FIFRA registration requirements for NMP as an inert in pesticide formulations. The SERs indicated that if NMP were prohibited there would be cost and testing requirements associated with registration of a new formulation
  - In written comments, while the processor SER did not mention related Federal rules, the SER indicated they expect health and safety practices to be enforced as part of typical health and safety protocols at refineries

Key Takeaways from Pre-Panel Outreach Meeting

- SERs discussed: Regulatory flexibility alternatives
  - A SER that formulates herbicides, fungicides, and pesticides preferred PPE requirements; the SER described how PPE changes would be less burdensome for their business, because engineering control requirements would incur capital costs
  - In contrast, a SER who plans to use NMP as an extraction solvent in re-refining used motor oil stated that administrative or engineering controls would be possible and preferable. This SER expressed a strong preference for exposure controls that would prevent a need for prohibition or reductions in concentration.
    - In written comments, a processor SER stated that an inability to use NMP would severely impair their planned business, since NMP is central to unique patented process they have been developing for 15 years at a cost of over $50 million dollars

Key Takeaways from Pre-Panel Outreach Meeting

- SERs described considerations for timeframes for implementation of regulatory restrictions:
  - One SER that processes NMP into industrial cleaners stated that they expected six to eight months to transition to a known substitute chemical due to compliance with additional requirements for that chemical (it is subject to a Significant New Use Rule under TSCA Section 5)
  - One SER that processes NMP into pesticides stated that additional testing could require one to two years; a different SER that processes NMP estimated that at least two to three years plus additional time for pesticide registration updates would be needed
  - One SER who plans to use NMP as an extraction solvent in re-refining used motor oil stated that in the event of a prohibition on NMP for this use, they expected that 10 to 15 years of testing and investment would be needed to identify an alternative

Overview of the Risk Evaluation for NMP

- Risk evaluation published December 30, 2020:
  - 37 conditions of use were evaluated
  - Risk evaluation follows a series of opportunities for public input into EPA's NMP risk evaluation activities
  - NMP draft risk evaluation: December 2019; NMP problem formulation: June 2018; NMP scope document: June 2017

Overview of the Risk Evaluation for NMP

- 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 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

Determination of Unreasonable Risk

- In the December 2020 risk evaluation, EPA determined that NMP presented unreasonable risk to health and the environment. In that risk evaluation, EPA determined that 26 of the 37 conditions of use (COU) of NMP presented unreasonable risk
- With EPA's policy change to a whole chemical approach, EPA has issued a revised whole chemical unreasonable risk determination without presuming use of PPE. The changes from that revised determination are included in this presentation and available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/final-risk-evaluation-n-methylpyrrolidone-nmp
- There may be some conditions of use that EPA has determined do not drive the unreasonable risk but may still be subject to regulation due to uses elsewhere in the supply chain that drive the unreasonable risk

Recent Changes to the Risk Determination

- EPA released for public comment a draft revision to the unreasonable risk determination for NMP on July 1, 2022
- EPA published the final revised risk determination on December 19, 2022
- Incorporates policy changes announced in June 2021
- Specifically, EPA has determined that:
  - Making an unreasonable risk determination for NMP as a whole chemical substance, rather than unreasonable risk determinations separately on each individual condition of use in the risk evaluation, is the most appropriate approach to NMP under the statute and implementing regulations
  - The risk determination does not rely on assumptions regarding the use of personal protective equipment (PPE) in making the unreasonable risk determination under TSCA section 6, even though some facilities might be using PPE as one means to reduce workers' exposures; rather, the use of PPE would be considered during risk management as appropriate

Recent Changes to the Risk Determination

- Removing the assumption that workers always and appropriately wear PPE in making the whole chemical risk determination for NMP result in:

  - Three additional conditions of use that drive the unreasonable risk determination for NMP:
    - Industrial and commercial use in ink, toner, and colorant products;
    - Industrial and commercial use in other uses soldering materials;
    - Industrial and commercial use in other uses in fertilizer and other agricultural chemical manufacturing—processing aids and solvents

Recent Changes to the Risk Determination Cont.

- Additionally, removing the assumption that workers always and appropriately wear PPE in making the whole chemical risk determination for NMP result in risks for acute non-cancer effects from inhalation and dermal exposures also driving the unreasonable risk in five conditions of use (where previously those conditions of use were identified as presenting unreasonable risk from chronic non-cancer effects):
  - Processing for incorporation into articles in paint additives and coating additives not described by other codes in transportation equipment manufacturing;
  - 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, powder coatings (surface preparation);
  - Industrial and commercial use paint additives and coating additives in multiple manufacturing sectors; and
  - Industrial and commercial use in adhesives and sealants including binding agents, single component glues and adhesives, including lubricant additives, two-component glues, and adhesives including some resins.

Recent Changes to the Risk Determination Cont.

- Overall, 29 conditions of use out of 37 EPA evaluated drive the NMP whole chemical unreasonable risk determination
- EPA has not conducted new scientific analysis on NMP; the risk evaluation continues to characterize risks associated with individual conditions of use
- The final risk determination is in docket EPA-HQ-OPPT-2016-0743 at regulations.gov

Recent Changes to the Risk Determination

- Separately, EPA is conducting a screening approach to assess potential risks from the air and water pathways for several of the first 10 chemicals, including NMP
  - This screening analysis was presented to the SACC in March and EPA is currently incorporating comments from the SACC and public commenters on revisions to the analysis
- Exposure pathways that were or could be regulated under another EPA-administered statute were excluded from the 2020 NMP risk evaluation, resulting in certain air and water pathways not being fully assessed
- EPA's screening approach will identify if there are risks that were unaccounted for in the risk evaluation for NMP
- If the results suggest there is additional risk, EPA will determine if the risk management approach being contemplated for NMP will protect against these risks or if the risk evaluation will need to be formally supplemented or revised

NMP Manufacturing and Processing Uses that Drive the 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 Drive the 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

NMP Industrial and Commercial Uses that Drive the Unreasonable Risk

- Industrial and commercial use as a solvent (for cleaning or degreasing) in electrical equipment, appliance and component manufacturing for use in semiconductor manufacturing
- Industrial and commercial use in ink, toner and colorant products in printer ink and inks in writing equipment
- 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 soldering materials

NMP Industrial and Commercial Uses and Disposal that Drive the Unreasonable Risk

- 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
- Industrial and commercial use in other uses in fertilizer and other agricultural chemical manufacturing, processing aids and solvents
- Disposal

NMP Consumer Uses that Drive the Unreasonable Risk

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

Basis for Unreasonable Risk Determination: Workers

- The unreasonable risk determination for workers is based on the following health hazards during occupational exposures to NMP:
  - Developmental effects from acute inhalation and dermal exposures
  - Reproductive effects from chronic inhalation and dermal exposures
- Consideration of Personal Protective Equipment (PPE):
  - EPA does not assume that workers are always provided or appropriately wear PPE, for the purposes of unreasonable risk determination
  - EPA does not assume that it is a standard industry practice that workers in some small commercial facilities (e.g., those performing cleaning or degreasing, using automotive care products, soldering materials, or commercial printing and copying) have a respiratory protection program or regularly employ dermal protection; therefore, the use of respirators and gloves is assumed to be unlikely for workers in these facilities
  - When no PPE is assumed to be in place, 29 of the 37 COUs drive the unreasonable risk
  - As previously noted, this assumption results in three additional COUs driving the unreasonable risk determination, and five conditions of use with acute effects in addition to chronic affects driving the unreasonable risk determination

Basis for Unreasonable Risk Determination: Consumers

- The unreasonable risk determinations for consumers is based on the following health hazards during consumer exposures to NMP:
  - Developmental toxicity from acute inhalation and dermal exposure

- The unreasonable risk determinations were based on the high intensity risk estimates for consumers

- EPA did not evaluate chronic exposures to NMP for consumer users because EPA considered the frequency of consumer product use to be too low to create chronic risk concerns

Related Regulations and TSCA Section 6 Authority

- NMP is subject to several federal laws and regulations in the United States and is also subject to regulatory actions by states
  - See separate document “Related Regulations (EPA, other Federal, State, and International)” for more information on the regulatory history of NMP
- EPA determined that NMP presents an unreasonable risk to workers and consumers in the TSCA risk evaluation
- Therefore, EPA is required to develop risk management actions under TSCA to address the unreasonable risk
- TSCA Section 9 allows EPA to use statutory authorities to a sufficient extent by action taken under a Federal law not administrated by the Administrator to reduce or eliminate identified risk to health or the environment

Risk Management Requirements

- Under TSCA, EPA is required to take action, to the extent necessary, to address chemicals that pose unreasonable risks to human health or the environment
- EPA must issue a TSCA section 6(a) rule following risk evaluation to address all identified unreasonable risks within two years:
  - Proposed rule one year after risk evaluation
  - Final rule two years after risk evaluation
- Specific requirements on consideration of alternatives, selecting among options and statement of effects apply to risk management rules
- Input from stakeholders is critical to the process and EPA is seeking stakeholder input now during the SBAR process and during the public comment period following the proposed rule

TSCA 6a Rule Requirements (15 U.S.C 2605(c)(2)):

- (A) Statement of effects
  - In proposing and promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to—
  - (i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture;
  - (ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture;
  - (iii) the benefits of the chemical substance or mixture for various uses; and
  - (iv) the reasonably ascertainable economic consequences of the rule, including consideration of—
    - (I) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;
    - (II) the costs and benefits of the proposed and final regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator; and
    - (III) the cost effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

- (B) Selecting requirements
  - In selecting among prohibitions and other restrictions, the Administrator shall factor in, to the extent practicable, the considerations under subparagraph (A) in accordance with subsection (a).

TSCA Section 6(a)

- TSCA provides EPA with authority to address unreasonable risks, and to regulate entities including:
  - Manufacturers (including importers and importers of articles)
  - Processors (e.g., formulators)
  - Distributors
  - Commercial users (workplaces and workers)
  - Entities disposing of chemicals for commercial purposes
- Cannot directly regulate consumer users
  - Under TSCA, EPA has authority to regulate at the manufacturing, processing and distribution levels in the supply chain to eliminate or restrict the availability of chemicals and chemical-containing products for consumer use
  - These authorities allow EPA to regulate at key points in the supply chain to effectively address unreasonable risks to consumers

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

Availability of Alternatives: TSCA Section 6(c)(2)(C)

- TSCA section 6(c)(2)(C) requires EPA "…in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action…to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect"
  - Substitute products and methods vary by condition of use
  - For example, alternatives to NMP in paint and coating removal include solvent-based alternatives like n-ethylpyrrolidone (NEP), benzyl alcohol, and other methyl acetate-based stripping formulations, or process-based alternatives like heat and sanding (https://dtsc.ca.gov/wp-content/uploads/sites/31/2019/09/Final-NMP-Paint-Stripper-Graffiti-Remover_Profile.pdf)

Effective Dates: TSCA Section 6(d)

- TSCA section 6(d) describes effective dates and compliance dates for TSCA section 6(a) rules
- In these rules, EPA must specify an effective date, which must be as soon as practicable
- Except for uses exempted under TSCA section 6(g), EPA must:
  - Specify mandatory compliance dates for all rule requirements, no later than five years after promulgation of the rule, or, in the case of a ban or phase-out:
    - Specify mandatory compliance dates for the start of a ban or phase-out requirements, which shall be as soon as practicable and no later than five years after promulgation of the rule, and
    - Specify mandatory compliance dates for full implementation of a ban or phase-out requirements, which shall be as soon as practicable
- EPA must also provide for a reasonable transition period

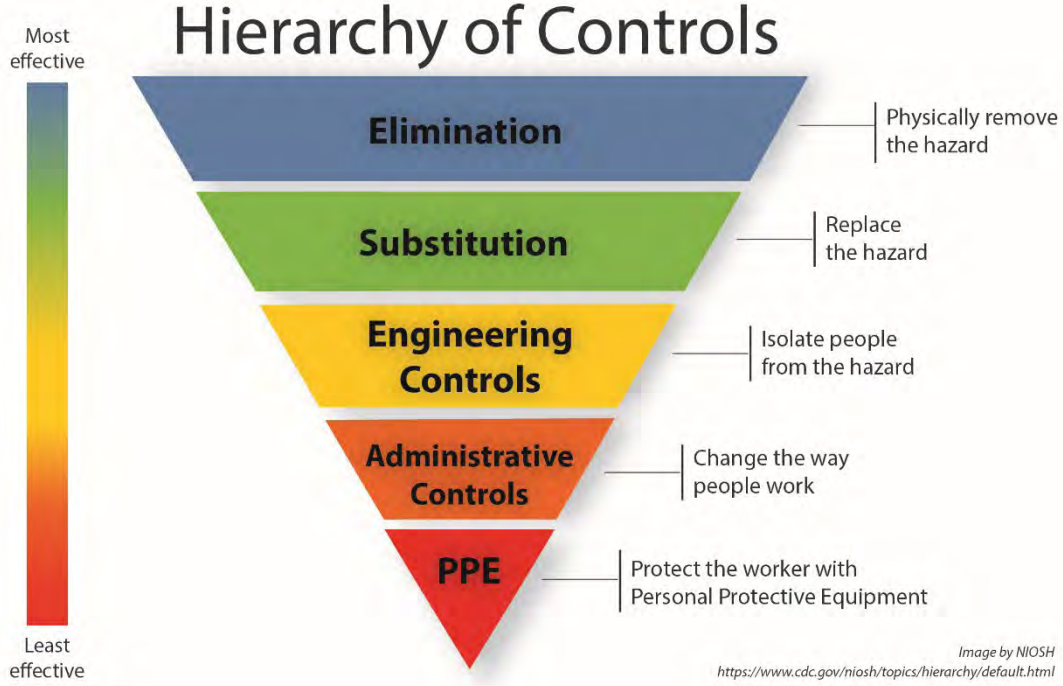
Critical or Essential Uses: TSCA Section 6(g)

TSCA Section 6(g) allows EPA to grant, by rule, a time-limited exemption from a section 6(a) rule for a specific condition of use

- EPA can provide an exemption under three conditions:
  - The specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available;
  - Compliance with the rule would significantly disrupt the national economy, national security, or critical infrastructure; or
  - The specific condition of use, as compared to alternatives, provides a substantial benefit to health, the environment, or public safety
- In granting an exemption, EPA must:
  - Provide a time limit for the exemption
  - Analyze the need for the exemption and make the analysis public
  - Include conditions, such as recordkeeping, monitoring, and reporting requirements, to the extent EPA determines they are necessary to protect health and the environment while achieving the purposes of the exemption
- EPA appreciates any information to inform whether it would be appropriate to propose an exemption under section 6(g), such as:
  - How the exemption request for a COU would meet one or more of the criteria under section 6(g) and information on specific impacts if the chemical were not available
  - Whether the chemical is used to meet requirements or specifications from other regulations, describe the process, timeline, and challenges for obtaining industry/government approval for use of an alternative substance or method
  - Description of how long a potential section 6(g) exemption would be needed and why

Hierarchy of Controls

- EPA is considering the NIOSH/OSHA hierarchy of controls when developing risk management actions
  - As described by NIOSH (https://www.cdc.gov/niosh/topics/hierarchy/default.html), the hierarchy of controls can be used to implement feasible and effective controls to protect workers
  - It typically includes elimination, substitution, engineering controls, administrative controls, and PPE on a scale of most to least protective
- Any regulatory requirement can be used alone or in combination to the extent necessary so that NMP no longer presents an unreasonable risk under its conditions of use



Potential Regulatory Options

- EPA has considered several regulatory options under TSCA section 6(a), and a wide range of risk reduction practices and options
- Through Agency review and stakeholder input, the following potential options have been identified as reducing exposures, so NMP no longer presents an unreasonable risk of injury to health
- These options are currently being considered and evaluated by EPA, and are not final at this time. EPA has not made a decision at this point about what regulatory options to propose
- Regulatory requirements could be used alone or in combination to the extent necessary so that NMP no longer presents an unreasonable risk under its conditions of use
  - Additionally, under TSCA section 6(g), EPA may propose a time-limited exemption for a specific condition of use under three circumstances, as discussed previously on slide 30

Potential Regulatory Options

- Prohibit use above a set concentration (concentration limits)
- Prescriptive PPE controls
- Prescriptive administrative controls
- Prescriptive engineering controls
- Combination of controls (non-prescriptive)
- Prohibit or restrict manufacturing, processing, and distribution
- Prohibit or restrict manufacturing, processing, and distribution for a particular use
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Training, certification, and limited access program

Potential Regulatory Options, cont.

- EPA has not decided on the primary regulatory options to propose in the rule.
- Nonetheless, EPA's primary performance metric for eliminating the unreasonable risk of injury to human health is to eliminate or reduce significantly direct dermal contact with NMP. EPA is considering the following regulatory options and seeking feedback on the impacts of applying one or more of the following regulatory options to address the unreasonable risk from NMP.
- Unlike some of the other chemicals currently undergoing risk management under TSCA section 6, EPA is not considering an airborne concentration limit for NMP and is focusing on dermal protection measures. The 2020 risk evaluation for NMP and revised unreasonable risk determination found that the unreasonable risk of injury to human health is driven by direct dermal contact with liquid NMP.

Potential Regulatory Options, cont.

- For processing, industrial, and commercial uses (occupational exposures) EPA is considering the following regulatory options to address the unreasonable risk:
  - Concentration Limit
    - A risk management option that would restrict the concentration or weight fraction within the formulation.
    - For example, if scientific analysis based on the 2020 Risk Evaluation supported it, EPA could limit the percentage amount of the chemical in the formulation if that percentage addressed the unreasonable risk and the formulation was still efficacious.
    - In the 2020 Risk Evaluation for NMP, EPA identified the expected weight fraction of NMP in liquid products based on publicly available information, public comments, and available products on the market (see separate handout: Information on Weight Fractions of NMP Evaluated in the 2020 Risk Evaluation). If ranges of NMP in formulations were identified, EPA generally assessed the lower bound of the range as the central tendency and the upper bound of the range as the high end.
      - Example: EPA identified and assessed the commercial use of NMP in paints, coatings, adhesives and sealants based on products with 2-53% NMP. At the high-end concentration, in the expected occupational exposure scenarios, these conditions of use drive the unreasonable risk.
      - Example: EPA identified and assessed the commercial use of NMP in metal finishing products with 60-90% NMP. At these concentrations, in the expected occupational exposure scenarios, this condition of use drives the unreasonable risk.
    - There is uncertainty if lowering the concentration limit may impact efficacy of the products. For a concentration or weight fraction limit to address the unreasonable risk, it would need to be lower than those that drove the unreasonable risk in the risk evaluation.

Potential Regulatory Options, cont.

- Prescriptive Engineering Controls
  - Would reduce worker exposure by requiring specific physical changes to the workplace to eliminate or reduce direct dermal contact
  - Examples: installing additional or different equipment, such as enclosed transfer liquid lines, closed loop container systems or a laboratory type fume hood, to reduce the exposure to the chemical
- Prescriptive Administrative Controls
  - Would reduce worker exposure by requiring processes or procedures in the workplace to eliminate or reduce direct dermal contact
  - Examples: Limit access to work areas (restricted areas) or confining operations (enclosed areas)
  - EPA's confidence that the unreasonable risk from NMP can be addressed is highest for highly standardized and industrialized settings, such as where NMP is used in a closed-loop system

Potential Regulatory Options, cont.

- Prescriptive PPE Controls
  - A risk management option that would require the use of specific PPE to minimize exposure. This may limit flexibility for the regulated entity
    - Some examples of potential PPE that could contribute to reducing the unreasonable risk are listed separately in Appendix F of the 2020 final risk evaluation, as well as the Potential Costs of Regulatory Options table later in this presentation
  - Requiring the use of dermal and inhalation PPE that provides an impervious barrier in combination with a set concentration limit of NMP would allow more flexibility for regulated entities to mitigate unreasonable risk
  - EPA anticipates that PPE would need to be combined with training and other controls in order to address the unreasonable risk from NMP

- Combination of Controls (non-prescriptive)
  - A combination of risk management approaches for conditions of use where strict industrial practices may already exist. Enables users to determine how to most effectively separate, distance, physically remove, or isolate workers from direct handling of NMP or from contact with equipment/materials for which NMP may exist based on what works best for their workplace and the ability to combine prescriptive controls
  - Would eliminate direct dermal contact in accordance with the Pollution Prevention Act and NIOSH hierarchy of controls
  - Could include engineering or administrative controls to reduce or eliminate exposure
  - If direct dermal contact could not be eliminated using elimination, substitution, engineering controls, or administrative controls, could require personal protective equipment that provides an impervious barrier
  - Examples: Automation, barriers, or design of tools

Potential Regulatory Options, cont.

- Prohibition
  - EPA could include prohibition on manufacturing, processing, distribution, use, or disposal for specific conditions of use or the chemical as a whole
  - EPA requests data and feedback about availability and viability of NMP alternatives, testing and analysis that SERs have completed of potential alternatives, the cost impacts of SERs switching to alternatives, and the overall impacts to SERs' businesses if NMP is prohibited.

Potential Regulatory Options, cont.

- For consumer uses, EPA is considering the following regulatory options to address the unreasonable risk:
  - Regulation at key points in the supply chain (manufacturing, processing, and/or distribution) to address unreasonable risks to consumers
    - Example: March 2019 rule to address unreasonable risks to consumers from methylene chloride in paint and coating removal prohibited manufacture (including import), processing, and distribution in commerce of methylene chloride for this use (including distribution to and by retailers)
  - Potential regulatory options:
    - Prohibition
    - Concentration Limits
    - Container size

Potential Regulatory Options, cont.

- Regulatory options applied broadly with other restrictions
  - Recordkeeping – example: ordinary business records to demonstrate compliance (for example not selling products to consumers)
  - Downstream notification – example: modify the SDS to indicate that the product should not be used in consumer products or indicate other regulatory requirements
  - Monitoring – example: monitor for compliance or concentration limits
  - Labeling – example: labeling products to indicate that they should not be used by consumers or to describe other regulatory requirements
  - Container size – example: a minimum or maximum container size (e.g., 32 ounce container, 55 gallon drum) to reduce likelihood of purchase by certain types of users (consumers or commercial users)
  - Limited access program – example: access only to users with certain equipment or types of facilities

Cost of Regulatory Options

Option/Type of Cost	Estimated Compliance Cost	Notes
Prohibition of manufacturing, processing, and distribution	Varies with condition of use	Cost will vary by condition of use. Potential activities could include changes in process and equipment, costs of alternatives, reformulation (see below), and more. Requires input from potentially regulated entities.
Prohibition of Use	Varies with condition of use	Cost will vary by condition of use. Potential activities could include changes in process and equipment, costs of alternatives, reformulation (see below), and more. Requires input from potentially regulated entities.
Reformulation of product to eliminate NMP	$60,000-$102,000 per product	Costs will vary by condition of use and will be dependent on reformulation approach. Requires input from potentially regulated entities.
Substitute Products (price per ounce)	Varies with condition of use DMSO: $0.73/ounce (vol) Furfural: $0.70/ounce (vol) Phenol (hydroxy benzene): $1.30/ounce (wt)	Would vary by price of NMP per ounce vs. substitutes, as well as the differences in efficacy of the substitute products. This is only a material cost and excludes changes in equipment, technology, training, testing, etc. Example prices are from a scientific retailer. Requires input from potentially regulated entities.
Reformulation of product to reduce NMP concentration	$17,000 per product	Costs reflect dilution reformulation approach. Requires input from potentially regulated entities.

Cost of Regulatory Options, cont.

Option/Type of Cost	Estimated Compliance Cost	Notes
Engineering/ Administrative Controls	Varies by control type and needs of user	Requires input from potentially regulated entities
Personal Protective Equipment (PPE) – (e.g., respirators)	APF 10: $1,800 APF 25: $1,300 APF 50: $1,700 APF 1000: $1,100 APF 10000: $2,000	Annualized costs are per person and include purchase of equipment (including filters), training, fit-testing, and medical clearance. The unit costs include a written respiratory program and equipment cleaning. Does not include existing PPE use nor PPE replacement due to employee turn-over. Includes both purified and supplied air respirators.
Personal Protective Equipment (PPE) (dermal)	Reusable gloves: $6-$55 Disposable gloves: $0.50 Reusable apron:$25-$34 Disposable apron: $4	Reusable glove costs are per pair of butyl, laminated polyethylene, neoprene, and natural rubber/latex gloves. Disposable glove costs are per pair of nitrile gloves. Disposable nitrile gloves are not used alone, but in combination with the reusable gloves. Reusable apron costs are per nitrile and neoprene apron. Disposable apron costs are per polyethylene apron.

Cost of Regulatory Options, cont.

Option/Type of Cost	Estimated Compliance Cost	Notes
Combination of controls (non-prescriptive)	Annualized costs of Exposure control plan: $560-$630 per facility costs $35 per worker costs One-time costs of Exposure control plan: - 40 hours one time cost to develop plan: $3,730 per facility - 4 hours annual cost for regular inspections: $370 per facility per year - 0.43 hours annual recordkeeping: $40 per facility per year Costs of engineering controls, monitoring, or PPE varies by control type and needs of user See PPE costs for glove and apron costs	Non-prescriptive approach would likely include development of an exposure control plan. Costs include costs for conducting regular inspections, PPE program plan documentation, records of plan implementation, and records of dermal exposure. Includes both per-facility and per-worker costs. Costs will depend on baseline PPE and dermal exposure control plan activities.

Cost of Regulatory Options, cont.

Option/Type of Cost	Estimated Compliance Cost	Notes
Product Label or Warnings	$830- $8,900 per product, one time cost	Costs will vary by condition of use. Potential activities may include graphic design changes, plate changes, discarded inventory, and labor.
Container Sizes	$9,500-$47,500 per product, one time cost	A change in container size would lead to costs at the lower end while a packaging material change would likely result in costs at the higher end.
Substitute Methods	Varies by job labor rate	This will primarily be labor cost and cost of alternative equipment.

Cost of Regulatory Options, cont.

Option/Type of Cost	Estimated Compliance Cost	Notes
Recordkeeping	$218-$340 per firm	Ongoing annual labor and material costs associated with documentation of ordinary business records.
Downstream Notification	$121-$138 per product, one time cost	Costs are per product and include labor and material costs to update a product's safety data sheet (SDS).
Limited Access Program	Varies with condition of use and type of distributor	Would vary by type of requirements for certification and any distribution processes or restrictions already in place.

In-Depth Discussion on Conditions of Use for NMP

1. Manufacturing, repackaging/recycling, and disposal
2. Commercial processing and formulation uses
3. Industrial and commercial paint, coating, and solvent uses
4. Industrial and commercial uses in manufacturing of electronic parts, semiconductors, and lithium-ion batteries
5. Consumer uses

NMP Group 1: Manufacturers, Repackaging/Recycling, and Disposal

- Relevant conditions of use:
  - Manufacturing (domestic manufacture)
  - Manufacturing (import)
  - Processing: repackaging in wholesale and retail trade
  - 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 for NMP Group 1: Manufacturing, Repackaging/Recycling, and Disposal

As noted previously EPA is considering the following regulatory options and is seeking your feedback. Any regulatory requirement could be used alone or in combination to the extent necessary so that NMP no longer presents an unreasonable risk under its conditions of use:

- Prescriptive Controls (Engineering, Administrative, PPE)
- Combination of Controls (Non-Prescriptive)
- Prohibition
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling

Discussion with Small Entity Representatives

Please provide your comments or questions regarding:

- Number and types of small entities affected
- Potential reporting, recordkeeping and compliance requirements
- Related Federal rules
- Regulatory flexibility alternatives

Discussion – Your Business and NMP

- How does your organization use NMP?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of NMP use in your organization?
- How important to your business is the function that NMP provides?
- Are there potential critical or essential uses?
- Are there uses for which there are no available technically or economically feasible alternatives?

Discussion – Workplace Exposure

- What is your experience with exposure control and risk reduction?
- How many employees are exposed to NMP, and for how long (days/years and hours/day)?
- What is the concentration of NMP in the product you use?
- What routine worker activities result in worker exposure to NMP and what type of exposure?
- What engineering controls are used to minimize exposure to NMP? Are additional controls feasible?
- What administrative controls and training do you use to minimize exposure to NMP?
- What respiratory and dermal PPE is regularly worn by workers to minimize exposure to NMP?

Discussion – Regulatory Options

- What regulatory approach should EPA take?
- Are there concerns about the ability to comply with any of the potential regulatory options?
- What advice do you have for reducing impacts on small businesses?
- What timeframe would your business need to comply with potential new regulations or restrictions?

NMP Group 2: Processors

- Relevant conditions of use
  - Processing – as a reactant or intermediate in plastic material and resin manufacturing and other non-incorporative processing
  - Processing – Incorporation into a 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 as a solvent (which becomes part of a product formulation or mixture) including in textiles, apparel and leather manufacturing
  - Processing – Incorporation into articles in paint additives and coating additives not described by other codes in transportation equipment manufacturing
  - Processing – Incorporation into articles in other sectors, including in plastic product manufacturing

- What is NMP used for? How is it 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 for NMP Group 2: Processors

As noted previously EPA is considering the following regulatory options and is seeking your feedback. Any regulatory requirement could be used alone or in combination to the extent necessary so that NMP no longer presents an unreasonable risk under its conditions of use :

- Concentration Limit
- Prescriptive Controls (Engineering, Administrative, PPE)
- Combination of Controls (Non-Prescriptive)
- Prohibition
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling

Discussion with Small Entity Representatives

Please provide your comments or questions regarding:

- Number and types of small entities affected
- Potential reporting, recordkeeping and compliance requirements
- Related Federal rules
- Regulatory flexibility alternatives

Discussion – Your Business and NMP

- How does your organization use NMP?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of NMP use in your organization?
- How important to your business is the function that NMP provides?
- Are there potential critical or essential uses?
- Are there uses for which there are no available technically or economically feasible alternatives?

Discussion – Workplace Exposure

- What is your experience with exposure control and risk reduction?
- How many employees are exposed to NMP, and for how long (days/years and hours/day)?
- What is the concentration of NMP in the product you use?
- What routine worker activities result in worker exposure to NMP and what type of exposure?
- What engineering controls are used to minimize exposure to NMP? Are additional controls feasible?
- What administrative controls and training do you use to minimize exposure to NMP?
- What respiratory and dermal PPE is regularly worn by workers to minimize exposure to NMP?

Discussion – Formulators of Products Containing NMP

- Product reformulation
  - How often do you reformulate your products?
  - What is the typical cost of reformulating your products?
  - What might reformulation costs be if you needed to reformulate your products without NMP? (For example, costs might include R&D, testing, capital costs of production changes, packaging, labeling)
- Product relabeling
  - How often do you relabel your products?
  - What is the typical cost of relabeling?

Discussion – Formulators of Products Containing NMP (Cont.)

- Alternatives
  - Do you sell another product that does not contain NMP that is designed for the same use or application as the NMP product?
    - If yes, what solvent replaces NMP in the alternative product? How does the alternative product compare in terms of safety, efficacy, and cost?
    - If no, if you needed to reformulate this product with a lower concentration of NMP, what would the implications be for the product in terms of cost and efficacy? What solvent would replace NMP? How do you think the alternative would compare in terms of efficacy and cost?
  - Are there any restrictions or other limitations that prescribe the use of NMP to perform your services (e.g., for aerospace or DOD customers)?
  - Is there a subset of uses for your product where using a product formulated without NMP would be problematic?

Discussion – Regulatory Options

- What regulatory approach should EPA take?
- Are there concerns about the ability to comply with any of the potential regulatory options?
- What advice do you have for reducing impacts on small businesses?
- What timeframe would your business need to comply with potential new regulations or restrictions?

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

- Relevant conditions of use:
  - Industrial and commercial use in paints, coatings, and adhesive removers
  - Industrial and commercial use 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 not described by other codes in multiple manufacturing sectors
  - Industrial and commercial use in ink, toner and colorant products in printer ink and inks in writing equipment
  - 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 soldering materials
  - Industrial and commercial use in anti-freeze and de-icing, automotive care products, and lubricants and greases
  - Industrial and commercial use metal products, lubricant and lubricant additives including hydrophilic coatings
  - Industrial and commercial use in laboratory chemicals
  - Industrial and commercial use in cleaning and furniture care products, including wood cleaners and gasket removers
  - Industrial and commercial use in fertilizer and other agricultural chemical manufacturing, processing aids, and solvents

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

As noted previously EPA is considering the following regulatory options and is seeking your feedback. Any regulatory requirement could be used alone or in combination to the extent necessary so that NMP no longer presents an unreasonable risk under its conditions of use:

- Concentration Limit
- Prescriptive Controls (Engineering, Administrative, PPE)
- Combination of Controls (Non-Prescriptive)
- Prohibition
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Container size

Discussion with Small Entity Representatives

Please provide your comments or questions regarding:

- Number and types of small entities affected
- Potential reporting, recordkeeping and compliance requirements
- Related Federal rules
- Regulatory flexibility alternatives

Discussion – Your Business and NMP

- How does your organization use NMP?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of NMP use in your organization?
- How important to your business is the function that NMP provides?
- Are there potential critical or essential uses?
- Are there uses for which there are no available technically or economically feasible alternatives?

Discussion – Workplace Exposure

- What is your experience with exposure control and risk reduction?
- How many employees are exposed to NMP, and for how long (days/years and hours/day)?
- What is the concentration of NMP in the product you use?
- What routine worker activities result in worker exposure to NMP and what type of exposure?
- What engineering controls are used to minimize exposure to NMP? Are additional controls feasible?
- What administrative controls and training do you use to minimize exposure to NMP?
- What respiratory and dermal PPE is regularly worn by workers to minimize exposure to NMP?

Discussion – Users of Products Containing NMP

- What chemicals or processes have you considered as an alternative to using NMP or a product containing NMP?
- Do you currently use any alternatives to NMP or products containing NMP?
- Did you try to switch to another chemical, process, or product, only to switch back? If so, what did you switch to, why did you switch back, and what made you switch in the first place?
- Are there any restrictions or other limitations that prescribe the use of NMP to perform your services (e.g., for aerospace or DOD customers)?
- What are the relative advantages and disadvantages of different substitutes and/or processes that you have considered, including in terms of exposure, cost, and hazard?

Discussion – Regulatory Options

- What regulatory approach should EPA take?
- Are there concerns about the ability to comply with any of the potential regulatory options?
- What advice do you have for reducing impacts on small businesses?
- What timeframe would your business need to comply with potential new regulations or restrictions?

NMP 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 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 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
  - Industrial and commercial uses in other uses in 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 for NMP Group 4: Industrial and Commercial Uses in Manufacturing of Electronic Parts, Semiconductors, and Lithium-Ion Batteries

As noted previously EPA is considering the following regulatory options and is seeking your feedback. Any regulatory requirement could be used alone or in combination to the extent necessary so that NMP no longer presents an unreasonable risk under its conditions of use :

- Prescriptive Controls (Engineering, Administrative, PPE)
- Combination of Controls (Non-Prescriptive)
- Prohibition
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling

Discussion with Small Entity Representatives

Please provide your comments or questions regarding:

- Number and types of small entities affected
- Potential reporting, recordkeeping and compliance requirements
- Related Federal rules
- Regulatory flexibility alternatives

Discussion – Your Business and NMP

- How does your organization use NMP?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of NMP use in your organization?
- How important to your business is the function that NMP provides?
- Are there potential critical or essential uses?
- Are there uses for which there are no available technically or economically feasible alternatives?

Discussion – Workplace Exposure

- What is your experience with exposure control and risk reduction?
- How many employees are exposed to NMP, and for how long (days/years and hours/day)?
- What is the concentration of NMP in the product you use?
- What routine worker activities result in worker exposure to NMP and what type of exposure?
- What engineering controls are used to minimize exposure to NMP? Are additional controls feasible?
- What administrative controls and training do you use to minimize exposure to NMP?
- What respiratory and dermal PPE is regularly worn by workers to minimize exposure to NMP?

Discussion – Users of Products Containing NMP

- What chemicals or processes have you considered as an alternative to using NMP or a product containing NMP?
- Do you currently use any alternatives to NMP or products containing NMP?
- Did you try to switch to another chemical, process, or product, only to switch back? If so, what did you switch to, why did you switch back, and what made you switch in the first place?
- Are there any restrictions or other limitations that prescribe the use of NMP to perform your services (e.g., for aerospace or DOD customers)?
- What are the relative advantages and disadvantages of different substitutes and/or processes that you have considered, including in terms of exposure, cost, and hazard?

Discussion – Regulatory Options

- What regulatory approach should EPA take?
- Are there concerns about the ability to comply with any of the potential regulatory options?
- What advice do you have for reducing impacts on small businesses?
- What timeframe would your business need to comply with potential new regulations or restrictions?

NMP Group 5: Consumer Uses

- Relevant condition of use:
  - Consumer use in adhesives and sealants in glues and adhesives, including lubricant adhesives and sealants

Potential Regulatory Options for NMP Group 5: Consumer Uses

As noted previously EPA is considering the following regulatory options and is seeking your feedback. Any regulatory requirement could be used alone or in combination to the extent necessary so that NMP no longer presents an unreasonable risk under its conditions 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
  - Container size

Discussion with Small Entity Representatives

Please provide your comments or questions regarding:

- Number and types of small entities affected
- Potential reporting, recordkeeping and compliance requirements
- Related Federal rules
- Regulatory flexibility alternatives

Discussion – Your Business and NMP

- How does your organization use NMP?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of NMP use in your organization?
- How important to your business is the function that NMP provides?
- Are there potential critical or essential uses?
- Are there uses for which there are no available technically or economically feasible alternatives?

Discussion – Distributors and Retailers

- What is your experience with exposure control and risk reduction?
- If you could no longer sell products containing NMP, how would this impact your business?
- Are there particular challenges to small business doing distribution of products containing NMP that are different from large distributors?
- What is your preferred method of downstream notification?
- If you were required to limit sales of NMP containing products to only persons who were certified to purchase it, what activities and costs would be involved? What guidance would be helpful from the Agency?

Discussion – Regulatory Options

- What regulatory approach should EPA take?
- Are there concerns about the ability to comply with any of the potential regulatory options?
- What advice do you have for reducing impacts on small businesses?
- What timeframe would your business need to comply with potential new regulations or restrictions?

Closing Session

- Closing remarks from EPA, SBA, and OMB
- Next steps
  - Written comments by June 7, 2023
  - The risk evaluation and supplemental materials are in docket EPA-HQ-OPPT-2019-0236, with additional materials supporting the risk evaluation process and the revised unreasonable risk determination in docket EPA-HQ-OPPT-2016-0743, on www.regulations.gov

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
- June 2021 Policy Changes: https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations
- NMP: Clara Hull (Hull.Clara@epa.gov, 202-564-3954)

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- OMB OIRA: Mike Ciccarone (Michael.j.Ciccarone2@omb.eop.gov)

Appendix

- Panel Outreach SER Questions for Discussion (separate document)
- Related Regulations (EPA, other Federal, state, and international) (separate document)
- Industry Sectors with Small Entities Potentially Affected by the Rulemaking (separate document)
- Personal Protective Equipment Respirator System Per Worker Unit Cost Breakdown (separate document)
- NMP Weight Fraction Table (separate document)
- Pesticide Inert Ingredients Interpretation (separate document)
- Example: OSHA Respiratory Protection Table (Slide 92)
- Dermal Personal Protective Equipment Unit Cost (Slide 93)

Dermal Personal Protective Equipment Unit Cost

Glove Material	Type	Average Price Per Pair (2021$)	Useful Life (pairs per year)
Butyl	Reusable	$54.53	4
Natural Rubber/Latex	Reusable	$6.16	4
Neoprene	Reusable	$11.25	4
Laminated Polyethylene	Reusable	$7.48	4
Nitrile	Disposable	$0.56	260

Apron Material	Type	Average Price per Apron (2021$)	Useful Life (per year)
Polyethylene	Disposable	$3.64	260
Neoprene	Reusable	$33.87	4
Nitrile	Reusable	$25.13	4

Industry Sectors with Small Entities Potentially Affected by the Rulemaking (updated from Pre-Panel version)

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-Methylpyrrolidone (NMP) under TSCA Section 6(a)

Industry Sectors with Small Entities Potentially Affected by the Rulemaking

Entities potentially regulated by this rulemaking to address the unreasonable risks from NMP include those entities relevant to the conditions of use of NMP that EPA evaluated, including domestic manufacturing, import, processing uses of NMP, repackaging and recycling, industrial and commercial uses of NMP (such as solvents for cleaning or degreasing, adhesives and sealants, lubricants and greases, paints and coatings, and in a variety of cleaning products), consumer uses (including adhesives and sealants), and disposal. Entities may include manufacturers (including importers), processors, formulators, industrial and commercial users, or distributors (such as retailers) of NMP or products containing NMP within the scope of this rulemaking.

Potentially affected entities will include both employer and non-employer firms and establishments identified within these sectors by the U.S. Census for each applicable North American Industry Classification System (NAICS) code. Since the Small Business Administration (SBA) size standard varies by NAICS code, they are also included in the table below. NAICS codes of potentially affected entities may include but are not limited to those in Table 1 below. Table 2 shows the estimated number of small firms by condition of use (COU).

Table 1: Potentially Affected Entities

NAICS	NAICS Description	SBA Size Standard
111110	Soybean Farming	$2.3 million
111120	Oilseed (except Soybean) Farming	$2.3 million
111130	Dry Pea and Bean Farming	$2.8 million
111140	Wheat Farming	$2.3 million
111150	Corn Farming	$2.5 million
111160	Rice Farming	$2.5 million
111191	Oilseed and Grain Combination Farming	$2.3 million
111199	All Other Grain Farming	$2.3 million
111211	Potato Farming	$4.3 million
111219	Other Vegetable (except Potato) and Melon Farming	$3.8 million
111310	Orange Groves	$4.0 million
111320	Citrus (except Orange) Groves	$4.3 million
111331	Apple Orchards	$4.5 million
111332	Grape Vineyards	$4.0 million
111333	Strawberry Farming	$5.5 million
111334	Berry (except Strawberry) Farming	$3.8 million
111335	Tree Nut Farming	$3.8 million
111336	Fruit and Tree Nut Combination Farming	$5.0 million
111339	Other Noncitrus Fruit Farming	$3.5 million
111411	Mushroom Production	$4.5 million
111419	Other Food Crops Grown Under Cover	$4.5 million
111421	Nursery and Tree Production	$3.3 million
111422	Floriculture Production	$3.8 million
111910	Tobacco Farming	$2.5 million

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-Methylpyrrolidone (NMP) under TSCA Section 6(a)

NAICS	NAICS Description	SBA Size Standard
111920	Cotton Farming	$3.3 million
111930	Sugarcane Farming	$5.0 million
111940	Hay Farming	$2.5 million
111991	Sugar Beet Farming	$2.5 million
111992	Peanut Farming	$2.5 million
111998	All Other Miscellaneous Crop Farming	$2.5 million
236115	New Single-family Housing Construction (Except For-Sale Builders)	$45.0 million
236116	New Multifamily Housing Construction (except For-Sale Builders)	$45.0 million
236117	New Housing For-Sale Builders	$45.0 million
236118	Residential Remodelers	$45.0 million
236210	Industrial Building Construction	$45.0 million
236220	Commercial and Institutional Building Construction	$45.0 million
237110	Water and Sewer Line and Related Structures Construction	$45.0 million
237120	Oil and Gas Pipeline and Related Structures Construction	$45.0 million
237130	Power and Communication Line and Related Structures Construction	$45.0 million
237310	Highway, Street, and Bridge Construction	$45.0 million
237990	Other Heavy and Civil Engineering Construction	$45.0 million
238110	Poured Concrete Foundation and Structure Contractors	$19.0 million
238120	Structural Steel and Precast Concrete Contractors	$19.0 million
238130	Framing Contractors	$19.0 million
238190	Other Foundation, Structure, and Building Exterior Contractors	$19.0 million
238210	Electrical Contractors and Other Wiring Installation Contractors	$19.0 million
238220	Plumbing, Heating, and Air-Conditioning Contractors	$19.0 million
238290	Other Building Equipment Contractors	$22.0 million
238310	Drywall and Insulation Contractors	$19.0 million
238320	Painting and Wall Covering Contractors	$19.0 million
238330	Flooring Contractors	$19.0 million
238910	Site Preparation Contractors	$19.0 million
238990	All Other Specialty Trade Contractors	$19.0 million
313210	Broadwoven Fabric Mills	1,000 employees
313320	Fabric Coating Mills	1,000 employees
316110	Leather and Hide Tanning and Finishing	800 employees
316210	Footwear Manufacturing	1,000 employees
321912	Cut Stock, Resawing Lumber, and Planing	500 employees
322220	Paper Bag and Coated and Treated Paper Manufacturing	750 employees
323111	Commercial Printing (except Screen and Books)	650 employees
323113	Commercial Screen Printing	500 employees
323117	Books Printing	1,250 employees
323120	Support Activities for Printing	550 employees
324110	Petroleum Refineries	1,500 employees
324191	Petroleum Lubricating Oil and Grease Manufacturing	900 employees
325110	Petrochemical Manufacturing	1,300 employees

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-Methylpyrrolidone (NMP) under TSCA Section 6(a)

NAICS	NAICS Description	SBA Size Standard
325120	Industrial Gas Manufacturing	1,200 employees
325180	Other Basic Inorganic Chemical Manufacturing	1,000 employees
325199	All Other Basic Organic Chemical Manufacturing	1,250 employees
325199	All Other Basic Organic Chemical Manufacturing	1,250 employees
325211	Plastics Material And Resin Manufacturing	1,250 employees
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	1,050 employees
325311	Nitrogenous Fertilizer Manufacturing	1,050 employees
325412	Pharmaceutical Preparation Manufacturing	1,300 employees
325510	Paint And Coating Manufacturing	1,000 employees
325520	Adhesive Manufacturing	550 employees
325611	Soap And Other Detergent Manufacturing	1,100 employees
325612	Polish and Other Sanitation Good Manufacturing	900 employees
325612	Polish and Other Sanitation Good Manufacturing	900 employees
325998	All Other Miscellaneous Chemical Product And Preparation Manufacturing	650 employees
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	750 employees
326199	All Other Plastics Product Manufacturing	750 employees
327390	Other Concrete Product Manufacturing	500 employees
327910	Abrasive Product Manufacturing	900 employees
331110	Iron and Steel Mills and Ferroalloy Manufacturing	1,500 employees
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	1,000 employees
331221	Rolled Steel Shape Manufacturing	1,000 employees
331222	Steel Wire Drawing	1,000 employees
331313	Alumina Refining and Primary Aluminum Production	1,300 employees
331314	Secondary Smelting and Alloying of Aluminum	750 employees
331315	Aluminum Sheet, Plate, and Foil Manufacturing	1,400 employees
331318	Other Aluminum Rolling, Drawing, and Extruding	750 employees
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	1,000 employees
331420	Copper Rolling, Drawing, Extruding, and Alloying	1,050 employees
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding	900 employees
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	850 employees
331511	Iron Foundries	1,000 employees
331512	Steel Investment Foundries	1,050 employees
331513	Steel Foundries (except Investment)	700 employees
331523	Nonferrous Metal Die-Casting Foundries	700 employees
331524	Aluminum Foundries (except Die-Casting)	550 employees
331529	Other Nonferrous Metal Foundries (except Die-Casting)	500 employees
332111	Iron and Steel Forging	750 employees
332112	Nonferrous Forging	950 employees
332114	Custom Roll Forming	600 employees

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-Methylpyrrolidone (NMP) under TSCA Section 6(a)

NAICS	NAICS Description	SBA Size Standard
332117	Powder Metallurgy Part Manufacturing	550 employees
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	500 employees
332215	Metal Kitchen Cookware, Utensil, Cutlery, and Flatware (except Precious) Manufacturing	1,000 employees
332216	Saw Blade and Handtool Manufacturing	750 employees
332311	Prefabricated Metal Building and Component Manufacturing	750 employees
332312	Fabricated Structural Metal Manufacturing	500 employees
332313	Plate Work Manufacturing	750 employees
332321	Metal Window and Door Manufacturing	750 employees
332322	Sheet Metal Work Manufacturing	500 employees
332323	Ornamental and Architectural Metal Work Manufacturing	500 employees
332410	Power Boiler and Heat Exchanger Manufacturing	750 employees
332420	Metal Tank (Heavy Gauge) Manufacturing	750 employees
332431	Metal Can Manufacturing	1,500 employees
332439	Other Metal Container Manufacturing	600 employees
332510	Hardware Manufacturing	750 employees
332613	Spring Manufacturing	600 employees
332618	Other Fabricated Wire Product Manufacturing	500 employees
332710	Machine Shops	500 employees
332721	Precision Turned Product Manufacturing	500 employees
332722	Bolt, Nut, Screw, Rivet, and Washer Manufacturing	600 employees
332811	Metal Heat Treating	750 employees
332812	Metal Coating, Engraving (except Jewelry and Silverware), and Allied Services to Manufacturers	600 employees
332813	Electroplating, Plating, Polishing, Anodizing, and Coloring	500 employees
332911	Industrial Valve Manufacturing	750 employees
332912	Fluid Power Valve and Hose Fitting Manufacturing	1,000 employees
332913	Plumbing Fixture Fitting and Trim Manufacturing	1,000 employees
332919	Other Metal Valve and Pipe Fitting Manufacturing	750 employees
332991	Ball and Roller Bearing Manufacturing	1,250 employees
332992	Small Arms Ammunition Manufacturing	1,300 employees
332993	Ammunition (except Small Arms) Manufacturing	1,500 employees
332994	Small Arms, Ordnance, and Ordnance Accessories Manufacturing	1,000 employees
332996	Fabricated Pipe and Pipe Fitting Manufacturing	550 employees
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	750 employees
333111	Farm Machinery and Equipment Manufacturing	1,250 employees
333112	Lawn and Garden Tractor and Home Lawn and Garden Equipment Manufacturing	1,500 employees
333120	Construction Machinery Manufacturing	1,250 employees
333131	Mining Machinery and Equipment Manufacturing	900 employees
333132	Oil and Gas Field Machinery and Equipment Manufacturing	1,250 employees
333241	Food Product Machinery Manufacturing	500 employees

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-Methylpyrrolidone (NMP) under TSCA Section 6(a)

NAICS	NAICS Description	SBA Size Standard
333242	Semiconductor Machinery Manufacturing	1,500 employees
333243	Sawmill, Woodworking, and Paper Machinery Manufacturing	550 employees
333244	Printing Machinery and Equipment Manufacturing	750 employees
333249	Other Industrial Machinery Manufacturing	750 employees
333314	Optical Instrument and Lens Manufacturing	1,000 employees
333316	Photographic and Photocopying Equipment Manufacturing	1,000 employees
333318	Other Commercial and Service Industry Machinery Manufacturing	1,000 employees
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	500 employees
333414	Heating Equipment (except Warm Air Furnaces) Manufacturing	500 employees
333415	Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing	1,250 employees
333511	Industrial Mold Manufacturing	500 employees
333514	Special Die and Tool, Die Set, Jig, and Fixture Manufacturing	500 employees
333515	Cutting Tool and Machine Tool Accessory Manufacturing	500 employees
333517	Machine Tool Manufacturing	500 employees
333519	Rolling Mill and Other Metalworking Machinery Manufacturing	500 employees
333611	Turbine and Turbine Generator Set Units Manufacturing	1,500 employees
333612	Speed Changer, Industrial High-Speed Drive, and Gear Manufacturing	750 employees
333613	Mechanical Power Transmission Equipment Manufacturing	750 employees
333618	Other Engine Equipment Manufacturing	1,500 employees
333912	Air and Gas Compressor Manufacturing	1,000 employees
333914	Measuring, Dispensing, and Other Pumping Equipment Manufacturing	750 employees
333921	Elevator and Moving Stairway Manufacturing	1,000 employees
333922	Conveyor and Conveying Equipment Manufacturing	500 employees
333923	Overhead Traveling Crane, Hoist, and Monorail System Manufacturing	1,250 employees
333924	Industrial Truck, Tractor, Trailer, and Stacker Machinery Manufacturing	900 employees
333991	Power-Driven Handtool Manufacturing	950 employees
333992	Welding and Soldering Equipment Manufacturing	1,250 employees
333993	Packaging Machinery Manufacturing	600 employees
333994	Industrial Process Furnace and Oven Manufacturing	500 employees
333995	Fluid Power Cylinder and Actuator Manufacturing	800 employees
333996	Fluid Power Pump and Motor Manufacturing	1,250 employees
333997	Scale and Balance Manufacturing	700 employees
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	700 employees
334111	Electronic Computer Manufacturing	1,250 employees
334112	Computer Storage Device Manufacturing	1,250 employees
334118	Computer Terminal and Other Computer Peripheral Equipment Manufacturing	1,000 employees
334210	Telephone Apparatus Manufacturing	1,250 employees

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-Methylpyrrolidone (NMP) under TSCA Section 6(a)

NAICS	NAICS Description	SBA Size Standard
334220	Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing	1,250 employees
334290	Other Communications Equipment Manufacturing	800 employees
334310	Audio and Video Equipment Manufacturing	750 employees
334413	Semiconductor And Related Device Manufacturing	1,250 employees
334510	Electromedical and Electrotherapeutic Apparatus Manufacturing	1,250 employees
334511	Search, Detection, Navigation, Guidance, Aeronautical, and Nautical System and Instrument Manufacturing	1,350 employees
334512	Automatic Environmental Control Manufacturing for Residential, Commercial, and Appliance Use	650 employees
334513	Instruments and Related Products Manufacturing for Measuring, Displaying, and Controlling Industrial Process Variables	750 employees
334514	Totalizing Fluid Meter and Counting Device Manufacturing	850 employees
334515	Instrument Manufacturing for Measuring and Testing Electricity and Electrical Signals	750 employees
334516	Analytical Laboratory Instrument Manufacturing	1,000 employees
334517	Irradiation Apparatus Manufacturing	1,200 employees
334519	Other Measuring and Controlling Device Manufacturing	600 employees
334613	Blank Magnetic and Optical Recording Media Manufacturing	1,250 employees
334614	Software and Other Prerecorded Compact Disc, Tape, and Record Reproducing	1,250 employees
335110	Electric Lamp Bulb and Part Manufacturing	1,250 employees
335121	Residential Electric Lighting Fixture Manufacturing	750 employees
335122	Commercial, Industrial and Institutional Electric Lighting Fixture Manufacturing	600 employees
335129	Other Lighting Equipment Manufacturing	1,250 employees
335210	Small Electrical Appliance Manufacturing	1,500 employees
335220	Major Household Appliance Manufacturing	1,500 employees
335311	Power, Distribution, and Specialty Transformer Manufacturing	800 employees
335312	Motor and Generator Manufacturing	1,250 employees
335313	Switchgear and Switchboard Apparatus Manufacturing	1,250 employees
335314	Relay and Industrial Control Manufacturing	750 employees
335911	Storage Battery Manufacturing	1,250 employees
335912	Primary Battery Manufacturing	1,250 employees
335921	Fiber Optic Cable Manufacturing	1,000 employees
335929	Other Communication and Energy Wire Manufacturing	1,000 employees
335931	Current-Carrying Wiring Device Manufacturing	600 employees
335932	Noncurrent-Carrying Wiring Device Manufacturing	1,000 employees
335991	Carbon and Graphite Product Manufacturing	900 employees
335999	All Other Miscellaneous Electrical Equipment and Component Manufacturing	600 employees
336111	Automobile Manufacturing	1,500 employees
336112	Light Truck and Utility Vehicle Manufacturing	1,500 employees

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-Methylpyrrolidone (NMP) under TSCA Section 6(a)

NAICS	NAICS Description	SBA Size Standard
336120	Heavy Duty Truck Manufacturing	1,500 employees
336211	Motor Vehicle Body Manufacturing	1,000 employees
336212	Truck Trailer Manufacturing	1,000 employees
336213	Motor Home Manufacturing	1,250 employees
336214	Travel Trailer and Camper Manufacturing	1,000 employees
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	1,050 employees
336320	Motor Vehicle Electrical and Electronic Equipment Manufacturing	1,000 employees
336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	1,000 employees
336340	Motor Vehicle Brake System Manufacturing	1,250 employees
336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	1,500 employees
336360	Motor Vehicle Seating and Interior Trim Manufacturing	1,500 employees
336370	Motor Vehicle Metal Stamping	1,000 employees
336390	Other Motor Vehicle Parts Manufacturing	1,000 employees
336411	Aircraft Manufacturing	1,500 employees
336412	Aircraft Engine and Engine Parts Manufacturing	1,500 employees
336413	Other Aircraft Parts and Auxiliary Equipment Manufacturing	1,250 employees
336413	Other Aircraft Part and Auxiliary Equipment Manufacturing7	1,250 employees
336414	Guided Missile and Space Vehicle Manufacturing	1,300 employees
336415	Guided Missile and Space Vehicle Propulsion Unit and Propulsion Unit Parts Manufacturing	1,250 employees
336419	Other Guided Missile and Space Vehicle Parts and Auxiliary Equipment Manufacturing	1,050 employees
336510	Railroad Rolling Stock Manufacturing	1,500 employees
337110	Wood Kitchen Cabinet and Counter Top Manufacturing	750 employees
337122	Nonupholstered Wood Household Furniture Manufacturing	750 employees
339112	Surgical and Medical Instrument Manufacturing	1,000 employees
339113	Surgical Appliance and Supplies Manufacturing	800 employees
339114	Dental Equipment and Supplies Manufacturing	750 employees
339115	Ophthalmic Goods Manufacturing	1,000 employees
339116	Dental Laboratories	500 employees
339950	Sign Manufacturing	500 employees
339999	All Other Miscellaneous Manufacturing	550 employees
423120	Motor Vehicle Supplies and New Parts Merchange Wholesalers	200 employees
423220	Home Furnishing Merchant Wholesalers	100 employees
423330	Roofing, Siding, and Insulation Material Merchant Wholesalers	225 employees
423390	Other Construction Material Merchant Wholesalers	100 employees
423490	Other Professional Equipment and Supplies Merchant Wholesalers	150 employees
423610	Electrical Apparatus and Equipment, Wiring Supplies, and Related Equipment Merchant Wholesalers	200 employees
423620	Electrical And Electronic Appliance, Television, And Radio Set Merchant Wholesalers	225 employees
423840	Industrial Supplies Merchant Wholesalers	125 employees

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-Methylpyrrolidone (NMP) under TSCA Section 6(a)

NAICS	NAICS Description	SBA Size Standard
423850	Service Establishment Equipment and Supplies Merchant Wholesalers	125 employees
423990	Other Miscellaneous Durable Goods Merchant Wholesalers	100 employees
424690	Other Chemical And Allied Products Merchant Wholesalers	175 employees
424710	Petroleum Bulk Stations and Terminals	225 employees
424720	Petroleum and Petroleum Products Merchant Wholesalers (except Bulk Stations and Terminals)	200 employees
424910	Farm Supplies Merchant Wholesalers	200 employees
441110	Automobile Dealers	200 employees
441110	New Car Dealers	200 employees
441120	Used Car Dealers	$30.5 million
441310	Automotive Parts and Accessories Stores	$28.5 million
442110	Furniture Stores	$25 million
453310	Used Merchandise Stores	$14 million
453920	Art Dealers	$16.5 million
453998	All Other Miscellaneous Store Retailers (Except Tobacco Stores)	$11.5 million
488410	Motor Vehicle Towing	$9.0 million
523930	Investment Advice	$47 million
531190	Lessors of Other Real Estate Property9	$34.0 million
541330	Engineering Services	$25.5 million
541380	Testing Laboratories	$19.0 million
561110	Office Administrative Services	$12.5 million
561210	Facilities Support Services	$47.0 million
561720	Janitorial Services	$22.0 million
561740	Carpet and Upholstery Cleaning Services	$8.5 million
562211	Hazardous Waste Treatment and Disposal	$47.0 million
562212	Solid Waste Landfill	$47.0 million
562213	Solid Waste Combustors and Incinerators	$47.0 million
562219	Other Nonhazardous Waste Treatment and Disposal	$47.0 million
562920	Materials Recovery Facilities	$25.0 million
711510	Independent Artists, Writers, and Performers	$9.0 million
712110	Museums	$34.0 million
811111	General Automotive Repair	$9.0 million
811112	Automotive Exhaust System Repair	$9 million
811113	Automotive Transmission Repair	$9 million
811118	Other Automotive Mechanical and Electrical Repair and Maintenance	$9 million
811121	Automotive Body, Paint, and Interior Repair and Maintenance	$9.0 million
811121	Automotive Body, Paint and Interior Repair and Maintenance	$9.0 million
811122	Automotive Glass Replacement Shops	$17.5 million
811191	Automotive Oil Change and Lubrication Shops	$11.0 million
811192	Car Washes	$9.0 million
811198	All Other Automotive Repair and Maintenance	$10.0 million
811412	Appliance Repair and Maintenance	$19.0 million

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-Methylpyrrolidone (NMP) under TSCA Section 6(a)

NAICS	NAICS Description	SBA Size Standard
811420	Reupholstery and Furniture Repair	$9.0 million
811430	Footwear and Leather Goods Repair	$9.0 million
811490	Other Personal and Household Goods Repair and Maintenance	$9.0 million
812310	Coin-Operated Laundries and Drycleaners	$13.0 million
812320	Drycleaning and Laundry Services (except Coin-Operated)	$8.0 million
812331	Linen Supply	$40.0 million
812332	Industrial Launderers	$47.0 million
Source: U.S. Small Business Administration Table of Small Business Size Standards Available at: https://www.sba.gov/document/support--table-size-standards		

Table 2: Small Entities Potentially Affected

Use Category	Estimated Number of Firms Using NMP	Percent of Firms That Are Small	Estimated Number of Small Firms Using NMP
Manufacture/Import	49	24%	12
Repackaging	32	95%	30
Processing: incorporation into a formulation, mixture or reaction product	70	59%	41
Lithium ion battery manufacturing	55	91%	50
Waste handling, disposal, treatment, and recycling	1,787	91%	1,620
Plastic and resin product manufacturing	983	93%	917
Textiles, leather, and apparel manufacturing	33	95%	31
Processing aids in petrochemical manufacturing, oil and gas activities, and functional fluids (closed systems)	479	89%	427
Laboratory use	56	93%	51
Paints and coatings	13,574	97%	13,198
Paint, coating, and adhesive removers	4,296	90%	3,886
Electronic product and semiconductor manufacturing	3,473	94%	3,266
Adhesives and sealants	7,012	97%	6,814
Cleaning and furniture care products	2,702	99%	2,665
Ink, toner, and colorant products	114	99%	113
Soldering	2,768	98%	2,711
Fertilizer and other agricultural chemical manufacturing	26,265	99%	26,017
Lubricants and lubricant additives	-	-	-
Anti-freeze and de-icing	-	-	-
Total	**63,748**	**97%**	**61,850**

Related Regulations (EPA, Federal, State, and International)

Same as Pre-Panel version, see Appendix A1, p.114

SER Questions for Discussion

Same as Pre-Panel version, see Appendix A1, p.123

Personal Protective Equipment Respirator System Per Worker Unit Cost Breakdown

Same as Pre-Panel version, see Appendix A1, p.132

Potential Regulatory Options and Estimated Costs (updated from Pre-Panel version)

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for n-Methylpyrrolidone (NMP) under TSCA Section 6(a)

Potential Regulatory Options and Estimated Costs

Any regulatory requirement could be used alone or in combination to the extent necessary so that NMP no longer presents an unreasonable risk under its condition of use. Additionally, under TSCA section 6(g), EPA may propose a time-limited exemption for specific conditions of use provided certain criteria are met.[1]

When considering practicability and a reasonable transition period, EPA works to account for various factors such as supply chains, availability of alternatives, and time needed for recertification, testing, and retrofitting. Any information on historical timelines from industry on replacing chemicals in the past are especially helpful in determining a reasonable transition period, along with the information mentioned in the previous sentence.

Unlike some of the other chemicals currently undergoing risk management under TSCA section 6, EPA is not considering an airborne concentration limit for NMP and is focusing on dermal protection measures. The 2020 risk evaluation for NMP and revised unreasonable risk determination found that the unreasonable risk of injury to human health is driven by direct dermal contact with liquid NMP.

EPA has not made a decision at this point about what regulatory options to propose. Nonetheless, EPA's primary performance metric for eliminating the unreasonable risk of injury to human health is to eliminate or reduce significantly direct dermal contact with NMP. EPA is considering the following regulatory options and seeking feedback on the impacts of applying one or more of the following regulatory options to address the unreasonable risk from NMP.

Concentration Limit

- A risk management option that would restrict the concentration or weight fraction within the formulation.
    - For example, if scientific analysis based on the 2020 Risk Evaluation[2] supported it, EPA could limit the percentage amount of the chemical in the formulation if that percentage addressed the unreasonable risk and the formulation was still efficacious.
    - In the 2020 Risk Evaluation for NMP, EPA identified the expected weight fraction of NMP in liquid products based on publicly available information, public comments, and available products on the market (see separate handout: Information on Weight Fractions of NMP Evaluated in the 2020 Risk Evaluation). If ranges of NMP in formulations were identified, EPA generally assessed the

[1] In order to propose an exemption under TSCA section 6(g), EPA must find that the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available; compliance with the rule would significantly disrupt the national economy, national security, or critical infrastructure; or the specific condition of use, as compared to alternatives, provides a substantial benefit to health, the environment, or public safety. In proposing the exemption, EPA must provide a time limit for the exemption; analyze the need for the exemption and make the analysis public; and include interim conditions to protect health and the environment.
[2] Available at https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0236-0081.

lower bound of the range as the central tendency and the upper bound of the range as the high end.
    - Example: EPA identified and assessed the commercial use of NMP in paints, coatings, adhesives and sealants based on products with 2-53% NMP. At the high-end concentrations, in the expected occupational exposure scenarios, this condition of use drives the unreasonable risk.
    - Example: EPA identified and assessed the commercial use of NMP in metal finishing products with 60-90% NMP. At these concentrations, in the expected occupational exposure scenarios, this condition of use drives the unreasonable risk.
- There is uncertainty if lowering the concentration limit may impact efficacy of the products. For a concentration or weight fraction limit to address the unreasonable risk, it would need to be lower than those that drove the unreasonable risk in the risk evaluation.

Prescriptive Engineering Controls

- A risk management option that would reduce worker exposure by requiring specific physical changes to the workplace to eliminate or reduce direct dermal contact.
    - Examples: installing additional or different equipment, such as enclosed transfer liquid lines, closed loop container systems or a laboratory type fume hood, to reduce the exposure to the chemical.
- EPA's confidence that the unreasonable risk from NMP can be addressed is highest for highly standardized and industrialized settings, such as where NMP is used in a closed-loop system.

Prescriptive Administrative Controls

- A risk management option that would reduce worker exposure by requiring processes or procedures in the workplace to eliminate or reduce direct dermal contact.
    - Examples: Limit access to work areas (restricted areas) or confining operations (enclosed areas)

Prescriptive PPE Controls

- A risk management option that would require the use of specific PPE to minimize exposure. This may limit flexibility for the regulated entity.
    - Some examples of potential PPE that could contribute to reducing the unreasonable risk are listed separately in in Appendix F of the 2020 final risk evaluation, as well as the Potential Costs of Regulatory Options table later in this document.
- Requiring the use of dermal and inhalation PPE that provides an impervious barrier in combination with a set concentration limit of NMP would allow more flexibility for regulated entities to mitigate unreasonable risk.

- EPA anticipates that PPE would need to be combined with training and other controls in order to address the unreasonable risk from NMP.

Combination of Controls (non-prescriptive)

- A combination of risk management approaches for conditions of use where strict industrial practices may already exist. Enables users to determine how to most effectively separate, distance, physically remove, or isolate workers from direct handling of NMP or from contact with equipment/materials for which NMP may exist based on what works best for their workplace and the ability to combine prescriptive controls
- This approach would eliminate direct dermal contact in accordance with the Pollution Prevention Act and NIOSH hierarchy of controls.
- This approach could also include engineering and administrative controls to reduce exposure.
- If direct dermal contact could not be eliminated using elimination, substitution, engineering controls, or administrative controls, EPA could require personal protective equipment that provides an impervious barrier.
- Examples: Automation, barriers, or design of tools

Prohibition

- EPA could include prohibition on manufacturing, processing, distribution, use, or disposal for specific conditions of use or the chemical as a whole.
    - For example, alternatives to NMP in paint and coating removal include solvent-based alternatives like n-ethylpyrrolidone (NEP), benzyl alcohol, and other methyl acetate-based formulations, or process-based alternatives like heat and sanding.
        - https://dtsc.ca.gov/wp-content/uploads/sites/31/2019/09/Final-NMP-Paint-Stripper-Graffiti-Remover_Profile.pdf
- EPA requests data and feedback about availability and viability of NMP alternatives, testing and analysis that SERs have completed of potential alternatives, the cost impacts of SERs switching to alternatives, and the overall impacts to SERs' businesses if NMP is prohibited.

Regulate the Manufacturing, Processing, and/or Distribution

- A risk management option for industrial, commercial, and consumer conditions of use. These authorities allow EPA to regulate at key points, including the manufacturing, processing, and distribution in commerce of a chemical or product in the supply chain.

Regulatory options applied broadly with other restrictions

- Recordkeeping and downstream notification
    - For example, EPA could require manufacturers, processors, and distributors to provide downstream notification to help ensure regulatory information (*i.e.*, prohibition) reaches all users in the supply chain.

  - Additionally, as an example, EPA could require manufacturers, processors, and distributors to maintain ordinary business records and an exposure control plan.
- Monitoring, labeling, and container sizes –
  - For monitoring, EPA could require initial or periodic monitoring of occupational exposure or for concentration limits.
  - For labeling, EPA could require that a prominent label be securely attached to each container with specific directions, limitation, and precautions, or that describes the health endpoints. EPA could also require labeling products to indicate that they should not be used by consumers or to describe other regulatory requirements.
  - For container sizes, EPA could require a minimum or maximum container size (e.g., 32 ounce container, 55 gallon drum) to reduce likelihood of purchase by certain types of users (consumers or commercial users)
- Limited access program
  - For example, restrict distribution of a chemical or product only to certain users, under a limited access program that could require training and certification, or restrict distribution only to users with certain equipment or type of facilities.

Potential Costs of Regulatory Options

Type of Cost	Estimated Compliance Cost	Notes
Prohibition of manufacturing, processing, and distribution	Varies with condition of use	Cost will vary by condition of use. Potential activities could include changes in process and equipment, costs of alternatives[3], reformulation (see below), and more. Requires input from potentially regulated entities.
Prohibition of Use	Varies with condition of use	Cost will vary by condition of use. Potential activities could include changes in process and equipment, costs of alternatives, reformulation (see below), and more. Requires input from potentially regulated entities.
Reformulation of product to eliminate NMP	$60,000-$102,000 per product	Costs will vary by condition of use and will be dependent on reformulation approach. Requires input from potentially regulated entities.
Substitute Products (price per ounce)	Varies with condition of use DMSO: $0.73/ounce (vol) Furfural: $0.70/ounce (vol) Phenol (hydroxy benzene): $1.30/ounce (wt)	Would vary by price of NMP per ounce vs. substitutes, as well as the differences in efficacy of the substitute products. This is only a material cost and excludes changes in equipment, technology, training, testing, etc. Example prices are from a scientific retailer. Requires input from potentially regulated entities.
Reformulation of product to reduce NMP concentration	$17,000 per product	Costs reflect dilution reformulation approach. Requires input from potentially regulated entities.
Engineering/Administrative Controls	Varies by control type and needs of user	Requires input from potentially regulated entities
Personal Protective Equipment (PPE) for NMP (respirators)	APF 10: $1,800 APF 25: $1,300 APF 50: $1,700 APF 1000: $1,100 APF 10000: $2,000	Annualized costs are per person and include purchase of equipment (including filters), training, fit-testing, and medical clearance. The unit costs include a written respiratory program and equipment cleaning. Does not include existing PPE use nor PPE replacement due to employee turn-over. Includes both purified and supplied air respirators.

[3] TSCA section 6(c)(2)(C) requires EPA "…in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action…to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect."

Type of Cost	Estimated Compliance Cost	Notes
Personal Protective Equipment (PPE) for NMP (dermal)	Reusable gloves: $6-$55 Disposable gloves: $0.50 Reusable apron: $25-$34 Disposable apron: $4	Reusable glove costs are per pair of butyl, laminated polyethylene, neoprene, and natural rubber/latex gloves. Disposable glove costs are per pair of nitrile gloves. Disposable nitrile gloves are not used alone, but in combination with the reusable gloves. Reusable apron costs are per nitrile and neoprene apron. Disposable apron costs are per polyethylene apron.
Combination of controls (non-prescriptive)	Annualized costs of Exposure control plan: $560-$630 per facility costs $35 per worker costs One-time costs of Exposure control plan: 40 hours one time cost to develop plan: $3,730 per facility 4 hours annual cost for regular inspections: $370 per facility per year 0.43 hours annual recordkeeping: $40 per facility per year Costs of engineering controls, monitoring, or PPE varies by control type and needs of user See PPE costs for glove and apron costs	Non-prescriptive approach would likely include development of an exposure control plan. Costs include costs for conducting regular inspections, PPE program plan documentation, records of plan implementation, and records of dermal exposure. Includes both per-facility and per-worker costs. Costs would depend on baseline PPE and dermal exposure control plan activities.
Product Label or Warnings	$830- $8,900 per product, one time cost	Costs will vary by condition of use. Potential activities may include graphic design changes, plate changes, discarded inventory, and labor.
Container Sizes	$9,500-$47,500 per product, one time cost	A change in container size would lead to costs at the lower end while a packaging material change would likely result in costs at the higher end.
Substitute Methods	Varies by job labor rate	This will primarily be labor cost and cost of alternative equipment.
Recordkeeping	$218-$340 per firm	Ongoing annual labor and material costs associated with documentation of ordinary business records.
Downstream Notification	$121-$138 per product, one time cost	Costs are per product and include labor and material costs to update a product's safety data sheet (SDS).

Type of Cost	Estimated Compliance Cost	Notes
Limited Access Program	Varies with condition of use and type of distributor	Would vary by type of requirements for certification and any distribution processes or restrictions already in place.

Information on Weight Fractions of NMP Evaluated in the 2020 Risk Evaluation

Same as Pre-Panel version, see Appendix A1, p.145

Key Takeaways from Pre-Panel Outreach Meeting

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on the Proposed Rulemaking for n-Methylpyrrolidone (NMP) under TSCA Section 6(a)

Key Takeaways from Pre-Panel Outreach Meeting

On March 28, 2023, EPA conducted a Pre-Panel outreach meeting with potential small entity representatives (SERs). Representatives from the Small Business Administration (SBA) and Office of Management and Budget (OMB) also participated. A total of 9 potential SERs participated in the meeting. EPA presented an overview of the Small Business Advocacy Review (SBAR) Panel process and Section 6 of the Toxic Substances Control Act (TSCA), an explanation of the forthcoming rulemaking, potential regulatory approaches, and cost estimates. EPA also provided opportunities for questions and feedback. EPA asked the potential SERs to provide written comments by April 11, 2023. One SER submitted a written comment.

At the Pre-Panel outreach meeting, SERs provided information on the number and type of entities that would be affected; including descriptions of their processing and/or use of NMP, their customer base, how their products are used; potential compliance requirements (including exposure and monitoring reduction, anticipated changes due to future requirements, and considerations for substitute chemicals), related Federal rules, and potential regulatory flexibility alternatives (including descriptions of challenges for small businesses and questions for EPA regarding the regulatory approach). Discussion from SERs focused on several conditions of use (processing into formulations for pesticides, herbicides, and fungicides and industrial cleaners, and using NMP as an extraction solvent in re-refining used motor oil); for most of the other industrial, commercial, and consumer uses of NMP, SERs did not express concerns regarding restrictions or prohibitions.

Summary of Comments from Potential Small Entity Representatives

Number and Types of Entities Affected

SERs discussed their import, manufacture, processing, and/or use of NMP, their customer base, and how their products are used. Specifically, SERs described:

- One SER described their business as a lawn care and agricultural fertilizer business that sells several products that contain NMP. The SER indicated they were looking to phase NMP out of their products.

- A chemical processor SER described their use of NMP in industrial cleaners. The SER described how, generally, NMP is blended into industrial cleaners with a final concentration of 1.5 to 15% NMP in the formula by weight. The SER also described how they can formulate products to specific consumer requests. The SER estimated that on a monthly basis, they process about four drums, or 2,000 lbs of NMP.

- Another chemical processor SER described their use of NMP in herbicides, fungicides, and pesticides. The SER provided an example of how they use NMP in six products registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) with concentrations of NMP in formulation of some products up to 10% by weight. For other products, the NMP may be present in the formulation in small amounts. Several of these

products are applied in the field in water-based solutions. The SER described how they test small volume formulations in a laboratory to complete specified consumer requests.

- A third chemical processor SER described their patented planned use of NMP as an extraction solvent in re-refining used motor oil. The SER is a start-up company and described their investment in the process that will use NMP; the investment described was over $50 million dollars and the SER emphasized how critical NMP is to the planned re-refining process, in order to yield a higher purity of re-refined oil.

    - In a written comment, this SER described in more detail their planned use of NMP as an extraction solvent in their patented technology that will enable used motor oil to be re-refined to produce base oils of high purity. The SER described their business as a "cleantech" company advancing sustainability. The SER in their comment quantified expected benefits from their technology to re-refine used motor oil based on expected reductions in carbon dioxide emissions from used motor oil currently being disposed of improperly of burned as a fuel. The SER described that in their patented process, NMP is critical, and they are expecting that it would be used at any future facilities.

Potential Reporting, Recordkeeping, and Compliance Requirements

SERs described their exposure monitoring and reduction practices, anticipated changes due to potential requirements from EPA, and considerations for substitute chemicals or processes. Specifically, SERs described, for themselves or their customers:

- One SER who processes NMP into industrial cleaners described their exposure control practices, which include PPE and engineering controls.

    - PPE: The SER described how workers receiving and unloading the NMP (in 55-gallon drums), wear PPE to reduce exposures. The SER described this PPE as an industrial uniform with standard boots, safety glasses and gloves for NMP. For other chemicals, the SER described how PPE may include face shields and chemically-resistant elbow-length gloves.

    - Engineering controls: The SER described how, once received, the NMP is pumped through tubes or vacuum suction devices (such as a diaphragm pump) into large mixing vessels/tanks (approximately 800 gallons). Once blended, the formulations are then pumped into totes (standard size is 275 gallons) or drums (55 gallons). The SER noted that outgoing products are checked with Fourier transform infrared when necessary to identify the components in the mixture and measure NMP concentration by weight, rather than manual sampling by workers. This SER indicated their pumps are cleaned after use by water rinse or emulsifier to remove any remaining NMP.

- One SER who formulates herbicides, fungicides, and pesticides with NMP described exposure reduction practices that include PPE, engineering controls, and administrative controls. The SER also provided insight on potential challenges for reformulation, and their feedback on potential compliance requirements.
    - Exposure controls: The SER described how they receive NMP in 55-gallon drums. The NMP is transferred to a blending tank that has vents that lead to carbon scrubbing filters. The SER described how worker protection is guided by SDS sheets, and that this provides guidance on chemically resistant material (e.g., barrier PPE) to NMP. The SER explained how within their internal laboratories, staff use standard PPE such as gloves, glasses, and lab coats, as well as additional control measures such as fume hoods. Staff are trained to follow good laboratory practices, and workers all have undergraduate degrees and experience working in labs. The SER also described how annual retraining is required.
    - Compliance requirements: This SER indicated PPE requirements would be the least burdensome option for their operations, because engineering control requirements would incur capital costs. This SER indicated that reformulating to avoid use of NMP would require additional laboratory testing and internal document revisions, which would require potentially one to two years. They indicated concern over the length of time required for EPA FIFRA registration, which they stated would need to be updated if their formulation changed.
- One SER who plans to use NMP as an extraction solvent in re-refining used motor oil described their planned use of pure NMP in what they characterized as a closed loop system. They expect to achieve this through engineering controls, operations staff training, reduced entry to the area where NMP is used and the use of warning signs. They expect to have operations that run continuously unless routine maintenance is required. The SER described how the NMP would be received in a large truck, held in a small onsite storage tank, and recycled within their system.
    - This SER stated that prohibitions on NMP would have significant negative impacts on their business, and would require an additional 10 to 15 years of testing and investment to identify an alternative.
    - In a written comment, the SER provided more details. While the SER did not describe the impact of potential reporting, recordkeeping, and compliance requirements, the SER did provide information on expected exposures and plans for minimization of worker risk. In the written comment, the SER detailed their expected operations and maintenance manual to track how many employees would be exposed to NMP and for how long. Re-refinery equipment, including a 60,000 gallon storage tank, are outside with open ventilation. The SER described how NMP is used in a Scheibel extraction column to extract low-quality products, aromatics and polar components from the used motor oil; these components are then distilled and separated from the desired output. The NMP is regenerated for

storage and reuse. The SER expects the facility to have four persons per shift with two outside operators, and that one person per shift would be in the area with the tank containing NMP. The SER estimated that the person in the area with the tank would be in that area for no more than one hour a day, and did not expect inhalation or dermal exposures during normal operations.

- The SER also plans to maintain industrial hygiene programs and regular occupational exposure evaluations as part of their worker health and safety protection plan. The comment further detailed expected protocols for engineering controls, which would be focused on a closed loop design using vapor recovery and spill containment systems. Additional engineering controls would include fully automated processing equipment. Administrative controls would be implemented through a standard operating procedure and written instructions for any activity with NMP to restrict access to the area where NMP is being used. PPE would be fitted and available to workers, and industrial hygiene programs and regular occupational exposure evaluations implanted.

- Several SERs discussed alternatives to NMP, and the challenges of using those alternatives if NMP were prohibited:
  - Two SERs (a chemical processor of industrial cleaners, and a chemical processor of herbicides, fungicides, and pesticides) each identified 1-butyl-2-pyrrolidone (or n-butylpyrrolidone (NBP), CASRN 3470-98-2)) as an alternative chemical for NMP but noted that it was less effective than NMP and required more product, degraded faster than NMP, and is subject to a TSCA section 5 Significant New Use Rule (SNUR). The SER indicated that using the chemical subject the SNUR required additional time (with an estimate of approximately 6-8 months delay to their process). Both SERs indicated that while they had used this alternative, they returned to using NMP.
  - A chemical processor SER also identified dimethyl sulfoxide (DMSO) (CASRN 67-68-5) as an alternative to NMP in herbicide and fungicide formulations, and stated their view that it is not as good as NMP at carrying chemicals across barriers or solubilizing organic chemicals. This SER noted it would be challenging to phase out of NMP because it would require lab work to develop a replacement formulation, two to three years of field and toxicology testing, and additional time if the reformulated products would need to be registered under FIFRA. This SER said their products are intended to have two to three year service lives. The SER estimated the cost of reformulation could be around $500,000.
  - A chemical processor SER noted that generally NMP was the chemical many processors in the industry had transitioned to as a replacement for other solvents they described as presenting higher hazards or other concerns (regrettable substitutes).

- In a written comment, a SER stated that their use of NMP as an extraction solved used to upgrade crude oil to base oil could be replaced with other solvents like furfural (CASRN 98-01-1) or phenol (hydroxy benzene) (CASRN 108-95-2). The SER described how these alternatives are less effective than NMP at extracting polar and aromatic compounds, as well as how, compared to those chemicals, NMP has a lower flammability, lower volatility, and greater thermal stability. For these reasons, according to the SER, NMP is essential for their planned process. The SER described extensive development of their unique process, during which they have been testing NMP for fifteen years at a cost of over $50 million. Similar to their comments at the pre-Panel outreach meeting, in written comments the SER described how prohibition or restriction in concentration of NMP for this use would severely impair their planned business, and would require 10 to 15 years to identify and integrate alternative chemical into their extraction and re-refining process.

Related Federal Rules

During the meeting, two SERs mentioned FIFRA registration requirements for NMP as an inert ingredient in pesticide formulations. The SERs indicated that if NMP were prohibited there would be cost and testing requirements associated with registration of a new formulation.

In the written comment the chemical processing SER did not mention related Federal rules. The SER indicated they expect health and safety practices to be enforced as part of typical health and safety protocols at refineries.

Regulatory Flexibility Alternatives

SERs identified several potential regulatory flexibility alternatives, challenges for small businesses, and provided recommendations:

- A SER that formulates herbicides, fungicides, and pesticides with NMP stated a preference for PPE requirements to address unreasonable risks; the SER described how PPE changes would be less burdensome for their business, because engineering control requirements would incur capital costs.
- In contrast, a SER who plans to use NMP as an extraction solvent in re-refining used motor oil stated that administrative or engineering controls would be possible and preferable. This SER expressed a strong preference for exposure controls that would prevent a need for prohibition or reductions in concentration.
    - In the written comment, this SER advised that EPA should focus the proposed regulation of NMP on engineering and administrative controls and PPE requirements instead of prohibitions, imposed concentration limits, or volume restrictions. This SER stated they did not believe additional requirements for their facility were needed, due to site specific operating protocols for health and safety practices including a closed loop system, engineering controls, rigorous operating procedures, employee/contractor training, appropriate PPE (including chemically impervious gloves),

warning signs, restrictions for at-risk personnel.

- Two SERs described considerations for timeframes for implementation of regulatory restrictions:
    - One SER that processes NMP as an inert ingredient in pesticides stated that reformulating to avoid use of NMP would require additional laboratory testing and internal document revisions, which would require potentially one to two years. They indicated concern over the length of time required for EPA FIFRA registration, which they stated would need to be updated if their formulation changed.
    - A different SER that processes NMP into pesticides provided a separate estimate of time that would be needed to reformulate products, which would include lab work to develop a replacement formulation, two to three years of field and toxicology testing, and additional time if the reformulated products would need to be registered under FIFRA.
    - One SER who plans to use NMP as an extraction solvent in re-refining used motor oil stated that in the event of a prohibition on NMP for this use, they expected that 10 to 15 years of testing and investment would be needed to identify an alternative.

Pesticide Inert Ingredients Interpretation TSCA and FIFRA

Pesticide Inert Ingredients Interpretation

This document contains:

1. A letter from EPA to Mark Duvall discussing EPA's interpretation of pesticide inert ingredients subject to the Toxic Substances Control Act prior to use as an ingredient in pesticide products regulated separately under the Federal Insecticide, Fungicide, and Rodenticide Act.
2. 42 FR 64586 (Comment 39) from 42 FR 64,572, 64,586 (Dec. 23 1977) available online at https://www.govinfo.gov/content/pkg/FR-1977-12-23/pdf/FR-1977-12-23.pdf

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mark N. Duvall
Beveridge & Diamond
1900 N Street, NW, Suite 100
Washington, DC 20036

Dear Mr. Duvall:

Thank you for your letter of April 26, 2021 requesting clarification as to whether the rule adopted by the U.S. Environmental Protection Agency (EPA) under the Toxic Substances Control Act (TSCA) for Phenol, Isopropylated Phosphate (3:1) (PIP (3:1)) is intended to preclude the processing and distribution of PIP (3:1) for use as an inert ingredient in pesticide products regulated separately under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The citation for the final rule is: 40 C.F.R. §751.407; Phenol, Isopropylated Phosphate (3:1) (PIP 3:1); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA section 6(h), 86 Fed. Reg. 894 (January 6, 2021).

In your letter you note that PIP (3:1) is an approved inert ingredient under FIFRA but that such use of PIP (3:1) as an inert ingredient in a registered pesticide product is not addressed in the alternative deadlines or exclusions adopted at 40 C.F.R. §751.407(a)(2) or (b). You further note, citing discussion in the preamble of an EPA 1977 rule, that EPA has taken the position that a substance intended for use as an inert ingredient in a pesticide product is subject to TSCA, not FIFRA, until it is actually formulated into the pesticide. You, however, state that "use of PIP (3:1) by a pesticide formulator as an inert ingredient in a registered pesticide product should not be directly affected by § 751.407, since EPA adopted that rule under TSCA, while pesticide products are excluded from TSCA regulation and instead subject exclusively to FIFRA." You cite the exclusion from the definition of "chemical substance" for "any pesticide when manufactured, processed or distributed in commerce for use as a pesticide" at TSCA § 3(2)(B)(ii).

As you correctly note in your letter, EPA has a longstanding interpretation of TSCA § 3(2)(B)(ii) that pesticide inert ingredients are subject to TSCA jurisdiction until becoming part of the pesticide product. See 42 Fed. Reg. 64,572, 64,586 (Dec. 23, 1977) (Comment 39, taking the position that a raw material, intermediate, or inert ingredient which is not itself a pesticide would be a chemical substance within the jurisdiction of TSCA and "would come within the jurisdiction of FIFRA when it becomes a component of a pesticide product"); 51 Fed. Reg. 15,096, 15,098 (Apr. 22, 1986) (reaffirming this position). This interpretation has not changed. Thus, the processing and distribution of PIP (3:1) prior to use by a pesticide formulator as an inert

ingredient in a registered pesticide product is subject to the newly adopted TSCA regulation for PIP (3:1).

Again, thank you for your letter. I hope this information has been helpful to you. If you have additional questions, please contact me, or you can contact Tanya Hodge Mottley, the Director of the Existing Chemical Risk Management Division at (202) 564-3152.

Sincerely,

Hartman, Mark

Digitally signed by Hartman, Mark
Date: 2021.05.25 11:26:21 -04'00'

Mark A. Hartman
Deputy Office Director

CC: Tanya Hodge Mottley, EPA/OPPT

would normally be limited to situations involving significant exposure. In the case of a research chemical which becomes a pesticide, these latter areas of concern would be addressed under FIFRA.

Comment 39: Various commenters maintained that raw materials, intermediates, and inert ingredients produced or used in the manufacture of a pesticide should be considered "pesticides" and excluded from regulation under TSCA. Other commenters argued that raw materials and intermediates produced or used in the manufacture of a pesticide are not "pesticides," are not covered under FIFRA, and should be regulated under TSCA.

Response: The Administrator agrees that raw materials, intermediates and inert ingredients produced or used in the manufacture of a pesticide are substances or mixtures which can be regulated under TSCA.

In order to be considered a pesticide, a substance must be intended for use as a pesticide. Raw materials, intermediates, and inert ingredients produced or used in the manufacture of a pesticide are not themselves regulated under FIFRA (unless they happen to be pesticides themselves) and, therefore, are subject to TSCA. The pesticide regulations at 40 CFR 162.4 are consistent with this view. A manufacturing use product is considered a pesticide. (40 CFR 162.4(b)(3)); an intermediate substance intended for the production of a pesticide product by chemical reaction with other substances is not considered a pesticide. (40 CFR 162.4(c)(6)).

The legislative history of TSCA also supports this view. TSCA was enacted to provide protection from harmful chemicals where legal authority was previously inadequate, cumbersome or inefficient. Congress intended to avoid the possibility that the risks from a chemical would not be subject to regulation. S. Rep. No. 94-698, 94th Cong., 2d Sess. 5 (1976). H. Rep. No. 94-1341, 94th Cong., 2d Sess. 6 (1976). In addition, Senator Allen of the Senate Committee on Agriculture and Forestry in attempting to conform the language of TSCA to that of FIFRA specifically addressed the interface between FIFRA and TSCA stating: "* * * any chemical or toxic substance would first be subject to the provisions of (TSCA) and yet when it becomes a component of a pesticide, it would be subject to FIFRA. In many instances the manufacturer and registrant of the component is also the manufacturer and registrant of the pesticide." Committee on Interstate and Foreign Commerce, 94th Cong., 2d Sess., Legislative History of the Toxic Substances Control Act 232 (1976). A raw material, intermediate, or inert ingredient which is not itself a pesticide would, accordingly, be a chemical substance within the jurisdiction of TSCA; it would come within the jurisdiction of FIFRA when it becomes a component of a pesticide product.

The manufacturer, processor, or distributor of the chemical substance who does not also manufacture, process or distribute a pesticide product will not be subject to the dual jurisdiction of TSCA and FIFRA. That person will only be subject to TSCA. The manufacturer, processor, and distributor of the raw material, intermediate, or inert ingredient who also manufactures the pesticide product will be subject to the jurisdiction of both acts. TSCA and its legislative history contemplates this, and EPA has no discretion to reach a different result since a raw material, intermediate, or inert ingredient (which is not itself a pesticide) cannot be regulated under FIFRA until it becomes a component of a pesticide product. As a matter of policy, however, EPA does not intend to impose duplicative requirements on these substances.

Comment 40: A substance should be considered a food, food additive, drug, cosmetic or device at the time that the Food and Drug Administration (FDA) regulates the substance.

Response: The Administrator agrees with this comment. As soon as the FDA regulates a product, its manufacture, processing, or distribution in commerce solely for a FDA regulated use will be excluded from the jurisdiction of TSCA. The FDA gives as examples of such points in time: when an application for exemption for an investigational use of a new drug is submitted (FFDCA 505(a); 21 CFR Part 312); when an application for exemption for investigational use of a new animal drug is submitted (FFDCA 512(a); 21 CFR Part 511); and when an application for exemption for investigational use of a device is submitted (FFDCA 520(g); 21 CFR Part 812, as proposed, 41 FR 35282, August 20, 1976).

Comment 41: Intermediates and catalysts intended solely for use in the production of a food, food additive, drug, cosmetic, or device are excluded from regulation under TSCA.

Response: The Administrator agrees with this comment. The definitions of the FFDCA provide that chemical substances which are intended for use as a component of a food, food additive, drug, cosmetic, or device are encompassed within the meaning of such terms, respectively. The FDA considers intermediates and catalysts to be such components. Therefore, they are subject to regulation under the FFDCA. Any such substance is excluded from regulation under TSCA insofar as it is actually manufactured processed or distributed in commerce solely for use in the production of a food, food additive, drug, cosmetic or device.

Comment 42: Substances which are approved for use by the Food and Drug Administration as foods or food additives, should be excluded from further regulation under TSCA even when used for commercial (non-food) uses.

Response: As discussed in response to comment 37, if a substance has multiple uses only some of which are regulated under the FFDCA, the manufacturing, processing, distribution, and use of the substance for the remaining uses comes within the jurisdiction of TSCA. Under these regulations, that substance should be reported for the inventory.

EPA does not intend to impose duplicative requirements on manufacturers and processors subject to regulation under another Federal authority. Accordingly, EPA will consult with FDA or any other Federal agency, as appropriate, prior to taking regulatory action on substances which are also regulated under other authorities.

CHEMICAL SUBSTANCES EXCLUDED FROM THE INVENTORY

Small Quantities for Research and Development

Comment 43: The exemption for "small quantities for research and development" should include small quantities used for quality control testing and for development of a chemical substance or product.

Response: The Administrator agrees, in part, with this comment. Chemicals used for quality control testing and for the development of a product are considered "small quantities for research and development" if they fall within the definition provided in § 710.2(y). Specifically, they must be manufactured or processed in quantities no greater than reasonably necessary for such purposes and, after publication of the revised inventory, they must be used by, or directly under the supervision of "technically qualified individual(s)," a term defined in § 710.3(aa). Substances can be "small quantities for research and development" even if they are distributed in commerce.

Comment 44: Numerical limits should be included in the definition of small quantities for research and development.

Response: The Administrator considered establishing upper limits for small quantities for research and development and found that different values might have to be assigned for various groups of substances depending upon their physical/chemical characteristics and intended uses. For example, many plastics and fibers are commonly produced in 100,000 pound quantities during the developmental phase, while additives or minor use substances may be manufactured in a few thousand pounds or less for research and development purposes. After compilation of the inventory, the Agency will consider developing a schedule of quantities to define small quantities for different chemical substances and different purposes.

For these reporting requirements, however, EPA will in large part rely on the qualitative test contained in the definition at § 710.2(y). In response to this comment, as provided in a note to the definition, if a substance is manufactured or imported in quantities of less than one thousand pounds annually, it will be presumed to be for research and development purposes. If a manufacturer wishes to report for inclusion on the inventory a chemical substance which is manufactured for commercial purposes in quantities of less than one thousand pounds annually, he must be able to certify that the substance is used for purposes other than for research and development. After the publication of the revised inventory, in order to qualify as a "small quantity for research or development," these quantities must be used by, or directly under the supervision of, a technically qualified individual.

Comment 45: The exemption for "small quantities" should not extend to research or analysis of chemical substances for the development of a product. The exemption should apply only to research in a laboratory and not to situations where production workers are exposed.

Response: The Administrator disagrees with this comment. The legislative history of the Act makes clear that Congress intended the exemption for "small quantities" to extend to chemical substances in the developmental period and not only to research chemicals in a laboratory. H.R. Rep. No. 94-1341, 94th Cong., 2d Sess. 29-30 (1976). The Congress contemplated that during the research and development phase, a chemical substance would be within the control of technically qualified individuals who would appreciate the risks from exposure to the substance and be able to minimize such risks. The regulations provide that a compound will only qualify for the "small quantities" exemption if it is used by, or directly under the supervision of, technically qualified individual(s). The Agency expects this requirement to provide workers in the development of a product the same protections as workers in the laboratory. In addition, section 5(b)(3) of the Act specifically provides that in order for a substance to be exempted from the requirements of premanufacture notification, all persons handling the chemical substance for the manufacturer or processor must be notified of any risk to health which the manufacturer, processor or the Administrator has reason to believe may be associated with it.

Comment 46: The exemption for "small quantities" should not extend to chemical substances distributed in commerce.

Response: The Administrator disagrees with this comment. Congress recognized that

APPENDIX B: Written Comments Submitted by Small Entity Representatives following the Pre-Panel and Panel Outreach Meetings

Appendix B is a compilation of all written comments submitted by SERs following the Pre-Panel Outreach meeting on March 28, 2023, contained in a separate attachment. One SER submitted written comments: ReGen III Corp.

No written comments were received following the Panel Outreach meeting.

O/Ref: REG-GE0-HS-LTR-0001

April 10, 2023

Ms. Lanelle Wiggins
RFA/SBREFA Team Leader 5
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, D.C. 20460

Re: Response to the Environmental Protection Agency Regarding the Pre-Panel Outreach Meeting on TSCA6a NMP Rulemaking (March 28, 2023)

Dear Ms. Wiggins,

This letter is regarding the U.S. Environmental Protection Agency (EPA) meeting on TSCA6a NMP Rulemaking, conducted on March 28, 2023. At this meeting, the EPA raised questions related to NMP and its use. Please find attached ReGen III's written responses to the questions provided in the meeting material.

ReGen III is a cleantech company, building a green project that is profitable, non-reliant on government subsidies, and sustainable. ReGen III owns a portfolio of patented technologies that enable used motor oil (UMO) to be re-refined to produce base oils at a higher value product mix than traditional methods provide. Not only does recycling of UMO produce high value products, it is also environmentally responsible because it replaces supply of base oils produced by traditional refining methods, which are substantially more energy intensive. Re-refining UMO also prevents it from being disposed improperly or burned as a fuel. The life-cycle assessment study estimates that CO2e emissions from the ReGen III process are 82% lower than comparable, traditionally produced refined base oils that are later used as fuel at end of life. Furthermore, our proposed facility in Texas is projected to reduce up to 903,000 mt CO2e / year from entering the atmosphere, the equivalent of removing 195,000 passenger vehicles from the road.

ReGen III is a start-up company that has been developing its process over the last fifteen years. ReGen III has invested over $50M during those years in research, testing and engineering, and are on the cusp of proceeding with our first full-size facility that will see over 1 million person-hours in direct construction labor as well as 40-50 full time jobs during operation.

At the heart of the process is the use of NMP. NMP was chosen and has been tested exclusively over the last fifteen years primarily because of its selectivity for polars and aromatics, compounds that must be removed to produce higher quality base oils. Alternative solvents do not provide the required level of selectivity.

The ReGen III UMO re-refinery is being designed with high standards for health and safety, typical of refineries. ReGen III will incorporate the following to manage exposure to NMP:

- A closed loop system to limit exposure pathways to NMP
- Incorporation of engineering controls to limit releases
- Development of rigorous operating procedures
- Extensive training for employees/contractors regarding the risks associated with NMP
- Provision of the appropriate PPE
- Placement of warning signs
- Restrictions for at-risk personnel entering the NMP area

ReGen III is a pre-revenue start-up and the project will be severely impaired, if developed at all, if NMP is prohibited or if a concentration limit is imposed. ReGen III will manage the NMP exposure with a closed loop design, engineering controls and operating procedures.

Sincerely,

Tom Lawlor, P.Eng
Chief Operating Officer
ReGen III (USGC) Corporation
tlawlor@regeniii.com
720.201.3815

Attachment

ATTACHMENT

Questions raised in NMP Pre-Panel Presentation

1. Discussion – Your Business and NMP

- ***How does your organization use NMP?***

ReGen III is building a facility to recycle used motor oil into Group II/II+ and high-value Group III base oils. Base oils are the foundation for several types of lubricants such as lubricating greases, motor oils, metal processing fluids, and miscellaneous lubricants. All lubricants require a base oil and automotive engine oils typically consist of 75% base oil and 25% additives. The majority of traditional refiners produce Group I and Group II base oils which are used to formulate motor oils for older passenger car engines or for use in some industrial applications. Approximately 70% of new cars require fully synthetic or blend oil, which utilize Group III or higher quality base oil. ReGen III's technology produces a 53% yield of Group III base oil. Group III base oil is the fastest growing group of base oils as more automakers require the use of better-quality motor oils.

The UMO re-cycling facility is a three-stage process. See Figure 1 for a block flow diagram.

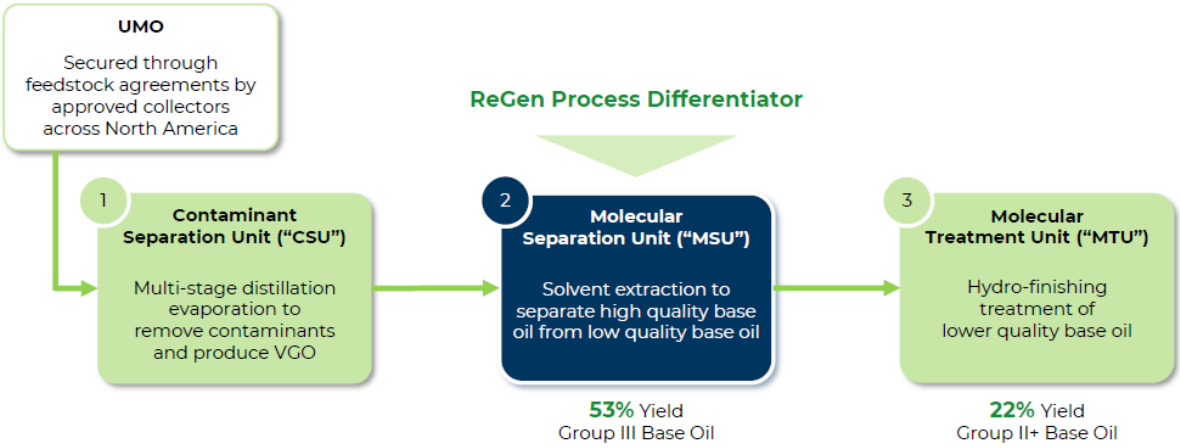

Figure 1. ReGen III Process Block Flow Diagram.

Stage 1 removes lighter hydrocarbons and contaminants such as metals and water. Stage 2 uses solvent extraction (with NMP) to remove aromatics and polars to produce Group III base oil. Stage 3 hydrotreats the extract from Stage 2 to produce Group II/II+ base oil.

Stage 2, or the Molecular Separation Unit (MSU), is designed to continually process the product of Stage 1 (vacuum gas oil, VGO). The system begins with the Scheibel® extraction column, which uses agitation and solvent extraction to purify the oil into two liquid streams, defined as the raffinate and the extract. The solvent, N-Methyl 2-Pyrrolidinone (NMP), has been selected to extract the low-quality products, aromatics and polar components.

In the extraction column, the VGO enters at the bottom of the tower while the NMP flows counter currently from the top of the tower. The extract stream, which contains the majority of the NMP and the lower

quality base oil (polars and aromatics are concentrated in this stream), is distilled under vacuum to and then further steam stripped to remove the NMP. The low-quality base oil is transferred to the 3rd stage for hydrotreating. The raffinate stream, having had the undesirable components (polars and aromatics) of the VGO removed by the NMP, flows to a stripper column and uses steam to remove the residual NMP. The bottoms product from this stripper is the primary product of the process, Group III base oil.

The NMP, removed from both the raffinate and extract streams, is regenerated in a closed system, returned to the storage tank where it is circulated back to the extraction column. The NMP circulation rate is approximately 330 usgpm and the storage tank (designed to API 650), with nitrogen blanketing, contains approximately 60,000 gallons.

- ***Can you describe the specific use, as well as the workplace and workplace setting where it is used?***

The specific use is described in the previous answer.

The re-refinery will be constructed on a 10-acre plot in Texas City (Advario Texas City site, located at 2800 Loop 197 S, Texas City, Texas), within an existing industrial site, on land previously occupied by DOW Chemicals and leased to ReGen III by Advario. In a partnership with Advario, ReGen III will design, build, own, and operate the re-refinery. Advario will be the Terminal Services Provider, responsible for receiving, storage and shipping UMO and products via truck, rail and barge, with their facilities split between their Advario Galveston and Advario Texas City sites.

All re-refinery equipment is installed outside with open ventilation. All areas where NMP is present will be bunded. All areas that use NMP (Stage 2 exclusively), will have specific safe operating procedures that include PPE requirements and restrictions for personnel from entering the NMP use area. Signs will be installed throughout the stage 2 facilities reminding workers of their training regarding risks to NMP exposure.

The ReGen III Process Safety Management system will include NMP considerations in the Process Safety Information, while conducting Process Hazards Analysis, in written operating and maintenance procedures, and as part of the mechanical integrity program.

- ***What is the trend of NMP use in your organization?***

NMP will remain the solvent of choice for all future facilities as the process technology is dependent on this solvent for its selectivity for polar and aromatic compounds which must be removed to generate Group III.

- ***How important to your business is the function that NMP provides?***

NMP was chosen and has been tested exclusively over the last fifteen years primarily because of its selectivity for polars and aromatics; compounds critical for removal to produce the higher quality base oils. Alternative solvents do not provide that required level of selectivity.

ReGen III is a pre-revenue start-up and the project will not severely impaired if NMP is prohibited or if there is a concentration limit imposed. ReGen III will manage the NMP exposure with a closed loop design, engineering controls and operating procedures.

- ***Are there potential critical or essential uses?***

No.

- ***Are there uses for which there are no available technically or economically feasible alternatives?***

North American Group III production is dominated by virgin crude refining, which is more energy intensive and less environmentally friendly. The ReGen III patented process has much lower CO2e emissions, being 82% lower than comparable, traditionally refined base oils produced from crude oil and subsequently combusted at end of life. The ReGen III process saves 3.4 kg CO2e emissions per kg of base oil produced compared to the traditional method of producing base oil from crude oil and burning UMO as fuel. Furthermore, ReGen III's proposed 5,600 bpd Texas facility is estimated to reduce up to 903,000 mt CO2e / year from entering the atmosphere by preventing combustion at end-of-life and by producing base oils more efficiently than the equivalent production from virgin crude oil. This would be the equivalent of removing 195,000 passenger vehicles from the road for a year according to the EPA.

In addition, the ReGen III process has a much lower ecotoxicity rating at 27.7% less than the ecotoxicity of traditional methods of producing base oils and combusting UMO and 99.7% less than the ecotoxicity of traditional methods of producing base oil and disposal of UMO inappropriately at end of life.

2. Discussion – Workplace Exposure

- ***What is your experience with exposure control and risk reduction?***

Engineering controls will be focussed on the closed loop design of the process and ensuring any potential releases are eliminated by using vapour recovery and spill containment systems. In addition, the processing equipment that uses NMP will be fully automated.

Administrative controls will be implemented including developing standard operating procedures and written working instructions for any activity that involves NMP with an aim to separate the worker from harm by restricting access to the area and ensuring workers are trained and fully aware of the risks.

Personal Protective Equipment (PPE) will be fitted and available for all workers that are required to work in the area where NMP is present.

Industrial hygiene programs and regular occupational exposure evaluations will be implemented as part of the worker health and safety protection plan.

- ***How many employees are exposed to NMP, and for how long (days/years and hours/day)?***

Although the Operations and Maintenance Manual is not finalized yet, the expected crew complement is 4 persons per shift with 2 outside operators managing the facility at any one time. It is expected that one person per shift will be in the Stage 2 area (where NMP is used) for less than 1 hour a day.

Note that the Stage 2 process area contains NMP in a closed loop system with no inhalation or dermal exposure risks during normal operations.

- ***What is the concentration of NMP in the product you use?***

100%

- ***What routine worker activities result in worker exposure to NMP and what type of exposure?***

Dermal exposure will be negligible given that NMP is contained in closed process equipment and workers will be required to wear chemical impervious gloves when conducting maintenance on equipment.

There is no routine work that could result in worker exposure to NMP however there may be infrequent activities where a breakdown in the primary mitigation occurs such as when human error happens, or a piece of equipment fails. These would be considered non-routine. In the unlikely case of there being exposure to NMP, PPE would protect the worker.

- ***What engineering controls are used to minimize exposure to NMP? Are additional controls* feasible?**

The NMP is circulated throughout the process system in a closed loop. There will be a vapour recovery, spill containment and fully automated systems included in the design. There will be signs restricting access to the area with warning signs reminding workers of their training on NMP exposure risks.

- ***What administrative controls and training do you use to minimize exposure to NMP?***

See above.

- ***What respiratory and dermal PPE is regularly worn by workers to minimize exposure to NMP?***

Given the facility is currently conducting FEL-3 engineering, the details of PPE have not been fully developed. However, ReGen III will implement best practices, consult the REACH guidance and adhere to any EPA requirements.

3. Discussion –Users of Products Containing NMP

- ***What chemicals or processes have you considered as an alternative to using NMP or a product containing NMP?***

The ReGen III technology of recycling used motor oil did not consider alternatives to NMP. All pilot testing and engineering studies over the last 15 years have been conducted exclusively on NMP due it its selectivity for polar and aromatic compounds which must be removed to produce Group III base oil.

However, there are a couple of different solvents used in upgrading crude oil to base oil that could be used in a solvent extraction process.

- Furfural
- Phenol (hydroxy benzene)

Furfural is less effective than NMP at extracting polar and aromatic compounds with a yield of base oil of 20 to 35% less than with NMP. In addition, the base oil produced with furfural does not meet the viscosity index specification for Group III base oil. Furfural also forms an azeotrope with water making regeneration of the solvent very difficult.

Phenols are less effective at extracting polar and aromatic compounds compared to both NMP and Furfural.

NMP has a lower flammability, lower volatility and greater thermal stability than both furfural and phenol. NMP is also less toxic than phenol.

- ***Do you currently use any alternatives to NMP or products containing NMP?***

No

- ***Did you try to switch to another chemical, process, or product, only to switch back? If so, what did you switch to, why did you switch back, and what made you switch in the first place?***

No

- ***Are there any restrictions or other limitations that prescribe the use of NMP to perform your services (e.g., for aerospace or DOD customers)?***

No

- ***What are the relative advantages and disadvantages of different substitutes and/or processes that you have considered, including in terms of exposure, cost, and hazard?***

N/A

4. Discussion – Regulatory Options

- ***What regulatory approach should EPA take?***

It is ReGenIII's opinion that there is no need for additional requirements from the EPA. Health and safety practices should be enforced as part of the typical health and safety protocols at a refinery. Site specific operating protocols will exist within the broader framework of the hazard management and safety programs. No restrictions on volume or concentration should be placed.

The project will be in serious jeopardy if NMP is prohibited or if there is a concentration limit imposed.

- ***Are there concerns about the ability to comply with any of the potential regulatory options?***

The Project will face severe challenges if NMP is prohibited or if there is a concentration limit imposed.

- ***What advice do you have for reducing impacts on small businesses?***

ReGen III advises that the EPA should limit its rule on NMP to engineering and administrative controls.

- ***What timeframe would your business need to comply with potential new regulations or restrictions?***

It is difficult for ReGen to assess the impact of any new restrictions. We are confident that we can quickly adopt PPE, administrative or engineering control requirements. A reduction of NMP concentration or its prohibition would set the company back 5-10 years.