FINAL REPORT
of the
Small Business Advocacy Review Panel on
EPA's Planned Proposed Rule

Toxic Substances Control Act (TSCA)
Section 6(a)
for N-Methylpyrrolidone (NMP)

September 14, 2023

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1. INTRODUCTION

This report is presented by the Small Business Advocacy Review Panel (SBAR Panel or Panel) that convened to review the planned proposed rulemaking by the U.S. Environmental Protection Agency (EPA) under section 6(a) of the Toxic Substances Control Act (TSCA) to regulate n-methylpyrrolidone (NMP), which was the subject of a TSCA risk evaluation under section 6(b). Section 6 of TSCA requires that EPA issue regulations to address identified unreasonable risks resulting from the manufacture (including import), processing, distribution in commerce, or use of the chemical, as well as any manner or method of disposal of NMP. Section 609(b) of the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), requires EPA to convene a Panel prior to publication of the initial regulatory flexibility analysis (IRFA) that EPA may be required to prepare under the RFA. In addition to EPA's Small Business Advocacy Chairperson, the Panel consists of the Deputy Director of the Office of Pollution Prevention and Toxics, the Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget, and the Chief Counsel for Advocacy of the Small Business Administration.

This report includes the following:

- Background information on the proposed rule being developed;
- Information on the types of small entities that may be subject to the proposed rule;
- A description of efforts made to obtain the advice and recommendations of representatives of those small entities; and
- A summary of the comments that have been received to date from those representatives.

Section 609(b) of the RFA directs the Panel to consult with and report on the comments of small entity representatives (SERs) and make findings on issues related to elements of an IRFA under section 603 of the RFA. Those elements of an IRFA are:

- A description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- A description of projected reporting, record keeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;
- An identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule; and
- A description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities. This analysis shall discuss any 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.

Once completed, the Panel report is provided to the agency issuing the proposed rule and is included in the rulemaking record. The agency is to consider the Panel's findings when completing the draft of the proposed rule. In light of the Panel report, and where appropriate, the agency is also to consider whether changes are needed to the IRFA for the proposed rule or the decision on whether an IRFA is required.

The Panel's findings and discussion are based on the information available at the time the final report is drafted. Given EPA's ongoing consideration of exposure pathways such as ambient air and drinking water to the general population and fenceline communities, there is a chance that some impacts of the proposed rulemaking may not have been fully considered by the Panel during its work. If EPA considers additional requirements impacting small businesses related to exposure pathways that were not presented to Small Entity Representatives (SERs) during the Panel Outreach meeting, then EPA will determine whether those additional requirements may have a significant impact on a substantial number of small entities. Under these unique circumstances, EPA would organize a supplemental opportunity for the Panel to consult with the SERs and additional small entities that might be significantly impacted prior the rule's proposal. EPA continues to conduct analyses relevant to the proposed rule, and additional information may be developed or obtained during the remainder of the rule development process.

Any options identified by the Panel for reducing the rule's regulatory impact on small entities may require further analysis and/or data collection to ensure that the options are practicable, enforceable, environmentally sound, and consistent with TSCA and its amendments.

2. BACKGROUND AND DESCRIPTION OF RULEMAKING

2.1 Risk Evaluation for NMP

In December 2016, EPA selected NMP as one of the first 10 chemicals for risk evaluation under section 6 of TSCA. EPA published the risk evaluation for NMP in December 2020. The risk evaluation as conducted pursuant to TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which requires EPA to conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." EPA published the scope of the risk evaluation document[1] in July 2017 (82 FR 31592, July 7, 2017), the NMP problem formulation document[2] in June 2018 (83 FR 26998, June 11, 2018), and the NMP draft risk evaluation[3]in November 2019 (84 FR 60087, November 11, 2019). EPA held a peer review meeting of the Science Advisory Committee on Chemicals (SACC) on the draft risk evaluation of NMP in December 2019. Public comments and external scientific peer review informed the development of the NMP risk evaluation[4] (85 FR 86558, December 30, 2020). With input from comments and peer review, EPA published a draft revision to the risk determination for the NMP risk evaluation in July 2022 (87 FR 39511, July 1, 2022) and a final revised unreasonable risk determination for NMP as a whole chemical substance

[1] Available at https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0743-0061.

[2] Available at https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0743-0076.

[3] Available at https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0236-0017.

[4] Available at https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0236-0081.

in December 2022[5] (87 FR 77596, December 19, 2020).

In the 2020 Risk Evaluation for NMP, EPA evaluated risks associated with 37 conditions of use within the following categories: manufacture (including import), processing, distribution in commerce, industrial and commercial use, consumer use, and disposal. The 2020 Risk Evaluation for NMP identified significant adverse health effects associated with exposure to NMP, including risks of developmental toxicity from acute inhalation and dermal exposures and reproductive toxicity from chronic inhalation and dermal exposures. Additional risks associated with other adverse effects (*e.g*., liver toxicity, kidney toxicity, immunotoxicity, neurotoxicity, irritation and sensitization) were identified for acute and chronic inhalation and dermal exposures.

The 2020 Risk Evaluation for NMP evaluated inhalation and dermal exposures together, rather than separately. The resulting risk characterization is described in section 4 of the 2020 Risk Evaluation. Section 4.3.7 provides details on how the unreasonable risk identified for NMP from the combined dermal, inhalation, and vapor-through-skin exposures are primarily driven by direct dermal contact with liquid NMP.

Small business may be regulated under all conditions of use that drive EPA's unreasonable risk determination for NMP. EPA's unreasonable risk determination for NMP is based on unreasonable risk of injury to health for workers and to consumers from consumer use. EPA did not identify an unreasonable risk of injury to the environment from NMP under the conditions of use.

On June 30, 2021, EPA announced policy indicating that EPA intends to move forward by revisiting the risk evaluations for the first ten chemical substances within a narrow scope that is supported by science and the law, including:

- Consideration of exposure pathways such as ambient air and drinking water to the general population and fenceline communities;
- Revisiting the assumption that personal protective equipment (PPE) is always used in occupational settings when making a risk determination for a chemical. Rather, EPA will no longer assume that PPE is always used when determining whether a chemical substance presents unreasonable risk; and
- Making the determination of unreasonable risk for the whole chemical rather than on a condition of use basis.

EPA will continue to provide risk calculations with no PPE and with various levels of PPE in the risk characterization section of the risk evaluation to help inform possible risk management options.

EPA has moved forward with the final revised risk determination for NMP, which determines that NMP, as a whole chemical substance, presents an unreasonable risk of injury to health under the conditions of use. This revision, published on December 19, 2022 (87 FR 77596), supersedes the condition of use-specific risk determination in the December 2020 NMP risk evaluation. The final revised risk determination does not reflect an assumption that all workers always appropriately wear PPE. EPA understands that there could be adequate occupational safety protections in place at certain workplace locations; however, not assuming use of PPE reflects EPA's recognition that unreasonable risk may exist

[5] The final risk evaluation and supplemental materials are in docket EPA-HQ-OPPT-2019-0236, with the July 2022 draft revised unreasonable risk determination, December 2022 final revised unreasonable risk determination, and additional materials supporting the risk evaluation process in docket EPA-HQ-OPPT-2016-0743, on www.regulations.gov.

for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards. In the case of NMP, OSHA has not issued a chemical-specific permissible exposure limit (PEL).

As a result of this revision, removing the assumption that workers always and appropriately wear PPE means that three additional conditions of use in addition to the original 26 drive the unreasonable risk for NMP, and for five conditions of use, acute effects in addition to chronic effects also drive the unreasonable risk to workers.

As described in the final revised unreasonable risk determination, 29 conditions of use (three in addition to the 26 conditions of use identified in the December 2020 risk evaluation) drive the unreasonable risk determination for NMP, listed below:

- Domestic manufacture
- Manufacture: import
- 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 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 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
- 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, 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 several manufacturing sectors
- Industrial and commercial use as a solvent (for cleaning or degreasing) use 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 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 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
- Consumer use in adhesives and sealants in glues and adhesives, including lubricant adhesives and sealants
- Disposal

The following conditions of use do not drive EPA's unreasonable risk determination for NMP:

- Distribution in commerce
- Consumer use in paint and coating removers
- Consumer use in adhesive removers
- Consumer use in paints and coatings in lacquers, stains, varnishes, primers and floor finishes
- Consumer use in paint additives and coating additives not described by other codes in paints and arts and crafts paints
- Consumer use in other uses in automotive car products
- Consumer use in other uses in cleaning and furniture care products, including wood cleaners and gasket removers
- Consumer use in other uses in lubricant and lubricant additives, including hydrophilic coatings

2.2 Regulatory History

NMP is subject to several Federal laws and regulations in the United States and is also subject to regulatory actions by States and other countries. A summary of the regulatory history for NMP and a list of related regulations (EPA, Federal, State, and International) for NMP is provided in this section.

Actions under EPA pertaining to NMP include:

- *Toxics Substances Control Act (TSCA) – Section 6(b):* EPA is directed 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 chemicals evaluated for unreasonable risk under TSCA (81 FR 91927, December 19, 2016).
- *Toxics Substances Control Act (TSCA) – Section 8(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 United States. NMP manufacturing (including importing), processing, and use information is reported under the CDR rule (76 FR 50816, August 16, 2011).
- *Federal Food, Drug, and Cosmetic Act (FFDCA) and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)*: 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 tolerance limit (40 CFR Part 180.920).
- *Clean Air Act (CAA)*: *Clean Air Act (CAA)*: 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. NMP is also 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. 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)*: 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). NMP was not identified on the proposed Fifth Contaminant Candidate List (86 FR 37948, July 19, 2021).

Other Federal actions pertaining to NMP include:

- *FFDCA:* 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."

- *Federal Hazardous Material Transportation Act (HMTA)*: 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).

State actions pertaining to NMP include:

- Two states, New Hampshire and Vermont list NMP in state air regulations. New Hampshire lists NMP as a regulated toxic air pollutant (Env-A 1400: Regulated Toxic Air Pollutants) and Vermont lists NMP as a hazardous air contaminant (Vermont air Pollution Control Regulations, 5261).
- California has a permissible exposure limit (PEL) for NMP of 1 part per million (ppm) as an 8-hr-time-weighted average (TWA) along with a skin notation for NMP (California Code of Regulations, title 8, section 5155). California also lists NMP on Proposition 65 due to reproductive toxicity (Cal. Code Regs. Title 27, Section 27001). California's Office of Environmental Health Hazard Assessment (OEHHA) lists a Maximum Allowable Dose Level (MADL) for inhalation exposure = 3,200 micrograms per day (µg/day) and 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 2006, the California Department of Public Health's Hazard Evaluation System and Information Service (HESIS) issued a Health Hazard Advisory on NMP and updated the Advisory in June 2014. The Advisory is aimed at workers and employers at sites where NMP is used.
- Several other states have adopted reporting laws for chemicals in children's products that include NMP. Minnesota has listed NMP as a chemical of concern to children (Minnesota Statutes 116.9401 to 116.9407).

International actions pertaining to NMP include:

- In 2011, NMP was listed on the Candidate list as a Substance of Very High Concern (SVHC) under regulation (EC) No 1907/2006 to the Regulation, Evaluation, Authorisation and Restriction of Chemicals (REACH). In 2018 the European Union added NMP to REACH Annex XVII, the restricted substances list. The restriction includes three conditions: that NMP shall not be placed on the market above 0.3% unless users have chemical safety reports and SDSs with set inhalation and dermal Derived No-Effect Levels (DNELs); NMP shall not be used above 0.3% unless appropriate risk management measures ensure that the exposure of workers is below the DNELs; and an exclusion from the regulation until May 9, 2024, for the use of NMP as a solvent or reactant in the process of coating wires.
- Several countries, including Australia, Belgium, Canada, Finland, Poland, and Spain have occupational exposure limits (OELs) for NMP (GESTIS International limit values for chemical agents OELs database, Accessed April 12, 2023).

2.3. Estimates of Exposed Populations

Populations exposed to NMP include workers and consumers using products containing NMP. EPA estimates the exposed population includes 199,428 workers. The number of consumers that use products containing NMP each year is unknown.

For the conditions of use that drive the unreasonable risk, EPA has identified industry sectors that are

likely affected (see Table 4.1), and the number of entities associated with those sectors (see Table 4.2). EPA estimates that the proposed rulemaking would affect approximately 63,748 small entities. Most (26,017) of these small entities are commercial users of NMP in fertilizer and other agricultural chemical manufacturing and application. EPA also estimates that 13,198 of these small entities use NMP in paints and coatings applications, 6,814 of these small entities use NMP in adhesives and sealants, 3,886 of these small entities use NMP in paint, coating, and adhesive removers, and 3,266 of these small entities use NMP for electronic product and semiconductor manufacturing. Additional estimates are provided in Table 4.2.

2.4. Description of Section 6(a) Regulatory Options and Scope

EPA is developing a proposed regulation under section 6(a) of TSCA to address the unreasonable risk of the chemical substance NMP so that NMP no longer presents an unreasonable risk under the conditions of use. As explained above, based on the December 2020 Risk Evaluation for NMP, on December 19, 2022 (87 FR 77596), EPA determined that NMP as a whole chemical substance presents an unreasonable risk, driven by 29 conditions of use.

EPA is considering an array of approaches under TSCA section 6(a) to determine which option will address the unreasonable risk from NMP. Table 2.4.1 below summarizes regulatory requirements EPA can utilize, separately or in combination, under TSCA section 6(a).

Table 2.4.1. Regulatory Requirements Available under TSCA Section 6(a)

TSCA Section	Option
6(a)(1)	A requirement **(A)** prohibiting the manufacturing, processing, or distribution in commerce of such substance or mixture, or **(B)** limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.
6(a)(2)	A requirement **(A)** prohibiting the manufacture, processing, or distribution in commerce of such substance or mixture for **(i)** a particular use or **(ii)** a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or **(B)** limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for **(i)** a particular use or **(ii)** a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.
6(a)(3)	A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such warnings and instructions shall be prescribed by the Administrator.
6(a)(4)	A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture and monitor or conduct tests which are reasonable and

TSCA Section	Option
	necessary to assure compliance with the requirements of any rule applicable under this subsection.
6(a)(5)	A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture.
6(a)(6)	**(A)** A requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes.[6]
6(a)(7)	A requirement directing manufacturers or processors of such substance or mixture **(A)** to give notice of such unreasonable risk of injury to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, **(B)** to give public notice of such risk of injury, and **(C)** to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.

EPA would consider regulatory options that would not duplicate other federal regulations. EPA has determined that current federal regulations discussed in Section 2.2 do not address the unreasonable risk that EPA has identified for NMP.

2.5. Overview of Options under Consideration

EPA is considering a number of regulatory options under TSCA section 6(a) for NMP to reduce exposures such that the risk from NMP inhalation and dermal exposure is no longer unreasonable. The unreasonable risk is primarily driven by direct dermal contact for most but not all conditions of use. Therefore, to mitigate the unreasonable risk, EPA is considering a variety of options that are focused on preventing direct dermal contact. Additionally, for some conditions of use, EPA is also considering reducing inhalation risks as well; this includes conditions of use where dermal exposure may not be able to be completely eliminated. For this reason, EPA presented materials to SERs that included inhalation protection (respirators) and asked about all worker exposure reductions. The options under consideration would address the unreasonable risk identified for NMP, which includes dermal and inhalation exposures, including chronic inhalation exposures.

The following options listed below, as presented to SERs, are currently being evaluated by EPA, and are not final at this time. Feedback from SERs on these options is in Section 7. EPA is considering the National Institute for Occupational Safety and Health (NIOSH) hierarchy of controls when developing risk management actions. As described by NIOSH, 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.[7] Any regulatory option can be used alone or in combination so that NMP no longer presents an unreasonable

[6] A requirement under subparagraph (A) may not require any person to take any action which would be in violation of any law or requirement of, or in effect for, a State or political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such disposal.
[7] NIOSH Hierarchy of Controls Overview: https://www.cdc.gov/niosh/topics/hierarchy/default.html

risk under the conditions 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.[8]

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 for most but not all conditions of use. For this reason, EPA is not considering an airborne concentration limit for NMP and is focusing on dermal protection measures to prevent direct dermal contact. However, some conditions of use have particularly high air concentrations, such as from an aerosol application or liquid NMP used at an elevated temperature, and a high concentration of NMP in formulation based on publicly available information[9]. For these conditions of use EPA is considering regulatory options to reduce the unreasonable risk driven by both inhalation and dermal exposures, including considering if variations in formulation may help mitigate the unreasonable risk. For this reason, EPA presented materials to SERs that included inhalation protection (respirators), NMP weight fractions evaluated, and asked about all worker exposure reductions. The options under consideration will address the unreasonable risk identified for NMP, which includes dermal and inhalation exposures, including chronic inhalation exposures.

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.

2.5.1 Concentration limit

Under this option, EPA would restrict the concentration or weight fraction of NMP within a 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. 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.

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.

Costs of concentration limits could include reformulation of the product to reduce NMP concentration (with an estimated cost of $17,000 per product, reflecting a dilution reformulation approach) and

[8] 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.

[9] Publicly available information about NMP concentrations in formulations are in the document "Information on Weight Fractions of NMP Evaluated in the 2020 Risk Evaluation" (see Appendix A) and the Uses and Market Profile for N-methylpyrrolidone (NMP) supplemental file found at https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0743-0060

reformulation of a product to eliminate NMP (with an estimated cost ranging from $60,000 - $102,000 per product). Costs would vary by condition of use and would be dependent on the reformulation approach.

2.5.2 Prescriptive Engineering or Administrative Controls

Under this option, EPA would require specific prescriptive controls to reduce the exposure to NMP to workers for manufacturing, processing, industrial, and commercial conditions of use. The requirements could include, but are not limited to:

- Engineering controls that reduce worker exposure by requiring specific physical changes to the workplace to eliminate or reduce direct dermal contact.
    - Examples of engineering controls that could be installed to reduce exposure to NMP include: 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.
- Administrative controls could reduce exposures for workers by requiring processes or procedures in the workplace to eliminate or reduce direct dermal contact. An example of an administrative control could be to limit access to work areas (restricted areas) or confining operations (enclosed areas).

Costs of implementing engineering and administrative controls would vary by control type and user needs and are dependent on the user's current practices. Potential impacts to small businesses could include (but may not be limited to) the cost of capital investments for engineering controls, maintenance, and other expenses related to implementing industrial hygiene practices, as well as potential costs associated with utilities and labor. Administrative controls could result in increased costs associated with developing and implementing new work practices.

2.5.3 Prescriptive Personal Protective Equipment (PPE)

Under this option, EPA would require specific PPE to minimize exposure. This may limit flexibility for the regulated entity. EPA could require the use of specific gloves that meet certain standards such as providing an impervious barrier to the chemical during expected durations and normal conditions of exposure. Some examples of potential PPE that could contribute to reducing the unreasonable risk include both purifying and supplied-air respirators with an assigned protection factor varying from APF 10 – 10,000, and dermal protection such as reusable or disposable gloves or aprons. Additional examples are listed in Appendix F of the 2020 risk evaluation for NMP.

Requiring the use of dermal or 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.

Potential impacts to small businesses include (but may not be limited to) the cost of purchase of equipment, routine cleaning of equipment, training, fit-testing, and medical clearance for estimated baseline PPE use. Respirator costs are associated with the APF level and range from $1,100 - $2,000 per worker per year. For example, for APF 10 respiratory protection costs are estimated as $1,800 per worker

per year and for APF 10,000 respiratory protection costs are estimated as $2,000. Total cost depends on the prevalence of current use, replace parts for the respirators, and number of workers required to use the respirators.

For gloves or other dermal PPE, costs include purchase of equipment and EPA estimates these costs would be $6 - $55 per pair of gloves reusable butyl, laminated polyethylene, neoprene, and natural rubber/latex. For disposable gloves, estimated costs are $0.50 per pair of nitrile gloves and disposable nitrile gloves are not used alone but in combination with reusable gloves. Input from potentially regulated entities is needed regarding which glove material type would be used. For aprons, costs include purchase of equipment. EPA estimates costs for a reusable apron to be $25 - $34 per nitrile and neoprene apron and cost for a disposable apron to be $4 per polyethylene apron.

2.5.4 Combination of Controls (non-prescriptive)

For processing, industrial, and commercial uses involving occupational exposures, a combination of risk management approaches could be used for conditions of use where strict industrial practices may already exist. This would enable 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 on which NMP may be present; users could determine what to do 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 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.

The costs of a 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. Costs would include both per-facility and per-worker costs, and would depend on baseline PPE and dermal exposure control plan activities. Generally, costs would vary based on the complexity of the site. Annualized costs would include an exposure control plan ($560 - $630 per facility costs, with $35 per worker costs). Additionally, EPA estimates a one-time cost to develop an exposure control plan of $3,730 per facility, regular inspection costs of $370 per facility per year, and potential recordkeeping costs $40 per facility per year. Costs of engineering controls, monitoring, or PPE as part of the non-prescriptive controls would vary by control type and the needs of the user, so they are not captured in these estimates.

2.5.5 Prohibition of manufacturing (including import), processing, and/or distribution

Under this option, EPA would prohibit the manufacturing (including import), processing, and/or distribution of NMP. Such prohibition would reduce exposures to NMP throughout the supply chain and possibly affect the distribution in commerce condition of use, which does not drive unreasonable risk. EPA may also prohibit conditions of use that have minimal ongoing use or have been or will be phased out. Under TSCA section 6(c)(2)(C), in deciding whether to prohibit or restrict in any manner that substantially prevents a specific condition of use, and in setting an appropriate transition period for such action, EPA is required to consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.

Costs of prohibitions would vary by condition of use. Potential activities could include changes in process and equipment, costs of alternatives, reformulation, shutting down the operation and more. Costs would vary by price of NMP per ounce compared to substitutes, as well as the difference in efficacy of the substitute products, and would also include changes in equipment, technology, training, testing, and more in addition to the material cost. As described earlier, costs of reformulation of a product to eliminate NMP are estimated to range from $60,000 - $102,000 per product). More precise cost estimates will require input from potentially regulated entities.

2.5.6 Recordkeeping, downstream notification, and other support for implementation

The TSCA section 6(a) activities listed below are options that could support the implementation of the regulatory approaches outlined in the preceding sections.

- Recordkeeping would require records and documentation for the purposes of demonstrating compliance with any option described above. Recordkeeping would aim to consist of ordinary business records already maintained to the extent possible.
- Downstream notification would support any of the control options described above (e.g., prescriptive controls, prohibitions) to disseminate information about restrictions and requirements through the supply chain.
- 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: EPA could, 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 impacts to small businesses associated with recordkeeping could include the annual labor and material costs associated with documentation of ordinary business records, estimated at $218 -$340 per firm. Downstream notification costs are per product (estimated cost $121 -$138) and include labor and material costs to update the product's safety data sheet (SDS).

For labeling, EPA estimates that costs could range from $830 to $8,900 per product as a one-time cost. Costs would vary by condition of use. Potential activities may include graphic design changes, plate changes, discarded inventory, and labor. Due to uncertainties and variations in product types, this estimate does not include potential impacts on sales. For a limited access program, costs vary with condition of use and type of distributor; in general, the costs would vary by type of requirements for certification and any distribution processes or restrictions already in place.

3. APPLICABLE SMALL ENTITY DEFINITIONS

The Regulatory Flexibility Act (RFA) defines small entities as including "small businesses," "small governments," and "small organizations" (5 USC 601). The RFA references the definition of "small business" found in the Small Business Act, which authorizes the Small Business Administration to further define "small business" by regulation. The SBA definitions of small business by size standards using the North American Industry Classification System (NAICS) can be found at 13 CFR 121.201.

The detailed listing of SBA definitions of small business for affected industries or sectors, by NAICS code, is included in Table 4.1 of Section 4, below.

4. SMALL ENTITIES THAT MAY BE SUBJECT TO THE PROPOSED REGULATION

Table 4.1 shows the SBA size standards by affected industry sector. Table 4.2 shows the estimated number of small firms by condition of use (COU).

Table 4.1. Industry Sectors and Definitions

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

NAICS	NAICS Description	SBA Size Standard
111339	Other Non-citrus 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
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

NAICS	NAICS Description	SBA Size Standard
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
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
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

NAICS	NAICS Description	SBA Size Standard
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
332117	Powder Metallurgy Part Manufacturing	550 employees

NAICS	NAICS Description	SBA Size Standard
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

NAICS	NAICS Description	SBA Size Standard
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
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

NAICS	NAICS Description	SBA Size Standard
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
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

NAICS	NAICS Description	SBA Size Standard
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

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
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 Countertop 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

NAICS	NAICS Description	SBA Size Standard
339999	All Other Miscellaneous Manufacturing	550 employees
423120	Motor Vehicle Supplies and New Parts Merchant 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
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 Property	$34.0 million
541330	Engineering Services	$25.5 million
541380	Testing Laboratories	$19.0 million

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
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
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 4.2. Estimated Number of Small Firms by Condition of Use (COU)

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**

5. LIST OF SMALL ENTITY REPRESENTATIVES

EPA consulted with Advocacy to develop the list of small entity representatives (SERs) in Table 5.1. EPA issued a press release inviting self-nominations by affected small entities to serve as potential SERs. The press release directed interested small entities to a web page where they could indicate their interest in serving as a SER. EPA launched the website January 5, 2021, and accepted self-nominations until January 19, 2021. EPA recruited additional potential SERs during and after the self-nomination process to address potential underrepresentation from certain affected industries. EPA sent Advocacy a Formal

Notification with the suggested list of potential SERs on August 24, 2022, and Advocacy responded on September 7, 2022.

Table 5.1: List of Small Entity Representatives

Entity	Contact
MOC Products Company, Inc.	Nasim Bagheri
GreenChem Industries	Leo Hernandez
American Distillation, Inc.	Donald Outlaw
PICO Chemical Corporation	Richard Pisarski, Jr.
Bulk Chemicals Incorporated	Harry Adams
ReGen III	Rowena Smith
TRInternational Inc.	Marjalena Santos
Franmar Chemical, Inc.	Dan Brown
Hentzen Coatings Inc.	George Curry
Hillyard Industries	Terry Hall
Leather Magic, Inc.	Danny Yunker
OWOSSO Graphic Arts, Inc.	Craig Ellenberg; Devin Ellenberg
Chemsynergy, Inc.	Aaislinn Chalecki
Celanese (Fortron)	Phil Brondsema
AMVAC Chemical Corporation	Jennifer Kelley
Knox Fertilizer Company	Randy Fritz
Turf Care Supply Corporation	Brain Kolesar

6. SUMMARY OF SMALL ENTITY OUTREACH

After identifying a list of potential SERs, EPA conducted a Pre-Panel Outreach meeting with potential SERs on March 28, 2023. To help SERs prepare for the virtual meeting/teleconference, EPA sent materials to each of the potential SERs via email on March 14, 2023. A list of the materials shared with the potential SERs during the pre-Panel outreach meeting is contained in Appendix A. For the March 28 Pre-Panel outreach meeting with the potential SERs, EPA also invited representatives from the Office of Advocacy of the Small Business Administration and the Office of Information and Regulatory Affairs within the Office of Management and Budget. A total of 9 potential SERs participated in the meeting. EPA presented an overview of the SBAR Panel process, section 6 of TSCA, an explanation of the forthcoming rulemaking, potential regulatory approaches, and cost estimates. EPA also provided opportunities for questions and feedback, with a meeting structure that aimed to provide productive discussion by grouping conditions of use.

The Pre-Panel outreach meeting was held to solicit feedback from the potential SERs on their suggestions for the upcoming rulemaking. EPA asked the potential SERs to provide written comments by April 11, 2023. Comments raised during the March 28 outreach meeting and written comments submitted by the potential SERS are summarized in sections 7.1 and 7.2, respectively, of this document. Written comments submitted after the meeting appear in Appendix B1.

The Panel conducted an outreach meeting with the SERs via a virtual meeting/teleconference on May 24, 2023. To help SERs prepare for the virtual meeting/teleconference, EPA sent materials to each of the SERs via email on May 10, 2023. A list of the materials shared with the SERs during the Panel outreach meeting is contained in Appendix A2. A total of 6 SERs participated in the meeting. EPA summarized SER comments during the pre-Panel outreach meeting and presented an overview of the SBAR Panel process, section 6 of TSCA, an explanation of the forthcoming rulemaking, potential regulatory approaches, and cost estimates.

This Panel outreach meeting was held to solicit feedback from the SERs on their suggestions for the upcoming rulemaking. EPA asked the SERs to provide written comments by June 7, 2023, and the deadline was later extended to June 12, 2023. Comments raised during the May 24, 2023, Panel outreach meeting are summarized in sections 7.3 of this document. No written comments were received.

7. SUMMARY OF COMMENTS FROM SMALL ENTITY REPRESENTATIVES

7.1. Summary of the Pre-Panel Outreach Meeting Discussion

At the Pre-Panel outreach meeting, SERs provided information on the number and type of entities that would be affected (including how their products are used); potential compliance requirements (including current exposure monitoring and reduction practices, and anticipated impacts of potential prohibitions); related Federal rules; and potential regulatory flexibility alternatives (including considerations for substitute chemicals).

Verbal comments from the meeting are summarized in the following subsections.

7.1.1. Number and Types of Entities Affected

SERs discussed their import, manufacturing, processing 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 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.

7.1.2. 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.
- 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 premanufacture notice, consent order, and significant new use rule (SNUR), which would likely include the uses of interest to the SERs (the use in industrial cleaners and as a solvent for production and formulation of active ingredients for agriculture). 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. DMSO is actively listed in the TSCA inventory. 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).

7.1.3. Related Federal Rules

Two SERs mentioned FIFRA approval requirements for NMP as an inert ingredient in pesticide formulations. EPA notes that a substance intended for use as an inert ingredient in a registered pesticide product is subject to TSCA, not FIFRA, until it is actually formulated into the pesticide. The SERs indicated that if the manufacturing or processing of NMP were prohibited, there would be cost and testing requirements associated with pesticide product reformulation, and the required registration amendment would be subject to EPA review and approval before the product could be offered for sale under FIFRA.

7.1.4. Regulatory Flexibility Alternatives

SERs identified several potential regulatory flexibility alternatives, challenges for small businesses, questions for EPA regarding the Agency's regulatory approach, and provided recommendations:

- 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).
- 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.
- 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.

7.2. Summary of Written Comments Following the Pre-Panel Outreach Meeting

SERs provided written responses to the Pre-Panel outreach questions for discussion, which aimed to seek feedback on NMP processing and use, workplace-specific practices, and experiences with NMP,

importance of NMP to the individual business, and current risk management controls. One SER provided written comments: ReGen III Corp.

7.2.1. Number and Types of Entities Affected

The written comment from the SER pertained to 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 or 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.

7.2.2. Potential Reporting, Recordkeeping, and Compliance Requirements

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.

Regarding use of alternatives in the event of prohibitions on NMP, in the written comment, the 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.

7.2.3. Related Federal Rules

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.

7.2.4. Regulatory Flexibility Alternatives

In the written comment, the 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.

7.3. Summary of the Panel Outreach Meeting Discussion

At the Panel outreach meeting, SERs provided information on the number and type of entities that would be affected (including descriptions of their processing and use of NMP, their customer base, and how their products are used); potential compliance requirements (including current exposure reduction practices and anticipated impacts of potential prohibitions); related Federal rules; and potential regulatory flexibility alternatives (including descriptions of challenges for small businesses and questions for EPA regarding the regulatory approach).

Verbal comments from the meeting are summarized in the following subsections.

7.3.1. Number and Types of Entities Affected

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

- A SER who uses NMP in formulating crop protection products described how NMP is polar solvent used for anti-crystallization. The SER estimated that their use of NMP is increasing.
    - The formulating SER described use of NMP in their laboratory and also a different use in product formulation.
    - The SER stated they have eight to ten products developed with NMP, and described their need for soluable, efficacious, aromatic solvents, with a preference for polar solvents.
- A SER who uses NMP in paint and powder removal products described how their products are used and some of their business practices. Specifically, the SER described:
    - Their products are used in industrial settings, at ambient temperatures. The SER described how their paint and powder removal products are used in metal finishing (preparing metals for subsequent coatings), and architectural coating removal (such as appliances, lighting, electronics, and machinery). The SER specified that their products are not used in automotive refinishing.
    - The SER described how, in the past, they formulated the products themselves, but now, due to cost considerations, they have outsourced their product line to a Canadian

company and import the formulated product at a more cost-effective price. The SER described importing products in 55-gallon drums or 275-gallon totes.

- A SER that plans to use of NMP as an extraction solvent briefly described how they will be using NMP in their patented technology to re-refine used motor oil to produce base oils of high purity. The SER described how they intend to maintain a closed system to recycle back into the process as much NMP as possible (stripping it out of the final product, which may contain trace amounts of NMP (approximately 20 ppm)).

7.3.2. 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:

- A SER who uses NMP to formulate crop protection products described their current exposure controls in their laboratory, in which they use NMP, and in their chemical manufacturing processes. Specifically, the SER described:
    - In the laboratory: Small number of workers (four or five staff), use of PPE (long sleeves and lab coat, butyl rubber gloves, goggles), engineering controls (fume hoods), and small amounts of NMP, not heated (ambient temperatures).
    - In the manufacturing part of their facilities: engineering controls (enclosed 2,000-gallon tanks with exhaust scrubbers, drums or totes directly connected to the tanks for mixing), PPE (Tyvek suits, full-face cartridge respirators). The SER described how the PPE was necessary due to other chemicals (organophosphates), rather than the NMP.
- The SER who plans to use NMP to re-refine used motor oil described engineering controls, administrative controls, and PPE that they said were consistent with a refinery environment. They described how they aim to limit the number of workers in the facilities.

7.3.3. Related Federal Rules

One SER mentioned FIFRA approval requirements for NMP as an inert ingredient in pesticide formulations. SERs were provided with a document in the Panel materials (included in Appendix A2) that summarizes EPA's 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). The SER indicated that if the manufacturing or processing of NMP were prohibited there would be significant costs and testing requirements associated with pesticide product reformulation, and the required registration amendment subject would be to EPA review and approval before the product could be offered for sale under FIFRA.

7.3.4. Regulatory Flexibility Alternatives

SERs identified several potential regulatory flexibility alternatives, challenges for small business, questions for EPA regarding the regulatory approach, and provided recommendations:

- SERs described how prohibitions on their use of NMP would present significant challenges:
    - A SER who uses NMP to formulate other chemical products described how they have researched several potential alternatives and have not yet found a chemistry that provides the solubility and anti-crystallization properties provided by NMP.

        - The SER noted that one potential alternative, NBP, is limited under TSCA section 5 to no more than 30% in the type of formulation that they would be developing, or else a pre-manufacture notice would need to be reviewed and approved by EPA.
        - The SER also described how they prefer not to reformulate their products once the customers have gotten used to them, and that costs of reformulation include research of new alternatives, development time, registration for any pesticides, and relabeling.
        - The SER stated that they do not have alternative products for the same applications as their NMP products.
    - A SER who uses NMP in paint and powder removal products described how they had identified a substitute chemical in the past (which they identified only by a proprietary trade name), but that the chemical had significant supply chain challenges and they could no longer purchase it. The SER described their preference to continue using NMP.
    - The SER who plans to use NMP to re-refine used motor oil stated that NMP is essential to their company, and if they are unable to use it, their planned company would close. The SER described how they have invested over $50 million over the last 15 years in developing the facility. The SER also described early experience with a potential alternative chemical (furfural) but the resulting re-refined base oils could not meet the viscosity standards set by the American Petroleum Institute, a trade association.

- Regarding concentration limits, a SER described the concentrations at which they use NMP. Specifically, a SER who uses NMP to formulate other chemical products described some formulated products that contain 10-12% NMP, while a small number of their products contain 60-70% NMP.
- SERs expressed a preference for exposure controls:
    - The SER who plans to use NMP to re-refine used motor oil described how they could retrofit their facility if needed, and could meet requirements for administrative and PPE changes if needed. The SER stated that engineering control changes could potentially be implemented within a year of being required.
    - The SER who uses NMP to formulate other chemicals described how their facility has a small number of employees in the laboratory and manufacturing areas, and how they could supplement currently Good Laboratory Practices (GLP) with additional administrative controls.

7.4. Summary of Written Comments Following the Panel Outreach Meeting

SERs had the opportunity to provide written responses to the Panel outreach questions for discussion, which aimed to seek feedback on NMP processing and use, workplace-specific practices, and experiences with NMP, importance of NMP to the individual business, and current risk management controls. No written comments were provided.

8. PANEL FINDINGS AND DISCUSSION

8.1. Number and Types of Entities Affected

The proposed rule potentially affects businesses that manufacture (including import), process, use distribute, or dispose of NMP which impacts industries that include fertilizer and other agricultural chemical manufacturing, chemical processors (including oil re-refiners), and formulators of paint and coating removal products. During the Panel outreach meeting, SERs discussed the types of small entities affected and included information on their use of NMP, with a focus on chemical processing and use of NMP in agricultural chemicals and oil re-refining. SERs commented on the approximate concentration of NMP in their products, the challenges of using alternative chemicals, the number of employees exposed, the number of product lines they had, and how their formulated products are used in lawn care and other agricultural sectors, architectural and equipment coating removal, and oil re-refining.

EPA estimates of the small entities to which the proposed rule may apply are described in Section 4 of this document. As shown in Table 4.2, 61,850 small entities, or 97% of the estimated number of firms using NMP, could potentially be impacted by the rule. Not all of the small firms indicated in the Table, however, are expected to be impacted by the proposed rule as elaborated on in Section 4.

8.2. 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 engineering controls (in laboratories, fume hoods; in manufacturing facilities, valves and direct connections between drums or totes and mixing tanks; ventilation and exhaust scrubbers; systems for stripping NMP out of the finished product and reusing it; and remote sampling devices (such as infrared)); PPE (full-face cartridge respirators, due to the presence of other chemicals; goggles and face-shields; long-sleeves, lab coats, or Tyvek suits; gloves including butyl rubber gloves, sometimes elbow-length); and administrative controls (such as limiting the number of personnel in an area where NMP is used, training in GLP, and other training).

Regarding alternative chemicals, SERs described how several alternative chemicals did not yield the results they were seeking in terms of product efficacy or purity, could not perform the functions of NMP, or were chemicals the SERs had previously used prior to the transition to NMP that the SERs identified as presenting concerns (such as DMSO). Most SERs described their preference for continuing to use NMP, and provided their rationales, with one SER describing how NMP was a key part of their planned business for re-refining used motor oil. SERs also described how, for pesticides formulated with NMP, if the manufacturing or processing of NMP were prohibited or restricted under TSCA it would result in changes to their products under FIFRA. SERs described how without NMP available as an inert ingredient, they would need an alternative ingredient, which would require pesticide product reformulation, and the required registration amendment subject to EPA review and approval before the product could be offered for sale, under FIFRA.

Overall, SERs expressed a preference for exposure controls and described current efforts to limit worker exposure to NMP.

8.3. Related Federal Rules

SERs discussed FIFRA approval requirements for NMP as an inert ingredient in pesticide formulations. SERs were provided with a document in the Panel materials (included in Appendix A2) that summarizes EPA's 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).The SERs indicated that if the manufacturing or processing of NMP were prohibited there would be significant costs and testing requirements associated with pesticide product reformulation, and the required registration amendment would be subject to EPA review and approval before the product could be offered for sale, under FIFRA. More information about the FIFRA inert ingredients overview and guidance is at https://www.epa.gov/pesticide-registration/inert-ingredients-overview-and-guidance. Review time for FIFRA approval depends on the type of petition as seen in the Pesticide Registration Improvement Act fee table found online at https://www.epa.gov/pria-fees/pria-fee-category-table-inert-ingredients.

8.4. Regulatory Flexibility Alternatives

Regarding regulatory flexibilities to reduce the impact of a potential regulation on NMP under section 6 of TSCA, SERs suggested that EPA require exposure controls such as engineering controls, administrative controls, or PPE requirements. Some SERs stated a preference for PPE requirements (which would not incur capital costs) while others said engineering controls could be implemented.

The Panel recommends that EPA consider additional activities listed below to determine if they are appropriate to provide flexibility to lessen impacts to small entities. Many of the recommended flexibilities may lessen impacts to all entities, and not only small entities:

Regulatory Options

Based on SER comments:

1. The Panel recommends that EPA describe in the NPRM how the inhalation and dermal exposures contribute to the identified unreasonable risk for NMP, including the importance of direct dermal contact in the unreasonable risk determination and special considerations for inhalation exposures for any particular conditions of use.
2. The Panel recommends that EPA consider and request comment on whether to allow the use of NMP by entities that could, based on demonstrated ability through recordkeeping and utilization of a combination of controls (including engineering controls, administrative controls, and PPE requirements), eliminate direct dermal contact with NMP to address the unreasonable risk.
3. The Panel recommends that EPA provide and request comment in the NPRM on reasonable compliance timeframes for small businesses. Specifically, the Panel recommends that EPA request comment on whether and how to provide longer compliance timeframes for transitioning to alternatives for uses requiring reformulation. As part of this effort, the Panel recommends that EPA seek comment on and consider compliance timelines based on the expected availability of technically and economically feasible alternatives, as well as any information that could be provided based on requirements for certification or standards relevant to pesticides, or as a solvent in products such as industrial cleaners, paint strippers, and oil refining. The Panel also recommends that EPA request comment in the NPRM on differing compliance or reporting requirements or timetables that account for the resources available to small entities. Additionally, the Panel recommends that EPA seek comment on and consider reasonable compliance timeframes for prohibitions or phase-outs on use of NMP in chemical processing and formulation, in response to SER input and other appropriate factors, such as the lifespan of equipment, capital costs for new equipment and certification, time to research alternatives, and time to reformulate products. In

addition, the Panel recommends that EPA take comment on any additional appropriate factors for identifying reasonable compliance timeframes and how to weigh the factors for chemical processing, agricultural product manufacturing, petrochemical refining, and other industries.

4. The Panel recommends that EPA provide readily available information on potential costs that could be incurred using strategies to meet requirements for any proposed exposure controls, such as engineering, administrative, or prescriptive controls (e.g., use of specialized systems, cost of new equipment, PPE, etc.), or concentration limit, as they apply to each relevant COU. The Agency should also provide its analysis on whether it is feasible to implement these strategies for the regulated entities.

5. The Panel recommends that EPA provide details and request public comment in the NPRM about the feasibility of use of alternatives to NMP and their availability for conditions of use that drive the unreasonable risk. Specifically, the Panel recommends that EPA provide, to the extent practicable, costs for the use of alternatives and information on the hazard profile of the alternatives. The Panel recommends that EPA should ensure that entities, with emphasis on small entities, are provided as much information as is available to the Agency about suitable alternatives for these conditions of use, potentially through the form of information generated as part of the rulemaking process (such as an alternatives assessment).

6. The Panel recommends that EPA provide an analysis for each use identified by SERs that would be subject to prohibition to demonstrate whether technically and economically feasible alternatives to NMP that benefit health or the environment, compared to the use proposed to be prohibited or restricted, would be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.

7. The Panel recommends that EPA consider and request public comment in the NPRM on a *de minimis* level in the case of an impurity or trace amounts of NMP in products.

8. The Panel recommends that EPA's RFA and cost-benefit analyses consider the impact of excluding, as viable alternatives, any chemicals identified by the Agency as part of the TSCA risk evaluation process as presenting an unreasonable risk of injury to health or the environment. The Panel recommends that EPA request comment on whether these chemicals as well as chemicals undergoing risk evaluation would be likely to be considered as viable alternatives and, if so, in which circumstances.

9. Based on SER comments providing diverse perspectives on preferences for exposure control technologies and methods, the Panel recommends that EPA consider and request comment on a regulatory approach for those conditions of use where EPA has confidence that exposures to NMP can be effectively controlled, would provide flexibility for regulated entities to incorporate the hierarchy of controls and reduce exposures so that the unreasonable risk is no longer present.

10. The Panel recommends that EPA explain in the NPRM the relationship of TSCA and FIFRA with regard to NMP conditions of use subject to the proposed rule.

11. The Panel recommends that EPA provide an overview of information reasonably available to EPA regarding engineering or administrative controls that could address dermal exposures expected for NMP. The panel recommends that EPA seek comment on state of the art equipment, engineering and administrative controls, and monitoring

for dermal exposures.

12. The Panel recommends that EPA consider and request public comment on a limited access program for the sale of products containing NMP that could require training and certification, or restrict distribution only to users with certain equipment that could reduce or eliminate dermal exposures or type of facilities.

Advocacy only recommendation

In addition, Advocacy specifically recommends that EPA allow the use of NMP by entities who, based on demonstrated ability through recordkeeping and utilization of a combination of controls (including engineering controls, administrative controls, and PPE requirements), can eliminate direct dermal contact with NMP to address the unreasonable risk.

APPENDIX A: Materials Shared with Small Entity Representatives for the Pre-Panel and Panel Outreach Meetings

Appendix A1 (separate document) is a compilation of all outreach materials shared with SERs for the Pre-Panel Outreach meeting held on March 28, 2023. Below is a list of those materials.

- Agenda
- Panel Process Presentation
- Pre-Panel Rulemaking Presentation
- Industry Sectors with Small Entities Potentially Affected by the Rulemaking Document
- Related Regulations (EPA, Federal, State, and International) Document
- Pre-Panel Outreach SER Questions for Discussion
- Personal Protective Equipment Respirator System Per Worker Unit Cost Breakdown Document
- Potential Regulatory Options and Estimated Costs Document
- Information on Weight Fractions of NMP Evaluated in the 2020 Risk Evaluation

Appendix A2 (separate document) is a compilation of all outreach materials shared with SERs for the Panel Outreach meeting held on May 24, 2023. Below is a list of those materials.

- Agenda (updated from pre-panel version)
- Panel Rulemaking Presentation (updated from pre-panel version)
- Industry Sectors with Small Entities Potentially Affected by the Rulemaking Document (updated from pre-panel version)
- Related Regulations (EPA, Federal, State, and International) Document (same as pre-panel version)
- Panel Outreach SER Questions for Discussion (same as pre-panel version)
- Personal Protective Equipment Respirator System Per Worker Unit Cost Breakdown Document (same as pre-panel version)
- Potential Regulatory Options and Estimated Costs Document (updated from pre-panel version)
- Information on Weight Fractions of NMP Evaluated in the 2020 Risk Evaluation (same as pre-panel version)
- Key Takeaways from Pre-Panel Outreach Meeting (updated from pre-panel version)
- Pesticide Inert Ingredients interpretation TSCA and FIFRA Document (New material)

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.