Executive Summary

September 14, 2023

The Honorable Michael Regan
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW Washington, DC 20460

Dear Administrator Regan:

Enclosed for your consideration is the Report of the Small Business Advocacy Review Panel (SBAR Panel or Panel) convened for EPA's planned proposed rulemaking entitled "N-Methylpyrrolidone (NMP); Rulemaking under Toxic Substances Control Act." This notice of proposed rulemaking is being developed by the U.S. Environmental Protection Agency (EPA) under section 6(a) of the Toxic Substances Control Act (TSCA).

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 was 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 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

[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.

[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.

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 changes 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 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

On May 10, 2023, EPA's Small Business Advocacy Chairperson convened this Panel under section 609(b) of the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA). In addition to its chairperson, the Panel consists of the Deputy Director of the EPA's Office of Pollution Prevention and Toxics, the Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB), and the Chief Counsel for Advocacy of the Small Business Administration (SBA). It is important to note that the Panel's findings and discussion are based on the information available at the time this report was drafted. EPA is continuing to conduct analyses relevant to the proposed rule, and additional information may be developed or obtained during this process as well as from public comment on the proposed rule. The options the Panel identified for reducing the rule's economic impact on small entities will require further analysis and/or data collection to ensure that the options are practicable, enforceable, protective of public health, environmentally sound and consistent with TSCA and its amendments.

SUMMARY OF SMALL ENTITY OUTREACH

Prior to convening the Panel, EPA conducted outreach with small entities that will potentially be affected by these regulations. In March 2023, EPA invited SBA, OMB, and nine potentially affected small entity representatives (SERs) to a meeting and solicited their comments on preliminary information sent to them. EPA shared the one SER written comment with the Panel as part of the Panel convening document.

After the SBAR Panel was convened, the Panel distributed additional information to the SERs on May 10, 2023, for their review and comment and in preparation for another outreach meeting. On May 24, 2023, the Panel met with the SERs to hear their comments on the information distributed to them. The SERs were asked to provide written feedback on ideas under consideration for the proposed rulemaking and responses to questions regarding their experience with the existing requirements. The Panel received no written comments from the SERs in response to the discussions at this meeting and the outreach materials. See Section 7 of the Panel Report for a complete discussion of SER comments. The full written comment is also included in Appendix B. In light of these comments, the Panel considered the regulatory flexibility issues specified by RFA/SBREFA and developed the findings and discussion summarized below.

PANEL FINDINGS AND DISCUSSION

Under section 609(b) of the RFA, the Panel is to report its findings related to the following four items:

1. A description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply.

2. A description of the projected reporting, recordkeeping 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.

3. Identification, to the extent practicable, of all relevant federal rules which may duplicate, overlap or conflict with the proposed rule.

4. A description of any significant alternatives to the planned proposed rule which would minimize any significant economic impact of the proposed rule on small entities consistent with the stated objectives of the authorizing statute.

The Panel's most significant findings and discussion with respect to each of these items are summarized below. To read the full discussion of the Panel findings and recommendations, see Section 8 of the Panel Report.

A. 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. 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 the Panel Report. As shown in Table 4.2 of the Panel Report, 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.

B. Recordkeeping, Reporting, and Other Compliance Requirements

SERs described their exposure monitoring and reduction practices 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.

C. 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.

The Panel acknowledges the above-referenced issues and considers SER comments in its recommendations.

D. 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:

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 will 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 will 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 the 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.

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.

Sincerely,

WILLIAM NICKERSON Digitally signed by WILLIAM NICKERSON Date: 2023.10.16 16:38:20 -04'00'

William Nickerson
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Enclosure