U.S. SMALL BUSINESS ADMINISTRATION
OFFICE OF ADVOCACY
REGULATION • RESEARCH • OUTREACH

July 29, 2024

VIA ELECTRONIC SUBMISSION

The Honorable Michael S. Regan
Administrator
Environmental Protection Agency
Washington, DC 20460

Re: Regulation under the Toxic Substances Control Act: n-Methylpyrrolidone (Docket ID: EPA-HQ-OPPT-2020-0744)

Dear Administrator Regan:

On June 14, 2024, the Environmental Protection Agency (EPA) published a proposed rule titled "Regulation under the Toxic Substances Control Act: n-Methylpyrrolidone."[1] This letter constitutes the Office of Advocacy's (Advocacy) public comments on the proposed rule.

Advocacy is concerned with the ability of small businesses to comply with the EPA's proposed workplace protection program for the use of NMP-containing products. Additionally, the economic analysis prepared by the EPA does not adequately reflect the impact of the proposed rule on small businesses. Advocacy recommends the EPA allow the continued use of NMP in industries that can prevent exposure risk and remove the prohibition on containers above sixteen ounces. Further, Advocacy asks the EPA to revise the economic analysis to better reflect the impact on small businesses.

I. Background

A. The Office of Advocacy

Congress established the Office of Advocacy under Pub. L. 94-305 to represent the views of small entities before federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA) that seeks to ensure small business concerns are heard in the federal regulatory process. Advocacy also works to ensure that regulations do not

[1] 89 Fed. Reg. 51134 (June 14, 2024).

unduly inhibit the ability of small entities to compete, innovate, or comply with federal laws. The views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration.

The Regulatory Flexibility Act (RFA),[2] as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),[3] gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, the RFA requires federal agencies to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.[4] Additionally, section 609 of the RFA requires the Consumer Financial Protection Bureau, the Occupational Safety and Health Administration, and the Environmental Protection Agency to conduct special outreach efforts through a review panel.[5] The panel must carefully consider the views of the impacted small entities, assess the impact of the proposed rule on small entities, and consider less burdensome alternatives for small entities.[6] If a rule will not have a significant economic impact on a substantial number of small entities, agencies may certify the rule.[7] The agency must provide a statement of factual basis that adequately supports its certification.[8]

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.[9] The agency must include a response to these written comments in any explanation or discussion accompanying the final rule's publication in the Federal Register, unless the agency certifies that the public interest is not served by doing so.[10]

Advocacy's comments are consistent with Congressional intent underlying the RFA, that "[w]hen adopting regulations to protect the health, safety, and economic welfare of the nation, federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public."[11]

B. The Proposed Rule

On June 14, 2024, the EPA published a proposed rule to restrict the use of n-Methylpyrrolidone (NMP) under the Toxic Substances Control Act (TSCA). NMP is a widely used solvent in a variety of industrial, commercial, and consumer applications, including the manufacture and production of electronics, polymers, petrochemical products, paints and coatings, and paint and coating removers. The TSCA requires that the EPA address and identify any unreasonable risk of injury to health or the environment in a TSCA risk evaluation to the extent necessary that the chemical no longer presents an unreasonable risk.[12] EPA evaluated 37 conditions of use of NMP

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[2] Pub. L. No. 96-354, 94 Stat. 1164 (1980) (codified at 5 U.S.C. §§ 601-612).
[3] Pub. L. No. 104-121, tit. II, 110 Stat. 857 (1996) (codified in scattered sections of 5 U.S.C. §§601-612).
[4] 5 U.S.C. § 603.
[5] *Id.* § 609.
[6] *Id.*
[7] *Id.* § 605(b).
[8] *Id.*
[9] Small Business Jobs Act of 2010, Pub. L. No. 111-240, §1601, 214 Stat. 2551 (codified at 5 U.S.C. § 604).
[10] *Id.*
[11] Regulatory Flexibility Act, Pub. L. No. 96-354, 94 Stat. 1164 (1980) (codified at 5 U.S.C. §§ 601-612).
[12] 15 U.S.C. §2605(a).

and determined that 29 of those conditions of use present an unreasonable risk of injury to health for workers and consumers.

Based on these risk determinations, the EPA proposes to ban the commercial use of NMP in automotive care products, cleaning and degreasing products, metal products, and cleaning and furniture care products. The EPA also includes a ban of the commercial use of NMP in fertilizers and other agricultural chemical manufacturing processes in the proposed rule. For the remaining conditions of use, the EPA proposes a workplace chemical protection program (WCPP) or prescriptive controls. As part of the WCPP, the EPA includes requirements to prevent direct dermal contact with NMP. The EPA outlines prescriptive controls for conditions of use where a WCPP is not believed to be sufficient to control direct dermal contact or where a prohibition is not practical. These prescriptive controls include concentration limits and dermal personal protective equipment (PPE) and respirators.

The proposal also includes recordkeeping and downstream notification requirements. In addition, the EPA includes a 16-ounce size restriction on consumer-use NMP products, new labeling requirements for consumer containers, and recordkeeping requirements.

The TSCA requires the EPA to discuss one or more primary alternative regulatory actions.[13] In this case, the agency provides one alternative regulatory action. The primary alternative includes a WCPP for several additional conditions of use and prohibitions instead of prescriptive controls for certain industries. It also provides longer compliance timeframes for prohibitions.

In advance of this proposed rule, the EPA convened a small business advocacy review panel under SBREFA to consult with small entity representatives (SERs). The report issued by that panel is available in the docket.[14]

II. Advocacy's Small Business Concerns

Advocacy has several concerns with the proposed rule. First, Advocacy is concerned that the EPA is exceeding its statutory authority under the TSCA by proposing to ban NMP for entities that can demonstrate the ability to prevent dermal contact. Second, Advocacy is concerned that some of the proposed policies create a disproportionate impact on small businesses, potentially resulting in a *de facto* ban of the use of NMP for entities that could comply with a WCPP. Last, Advocacy is concerned that the EPA is underestimating the costs of the rule and has not properly identified all the potential economic impacts to small businesses.

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[13] 15 U.S.C. §2605(c)2(A)(iv)(II)-(III).
[14] U.S ENV'T PROT. AGENCY, FINAL REPORT OF THE SMALL BUSINESS ADVOCACY REVIEW PANEL ON EPA'S PLANNED PROPOSED RULE FOR N-METHYLPYRROLIDINE (NMP), (Sept. 14, 2023), https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0744-0058.

A. Advocacy recommends the EPA allow the continued industrial and commercial use of NMP for industries that can prove compliance with the WCPP.

As expressed in Advocacy's public comments on the proposed risk management rules for methylene chloride and perchloroethylene,[15] Advocacy remains concerned about the EPA's practice of prohibiting uses based on its independent determination about a business's compliance capability with the WCPP.

According to the TSCA, once the EPA determines that a chemical substance presents an unreasonable risk of injury to health or the environment, it must apply one or more requirements listed in section 6(a) "*to the extent necessary* so that the chemical substance or mixture no longer presents such risk."[16] In the proposal, the EPA determines risks from NMP are primarily driven by dermal exposure rather than inhalation exposure.[17]

The EPA proposes to ban or implement prescriptive controls for many of the industrial and commercial uses of NMP, rather than allow the regulated entities to determine compliance feasibility. For example, businesses could demonstrate their ability to prevent direct dermal contact (DDC or skin contact) by using PPE such as gloves to prevent skin contact during use. The EPA cites uncertainties regarding the feasibility of implementing workplace safety control measures and the availability of alternatives as reasons to prohibit use of NMP or require prescriptive controls for the use of NMP.[18] It is important to note that the TSCA does not specify any level of certainty or compliance capability. It simply requires that the unreasonable risk must be addressed only to the extent necessary. Because the EPA has identified controls and WCPP requirements that could prevent dermal exposure in some conditions of use, a user that can comply with these requirements should be able to eliminate unreasonable risk. Speculating about compliance capability goes beyond the scope of the statute.

For certain conditions of use where a WCPP is not believed sufficient by the agency to control direct dermal contact, but for which prohibition is not practical, the EPA is specifying certain prescriptive controls. Specifically, these conditions of use would be required to adhere to certain concentration limits of NMP and the use of dermal PPE and respirators where necessary. The EPA notes a variety of concentration limits by weight based on the identified condition of use. In reviewing both the proposed rule and the risk assessment, Advocacy noted that the EPA failed to explain how it identified these proposed concentration limits as preventing unreasonable risk. Advocacy is further concerned that the EPA has not assessed how these new concentration limits may impact the way small businesses within these conditions of use operate.

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[15] U.S. Small Bus. Admin., Off. Of Advocacy, Comment Letter on Proposed Rule for Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA) (July 3, 2023), https://advocacy.sba.gov/2023/07/03/advocacy-provides-public-comment-on-epas-proposed-risk-management-for-methylene-chloride-under-the-toxic-substance-control-act/. U.S. Small Bus. Admin., Off. Of Advocacy, Comment Letter on Proposed Rule Perchlororoethlyne (PCE); Regulation Under the Toxic Substances Control Act (TSCA) (Aug. 15, 2023), https://advocacy.sba.gov/2023/08/15/advocacy-provides-public-comment-on-epas-proposed-risk-management-for-perchloroethylene-under-the-toxic-substance-control-act/.

[16] 15 U.S.C. §2605(a) (emphasis added).

[17] 89 Fed. Reg. 51134 (June 14, 2024).

[18] *Id.*

During a June 20 public webinar hosted by the EPA, one small business owner in the historical preservation and restoration industry noted that he has used NMP as a solvent in his business for over 30 years. During public comments, this business owner noted that a reduced concentration of NMP might not work as effectively as the current concentration, leading to longer use times of the product, which could increase exposure risk.[19] During a roundtable held by the Office of Advocacy on July 17, other entities noted that there were other potential consequences of changing the chemical composition of NMP, including additional disposal risks or the need for additional chemicals to supplement the product if it was not as effective. None of this analysis is mentioned in the proposed rule nor the risk assessment. Therefore, Advocacy urges the agency to consider a WCPP in place of prescriptive controls, specifically those which may have unintended consequences that could impact workplace safety.

1. Advocacy recommends that the EPA not create a disproportionate impact on small businesses by creating container limit sizes for consumer products.

The EPA notes in the proposed rule that most consumer uses of NMP do not contribute to the unreasonable risk. However, to prevent consumer products from being used in commercial activities, the EPA is proposing to prohibit the import, processing, and distribution in commerce of NMP or NMP-containing products in containers larger than 16 ounces. The intent of this proposal is to dissuade commercial users from buying large quantities of NMP-containing products for commercial use.

Advocacy is concerned that this proposal would disproportionately impact small entities by increasing costs, creating more hazard from disposal, and potentially creating a *de facto* prohibition on the use of NMP-containing products, as small entities are more likely to be unable to obtain large quantities of NMP-containing products. As Advocacy recommends removing the prohibition and prescriptive controls for entities that can prove compliance with a WCPP, Advocacy additionally urges the EPA not to limit container sizes of NMP-containing products for entities that can prove compliance with a WCPP. The potential consequences of this proposal impact both the economic viability of small entities, create conditions for new hazards when disposing of the NMP-containing products, and would likely have a disproportionate impact on small businesses.

B. Advocacy recommends that the EPA consider all important adverse effects of the proposed rulemaking.

Under the TSCA, the EPA is obligated to consider the reasonably ascertainable economic consequences of the rule, including the likely effect of the rule on the national economy, small businesses, technological innovation, the environment, and public health.[20] Advocacy is concerned that the EPA's economic analysis underestimates the impact to small businesses by understating the number of small businesses using NMP, improperly quantifying the costs to

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[19] U.S. ENV'T. PROT. AGENCY, TRANSCRIPT OF WEBINAR ON PROPOSED REGULATION OF N-METHYLPYRROLIDONE UNDER THE TOXIC SUBSTANCES CONTROL ACT (TSCA), (June 20, 2024) https://www.epa.gov/system/files/documents/2024-07/proposed-rulemaking-of-nmp-tsca-transcript_07.16.pdf

[20] 15 U.S.C. §2605(c)(2)(A)(iv)(I).

small businesses of the proposed rule and the primary alternative, as well as by failing to consider the possibility that a firm may use NMP under multiple use categories.

The EPA proposes to prohibit the use of NMP in fertilizers and cleaning and furniture care products. In the economic analysis for these two conditions of use, the EPA only lists rule familiarization expenses as a cost for small businesses.[21] Based on stakeholder feedback, some of these firms would be substantially impacted by the proposals, which is not accurately portrayed in the EPA's economic analysis. Advocacy encourages the EPA to consider the full costs of identifying and implementing substitutes for NMP-containing products before evaluating whether a prohibition or WCPP is the most appropriate control measure.

Additionally, the EPA uses its "best professional judgment" of the number of firms using NMP in baseline in the economic analysis. Notable assumptions are in adhesives and sealants, with estimated 5% usages; cleaning and furniture care products at 1% usage; and fertilizer and other agricultural chemical manufacturing at 5% usage. If the EPA is wrong in these estimates, the costs of the rule will vary substantially for small businesses. Further, the EPA does not consider the possibility that a firm may use NMP under multiple use categories, even though many overlap in North American Industry Classification System (NAICS) codes identified by the agency in the proposed rule. Advocacy recommends the EPA consider alternatives that do not disproportionately burden small entities that use NMP under multiple conditions of use.

III. Conclusion

Advocacy is concerned that the agency's proposal exceeds its statutory authority by prohibiting commercial and industrial uses of NMP in a way that disproportionately impacts small entities. As noted in the final report of the SBREFA panel, Advocacy strongly recommends that the 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 unreasonable risk."[22] This includes changing any policies that might indirectly create a barrier to the safe use of NMP, such as the development of container size limits.

Advocacy recommends the EPA reconsider the proposed rule. Advocacy urges the agency to consider feedback from small businesses on these important issues.

If you have any questions or require additional information, please contact me or Assistant Chief Counsel Emily Jones at (202) 205-6368 or by email at Emily.Jones@sba.gov.

Sincerely,

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[21] U.S. ENV'T. PROT. AGENCY, OFF. OF POLLUTION, PREVENTION & TOXICS, ECONOMIC ANALYSIS FOR THE PROPOSED REGULATION UNDER THE TOXIC SUBSTANCES CONTROL ACT: N-METHYLPYRROLIDONE ES-7 (June 2024), https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0744-0255.

[22] U.S. ENV'T. PROT. AGENCY, *supra* note 19, at 41.

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