Before the United States
Environmental Protection Agency
n-Methylpyrrolidone (NMP); Regulation Under the Toxic Substances Control Act
89 Fed. Reg. 51134 (June 14, 2024); Docket EPA-HQ-OPPT-2020-0744

Comments of the Chemical Users Coalition

The Chemical Users Coalition ("CUC")[1] appreciates the opportunity to provide these comments regarding the U.S. Environmental Protection Agency's ("EPA's" and "the Agency's") Proposed Rule for the Regulation of n-Methylpyrrolidone (NMP) under Section 6(a) of the Toxic Substances Control Act ("TSCA") (the "Proposed Rule"). CUC is an association of companies from diverse industries that typically acquire and use, rather than manufacture or import, chemical substances. Our members depend on the availability of certain existing substances for which there are not technically feasible substitutes as well as a reliable pipeline for innovative new chemistries to be able to thrive in a competitive, global economy. Consequently, our members encourage EPA to develop regulatory approaches that encourage innovation and permit sustainability. Thus, CUC supports measures that protect health and the environment in a manner that enables the regulated community to pursue technological innovation simultaneously with economic development in the United States. This is critical in the area of chemical regulatory policy, which necessarily addresses emerging information about health and environmental risk.

Background

CUC has been an active participant in the TSCA regulatory process since the formation of the organization prior to the TSCA amendments in 2016 and in the Agency's various efforts to implement the amendments. This has included submitting comments on EPA's initial risk evaluation process released for NMP and the revisions made reflecting certain policy changes surrounding TSCA risk evaluations which EPA announced in 2021. EPA's final revised TSCA risk determination for NMP in December 2022 reflected these policy changes, including some with which CUC disagreed. EPA determined that NMP presents an unreasonable risk of injury to health due to the significant adverse health effects associated with exposure to NMP, including developmental post-implantation fetal loss from short-term exposure and reduced fertility and fecundity from long-term exposure. EPA found additional adverse effects associated with

[1] The members of CUC are Airbus S.A.S., The Boeing Company, Carrier Corporation, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, National Electrical Manufacturers Association, RTX Corporation, Sony Electronics Inc., and TDK U.S.A. Corporation.

exposure to NMP including liver toxicity, kidney toxicity, immunotoxicity, neurotoxicity, skin irritation, and sensitization.

Overview of CUC Comments

CUC believes that the approach EPA has adopted in the Proposed Rule is more refined and the risk management measures more appropriately tailored than what EPA has proposed in other TSCA risk management rules. However, there are certain compliance requirements being proposed for which EPA appears to be taking a more expansive approach than needed. Furthermore, as with prior proposed rules, EPA is clearly focusing significantly on workplace exposures. However, EPA does not appear to be fully recognizing and considering certain best practices and standards followed in the discipline of industrial hygiene. In addition, the exercise of EPA authority in regulating workplace practices in the manner proposed presents significant challenges, both for the EPA and for the regulated community. Before EPA finalizes a risk management rule for NMP, it should provide more information to stakeholders and the public about the planned framework for the Agency's likely compliance and enforcement efforts, and the Agency should consider whether revisions to the Proposed Rule are needed to facilitate more effective implementation and compliance in light of the planned framework.

De Minimis Content, NMP-containing Articles and Research and Development

In the Proposed Rule, EPA is proposing that products containing NMP at concentrations less than 0.1% by weight would not be subject to the detailed prohibitions and restrictions. CUC supports both the inclusion of a de minimis level and the proposed level of 0.1%. CUC requests that EPA clarify that the de minimis exemption is not just pertinent to the proposed prohibitions and restrictions, but for all of the proposed requirements as well, such as recordkeeping. Accordingly, EPA should amend the proposed 751.201(b) to state:

> (b) De minimis level. Unless otherwise specified in this subpart prohibitions, ~~and~~ restrictions *and requirements* of this subpart do not apply to products containing NMP at levels less than 0.1 percent by weight.

CUC also suggests that EPA should explicitly exclude NMP from the restrictions when present in manufactured articles. There are substantial constraints on the ability of entities who import articles that may contain NMP to determine whether such articles do in fact contain NMP. Such entities assemble, manufacture, and distribute exceptionally complex products; some can be minute, while others are of immense scale and often have incredible levels of intricacy. These articles are used in the aerospace and defense industries, commercial equipment, automotive and agricultural equipment, transportation products, IT equipment, and other industrial and commercial uses as well as in consumer use application. The articles may require and contain thousands of components and parts acquired and assembled by potentially thousands of global suppliers, each of whom may never have a direct business relationship or contact with the manufacturer of the finished good. Given the potentially thousands of suppliers involved in the

production of components in any single article or end-use product, and in light of the fact that no risk from exposure to NMP in articles has been identified, the final rule should explicitly state that articles containing NMP are exempt from restrictions.

Additionally, to avoid confusion, the final rule should define "article" and explain how the Agency interprets the term in comparison to its use of the term "product." For example, the preamble to the proposed rule makes references to conditions of use including "processing and incorporating NMP into articles in lubricants and lubricated additives in machinery." However, the traditional definition of article for TSCA purposes has generally excluded liquids. Further guidance on the distinction between EPA's use of the terms an "article" and a "product" should be provided to ensure this is clarified for compliance and enforcement purposes.

CUC also recommends that EPA explicitly exclude from the restrictions NMP when used for research and development purposes. The Proposed Rule does not address this condition of use. EPA acknowledges that a goal of the Proposed Rule is to provide time for commercial users of NMP to explore alternative substances to determine their technical feasibility in specific conditions of use. Such research and development efforts will likely require comparative tests and studies that will, by necessity, require use of NMP. To promote such efforts and to avoid any confusion in the regulated community, EPA should explicitly state both in the final rule and in the preamble thereto that use of NMP in research and development efforts is fully exempt from the restrictions.

Consumer Use Restrictions

Although EPA found that certain commercial uses of NMP contribute to the finding of unreasonable risk due to the increased exposure, EPA determined that the consumer uses of NMP do not contribute to the unreasonable risk. Nevertheless, EPA has proposed to prohibit the import, processing, and distribution in commerce of NMP or NMP-containing products for the consumer uses of NMP if the containers exceed a volume of more than 16 ounces to avoid the "diversion" of small content product to restricted commercial uses. Additionally, the Proposed Rule sets labeling requirements for a variety of consumer uses of NMP as well as a concentration limit for consumer uses.

If EPA finds that labeling and package size limitations are sufficient for ensuring that risks in consumer use contexts are avoided, it follows that such an approach could be adopted for commercial uses as well. EPA should explicitly evaluate and more reasonably consider whether the container size, labeling, and concentration limit approach could be adopted for all or some commercial uses to avoid unnecessary prohibitions on certain important commercial uses.

Prescriptive Controls

Respiratory PPE

EPA is proposing to require specific prescriptive controls for certain occupational uses of NMP, such as concentration limits, dermal personal protective equipment ("PPE"), and respiratory PPE. EPA has stated that the unreasonable risk of injury to human health from NMP is mainly driven by direct dermal contact with NMP. (As will be discussed later in this submission, EPA did not include an Existing Chemical Exposure Limit ("ECEL") because of the fact that dermal contact is the driver for the finding of unreasonable risk). Although EPA has stated that inhalation risks contribute to the unreasonable risk from NMP for certain conditions of use, EPA did not explicitly address whether by addressing dermal contact risks alone, the requirements would mitigate the unreasonable risk from NMP. CUC recommends EPA should remove the requirement of respiratory PPE as a prescriptive control absent specific findings it is required for conditions of use.

This is particularly important as OSHA places profound demands on both management and labor when there is use of respirators in the workplace, including employee training, fitting, and medical examinations. OSHA considers respirator use to be implemented only after reasonable engineering and administrative controls have been exhausted, in part because when a respirator is used, there is added physical exertion for the worker. CUC believes that the low vapor pressure of NMP and the work practices mandated by both EPA and OSHA combined obviates the need for respirators, and in keeping with the OSHA philosophy for respirator use, the respirator requirement is not needed and should be removed.

Furthermore, the requirement for respirators with organic vapor cartridges will be challenging to implement. Typically, the replacement of the cartridges in such respirators is based on exposure limits as indicated by the manufacturer. As CUC supports EPA's decision to not include an ECEL for NMP, CUC recommends that any final rule make clear that determinations concerning appropriate changes to respirator cartridges should be left to the employer, relying on manufacturer specifications, established standards, and professional judgement.

Concentration Limits

EPA is proposing to limit the concentration of NMP in formulated products for specified conditions of use. NMP is a critical and often unique, specialty chemical, and as EPA has stated, for certain applications these is no readily available substitute. In those situations where substitution is impossible, it is often also the case that there is no readily available diluent for NMP that will preserve the chemical function of NMP. For example, in the magnet wire industry, high-performance magnet wire products are being produced with raw enamels containing NMP in concentrations greater than 45% before the wet enamels are processed within a magnet wire oven to remove and ultimately combust NMP vapors. Work practices utilized by industry can manage NMP exposures regardless of NMP concentration. The concentration limits for certain

applications will result in a de facto ban on certain uses of NMP where no substitute is available. EPA should therefore remove the concentration limits and allow the use with appropriate occupational exposure controls.

WCPP

For occupational uses that are not subject to prescriptive controls, EPA is proposing to require the development of an NMP Workplace Chemical Protection Program (WCPP) and require recordkeeping and downstream notification requirements. The WCPP includes a Direct Dermal Contact Control ("DDCC") requirement and a Personal Protective Equipment program.

Respiratory Limits - EPA stated that it is not proposing an ECEL for NMP because the proportion of the exposure largely driving the unreasonable risk to workers is due to dermal contact with liquid NMP and an ECEL would only address risk from inhalation and vapor-through-skin (dermal exposure to vapor but not direct dermal contact with a liquid) exposures. CUC supports this risk-based approach.

Recordkeeping Requirements - As mentioned above, the WCPP includes recordkeeping requirements. EPA states that it is proposing to require that owners and operators document in the exposure control plan, or other documentation of the facility's safety and health program, information relevant to any PPE program, as applicable, including the name, workplace address, work shift, job classification, and work area of each person reasonably likely to directly handle NMP or handle equipment or materials on which NMP may be present and the type of PPE selected to be worn by each of these persons. This can be an incredibly burdensome if not logistically impossible task to accomplish. EPA is not merely proposing these requirements for those employees who actually handle NMP, but even for those who are "reasonably likely" to handle NMP. In large scale operations, with many employees in an available pool to perform tasks, this requirement could translate into the need to collect information for a significant number of employees who may never actually come in to contact with NMP, but theoretically could. In addition, the recordkeeping requirements in the Proposed Rule differ from those required by OSHA for the same employees and activities. This imposes a huge burden and creates significant logistical complexities. CUC recommends a more modest record keeping requirement, such as one which requires keeping records of the determinations made with regard to the specific job functions and efforts in which employees are engaged that are likely to result in direct dermal exposures.

Responsible Party - This complexity of the WCPP requirement is further heightened by another element of the Proposed Rule on which CUC has commented repeatedly for other proposals. Specifically, EPA has selected the ''owner or operator'' as the entity responsible for implementing the WCPP (and other requirements such as Prescriptive Controls). The term includes any person who owns, leases, operates, controls, or supervises such a workplace.

EPA's proposal to place these obligations on the facility "owner/operator" results in a different workplace protection compliance obligation for the TSCA regulations than under OSHA requirements. Under the Proposed Rule, "Owners/operators" are responsible for providing personal protective equipment, dermal and respiratory as required. This includes providing such equipment to the owners'/operators' employees as well as to others who may be present in the workplace. However, under 29 CFR 1910.134, "employers'' are required to develop and implement respiratory protection programs, provide the needed protection to "employees," and are also responsible for other OSHA Respiratory Protection program elements including training and fit testing on the specific respirator model provided, as well as medically approving the use of the type of respirator provided.

OSHA recognizes that the employer has direct supervisory control over employees, is aware of the occupational setting in which the employees operate and is therefore best positioned to ensure that regulatory requirements for workplace protection are followed and that employees are protected. EPA's proposal shifts the burden of compliance onto an entity that may not have direct knowledge of the specific personnel operating in any particular workplace and has no direct authority to mandate any specific behavior.

Many facilities may have contractors performing work in the facility. The owner/operator of the facility may have limited ability to mandate specific compliance actions to employees of contractors and not its direct employees. For example, the owner/operator does not have the authority to conduct OSHA mandated medical evaluations and examinations for those workers using respirators. Employers have the ability to require certain actions from their employees and are legally obligated to ensure that their employees work in a safe environment. While owners/operators may, in some instances, have the ability to specify workplace practices in an agreement with a contractor, ultimately the specific performance of these practices is the obligation of the contractor, not the owner/operator.

In addition to the practical difficulties involved in EPA's imposition of compliance obligations on the owner/operator, this approach creates a direct conflict with the legal obligations placed on an employer under OSHA. Prior to finalizing the Proposed Rule, EPA must address the conflict created by EPA's proposed imposition of obligations on an owner/operator and OSHA's imposition of the same obligations on an employer. Failure to do so will create needless confusion and duplicative compliance burdens.

Furthermore, some facilities are co-owned by two or more entities and jointly managed. Some are managed by only one of the owners/operators. Other facilities may appear to be a singular facility but in actuality are two or more co-located facilities with different owners/operators. These situations present compliance questions: Are all co-owners responsible for implementation of a WCPP? Is just a managing owner/operator responsible for compliance? Does EPA require one WCPP to cover an entire facility or can there be multiple WCPPs for different parts of the

facility? EPA must provide clarification for who EPA considers the responsible entity in these scenarios.

CUC therefore recommends that EPA adopt the approach of requiring "employers" to be the entities responsible for *providing* dermal protection and other PPE to their employees while the owner/operator is identified as the entity responsible for ensuring overall compliance with the WCPP. For example, the owner/operator could be responsible for ensuring that training of those working in its facilities is completed; however, the employer would be the entity responsible for providing the training. This language change would be consistent with current OSHA practice and ensure protections are in place while not being overly burdensome. The recordkeeping requirements also could be adjusted and clarified with these changes in mind.

Dermal Contact controls - EPA has proposed to require each owner and operator to reduce to the extent practicable the potential for direct dermal contact with NMP in the workplace by using engineering and administrative controls and to supplement these controls using PPE. EPA requested comment on monitoring and sampling to determine the effectiveness of dermal protection control implemented, specifically referencing charcoal patch testing.

Dermal patch testing is not currently a best practice utilized by industrial hygiene professionals. When industrial hygienists select "impervious barriers" for dermal protection, they rely on chemical permeation, penetration, and degradation data from chemical protective clothing suppliers that test their products using ASTM methodologies. This data ensures the selected materials prevent direct dermal contact when work tasks put workers in situations where they would otherwise experience direct contact or incidental contact if there is the potential for splashing in conceivable failure scenarios. Furthermore, chemical protective materials are selected based on their ability to provide an impervious barrier to the specific chemical in question.

Requiring owners to validate the ASTM testing results of chemical protective clothing suppliers via charcoal patch testing is a duplicative, complex, non-standard, expensive, and an unnecessary means of validating PPE selection that will not result in improved PPE performance or improved worker safety. CUC therefore recommends that EPA should rely on the standards testing (and product certifications) of the PPE by the manufacturer and not require any further validation of performance by the downstream purchaser/user.

Restricted Areas

EPA is proposing to require that each owner or operator subject to a WCPP designate any area where direct dermal contact with NMP may occur as a ''restricted area.'' This restricted area would be demarcated using administrative controls such as highly visible signifiers, in multiple languages as appropriate, placed in conspicuous areas and documented through training and recordkeeping. EPA is proposing to require that each owner or operator prevent access to the

‘‘restricted area’’ for any potentially exposed person that lacks proper training; is not wearing required PPE; or is otherwise unauthorized to enter.

CUC believes that the creation of restricted areas is challenging to implement in certain workplace settings. Depending on the size of the area, it could be extremely difficult to manage people moving within the area, as not every employee may anticipate being dermally exposed to NMP. Accordingly, CUC requests clarification on how to determine the necessary size of a restricted area where people are potentially exposed to NMP.

Exposure Control Plan

CUC Members generally support EPA's objective as stated in the Proposed Regulation that facilities should implement the WCPP "in accordance with the hierarchy of controls" and use "pollution prevention to control exposures whenever practicable." Nevertheless, CUC Members do not agree that the terms of the NMP regulation should mandate that companies implementing the WCPP requirements should need to document in the Exposure Control Plan the identification and rationale (and hierarchical determinations made) of exposure controls selected or not used to prevent or reduce direct dermal contact with NMP in the workplace. While industrial hygiene professionals work with their colleagues to implement the hierarchy of controls when determining the most appropriate methods to mitigate workplace exposures to chemical substances, CUC considers it to be unnecessary for EPA to expect a business to create records reflecting how such determinations were made. This is especially concerning to CUC Members because in many cases where NMP has been in use for decades or more[2], such analyses would have been made years ago and newly required records may need to be created (or recreated). This requirement is unworkable and should be abandoned before the NMP rule is finalized.

Relationship to Prescriptive Controls

CUC acknowledges that both the Prescriptive Controls and the WCPP mandate the use of PPE. The current structure of proposed regulations, however, contain cross references that make it somewhat difficult to discern if a certain provision applies specifically to the Prescriptive Control scenario or also to a WCPP. For example, there are references to respiratory protection within the WCPP section which appear to only relate to the prescriptive controls.[3] CUC requests that EPA clarify which requirements are applicable to Prescriptive Controls, which to the WCPP, and if to both, that should be explicitly stated as well.

DOD/NASA Applications

For conditions of use for which EPA has proposed concentration limits, EPA is further proposing that the WCPP be allowed for use of NMP at high concentrations by DOD, NASA, or their

[2] EPA acknowledges that, for example, the semiconductor sector has already provided information to EPA on exposure reduction measures used in their facilities.
[3] 751.209 (e)(6), respiratory protection is included in the WCPP section but refers to § 751.211(b) which is Prescriptive Controls.

contractors for specific conditions of use. However, each entity must provide a self-certification describing: (1) their status as either DOD or NASA, or a contractor to DOD or NASA; and (2) their implementation of and compliance with the WCPP to purchase and use NMP-containing products that exceed the concentration limits for other industrial and commercial users.

While the proposal established compliance deadlines, CUC believes additional clarity is needed specifically for when the downstream notification requirement and the labeling requirements for NMP for DOD and NASA applications becomes effective.

Furthermore, there are additional conditions of use of NMP that are carried out in the aviation/aerospace sector, both for DOD and civilian uses that EPA has not specifically addressed. These critical uses of NMP for which no alternatives are currently available are:

- An approved anti-friction compound used on aircraft engine components as a low-friction coating contains NMP. The concentration in the compound may exceed the proposed 45% maximum NMP concentration. The compound is required for use in both engine maintenance, repair and overhaul and in engine production.
- NMP is used as a component in various adhesive products. Typically, it is present as a catalyst for 2-part adhesive systems, or as a component of an adhesive/sealant system. Examples of this include core splice adhesive and potting compounds.
- NMP-containing products are used in various electronic assemblies that are sensitive to vibration or that require elevated temperature cure resins in the bonding process.
- Conformal coatings, two-component polyurethane systems, and lubrication film coatings must be corrosion resistant and must serve as a lubrication film coating in high friction applications.
- Solvent and cleaner applications using NMP-containing formulations are required to dissolve or remove cured epoxy, urethane, and silicone, remove conformal coating, remove cured polyimide materials and clean equipment used in epoxy and coating applications. These products must be appropriate for use in aerospace settings.
- NMP is used as a solvent in the resin package of certain specification qualified composites. It plays a crucial role in the formation of high-temperature resistant polyimide composites, which are extensively used in high temperature applications such as engine parts, propulsion, and structural parts.

Performance requirements for such products in some applications are set by the US Federal Aviation Agency. Accordingly, EPA must provide for continued use of these sensitive applications above proposed concentration limits with appropriate exposure controls in both civilian and DOD applications.

Conclusion

CUC supports EPA's efforts to appropriately manage risks presented by high priority substances. CUC appreciates the effort that EPA is expending to more appropriately tailor risk management

requirements to specific conditions of use. However, CUC believes that EPA has more work to do to ensure that the Proposed Rule is consistent with well accepted industrial hygiene principles and requirements under the jurisdiction of OSHA. Accordingly, CUC asks that EPA take a closer look at real-world and generally accepted industrial hygiene practices, existing requirements under OHSA, and adjust requirements in the Proposed Rule accordingly.

CUC Members would be glad to make themselves available to discuss any questions EPA personnel may have concerning CUC's comments and/or to discuss any issues related to the Agency's efforts to evaluate and to mitigate risks associated with the use of high priority substances.