

**Comments of the
Semiconductor Industry Association (SIA)
To the
Environmental Protection Agency (EPA)
On the
Proposed Rule on n-Methylpyrrolidone (NMP)
Regulation Under the Toxic Substances Control Act (TSCA)
EPA-HQ-OPPT-2020-0744 / FRL-8330-02-OCSP
July 29, 2024**

The Semiconductor Industry Association (SIA)¹ appreciates the opportunity to submit these comments to the Environmental Protection Agency (EPA) regarding its proposed rule on the risk management of n-Methylpyrrolidone (NMP).²

SIA generally supports EPA's approach to risk management for the semiconductor manufacturing sector and appreciates EPA's recognition of the semiconductor industry's existing administrative and engineering control practices to prevent worker exposure to NMP. SIA concurs with the Agency's assessment that current practices of SIA member companies are generally consistent with the proposed Workplace Chemical Protection Program (WCPP) framework requirements. We support EPA's proposal to address any potential risks of NMP exposures to semiconductor workers through continuation of a WCPP consistent with existing industry practices. To ensure any final NMP regulation is implemented in a manner to best achieve the Agency's environmental and worker protection goals in the most effective and efficient manner, SIA recommends EPA modify a number of items in its proposed rule in certain respects as discussed further in our comments below.

1. SIA Supports EPA's Recognition of Existing Practices in the Semiconductor Manufacturing Industry

SIA has engaged with EPA on TSCA review and potential regulation regarding NMP since 2016, when NMP was first chosen by EPA to undergo risk evaluation. In the 8 years since, SIA has provided EPA with voluminous information about the industry's use of NMP and how worker exposures in the semiconductor manufacturing industry are limited in a manner which mitigates unreasonable risks. Appendix A of this submission includes a chronology of SIA's engagement with EPA through public comment and stakeholder meetings, as well as by conducting exposure studies and providing the results and industrial hygiene data. This information documents the longstanding and stringent workplace controls adopted by the semiconductor industry to prevent direct exposures to NMP and minimize the risk to workers in the sector. Although SIA continues to disagree with EPA's risk evaluation finding that NMP poses an "unreasonable risk" to

¹ SIA is the voice of the semiconductor industry, one of America's top export industries and a key driver of America's economic strength, national security, and global competitiveness. Semiconductors – the tiny chips that enable modern technologies – power incredible products and services that have transformed our lives and our economy. The semiconductor industry directly employs over a quarter of a million workers in the United States, and U.S. semiconductor company sales totaled \$264 billion in 2023. SIA represents 99 percent of the U.S. semiconductor industry by revenue and nearly two-thirds of non-U.S. chip firms. Through this coalition, SIA seeks to strengthen leadership of semiconductor manufacturing, design, and research by working with Congress, the Administration, and key industry stakeholders around the world to encourage policies that fuel innovation, propel business, and drive international competition. Additional information is available at www.semiconductors.org.

² n-Methylpyrrolidone (NMP); Regulation Under the Toxic Substances Control Act (TSCA), 89 Fed. Reg. 51134 (proposed June 14, 2024) (to be codified at 40 C.F.R. § 751).

<https://www.federalregister.gov/documents/2024/06/14/2024-12643/n-methylpyrrolidone-nmp-regulation-under-the-toxic-substances-control-act-tsca>.

semiconductor workers, SIA is pleased that EPA's risk management proposal recognizes the adoption of the industry's stringent controls through the proposed Direct Dermal Contact Control (DDCC) requirements as an effective method to reduce potential risks to workers.

EPA's proposed WCPP for industrial uses, including in semiconductor manufacturing, ensures that workers will continue to be protected while allowing for continued operations. In the proposed rule's preamble, EPA repeatedly recognizes that the semiconductor manufacturing sector serves as a model for the appropriate use of NMP:

- "In many of these industries, EPA expects that facilities will already have in place the types of exposure controls that EPA proposes to require. For example, EPA understands that most workplaces using NMP in semiconductor manufacturing already have stringent controls in place that reduce workplace exposures." (89 FR 51137)
- "When characterizing the risk during risk evaluation under TSCA, EPA believes it is appropriate to evaluate the levels of risk present in scenarios where no mitigation measures are assumed to be in place for the purpose of determining unreasonable risk (see Unit II.C.2.a.). However, there are some cases where scenarios may reflect certain mitigation measures, such as in instances where exposure estimates are based on monitoring data at facilities that have existing engineering controls in place. For example, in the 2020 Risk Evaluation for NMP, EPA used data received from the Semiconductor Industry Association to develop the occupational exposure scenario used for several conditions of use of NMP in semiconductor manufacturing. The data included full-shift personal breathing zone sampling results at semiconductor fabrication facilities during container handling of both small containers and drums, by workers inside the fabrication rooms, maintenance workers, workers unloading trucks containing virgin NMP, and workers loading trucks with waste NMP (Ref. 1)." (89 FR 51141)
- "EPA is proposing to require owners or operators to implement DDCC requirements in accordance with the hierarchy of controls and encourages the use of pollution prevention to control exposures whenever practicable. EPA recognizes that some owners or operators may have industrial hygiene practices already preventing direct dermal contact with NMP in the workplace. For example, the semiconductor sector has provided EPA with information about the exposure reduction measures in their facilities, which are aligned with industrial hygiene best practices to prevent direct dermal contact with NMP, similar to that EPA is proposing." (89 FR 51153)
- "EPA understands that most workplaces using NMP in semiconductor manufacturing and lithium ion battery manufacturing already have stringent controls in place that reduce workplace exposures. As described in public comments and through engagement with the Semiconductor Industry Association (SIA), the Lithium Ion Cell Manufacturers' Coalition (LICMC), and individual companies, these manufacturing facilities use NMP in frequent, closed processes, where it does not present opportunity for human exposure and where NMP is completely removed from the final product (Refs. 42, 44)." (89 FR 51167)

SIA agrees with EPA's conclusion that continued implementation of existing administrative and engineering controls and practices at semiconductor facilities, as set forth in the proposed DDCC provisions of a WCPP, will adequately protect workers from any risks posed by NMP at semiconductor fabs.

2. SIA's Recommended Improvements to the Proposal

SIA supports the adoption of the proposed DDCC features of the WCPP to fully address any potential risks to workers posed by NMP at semiconductor fabs. However, we urge EPA to modify the proposal in certain limited respects to ensure that the WCPP can be implemented in an efficient manner.

A. Improvements to Ensure Consistency of WCPP with Existing OSHA Requirements

The proposed rule creates an unnecessary conflict between EPA's WCPP approach and OSHA's approach to worker safety. While EPA proposes that the WCPP covers all workers at an *owner's/operator's* worksite that use or encounter NMP, OSHA requires each *employer* at a multi-employer worksite to implement the equivalent of a WCPP when its workers may come in contact with a given chemical substance. SIA urges EPA to make changes to clarify the proposal in certain limited respects to achieve consistency with existing OSHA requirements.

By imposing the WCPP requirements on the owner/operator of the facility, EPA fails to take into account that many semiconductor manufacturing facilities' owners/operators may rely on independent contractors or other entities that work onsite and are considered to be the legal employers of their own personnel who are performing certain jobs and functions at those facilities. SIA recommends EPA modify its proposal before codifying a final rule to require the owner/operator *and independent contractors* to *implement measures to ensure* that the final WCPP is followed, while not specifically requiring the owner/operator to *provide* certain training, PPE, etc. to personnel on site who are not the owner/operator's "employees."

For example, in the semiconductor manufacturing industry, due to the specialized nature of the fabrication process and the use of complex machinery and equipment, employees of semiconductor equipment manufacturers are regularly present at a semiconductor fab to conduct maintenance, operations, or upkeep of various specialized tools (i.e., dedicated pieces of manufacturing equipment). Under these longstanding and commonplace arrangements, the owner/operator of the fab holds its suppliers/contractors responsible for training their employees and to require all employees to follow facility worker safety procedures. The contractors also are responsible for outfitting their employees with appropriate protective garments and PPE.

The difference between EPA's *owner/operator* approach and OSHA's requirements, which impose responsibility on the *employer*, creates a direct conflict with co-employment law, legal precedent, and supplier contract management, and has significant implications in determining responsibilities and potential liabilities. Shifting responsibility from the employer to the owner/operator for compliance with an EPA rule imposing employee training, PPE, and other requirements for a single chemical substance – NMP – would create unnecessary confusion, impose substantial additional costs, and cause legal and practical complexities when managing regulatory compliance at a complex and multi-employer worksite, without providing any enhanced benefit to established systems that ensure worker safety.

EPA attempts to address this issue in the proposed rule by stating all items in the OSHA rules that pertain to "employees" and "employers" would apply to workers and the owner/operator in the TSCA proposed rule. Unfortunately, this reasoning does not resolve the co-employment law conflict. It also creates an unmanageable patchwork from compliance responsibility between employers and owners/operators – across different chemicals in a multi-employer work site with many regulated chemicals present – most of which are not subject to TSCA risk management regulations.

More specifically, under the proposed rule, “owners/operators” would be responsible for providing PPE, employee training, and satisfying related requirements. Under the proposal, this would include providing such equipment to the owners’/operators’ employees, as well as to other potentially exposed personnel who may be present in the workplace. However, under the relevant (and cross-reference) provisions in the OSHA standards in 29 CFR Part 1910 (e.g., Sections 1910.132, 133, and 134), “employers” are the persons required to develop and implement worker protection programs (including selecting and providing the appropriate PPE and performing corresponding fit testing and other obligations) for their “employees.”

SIA recommends the proposed revisions below be incorporated in all relevant provisions in the proposed NMP rule to enable EPA to retain the intent of the rule (i.e., providing worker protections when needed), while addressing the TSCA-OSHA conflict, vocabulary differences, and co-employment law challenges. In semiconductor manufacturing facilities, companies are able to ensure that all workers are following stipulated requirements and PPE, respiratory protection, and other components of the WCPP through direct requirements, contractual arrangements, and oversight and enforcement. We believe this meets the same intent and achieves the same worker protection and environmental objectives of the proposed requirements in a more comprehensive fashion while successfully addressing the issues we have identified concerning OSHA standards and co-employment law.

Accordingly, SIA recommends the following revision to proposed § 751.209(e)(3) as an example to clarify and align the EPA owner/operator framework with the OSHA employer-employee framework. The changes shown in the provision immediately below should be carried over in all similar passages in the proposal (e.g., throughout § 751.209, § 751.213, and potentially elsewhere in the entire rule as required to harmonize the relevant provisions).

(3) Owners and operators **and independent contractors** must **implement measures to ensure** ~~provide~~ PPE training **is provided** in accordance with 29 CFR 1910.132(f) to all persons required to use PPE prior to or at the time of initial assignment to a job involving potential exposure to NMP. ~~For the purposes of this paragraph (e)(3) of this section, provisions in 29 CFR 1910.132(f) applying to an “employee” also apply equally to potentially exposed persons, and provisions applying to an “employer” also apply equally to owners or operators.~~

B. Improvements to Recordkeeping Requirements

The proposed Recordkeeping Requirements of §751.213 impose several requirements which are unnecessarily burdensome. The burdensome requirements include retaining records of, among other things, 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 present and the type of PPE selected to be worn by each of these persons.” This seemingly exhaustive requirement would impose unnecessary recordkeeping and administrative burdens on large work sites with preexisting systems for centralized training, work procedures, and certification systems and recordkeeping. Rather than constantly updating the individual names of workers that are routinely added or deleted in such systems, SIA submits it would be more effective and less burdensome to instead track the job types, descriptions, and certifications of individuals that work with NMP within their job scope through existing training and records management systems.

Recordkeeping for all employees will be more effective and straightforward through the identification and management of training requirements in enterprise company-wide systems.

This will allow up to date systems to remain in place and still enable the facility to identify covered employees, rather than needing to separately and manually update NMP-specific records with each employee change. Tracking by name does not help administer the OSHA and EPA requirements any more than tracking by job types, descriptions, and certifications, nor will it allow better adherence to training and work practice requirements. Instead, it creates an extra administrative burden that does not improve worker safety.

Therefore, SIA recommends the following revisions to § 751.213(b)(ii) and (iii) to permit a regulated entity to track job types, descriptions, and certifications in the Exposure Control Plan instead of specific employee names. The changes shown in the provisions immediately below should be carried over in all similar passages throughout the proposal.

(b) *Workplace Chemical Protection Program (WCPP) compliance—*

(1) *DDCC compliance.* Owners or operators **and independent contractors** subject to DDCC requirements described in § 751.209(b) must retain records of:

(i) Exposure control plan as described in § 751.209(c);

(ii) Dermal protection used by ~~each~~ potentially exposed persons and PPE program implementation as described in § 751.209(e), including:

(A) **Descriptions of the tasks, and work areas in which potentially exposed individuals are 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; and a means of demonstrating how individuals working in the areas described above are identified and documented as having been trained;**

[...]

(iii) Information and training provided by the regulated entity to ~~each person~~ **working in the areas described in § 751.213(b)(ii)(A)** prior to or at the time of initial assignment to a job involving potential direct dermal contact with NMP and any re-training as required in § 751.209(f).

3. Comments on Items Related to the Proposed Rule and Future Regulation

A. Risk Evaluation

Any future finding of “unreasonable risk of harm” to semiconductor workers should specify that such risk exists only in the absence of measures already implemented by the semiconductor industry (e.g., engineering and administrative controls, PPE, training, etc.). EPA’s risk evaluation for NMP found an “unreasonable risk” of harm to workers without any further elaboration, thereby giving the mistaken impression that there was an actual and existing risk to semiconductor workers despite the “stringent controls” in the semiconductor industry that EPA recognizes in the preamble to the proposed rule. To avoid any future misunderstandings in this regard and to accurately support risk communication efforts to semiconductor workers, in future risk evaluation rulemakings, EPA should make clear the “conditions of use,” including the absence of management practices, that may give rise to such a risk. As is the case with regard to NMP, SIA is confident that EPA will conclude that existing chemical management practices employed by the semiconductor industry are sufficient to address risks to workers.

B. Mandatory Respiratory Protection

While the semiconductor industry is not within scope of the respiratory protection requirements in the proposed rule, SIA has concerns about how mandating of respiratory protection could be applied in future TSCA rulemaking.

For purposes of the proposed NMP rule, EPA appears to be mandating respiratory protection for certain industries in the absence of having done the assessments necessary to quantify an inhalation hazard under those specific conditions of use. Given the proposal represents EPA's intent to implement various product concentration limits and reduce human exposures to NMP in the workplace in particular, it would be premature to conclude that the respiratory protection requirements being proposed as prescriptive WCPP requirements would be needed.

This approach to requiring the use of respiratory protective measures conflicts with the OSHA respiratory protection standards and methodologies, as well as the NIOSH respiratory protection framework. Potential inhalation exposure should first be better quantified after the product concentration limits are in effect. Only then should the potential risks to workers be reassessed to ensure the correct (if any) respiratory protection measures are identified, selected, and deployed. Mandating respiratory protection in the absence of first quantifying a hazard does not reflect use of the "best available science." Moreover, given EPA's assessment that 90% of NMP workplace exposure is due to direct dermal contact, it is not clear that mandating respiratory protection in addition to product content and dermal protection requirements is even necessary in some industries.

Additionally, with respect to future rulemakings that may be relevant to the semiconductor industry, EPA should consider collaborating with NIOSH, ACGIH, or a comparable guidance body to establish occupational exposure limits (OELs). OELs are important for manufacturers to engineer their systems and establish industrial hygiene practices in reference to a particular, detectable benchmark that is determined to be protective for workers.

C. Preventing Direct Dermal Contact

EPA requests comment on the possible use of dermal charcoal patch testing to quantify potential dermal exposure. Dermal patch testing by IH professionals is not currently considered to be a best practice, and to SIA's knowledge there are not current standardized methods. Rather, there remain concerns among IH professionals about the feasibility of dermal patch testing and confusion about what the results would indicate (i.e., quantification of vapor versus quantification of liquid breakthrough or permeation).

In the industrial hygiene profession, practitioners select "impervious barriers" by relying on chemical permeation, penetration, and degradation data from chemical protective clothing suppliers that test their products using ASTM methodologies. These data ensure the selected materials prevent direct dermal contact when work tasks put workers in situations where they will experience direct contact or may encounter incidental contact if there is the potential for splashing in conceivable failure scenarios. Chemical protective materials are selected based on their ability to provide an impervious barrier to the chemicals in question. Ultimately, the selection of chemical protective PPE is built on chemical protective clothing supplier testing, and results demonstrating that the materials used provides an effective barrier against the chemicals in question.

Requiring facility owners/operators (or independent contractors) to perform their own testing (e.g., charcoal patch testing) to validate chemical protective clothing suppliers' ASTM testing results are in fact impervious barriers is a duplicative, complex, non-standard, expensive, and unnecessary means of validating PPE selection. Doing such testing will not result in improved PPE performance or enhanced worker safety. Requiring double validation of impervious PPE selections and performance capabilities is comparable to requiring lung lavage with chemical analysis to validate NIOSH cartridge respirator certification methods are preventing inhalation exposures.

D. Other Clarifications Recommended – R&D and Manufactured Articles

SIA also recommends EPA clarify the proposed regulation to explicitly exclude NMP when used for research and development (R&D) purposes. The regulation being proposed, and the preamble, do not explicitly address this topic. Presumably, one of the effects of EPA's actions with respect to NMP will be to further expand efforts among commercial users of NMP to explore alternative substances to determine their technical feasibility in specific uses. Such efforts will require comparative tests and studies which will involve extensive R&D exercises that will, by necessity, require use of NMP. To encourage such efforts, and to avoid any confusion in the regulated community, EPA should explicitly do so in the preamble to the final rule and in a specific statement in the rule language that use of NMP in research and development efforts are fully exempt.

Finally, SIA suggests EPA explicitly exclude NMP when present in a manufactured article. The proposed regulation addresses certain processing activities in which articles are mentioned, but for which the finished articles themselves do not appear to be restricted (e.g., "processing of NMP for incorporation into articles in lubricants and as a lubricant additive in machinery"). The phrasing of such provisions, if not clarified, will create ambiguity that will lead to confusion in the regulated community and potentially create risks of non-compliance for entities that might import or use (and need to service) complex articles and even manufacturing equipment that might contain such NMP containing articles or components. The rule and any preamble should clarify that existing and new articles that contain NMP are not themselves prohibited, nor is their movement in commerce including their importation affected by the proposed NMP rule.

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SIA appreciates the opportunity to comment on this proposal, and we look forward to continuing to work with EPA in the development and implementation of TSCA regulation.

Appendix A

NMP information provided by the Semiconductor Industry, 2017-2023

Date	Type	Topic	Submitter	Hyperlink
30-Nov-2023	Meeting	SIA-OMB Meeting on n-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-) (NMP): TSCA Risk Management Proposal	SIA	https://www.reginfo.gov/public/do/viewEO12866Meeting?viewRule=true&rin=2070-AK85&meetingId=240273&acronym=2070-EPA/OCSP
16-Jun-2023	Meeting	SIA-EPA Meeting on n-Methylpyrrolidone	SIA	https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0744-0038
30-Jun-2022	Meeting	SIA-EPA Meeting on n-Methylpyrrolidone	SIA	https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0744-0033
3-Jun-2021	Request for Correction	Request for Correction by the Semiconductor Industry Association (SIA) On the Toxic Substances Control Act (TSCA) Risk Evaluation for N-Methylpyrrolidone (NMP), 85 Fed. Reg. 86558 (Dec. 30, 2020) [EPA–HQ–OPPT–2019–0236; FRL–10017–18]	SIA	https://www.epa.gov/quality/rfc-21004-n-methylpyrrolidone-nmp
3-Jun-2021	Report	Review of TSCA Section 6 Risk Evaluation of the Conditions of Use of NMP in the Semiconductor Industry prepared by Cardno Chemrisk, May 24, 2021	SIA	https://www.epa.gov/quality/rfc-21004-n-methylpyrrolidone-nmp
23-Feb-2021	Meeting	SIA-EPA Meeting on n-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-) (NMP), EPA-HQ- OPPT-2019-0236	SIA	https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0744-0003
12-Mar-2020	Meeting	Informal discussion with EPA (bulleted list submitted)	SIA	https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0743-0115
21-Jan-2020	Comments	Comments of the Semiconductor Industry Association (SIA) On the Draft Toxic Substances Control Act (TSCA) Risk Evaluation for N-Methylpyrrolidone (NMP); 84 Fed. Reg. 60,087 (Nov. 7, 2019); [EPA–HQ–OPPT–2019–0236; FRL–10001–87]	SIA	https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0236-0052
21-Jan-2020	Comments	Comments of Intel To the United States Environmental Protection Agency On the Draft Toxic Substances Control Act (TSCA) Risk Evaluation for N-Methylpyrrolidone (NMP); 84 Fed. Reg. 60,087 (Nov. 7, 2019) [EPA–HQ–OPPT–2019–0236; FRL–10001–87]	Intel	https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0236-0064

26-Nov-2019	SACC Comments	Semiconductor Industry Association, Nov. 2019. Comments of the Semiconductor Industry Association (SIA) To the Science Advisory Committee on Chemicals (SACC) On the Draft Toxic Substances Control Act (TSCA) Risk Evaluation for N-Methylpyrrolidone (NMP), 84 Fed. Reg. 60,087 (Nov. 7, 2019) [EPA-HQ-OPPT-2019-0236; FRL-10001-87]	SIA	https://www.regulations.gov/comment/EPA-HQ-OPPT-2019-0236-0031
5-Dec-2019	SACC Comments	Intel Comments to: Science Advisory Committee on Chemicals (SACC) On the Draft Toxic Substances Control Act (TSCA) Risk Evaluation for N-Methylpyrrolidone (NMP)	Intel	https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0236-0037
7-Nov-2019	Comments	Comments of Intel To the United States Environmental Protection Agency On the Draft Toxic Substances Control Act (TSCA) Risk Evaluation for N-Methylpyrrolidone (NMP); 84 Fed. Reg. 60,087 (Nov. 7, 2019) [EPA-HQ-OPPT-2019-0236; FRL-10001-87]	Intel	https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0236-0064
22-Feb-2019	Report	N-Methylpyrrolidone Risk Management Measures and Worker Exposure Monitoring Results	SIA	NOTE: This study was determined to be of high quality by EPA assessors.
16-Jul-2018	Comments	SIA Comments on Problem Formulation of the Risk Evaluation for N-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-) CASRN: 872-50-4, EPA-HQ-OPPT-2016-0743	SIA	https://www.regulations.gov/comment/EPA-HQ-OPPT-2016-0743-0100
11-Apr-2018	Meeting	SIA Meeting with EPA: NMP Worker Exposure and Controls in the Semiconductor Industry	SIA	
8-Nov-2017	Meeting	SIA Meeting with EPA on NMP use in the semiconductor industry	SIA	
18-Sep-2017	Comments	SIA Comments To the EPA Docket on Methylene Chloride and N-Methylpyrrolidone (NMP), EPA Docket # EPA-HQ-OPPT-2016-0743	SIA	https://www.regulations.gov/comment/EPA-HQ-OPPT-2016-0743-0063
19-May-2017	Comments	SIA Comments on EPA Proposal on Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a) 82 Fed. Reg. 7464 (Jan. 19, 2017), EPA Docket # EPA-HQ-OPPT-2016-0231	SIA	https://www.regulations.gov/comment/EPA-HQ-OPPT-2016-0231-0593
15-Mar-2017	Comments	SIA Comments On the Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: N-Methylpyrrolidone (NMP), EPA-HQ-OPPT-2016-0743	SIA	https://www.regulations.gov/comment/EPA-HQ-OPPT-2016-0743-0019