SEMICONDUCTOR INDUSTRY ASSOCIATION

Comments of the
Semiconductor Industry Association (SIA)
To the
Environmental Protection Agency (EPA)
On the
Proposed Rule: "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)"

90 Fed. Reg. 45690 (Sept. 23, 2025)
[EPA–HQ–OPPT–2025–0260; FRL–8529.1– 01–OCSPP]

November 7, 2025

The Semiconductor Industry Association (SIA)[1] appreciates the opportunity to submit comments on the proposed rule of the U.S. Environmental Protection Agency (EPA) to amend its "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)," ("the Proposal") 90 Fed. Reg. 45690 (Sept. 23, 2025).[2]

SIA supports EPA's proposed amendments to the current Risk Evaluation Procedural Rule. The proposal would make necessary and overdue changes to the Agency's approach to the procedures EPA uses to evaluate risk of existing chemicals under TSCA. Adopting these changes will improve EPA's process by focusing the assessment of the potential risks posed by existing chemicals on their actual conditions of use. Consequently, EPA can focus its risk evaluations on those uses and exposures that pose the greatest risks, which may reduce administrative resources used within EPA and regulatory burdens in general if the Agency can spend less time and personnel on uses and exposures presenting minimal or no risks. Taken as a whole, these changes could allow for improved protection of human health and the environment if greater effort can be placed on the efficient use of government and industry resources to ensure timely reviews and more focused risk evaluations. Then, EPA's risk mitigation efforts addressing chemicals and conditions of use presenting unreasonable risks could be accelerated.

In brief, SIA supports changes allowing EPA to exercise its discretion during the risk evaluation "scoping" process to: (a) articulate and limit the conditions of use it plans to evaluate; (b) consider the use of personal protective equipment and other occupational controls in "real-world" conditions of use; and (c) exclude from further (or overly detailed) review those conditions of use for which there may be *de minimis* exposures or low risks to human health and/or the environment. SIA also supports EPA's proposal to streamline the procedures the Agency may use to revise previously completed risk evaluations.

The experience of the U.S. semiconductor industry, as interested parties in the risk evaluation for N-Methylpyrrolidone (NMP), illustrates the need for the improvements being proposed by EPA. SIA engaged early, and often, with EPA, commencing such engagement prior to EPA releasing its draft scoping document (see Appendix A). In support of these interactions, SIA provided volumes of information and data to EPA in multiple submissions, including workplace

[1] The Semiconductor Industry Association (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. SIA represents 99% of the U.S. semiconductor industry by revenue and nearly two-thirds of non-U.S. chip firms. Learn more at www.semiconductors.org.
[2] 90 FR 45690, https://www.federalregister.gov/documents/2025/09/23/2025-18431/procedures-for-chemical-risk-evaluation-under-the-toxic-substances-control-act-tsca

exposure monitoring data that EPA judged to be "high quality." SIA participated in multiple meetings with the Agency, including during site visits made by EPA's senior managers and staff to semiconductor fabrication facilities. SIA members gave in-person testimony to EPA's peer review panel for NMP and provided supplemental information. SIA's submissions demonstrated that semiconductor fabs' use of NMP occurs under highly controlled conditions of use that substantially mitigate opportunities for direct exposures to NMP and significantly reduce potential risks to semiconductor workers.

Unfortunately, despite the extensive record SIA provided through these submissions, EPA concluded in the 2020 risk evaluation that the use of NMP in the semiconductor industry present an "unreasonable risk" to semiconductor workers. The Agency's conclusions appeared to be based on EPA estimates of dermal exposures to workers in semiconductor manufacturing operations for extensive periods from contact with the substance, even though there was no information in the materials supplied by SIA to support those assumptions, and there was no reasonably available information supporting such an assumption given the workplace practices and equipment in the conditions of use in semiconductor manufacturing.

To address these alleged risks, EPA proposed in the risk management phase of the TSCA Section 6 process to require a Workplace Chemical Protection Program (WCPP), including recordkeeping and downstream notification requirements that largely codify the practices already employed by the industry. Modifying the risk evaluation procedure consistent with EPA's Proposal would have resulted in a more rational outcome from the NMP risk evaluation (and risk management phase) and would still have resulted in semiconductor workers continuing to receive state-of-the art worker protection, while requiring fewer EPA and industry resources needed for implementing the proposed WCPP.

I. SIA Supports Consideration of Individual Condition of Use, Scoping, and EPA Discretion

SIA supports EPA's proposal to "determine whether the chemical substance presents an unreasonable risk . . . by making separate risk determinations for each condition of use," rather than the previous "whole chemical" approach. A separate risk determination for each condition of use is essential for industries such as the semiconductor industry that employ unique processes and controls to meet operational and business needs and reduce risks.

SIA supports the proposed approach set for in the Proposal because it is consistent with the statute. TSCA section 6(b)(4)(A) provides that EPA is to conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk . . . under the conditions of use." 15 U.S.C § 2605(6)(b)(4)(A). The statute defines "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of." 15 U.S.C. § 2602(4). The statute plainly requires an individual assessment of the conditions of use specific to an individual industry or type of use. Under the current approach, by evaluating the "whole chemical" rather than assessing each individual condition of use, EPA fails to consider the actual conditions of use in specific industries, such as the semiconductor sector.

SIA also considers the Scoping Process that Congress specified in the amended statute to provide the appropriate opportunity for EPA to exercise its discretion to articulate the conditions of use EPA will evaluate and to potentially eliminate from the scope of the Rick Evaluation uses which result in little or no exposure to humans or environmental release. SIA supports the amendments in the Proposal to the scoping process set forth at 40 CFR 702.39 to be used for

such purposes. The scoping process will allow EPA to eliminate or to narrowly define conditions of use to ensure Agency personnel and technical resources are not devoted to analyses that are not necessary, might be redundant or repetitive, and could inhibit EPA productivity.

Semiconductor fabrication is a highly complex process requiring the use of sophisticated equipment functioning under exacting operating conditions needed to fabricate circuits at the nanoscale. As explained in prior comments to EPA (see, for example, the comments provided to EPA in the risk evaluation for NMP, set forth at Appendix A), chemical use is carefully controlled, not only to protect workers and the environment but also to ensure quality control of the process and output. In short, these controls are an operational and business necessity to ensure a successful commercial operation. As a result, the use of chemicals in the semiconductor industry is likely to be substantially different than the uses of chemicals in other industrial settings, and the potential risks are also likely to differ substantially. To accommodate these different conditions of use and their potential risks, it is essential for EPA to make a separate, specific risk determination for each condition of use. An accurate assessment of the risks of chemical use in the semiconductor industry requires an evaluation of these conditions of use, based on all information reasonably available, including taking into consideration the "real-world" circumstances of use in the sector. Of necessity, this should include the occupational exposure controls employed by the industry, such as engineering controls, administrative controls, and the use of personal protective equipment (PPE).

II. SIA Supports Consideration of Occupational Exposure Controls

SIA supports the amendments to 702.39 in the Proposal to allow for the consideration of reasonably available information on occupational exposure controls used to protect employees from exposure to a chemical substance. The proposed rule states:

> In determining whether unreasonable risk is presented, EPA's consideration of occupational exposure scenarios will take into account reasonably available information on the implementation and use of occupational exposure control measures such as engineering and administrative controls and personal protective equipment.

SIA believes this approach is essential to accurately characterizing the risks of chemical use in the semiconductor industry. Occupational exposure controls are business essentials and standard operating procedures in the industry. Failing to consider such controls would be contrary to the language in TSCA and would also ignore the realities of chemical use in the semiconductor industry. Detailed information on occupational exposure controls in the semiconductor sector was included in SIA's prior comments to EPA on NMP (see Appendix A) and were presented during the public peer review proceedings hosted EPA.

III. SIA Encourages the Proposal to be Applied to Prior Risk Evaluations, Such as for NMP

Proposed Section 702.31(c) states: "The requirements of this part apply to all chemical substance risk evaluations initiated . . . beginning [a date to be insert which is 30 days after the date of publication of the final rule]." It further states: "For risk evaluations initiated prior to this date, but not yet finalized, EPA will seek to apply the requirements in this subpart to the extent practicable. The requirements shall not apply retroactively to risk evaluations already finalized."

SIA calls on EPA to delete the sentence in the Proposal stating: "[t]he requirements [of the new rule] shall not apply retroactively to risk evaluations already finalized." Instead, EPA should retain the discretion to apply the new risk evaluation procedures to risk evaluations already finalized, such as the risk evaluation completed for NMP. As discussed previously, SIA believes the risk evaluation for NMP erroneously concluded that the use of this chemical posed an "unreasonable risk" to semiconductor workers. EPA previously reached this conclusion by failing to consider the extensive occupational exposure controls present in semiconductor operations. SIA urges EPA to remedy this error by retaining the authority to revisit final risk evaluations where appropriate to correct prior erroneous conclusions.

Accordingly, SIA supports EPA's proposal to streamline the provisions in 702.43 for making changes to final risk evaluations and related determinations to enable EPA to use simple notice and comment procedures set forth in 702.43(c) and to conduct peer review, if appropriate, in accordance with 702.41. SIA considers it imperative to modify EPA's risk determination for use of NMP in semiconductor manufacturing. If EPA had conducted its risk evaluation in accordance with the process and methods contained in the Proposal, the NMP risk findings would not have been issued as they were. Thus, SIA believes EPA should revise the final risk evaluation for NMP to reflect the outcomes (concerning taking into consideration the exposure and engineering controls and PPE in the workplace) that would have been possible under the provisions contained in the Proposal.

IV. SIA Comments on Other Issues

- SIA encourages EPA to remove from the current Procedural Rule text provisions in Section 702.39 that the Agency has interpreted as prohibiting EPA from taking into consideration in its risk evaluations the risk mitigation achieved in workplaces through compliance with the standards of other governmental agencies, such as the Occupational Safety and Health Administration (OSHA). Furthermore, SIA recommends EPA ensure when implementing its amended Risk Evaluation procedural rule (and its previously issued Section 6(a) risk mitigation rules) that EPA personnel have contact with their counterparts in OSHA to gain a complete awareness of workplace practices that are common in the industries already engaged in a condition of use being evaluated to ensure assumptions EPA might make about industry practices and worker protection are well founded. Moreover, SIA recommends that during the post-risk evaluation *risk mitigation phases*, that EPA continue to coordinate with OSHA personnel to strive for consistency in EPA's regulatory language and terminology used when drafting proposed TSCA Workplace Chemical Protection Programs (WCPP) with terminology used by OSHA in its existing requirements (e.g., by harmonizing terms such as "owner/operator" under TSCA WCPP with OSHA's terminology for requirements applicable to "employers").

- SIA recommends when EPA is considering establishing Existing Chemicals Exposure Limits (ECELs) EPA first consult with industrial hygiene professionals to assess whether there may already be pertinent consensus standards or commonly accepted exposure limits which might be useful for EPA to reference, rather than generating entirely new (and overly challenging) occupational exposure values. When establishing any workplace exposure limit, EPA should alert the public of this possibility during the scoping and draft risk evaluation phases, invite consultation with industrial hygienists, and provide for potential peer review of any proposed ECEL being considered.

- SIA supports EPA including in the Risk Evaluation Procedures Rule a definition of "reasonably foreseen condition of use" or, at a minimum, specific guidance as to how the

Agency intends to determine whether a condition of use is "reasonably foreseen." For example, the document EPA references in the Proposal contains footnote language which the Agency could provide as guidance in the Preamble to the rule, when amended, or in a separate publication to be issued separately for the benefit of its use in both the existing and new chemicals evaluation processes. A separate guidance document on "reasonably foreseen conditions of use" determinations would increase the transparency of the Agency's internal decision-making processes for scoping of risk evaluations (and could likely be of benefit to PMN and SNUN submitters, as well as the producers and users of existing chemical substance). See FN 1 in Reference 18 in the Proposal: https://www.epa.gov/system/files/documents/2025-05/p-16-0218_determination_non-cbi_final.pdf.

- SIA supports EPA using the scoping process (and if necessary, use its findings as a result of the risk evaluation process) to identify and articulate those conditions of use which it considers to be *de minimis* such that unreasonable risks are unlikely to be presented by that use. If this cannot be achieved during scoping, but this circumstance becomes apparent during the risk evaluation process, then the Agency also could effectively articulate such *de minimis* or lower risk determinations at the outset of the risk management phases of its Section 6 process. This could enable further resource efficiencies by omitting such conditions of use from further consideration for regulations to be proposed or imposed for other uses of the same substance. SIA recommends EPA make clear in the final amendments and its preamble that the proposed use-by-use determination process set forth in the Proposal is intended to support and enable such an approach.

Conclusion

SIA appreciates the opportunity to comment and engage with EPA on issues relating to the safe use of chemicals in the semiconductor industry.

SEMICONDUCTOR INDUSTRY ASSOCIATION

Appendix A
NMP information provided by the Semiconductor Industry, 2017-2023

Date	Type	Topic	Submitter	Hyperlink
29-July-2024	Comments	Comments of the Semiconductor Industry Association (SIA) on the Proposed Rule on n-Methylpyrrolidone (NMP) Regulation Under the Toxic Substances Control Act (TSCA); [EPA-HQ-OPPT-2020-0744 / FRL-8330-02-OCSPP]	SIA	https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0744-0310
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/OCSPP
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