SEMICONDUCTOR INDUSTRY ASSOCIATION

Comments of the
Semiconductor Industry Association (SIA)
To the
Environmental Protection Agency
On the
Proposed Rule on Perchloroethylene (PCE)
Regulation Under the Toxic Substances Control Act (TSCA)

EPA-HQ-OPPT-2020-0720 / FRL-8329-02-OCSPP

88 Fed. Reg. 39652 (June 16, 2023)

Submitted August 15, 2023

The Semiconductor Industry Association (SIA)[1] appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) in response to the Proposed Toxic Substances Control Act (TSCA) Risk Mitigation Rule for Perchloroethylene (PCE).

As discussed in greater detail, SIA encourages EPA to substantially revise the PCE Risk Mitigation Proposal to effectively harmonize the proposed requirements with current procedures and practices followed in the course of implementing the standards and requirements of the Occupational Safety and Health Administration (OSHA) and to significantly streamline the Proposal to enable facilities that already use PCE to more readily adapt to the requirements of any final rule and to integrate such new requirements into existing procedures (such as existing employee training and hazard communications practices).

I. Representation and Consultation of the Industrial Hygiene (IH) Community

Implementation of the Proposed Rule on PCE risk mitigation will present challenges to industrial hygiene (IH) professionals, who currently operate in a different regulatory framework, and employ certain best practices that are not reflected in the proposed regulation. Moreover, it does not appear the IH professional and scientific community is represented on EPA's Scientific Advisory Committee on Chemicals (SACC), and it is not apparent that the professional IH community (OSHA, NIOSH, AIHA, and ACGIH) was extensively engaged as partners or consultants in the risk mitigation rulemaking process.

In order to represent IH best practices in the rulemaking process, SIA encourages EPA to ensure representation and consultation of industrial hygienists on this and future rulemakings, including those IH professionals with expertise in the semiconductor industry.

II. Consistency with OSHA Rulemaking

The EPA PCE risk mitigation rule should be amended before being finalized to ensure consistent application of EPA and OSHA rules and practices that are intended to mitigate

[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. 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. Learn more at www.semiconductors.org.

potential chemical exposures in the workplace. By assuming that workplaces are not consistently implementing and following existing OSHA rulemaking, the proposed PCE TSCA rulemaking will be confusing for those involved in establishing practices in workplaces that are currently adhering to the existing OSHA requirements (e.g., PPE Standards, Respiratory Protection Standards, etc.) as means of preventing unreasonable risk.

The impact of this inconsistency is that it may signal to workers that the existing OSHA regulatory requirements and practices result in unreasonable risks, and the controls deployed are ineffective in preventing illness. By not taking PPE and respiratory protection equipment (RPE) into account, EPA will create confusion among workers about past and future practices.

It is most helpful for the semiconductor industry and its workers when EPA and OSHA speak with one voice. Consistency in these policies provides predictable expectations as well as efficiency in implementation strategy.

III. SIA Comments on the Workplace Chemical Protection Program (WCPP)

A. Scope of Compliance Responsibility

EPA proposes that the WCPP must be implemented by the owner-operator in a way that will cover all workers at a worksite that use or encounter the chemical in question. Meanwhile, OSHA requires each employer at a multi-employer worksite to implement the equivalent to a WCPP when its workers come in contact with the chemical in question. A conflict is created between the EPA's WCPP approach and the OSHA approach to its PPE and Respiratory Protection rulemakings. The discrepancy between owner-operator responsibility versus employer responsibility conflicts with co-employment law, legal precedent, supplier contract management, and has significant implications in the assignment of liability. The cost and complexity of managing a different compliance scheme for one chemical at a complex multi-chemical, multi-employer worksite is substantial, including in situations such as here, where there are existing OSHA standards for a specific substance, and significantly more restrictive EPA standards are being proposed.

B. Industrial Hygiene Professionals Use of Consensus Limits

As part of the proposed WCPP, EPA has developed its own Existing Chemical Exposure Limit (ECEL) and Action Limit which will be used to frame which workplace controls and requirements must be implemented to mitigate workplace exposures. This is similar in concept to the OSHA vertical chemical standards that use the permissible exposure limits (PELs) and action limits to frame the workplace controls and requirements that must be implemented to prevent workplace exposures.

IH professionals use the American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit values (TLVs) as the starting point for comparing chemical exposure assessment data, as the OSHA PELs generally do not reflect the current state of knowledge regarding chemical toxicology research and exposure assessment science. ACGIH is a trusted partner in the industrial hygiene community and its TLV development process is well understood by most IHs. ACGIH publishes new and revised limits annually, and the supporting documentation is invaluable in explaining how the limit was derived and what studies were considered in the limit's development. For example, ACGIH categorizes the data considered in TLV development and makes it clear how the limits are related to that data (e.g., Confirmed Human Carcinogen,

Suspected Human Carcinogen, Confirmed Animal Carcinogen, Not Classifiable as Human Carcinogen, Not Suspected as a Human Carcinogen, Dermal Sensitization, Respiratory Sensitization, Skin / Danger of Absorption, etc.). These categorizations help the IH community understand the type of controls necessary to protect workers against the chemical hazard.

The data that were considered in establishing the PCE ECEL appears to be based on five papers. The EPA values are significantly different than that of other current consensus non-governmental limits. EPA is proposing a PCE ECEL of 0.14 ppm as compared to the current ACGIH TLV of 25 ppm. The ACGIH TLV references 46 PCE papers and publications. The Agency has not provided a clear and scientifically defensible explanation for the use of the proposed, remarkably conservative ECEL when consensus standards, such as the ACGIH TLV is considered credible by IH professionals. SIA recommends EPA adopt what IH professionals would identify as a best practices approach and establish the ECEL based on the ACGIH values in the final rule.

The significant difference in approach EPA has taken to developing Existing Chemicals (Occupational) Exposure Limits creates worker hazard communication issues for the industrial hygiene community that has historically used consensus (e.g., ACGIH) TLVs to manage their workplace. Furthermore, this difference in approach undermines trust and confidence in the ability of a facility to manage risk and effectively communicate to workers and creates a situation where a small handful of EPA-developed ECELs will be potentially 30-100x more conservative than the over 600 ACGIH TLVs used daily for all other chemicals in the workplace. It does not appear that ACGIH was consulted during the EPA development of the PCE ECEL, an oversight that EPA should address before finalizing the rule.

C. Chemical Exposure Assessment

EPA's PCE Proposal will impose numerous unnecessary and onerous new requirements that will not reduce worker exposure.

For example, EPA is proposing an ECEL action level of 0.07 ppm, concentrations above which require more frequent monitoring and exposure assessment. While EPA states that it will consider "industry or sector best practices for industrial hygiene," the current best practice for industrial hygiene exposure assessment as published by the American Industrial Hygiene Association (AIHA) is not referenced in this proposed PCE rulemaking; the AIHA best practice is to use parametric statistics to characterize exposure assessment data sets, and set priority based on the predictive power of data already collected. This is especially important in workplaces that have substantial engineering and administrative controls implemented that prevent worker exposures and substantial collection of exposure assessment data that is below the action limit and below limits of detection for the analytical method.

The assessment methods EPA is proposing will not permit facilities to rely on monitoring data that are more than 5 years old. This provision is onerous and will require additional data to be gathered in a facility that may have data greater than 5 years old that are perfectly valid. If a more flexible requirement in this regard is not adopted for PCE, and for similar potential future rulemakings such as NMP, workplace monitoring data gathered by SIA members specifically to assist EPA's NMP risk evaluation will go to waste. In 2018, SIA coordinated an industry effort to inform the EPA Risk Evaluation (well in advance of a potential rulemaking) for NMP by collecting significant numbers of industrial hygiene exposure assessment samples. Those results were shared with EPA in 2019, and again in 2023. The controls, work practices, and

equipment configurations have not changed significantly since 2018 and 96% of the more than 118 samples collected were below the limits of detection for NMP. If a future NMP rule is developed with requirements similar to the PCE proposal, and is not promulgated until 2024, SIA members would be required to repeat their baseline assessment work in spite of the fact that there were no quantifiable exposures to NMP previously, even if there have been no material changes in workplace practices and equipment to affect this conclusion. EPA should allow the use of legacy data without a 5-year limit if workplace processes and exposure controls have not changed and if analytical method detection limits continue to be valid.

Requiring workplaces to reevaluate work areas every five years whether or not processes change have occurred is inconsistent with the OSHA vertical standards and will potentially require expenditure of resources to recharacterize chemical exposures that have been extensively studied previously at the expense of characterizing potential chemical exposure where there are new processes, production changes, or the introduction of new chemicals where there are no EPA ECELs in existence.

EPA is also proposing additional monitoring to be performed after the cleanup of a spill, leak, rupture, or other breakdown. This is not consistent with existing OSHA rules or practices. It is also not clear the benefit of monitoring after a cleanup activity is complete and the process has returned to normal conditions; moreover, the time delay between sampling and receiving results back from a laboratory does not inform the event response or immediate mitigation actions.

Confusingly, EPA is also proposing repeat monitoring within 15 working days after the receipt of results that indicate non-detectable unless a CIH reviews the results and determines re-monitoring is not necessary. It is not clear what the benefit of this is. A very large percentage of exposure assessment results for the semiconductor industry are predictably going to be non-detectable. Requiring most IH sampling to be repeated in this instance unless a CIH reviews the results is also not consistent with existing OSHA rules and practices, and this will have no bearing on reducing risk to workers in the semiconductor industry and other facilities where non-detection results are likely.

D. Timing of ECEL Requirements Should Be Extended and Phased-In

SIA recommends EPA consider more practical timelines for implementation of the ECELs and WPCC. SIA suggests EPA consider industry-specific phase-in periods for facilities in differing commercial sectors.

The numerous additional and often confusing measures EPA has proposed for PCE will require many new actions to be taken, including in workplaces already using PCE in accordance with established IH programs. SIA suggests EPA consider adopting a phase in approach for the ECEL portion of the requirements in particular. Perhaps EPA should permit any facility that already meets the OSHA PEL to make progress toward achieving compliance ECEL, such as by meeting the ACGIH TLV of 25 ppm within two years from the effective date of the TSCA PCE rule. If EPA's proposed ECEL is to remain unchanged, facilities meeting the ACGIH standard within two years would have an additional two years thereafter to permit them to transitions to the EPA ECEL.

E. Training

Although EPA refers to the OSHA PPE framework, the Proposed Rule requires annual training related to PCE. It is not clear in the EPA proposed rulemaking if the training requirements are tied to the results of a facility's PCE exposure assessment and how the results compare to the ECEL. PCE being present or used in the workplace does not necessarily equate to potential for worker exposures and a need for mandatory training. The Agency's rule should be modified to tie the training requirements to the results of monitoring for PCE.

F. Exposure Control Plan

The Exposure Control Plan requires the inclusion of the name of all workers who may be potentially exposed to PCE. In large work sites with centralized training, work procedure and certification systems (each covering potentially multiple chemical substances and workplace operations), tracking training and certification of workers often is performed using enterprise company-wide systems. It will be exceptionally burdensome for workplaces to need to create a separate, chemicals-specific system to record the name of every worker in a dynamic multi-employer worksite (employees and contractors) just for TSCA recordkeeping purposes.

A better approach would be to include the job types-descriptions-certifications in the Exposure Control Plan instead of specific employee names. The number of resources needed to update the Exposure Control Plan with changing names of workers that are routinely added or deleted from such a plan does not create better adherence to training and work practice requirements and creates an administrative burden that does not improve worker safety.

G. Preventing Direct Dermal Contact

EPA is seeking comment on the possible use of dermal charcoal patch testing to quantify potential dermal exposure.

Dermal patch testing is not currently a best practice by IH professionals due to concerns about the feasibility of dermal patch testing and confusion about what the results indicate (e.g., quantification of vapor versus quantification of liquid breakthrough or permeation).

In the industrial hygiene profession, staff rely on chemical permeation, penetration, and degradation data from chemical protective clothing suppliers that test their products using ASTM methods. This data ensures 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 chemical in question. Ultimately, the selection of chemical protective PPE is still built on chemical protective clothing supplier testing and the material's effectiveness as a barrier against the chemicals in question. The regulation should be clarified to permit reliance on such information.

IV. Additional Areas of Concern to SIA Members

A. Hierarchy of Controls Requirements are Confusing and Ambiguous

SIA generally supports, and IH professionals agree, that that facilities should implement their IH programs taking into consideration "the hierarchy of controls" and that facilities making use of potentially hazardous substances should use "pollution prevention to control exposures whenever practicable." However, SIA does not support the requirements in the proposed PCE rule that would mandate that facilities implementing the WCPP requirements create records or otherwise substantiate that they have "institute[d] one or a combination of elimination, substitution, engineering controls or administrative controls to reduce exposure to or below the ECEL" or to "demonstrate that such controls are not feasible." Industrial hygiene professionals designing programs must ensure such programs reflect a facilities' physical plant, existing technologies and equipment, and other pertinent factors. In certain instances, a chemical substance may be one which is essential to ensuring product performance and a chemical for which no technically feasible alternative exists. SIA considers it to be inappropriate for EPA to create and impose a requirement that a business to create records reflecting how such "hierarchy of controls" and "pollution prevention" determinations were made. Such a requirement is likely to lead to opportunities for Agency enforcement personnel to review such records and to potentially question whether an on-site, or "in-house" IH professional's judgments were properly made and/or documented. SIA opposes including such ambiguous requirements which will create one more administrative burden and unnecessary opportunities for compliance issues to arise which will have no direct relationship to mitigating potential exposures in the workplace.

B. Critical Uses

SIA recommends EPA take steps as soon as possible to articulate guidelines or a framework of regulatory standards it is and intends to routinely follow for proposing (or considering requests for) TSCA 6(g) "critical" or "essential" use exemptions. SIA members are aware of numerous chemical substances in use at their facilities that are absolutely essential to the continued production of reliable semiconductors and to the expansion of production facilities and capabilities in the U.S. pursuant to the CHIPS and Science Act. There is little doubt that the necessary findings can be made for the continued use of such substances under Section 6(g)(1)(A), (B), and (C). SIA would be pleased to assist EPA in developing such guidelines.

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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 Section 6 rules.