HEALTHIER WORKPLACES | A HEALTHIER WORLD

July 19, 2023

Michael S. Regan
Administrator
United States Environmental Protection Agency

AIHA's Recommendations on EPA's Proposed Rule on Perchloroethylene (PCE)

Agency/Docket Numbers: EPA-HQ-OPPT-2020-0720 / FRL-8329-02-OCSPP
RIN: 2070-AK84

Dear Administrator Regan:

AIHA, the association for scientists and professionals committed to preserving and ensuring occupational and environmental health and safety (OEHS), appreciates the opportunity to provide feedback on the United States Environmental Protection Agency's (EPA) proposed rule on perchloroethylene (PCE). We hope you find our feedback useful and are happy to answer any questions you may have.

1. EPA is requesting public comment on all elements of the proposed regulatory action and the alternative regulatory actions.

AIHA recognizes and applauds EPA's actions to reduce harmful exposures to chemical substances which have toxic properties to people, property and the environment. However, a more thorough examination is needed with an explanation of how enforcement will be conducted with respect to Occupational Safety and Health Administration (OSHA) statutory responsibilities for worker health and safety.

AIHA encourages EPA to provide additional emphasis and clarification on PCE air sampling statistics and PCE analytical methods that includes sampling and analysis limitations. Further, AIHA believes that EPA's underlying risk assessment fails to comply with TSCA Section 6(b) risk evaluation requirements, including accounting for exposures with real world industrial hygiene (IH) practices under the conditions of use, describing the weight of scientific evidence for the identified hazard and exposure, using scientific information employed in a manner consistent with reproducible data using the best available science, and considering the extent of independent verification and peer reviewed information. Under TSCA, EPA in general should build on available published data to construct a more realistic risk evaluation.

AIHA also suggests that EPA consider a more global approach and include review and consideration of the European Union (EU) rules for the Registration, Evaluation, Authorization and Restriction (REACH) from the European Chemicals Agency, and coordination with REACH with a global perspective with global harmony.[1] For example:

> "REACH is a regulation of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. It also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals. In principle, REACH applies to all chemical substances; not only those used in industrial processes but also in our day-to-day lives, for example in cleaning products, paints as well as in articles such as clothes, furniture and electrical appliances. Therefore, the regulation has an impact on most companies across the EU."

AIHA believes that EPA should more accurately define the level of exposure that is considered significant regarding PCE.

AIHA encourages EPA to provide documentation from peer reviewed research. For example, the EPA 2020 PCE "Unreasonable Risk Determination"[2] has no peer reviewed research articles in the references' section and lists only nine U.S. government references.

AIHA believes that EPA should provide a comprehensive list of references and citations from published research confirming this characterization and any other adverse health effects from PCE. For example, the references from the Documentation of PCE TLV published by the American Conference of Governmental Industrial Hygienists, and IARC Monograph 106 for (tetrachloroethylene) PCE available at https://monographs.iarc.who.int/wp-content/uploads/2018/06/mono106-002.pdf. This thorough examination of PCE by the IARC Working Group is 350 pages with references.

4. EPA requests comment on whether EPA should promulgate definitions for the conditions of use covered by the 2020 Risk Evaluation for PCE that would not be prohibited, and, if so, whether the descriptions in this unit are consistent with the conditions of use evaluated in the 2020 Risk Evaluation for PCE and whether they provide a sufficient level of detail to improve the clarity and readability of the regulation.

AIHA encourages EPA to provide additional clarification regarding the proposed definitions and does not believe that the level of detail in the 2020 Risk Evaluation for PCE is sufficient for clarity, readability, understanding, and implementation of the proposed regulation.

[1] https://echa.europa.eu/legislation

[2] https://www.epa.gov/system/files/documents/2022-12/PCE_Final%20Revised%20RD_12-5-22.pdf

5. EPA requests comment on the impacts, if any, a prohibition on the processing of PCE into a formulation, mixture or reaction product in other chemical products and preparations, or other aspects of this proposal, may have on the production and availability of any pesticide or other substance excluded from the TSCA definition of "chemical substance."

AIHA concurs with the Halogenated Solvents Industry Alliance (HSIA) concerns regarding the EPA PCE risk evaluation.[3] Specifically,

> "These comments describe how the PCE risk evaluation was not conducted pursuant to, or in a manner that satisfies the TSCA risk evaluation requirements in Section 6(4), and therefore do not provide an adequate basis for either the initial risk determination or this proposed revised risk determination. Particularly for conditions of use evaluated in the manufacture and processing as a reactant/intermediate, the exposure assessments were not realistic and do not reflect current industrial hygiene practices. For the Risk Evaluation in general, the analysis of the Cavalleri et al. (1994) study was flawed, and EPA's evaluation of the mouse liver tumor mode-of-action (MOA) was inaccurate and did not represent the best available science."

9. EPA requests comment on allowing a de minimis level of PCE in products (*i.e.,* concentrations less than 0.1% by weight) to account for impurities.

AIHA believes a de minimus concentration may not prevent possible exposures above the ECEL. More research in this area is needed.

10. EPA is soliciting comment regarding an ECEL action level that is half the ECEL and any associated provisions related to the ECEL action level when the ECEL is significantly lower than the OSHA PEL.

AIHA encourages EPA to clarify its position on the OSHA PEL for PCE and whether the EPA limit excludes and disallows use of the current OSHA PCE PEL or other international exposure limits, including the ACGIH TLV®.

11. EPA is requesting comment on issues around the viability of current analytical methods and detection limits for occupational perchloroethylene sampling and/or monitoring methods.

Please refer to NIOSH Manual of Analytical Methods #1003 for workplace air sampling.

[3] https://hsia.org/wp-content/uploads/2022/08/HSIA-Comments-Revised-PCE-Risk-Determination.pdf

12. EPA is soliciting comments regarding the timing of the initial exposure monitoring so that it would be representative of all tasks involving PCE where exposures may approach the ECEL. EPA is also soliciting comments regarding use of area sampling instead of personal breathing zone as a representative sample of exposures.

Area samples alone are never a substitute for a comprehensive IH evaluation with personal air samples and evaluation of possible routes of exposure with feasible controls.

13. EPA requests comment on the timeframes for periodic monitoring outlined in Table 1 of this unit.

Periodic monitoring is determined from a comprehensive industrial hygiene evaluation and possible need for additional air monitoring, skin absorption potential with possible biological (urine, exhaled air or blood) monitoring.

14. EPA is soliciting comment on requiring warning signs to demarcate regulated areas, such as the requirements found in OSHA's General Industry Standard for Beryllium.

OSHA determines “regulated areas” in its current workplace health and safety standards. Currently, there are no existing PCE regulated areas required by OSHA.

15. EPA requests comment on available methods to measure the effectiveness of engineering and administrative controls in preventing or reducing the potential for direct dermal contact to PCE. EPA is also requesting comment on available monitoring methods, such as charcoal patch testing, as feasible or effective methods to measure potential direct dermal contact with PCE.

AIHA concurs with HSIA: “any potential PCE dermal exposures are for short durations and, combined with the industry standards for good IH practices, require removal and disposal of potentially contaminated gloves and hand washing after each task completion, do not justify an 8-hour period for absorption of PCE through skin.”[4]

[4] https://hsia.org/wp-content/uploads/2022/08/HSIA-Comments-Revised-PCE-Risk-Determination.pdf.

16. EPA is requesting comment on whether there should be a requirement to replace cartridges or canisters after a certain number of hours, such as the requirements found in OSHA's General Industry Standard for 1,3-Butadiene, or a requirement for a minimum service life of non-powered air-purifying respirators such as the requirements found in OSHA's General Industry Standard for Benzene.

Respirator cartridge change-out schedules are dependent on potential air concentrations, specific work conditions and contaminant breakthrough time. These elements are part of a comprehensive respiratory protection program administered by an industrial hygienist.

17. EPA is soliciting comments on the requirements proposed for appropriate PPE selection, the effectiveness of PPE in preventing direct dermal contact with PCE in the workplace, and general absorption and permeation effects to PPE from direct dermal exposure. In addition, EPA understands that some workplaces rinse and reuse PPE after minimal use and is therefore soliciting comments on the impact on effectiveness of rinsing and reusing certain types of PPE, either gloves or protective clothing and gear. EPA also requests comment on the degree to which additional guidance related to use of PPE might be appropriate

AIHA concurs with HSIA:

> "...the models EPA used to estimate the amount of PCE that is retained by workers from dermal contact was not based on any supporting information and overestimated any potential exposure. These "worst-case scenarios" assumed unrealistic dermal exposure durations and failed to recognize basic industrial hygiene (IH) practices, including implementation of OSHA-compliant standard operating procedures (SOPs)..."[5]

Furthermore:

> "Despite the SOPs in place to prevent any exposure and potential for exposure limited to the short-term tasks, EPA estimated dermal exposure to PCE for workers in manufacturing and processing using Kasting and Miller (2006) with the following assumptions: (1) one dermal contact with undiluted PCE which coats fully one or both hands per work shift; (2) workers do not wash their hands at any point during the 8-hour work shift if gloves are not worn; and (3) a worker wears the same pair of gloves for the entire 8-hour work shift without stopping to wash their hands and/or change their gloves. EPA provides no documentation or justification for these assumptions other than the intent to establish a theoretical "worst-case scenario." As a result of these assumptions, EPA very substantially overestimated worker exposure

[5] https://hsia.org/wp-content/uploads/2022/08/HSIA-Comments-Revised-PCE-Risk-Determination.pdf

to PCE from dermal contact in facilities that manufacture and use PCE as a reactant or intermediate."[6]

18. EPA is requesting comment on how owners and operators can engage with potentially exposed persons on the development and implementation of an exposure control plan and PPE program.

We believe that EPA should coordinate with OSHA in identifying the compliance details for the development and implementation of an exposure control plan and PPE program. Potentially exposed persons can best be engaged through a site-specific training program developed by an experienced industrial hygienist.

22. EPA requests comment on the primary alternative regulatory action (a combination of prohibitions, requirements for a WCPP, and prescriptive controls) and whether any elements of this primary alternative regulatory action described in this unit should be considered as EPA develops the final regulatory action. In particular, EPA is requesting comment on the likelihood of successful compliance with a PCE WCPP, as described in Unit IV.A., for the conditions of use listed for the primary alternative regulatory action of PCE WCPP in Unit IV.B. Further, EPA is soliciting comment on prescribing specific engineering or administrative controls that would reduce inhalation and dermal exposures enough to address the unreasonable risk across all workplaces engaged in a condition of use. EPA also requests comment on any advantages or drawbacks for the timelines outlined in this unit compared to the timelines identified for the proposed regulatory action in Unit IV.A.

AIHA does not believe that in certain instances engineering controls can reduce exposures to below the level specified with the ECEL in the WCPP. More research is needed in this area and should be funded through NIOSH.

AIHA concurs with HSIA: "Risk evaluations under TSCA § 6(b) are not screening level risk assessments, but are intended to "use scientific information, technical procedures, measures, protocols, methodologies and models consistent with the best available science."[7] Instead of assuming a theoretical worst-case scenario, EPA in its dermal exposure model should use assumptions that are relevant and appropriate to actual workplace practices

[6] https://hsia.org/wp-content/uploads/2022/08/HSIA-Comments-Revised-PCE-Risk-Determination.pdf
[7] https://hsia.org/wp-content/uploads/2022/08/HSIA-Comments-Revised-PCE-Risk-Determination.pdf

using sound IH practices. But the EPA PCE Risk Evaluation fails to acknowledge sound IH practices.

25. EPA is soliciting comment on prescribing specific dermal PPE, such as gloves, for each condition of use that should be considered as EPA develops the final regulatory action. Additionally, EPA is soliciting comment on prescribing specific respirators or APFs for respirators for each condition of use that should be considered as EPA develops the final regulatory action.

PPE controls should be based on the results of a comprehensive IH study on a case-by-case basis. EPA should consider coordinating with OSHA in identifying the compliance details for the development and implementation of an exposure control plan and PPE program.

26. EPA is requesting comment on specific controls that mitigate the unreasonable risk from PCE and that could be included as part of a prescriptive workplace controls requirement, which could be considered as EPA develops the final regulatory action. Specifically, EPA is soliciting comment on combinations of specific engineering controls, administrative controls, and PPE that would reduce inhalation exposures to at or below the ECEL of 0.14 ppm as an 8-hour TWA or prevent direct dermal contact with PCE for all workplaces where such controls would be required. EPA also is soliciting comment on the extent to which such requirements could reduce inhalation exposures to at or below the ECEL of 0.014 ppm as an 8-hour TWA. Additionally, EPA is requesting comment on the compliance timeframe needed to implement engineering controls, administrative controls, and PPE that reduce inhalation exposures to at or below the ECEL of 0.14 ppm as an 8-hour TWA or prevent direct dermal contact with PCE for all regulated entities.

AIHA does not believe 0.014 ppm (14 ppb) ECEL is a feasible limit with current sampling and analytical errors and limitations. To provide comments, AIHA would need to know what EPA coordination with OSHA is proposed and the compliance enforcement plan for EPA ECEL requirements. Who is going to enforce ECEL requirements? Is EPA considering a new 14 ppb PEL? Will OSHA or EPA enforce the new ECEL?

35. EPA is requesting comment on the de minimis concentration limit of PCE in products or formulations.

AIHA understands the GHS for safety data sheets has an existing rule for de minimis concentrations in mixtures.

36. EPA is requesting comment on the extent to which facilities engaged in the industrial and commercial use of PCE as a processing aid in catalyst regeneration in petrochemical manufacturing may already meet the requirements in the proposed and alternative regulatory actions described in Unit IV. to address the unreasonable risk and is soliciting comment on the impact of such requirements on petroleum refining, with special attention to the price of gasoline.

AIHA believes the underlying EPA PCE risk evaluation fails to comply with the TSCA Section 6(b) risk evaluation requirements, including accounting for exposure under the conditions of use with sound industrial hygiene practices, describing the weight of the scientific evidence for the identified hazard and exposure, using scientific information employed in a manner consistent with the best available science, and considering of the extent of independent verification or peer review of information. We believe that EPA should construct a realistic risk evaluation based on the most current peer reviewed research findings.

37. EPA is requesting comment on whether preventing dermal contact with PCE through dermal PPE and training would adequately address the unreasonable risk from dermal exposures for the industrial and commercial use in laboratory chemicals.

Dermal exposure to PCE can play a part in body burden. However, airborne exposures are the most prevalent route of exposure for chlorinated hydrocarbons. ACGIH has a 25 ppm Threshold Limit Value and a 100 ppm short term exposure limit, with an A3 carcinogen designation (confirmed animal carcinogen with unknown relevance to humans). An A3 designation indicates that PCE "is unlikely to cause cancer in humans except under improbable routes or levels of exposure" (2023 ACGIH). ACGIH does not have a "skin" designation for PCE. AIHA believes that more research is needed for dermal exposure body burdens and different types of PPE adequacy.

AIHA believes that any PCE training should be site specific and dependent on several factors regarding the presence of PCE in the workplace, and a site-specific IH evaluation.

38. EPA is requesting comment on whether to include a self-certification requirement for purchasing PCE or PCE-containing products.

AIHA believes that EPA should provide more information regarding allowable self-certification methods for purchasing PCE and more specific information for concentration limits for products that contain PCE and how PCE can be released.

39. As part of the primary alternative regulatory action, EPA is soliciting comment on prescribing specific engineering or administrative controls that would reduce inhalation and dermal exposures enough to address the unreasonable risk across all workplaces engaged in a condition of use.

AIHA believes the ACGIH "Ventilation Manual: A Manual of Recommended Practice for Design", and its companion document "Industrial Ventilation: A Manual of Recommended Practice for Operation and Maintenance", provides engineering control methods, and operation and maintenance information.

Administrative controls depend on the results of a comprehensive industrial hygiene study on a case-by-case basis.

42. EPA requests comment on whether owners and operators should be required to attest to whether and why the exposure controls they have selected would not result in increased air releases of PCE from the workplace, and keep records of that statement as part of the WCPP exposure control plan.

AIHA believes that EPA should provide more clarification regarding OSHA's role in WCPP, enforcement responsibilities for EPA TSCA rule compliance and the NIOSH role for research.

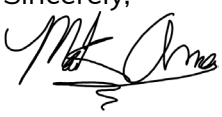
45. EPA requests comments on whether it should incorporate in the rule voluntary consensus standards that meet specified performance criteria for environmental monitoring or measurement and seeks information in support of such comments regarding the availability and applicability of voluntary consensus standards that may achieve the sampling and analytical requirements of the rule in lieu of the proposed approach.

AIHA supports any applicable consensus standards which could affect the specified performance criteria for environmental monitoring or measurement, and voluntary consensus standards that may achieve the sampling and analytical requirements.

Conclusion

If you have any questions about AIHA's comments on this proposed rulemaking or other matters, please contact me at mames@aiha.org or (703) 846-0730. Thank you for your time and consideration.

Sincerely,



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AIHA

About AIHA

AIHA is the association for scientists and professionals committed to preserving and ensuring occupational and environmental health and safety in the workplace and community. Founded in 1939, we support our members with our expertise, networks, comprehensive education programs, and other products and services that help them maintain the highest professional and competency standards. More than half of AIHA's nearly 8,500 members are Certified Industrial Hygienists, and many hold other professional designations. AIHA serves as a resource for those employed across the public and private sectors as well as to the communities in which they work. For more information, please visit www.aiha.org.