HEALTHIER WORKPLACES | A HEALTHIER WORLD

August 29, 2023

Michael S. Regan
Administrator
United States Environmental Protection Agency

AIHA's Recommendations on EPA's Proposed Rule on Carbon Tetrachloride

Agency/Docket Numbers: EPA-HQ-OPPT-2020-0592 / FRL-8206-01-OCSPP
RIN: 2070-AK82

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 carbon tetrachloride (CTC). We hope you find our feedback useful and are happy to answer any questions you may have.

1. EPA is requesting public comment on the proposed regulatory action and alternative regulatory action.

AIHA's comments are from our members who have practical experience in evaluating workplace health hazards while handling, disposing, and working with hazardous chemicals. Industrial hygienists are the professionals who quantify health and safety risks from these substances. Industrial hygienists focus on the hierarchy of controls and follow accepted industrial hygiene principles as a science and art. AIHA concurs where a workplace chemical protection program (WCPP) would require consideration of the hierarchy of controls before use of respirators and other PPE.

EPA should also consider existing standards for environmental and occupational exposures, and peer reviewed research for risk evaluation. For example, EPA's *Risk Evaluation for Carbon Tetrachloride*[1] lacks peer reviewed carbon tetrachloride research as provided in the TLV® documentation and, for example in the Agency for Toxic Substances and Disease Registry (ATSDR) *Toxicological Profile for Carbon Tetrachloride.*

[1] https://www.epa.gov/sites/default/files/2017-06/documents/ccl4_scope_06-22-17.pdf

The Frank R. Lautenberg Chemical Safety for the 21st Century Act was intended to achieve a "more predictable and uniform" approach to chemical regulation. EPA is proposing several new rules for individual chemicals which share similar uses and control measures. To achieve greater predictability for the regulated community and simplified compliance measures, EPA should consider a single rule for all solvents it wishes to regulate.[2]

2. EPA is requesting public comment regarding the need for exemptions from the rule (and under what specific circumstances) pursuant to the provisions of TSCA section 6(g).

AIHA concurs that EPA in coordination with the National Institute for Occupational Safety and Health (NIOSH) research may consider granting a time-limited exemption from a requirement of a Toxic Substances Control Act (TSCA) section 6(a) rule for a specific condition of use if EPA finds that: (1) The specific condition of use is a critical or essential use for which no technically and economically feasible, safer alternative is available, taking into consideration hazard and exposure; (2) compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or (3) the specific condition of use of the chemical substance, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

However, EPA should coordinate with NIOSH to provide a non-mandatory appendix identifying possible safer chemical alternatives, and examples of critical or essential uses for which no technical and economically feasible safer alternative exists.

5. EPA is requesting comment on the proposed rule's rationale.

AIHA recommends EPA coordinate with NIOSH for research into the identification and rationale of exposure controls including: elimination of CTC, substitution of CTC, engineering controls, and administrative controls and how to reduce inhalation exposures in the workplace to either at or below the existing chemical exposure limit (ECEL) or to the lowest level achievable and to prevent or reduce direct dermal contact with CTC in the workplace, and the rationale explaining why each exposure control was selected (e.g., the hierarchy of controls, feasibility, effectiveness, or other relevant considerations.) AIHA believes, however, that EPA needs to operationally define "lowest achievable level" and how and when employers need to "reduce direct dermal contact."

[2] https://www.epw.senate.gov/public/index.cfm/tsca-one-stop-shop

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

AIHA recommends coordination with OSHA for compliance and NIOSH for research in establishing an ECEL action level. AIHA questions the rationale and provisions for the proposed ECEL and its associated action level.

EPA proposes an ECEL of 0.03 ppm as an 8-hour time-weighted average (TWA) to address risk from inhalation exposure in combination with direct dermal contact. However, no standard method is currently available for the determination of skin exposures. Additionally, the NIOSH method 1003 limit of detection is well above the proposed ECEL, therefore the regulated community has no feasible sampling method to ensure compliance.

The NIOSH recommended CTC occupational exposure limit is 2 ppm. The ACGIH TLV® 8-hour TWA is 5 ppm with a 10 ppm short term exposure limit with a suspected carcinogen designation. ACGIH TLV® Documentation states that their recommendations may not be protective for persons who consume alcoholic beverages or who have compromised liver function. The Division of Occupational Safety and Health (Cal/OSHA) also has a 2 ppm permissible exposure limit.[3] In 2005, ATSDR published comprehensive review of the toxicology of carbon tetrachloride with references from CTC research.[4]

> "ATSDR has established an acute duration (1-14 days) inhalation minimal risk level (MRL) of 1.3 mg/m3 (0.2 parts per million [ppm]) based on liver effects in rats, and an intermediate duration (14-365 days) MRL of 0.3 mg/m 3 (0.05 ppm) also based on liver effects in rats. The MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects over a specified duration of exposure."[5]

[3] https://www.osha.gov/chemicaldata/844
[4] https://www.atsdr.cdc.gov/toxprofiles/tp30.pdf
[5] Agency for Toxic Substances and Disease Registry (ATSDR). Toxicological Profile for Carbon tetrachloride (Update). Public Health Service, U.S. Department of Health and Human Services, Atlanta, GA. 1994.

7. EPA is requesting comment regarding the amount of time, if any, it would take the regulated community to develop a method to measure at or below the ECEL over an entire work shift. EPA is interested in what levels of detection are possible over an entire work shift based on existing monitoring methods, justification for the timeframe of the specific steps needed to develop a more sensitive monitoring method, cost associated with a more sensitive monitoring method, and any additional detailed information related to establishing a monitoring program to reliably measure CTC at or below the ECEL.

AIHA is concerned that EPA is setting workplace CTC exposure limits without considering the analytical method sensitivity and specificity, the TLV documentation, ATSDR Minimum Risk Levels, AIHA Emergency Response Planning Guidelines™ (ERPGs) or the NIOSH Standard Method for the chlorinated hydrocarbons limit of detection, limit of quantification or reporting limits. By setting an exposure limit in the part per billion range, air sampling analysis may not be practically measurable using current NIOSH Standard Methods especially since CTC skin exposure adds to the body burden because CTC is absorbed through the skin. No exposure limit currently exists for skin exposure.

In addition, AIHA believes that EPA needs to establish a laboratory accreditation process to ensure CTC laboratory exposure value validation. AIHA recommends a TSCA requirement for CTC analytical laboratory participation like the U.S. Food and Drug Administration's Laboratory Accreditation for Analysis of Foods Program.[6] This TSCA requirement should be implemented by organizations in compliance with ISO standard ISO/IEC 17011:2017, *Conformity Assessment – Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies.*

8. EPA requests comment on whether EPA should promulgate definitions for the conditions of use covered by the 2020 Risk Evaluation for Carbon Tetrachloride, and, if so, whether the descriptions in Unit III.B.1. are consistent with the conditions of use evaluated in the 2020 Risk Evaluation for Carbon Tetrachloride and whether they provide a sufficient level of detail such that they would improve the clarity and readability of the regulation if promulgated.

EPA should provide clarification of "critical" and "essential" and direction with specific conditions of use if EPA finds that: (1) The specific condition of use is a critical or essential use for which no technically and economically feasible, safer alternative is available, taking into consideration hazard and exposure; (2) compliance with the requirement, as applied

[6] https://www.fda.gov/food/food-safety-modernization-act-fsma/fda-recognized-accreditation-bodies-laboratory-accreditation-analyses-foods-laaf-program

with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or (3) the specific condition of use of the chemical substance, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

12. EPA is requesting comment on whether the Agency should require a WCPP or prescriptive controls, including respirators and dermal PPE, for any of the conditions of use EPA is proposing to prohibit.

AIHA supports uniformity to avoid any confusion for these regulatory requirements and emphasizes that the hierarchy of controls should be considered with efforts to minimize the use of PPE.

13. EPA is requesting comment on the proposed implementation timeframe for the WCPP requirements; EPA proposes that they would take effect 180 days after publication of the final rule, at which point entities would be required to conduct initial exposure monitoring and develop an exposure control plan.

AIHA has no comments for this request other than coordination with OSHA is needed for WCPP requirements.

14. EPA is soliciting comments regarding when and how owners and operators could conduct initial exposure monitoring to ensure that it is representative of all tasks likely to be conducted by potentially exposed persons.

A case-by-case approach is needed for how owners and operators could conduct initial or periodic exposure monitoring to ensure that it is representative of all tasks likely to be conducted by potentially exposed persons. An industrial hygiene evaluation depends on how and where chemical substances are used, routes of exposure and development of an air sampling and analysis plan. AIHA recommends sampling plans be developed and implemented by persons certified by the Board of Global EHS Credentialing® (BGC®).

17. EPA is requesting public comments on the proposed conditions for discontinuation of periodic exposure monitoring for the CTC ECEL as part of implementation of the WCPP.

AIHA recommends any WCPP be developed and supervised by an industrial hygienist certified by the Board of Global EHS Credentialing®. A case-by-case approach is needed for

periodic exposure monitoring for the CTC ECEL as part of implementation of the WCPP based on professional judgement and experience of a qualified industrial hygienist.

18. EPA requests comment on the use of area source monitoring instead of personal breathing zone as a representative sample of exposures when monitoring for the ECEL.

Area source sampling is not a replacement for representative industrial hygiene breathing zone sampling of exposures when monitoring for the ECEL.

19. EPA requests comment on available methods to measure the effectiveness of controls in preventing or reducing the potential for direct dermal contact to CTC.

Effective controls reducing the potential for direct dermal contact to CTC depend on the results of an industrial hygiene exposure and control assessment.

20. EPA is requesting comment on available monitoring methods, such as charcoal patch testing, as feasible or effective methods to measure potential direct dermal contact with CTC.

Liver function tests and breath analysis may be helpful for measuring potential CTC body burden. No skin testing for CTC exposure is currently known. More research in this area is needed.

21. EPA requests comment on how the proposed prohibition of increased releases of CTC to outdoor air associated with the implementation of the WCPP/ECEL may impact the availability, feasibility, or cost of engineering controls as a means to reduce workplace exposures to or below the proposed ECEL.

Air captured in the workplace for the control of CTC may be discharged to the outside making the prohibition of environmental releases problematic, although costly charcoal filtration may be effective for reducing environmental CTC release.

23. EPA is soliciting comment on whether any of the requirements for the exposure control strategies, including EPA's proposed prohibition of rotating work schedules for potentially exposed persons, should be modified and considered in the final rule.

The rotation of workers is an administrative control that falls within the hierarchy of controls.

24. EPA requests comment on the requirements proposed for appropriate PPE selection, the effectiveness of PPE in preventing direct dermal contact with CTC in the workplace, and general absorption and permeation effects to PPE from direct dermal exposure.

Most glove materials are not resistant to CTC. The recommended glove material for CTC is polyvinyl alcohol (PVA) or Viton®. However, PVA and Viton are very expensive and PVA is water sensitive. Specific mixtures containing CTC for PPE should be tested according to ASTM F739, *Standard Test Method for Permeation of Liquids and Gases Through Protective Clothing Materials Under Conditions of Continuous Contact*.

25. EPA requests comment on the impact on effectiveness of rinsing and reusing certain types of PPE, either gloves or protective clothing and gear.

Contaminated gloves or certain protective clothing and gear should not be rinsed or reused unless recommended by the PPE manufacturer. Once CTC contacts PPE, permeation and degradation of the material begins.

26. EPA is requesting comment on whether there should be a requirement to replace cartridges or canisters of respirators after a certain number of hours, such as the requirements found in OSHA's General Industry Standard for 1,3-Butadiene (29 CFR 1910.1051(h)), 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 (29 CFR 1910.1028(g)(3)(D)).

Chemical breakthrough time depends on concentration of the contaminant and other environmental factors (RH). The replacement of cartridges or canisters of respirators after a certain number of hours is defined in a location-specific respirator program developed by an industrial hygienist.

27. EPA is soliciting comment on whether 9 months is a reasonable timeframe to implement a respiratory protection program or if additional time is needed.

Respirator programs should be developed before respirators are used in the workplace.

28. EPA requests comment on the degree to which additional guidance related to use of dermal PPE might be appropriate.

EPA should provide guidance for recommended materials which will protect against CTC. See item 24 above.

29. 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.

AIHA believes that employees should be engaged for potentially exposed persons on the development and implementation of an exposure control plan and PPE program. This engagement is best completed during PPE and respirator training.

30. EPA requests comment on the 15-day timeframe for notification of potentially exposed persons of monitoring results and the possibility for a shorter timeframe, such as 5 days.

AIHA believes that a 15-day timeframe for notification of potentially exposed persons of monitoring results is reasonable.

31. EPA will consider compliance timeframes that may be substantially longer or shorter than the proposed timeframes for owners or operators to conduct initial exposure monitoring for the ECEL, implement the DDCC requirements, and any procedural adjustments needed to comply with the requirements outlined as part of the WCPP, and is requesting comment on the feasibility of the proposed compliance timeframes, as well as longer or shorter timeframes.

AIHA is neutral with respect to timeframes that may be substantially longer or shorter than the proposed timeframes for owners and operators to conduct initial exposure monitoring for the ECEL, implement the DDCC requirements, and any procedural adjustments needed to comply with the requirements outlined as part of the WCPP. However, owners or operators should be given sufficient time to implement any new requirements which could involve substantial investments.

32. EPA is soliciting comment regarding the exposure control strategies required under the WCPP and documented in the exposure control plan, including the implementation of additional engineering controls, increase frequency of exposure monitoring, implementation of respiratory and dermal protection and notification of monitoring, and associated costs with the WCPP exposure control strategies implementation.

The compliance and exposure control plan developed by owner or operator management should specify exposure control strategies required under the WCPP including the implementation of additional engineering controls, the frequency of exposure monitoring determine by an industrial hygienist with implementation of respiratory and dermal protection with notification requirements, and associated costs with the WCPP exposure control strategies' implementation.

33. EPA is requesting comment on the types and costs of administrative and engineering controls that potentially regulated facilities use or could potentially use to control exposures in the workplace. EPA is also requesting comment on the baseline use of each identified control. In addition, EPA is requesting comment regarding the effectiveness of any existing administrative and engineering in controlling and/or reducing exposures. EPA requests comment on whether any engineering and administrative controls known by potentially affected sites would have higher or lower per-facility costs than the annualized per-facility costs in the proposed regulatory action. For example, Executive Summary table ES–4 of the Economic Analysis shows that, annualized over 20 years at a 3% discount rate, the per-facility cost of the proposed regulatory action in the Manufacturing condition of use would be $604,787 (this condition of use has an average of 300 workers per site), and the per-facility cost for the Processing as a reactant condition of use would be $231,954 (this condition of use has an average of 113 workers per site).

AIHA recommends consulting NIOSH for EPA regarding the effectiveness of any existing administrative and engineering in controlling and/or reducing exposures including new research for whether any engineering and administrative controls known by potentially affected sites would have higher or lower per-facility costs than the annualized per-facility costs in the proposed regulatory action.

AIHA questions the validity of the EPA cost estimates, which could vary from location to location, especially regarding any manpower or consulting needs, and engineering or environmental controls which would be needed.

34. EPA is soliciting comment on non-prescriptive DDCC requirements as compared to the prescriptive workplace controls of dermal PPE EPA is proposing in Unit IV.A.2.

Please see item 44 below.

35. EPA requests comment on whether it should incorporate in the rule best practices to ensure proper and adequate performance of laboratory fume hoods, such as those identified in OSHA's 29 CFR 1910.1450, Appendix A National Research Council Recommendations Concerning Chemical Hygiene in Laboratory.

AIHA recommends EPA include a non-mandatory reference 29 CFR 1910.1450, Appendix A National Research Council Recommendations Concerning Chemical Hygiene in Laboratory.

36. EPA is requesting comment on whether it should incorporate in the rule specific requirements for laboratory hoods, such as design characteristics and/or a range of face velocities, or some other type of performance standard.

Specific requirements for laboratory hoods including design characteristics and/or face velocities, energy use and expenditures would depend on location specific needs and existing ventilation systems in use. Industrial ventilation design is a subspecialty of industrial hygiene requiring special training and experience. EPA requirements for specific containment devices or other local ventilation systems are not practical. More research is needed on different engineering controls for different systems using CTC. The ACGIH *Industrial Ventilation Manual* is one source of this information.

Additionally, the prescriptive engineering controls for laboratory uses are restricted to chemical fume hoods only. EPA should add other effective engineering controls for laboratory use such as glove boxes. Glove boxes are specifically mentioned in 1910.1450(e)(3)(viii)(B).

37. EPA is proposing to require that each owner or operator of a workplace engaged in the industrial and commercial of CTC as a laboratory chemical ensure fume hoods are in use and functioning properly and that dermal PPE is provided to all potentially exposed persons with direct dermal contact with CTC within 6 months after publication of the final rule. While EPA is proposing requirements within 6 months of publication of the final rule, the Agency will consider compliance timeframes that may be substantially longer or shorter than the proposed timeframe and is soliciting comments on the feasibility of the proposed compliance timeframes, as well as longer or shorter timeframes.

Timelines should be developed in coordination with current OSHA chemical specific requirements.

41. Primary alternative regulatory action: EPA requests comment on engineering controls, administrative controls, PPE, and any combinations of these controls that reduce inhalation exposures to at or below the ECEL or prevent dermal exposure from direct handling of CTC or from contact with surfaces that may be contaminated with CTC and any associated cost related to these controls.

A worksite compliance plan should identify necessary engineering controls, any associated cost related to these controls, feasible administrative controls, PPE and any combinations of these controls that reduce inhalation exposures below the ECEL; and prevent dermal exposure from direct contact or from surfaces that may be contaminated with CTC.

42. Primary alternative regulatory action: EPA is soliciting comments on information to support the consideration of other APFs that are also protective of the highest possible lengths of exposures and on whether or how monitoring should be considered for the alternative regulatory action.

Respirator Assigned Protection Factor, fit testing and training requirements should be included in a site-specific respirator program which should be developed and implemented by an industrial hygienist whenever respirators are required.

43. Primary alternative regulatory action: EPA is requesting comment on whether any of the uses the Agency is proposing to prohibit are ongoing and if EPA should consider a WCPP for those conditions of use of CTC.

EPA should consider a WCPP for those conditions of use of CTC while considering uniformity accurately defined by EPA.

44. Primary alternative regulatory action: EPA is requesting comment on non-prescriptive DDCC requirements as compared to the prescriptive workplace controls of dermal PPE EPA is proposing in Unit IV.A.2.

AIHA concurs that direct dermal contact control (DDCCP) requirements should allow more flexibility to owners and operators to choose their controls when compared with requiring specific prescriptive controls. The exposure control plan including engineering controls, the frequency of exposure monitoring, implementation of respiratory and dermal protection and notification of monitoring, and associated costs with the WCPP exposure control strategies are notable. The use of dermal PPE for CTC could be problematic because most glove materials do not provide protection from CTC skin contact.

The required PPE recordkeeping including "The name, workplace address, work shift, job classification, and work area of each person reasonably likely to directly handle CTC or handle equipment or materials on which CTC may present and the type of dermal PPE selected to be worn by each of these persons;"[7] is overly difficult to comply with, particularly for laboratory uses.

45. The Agency is requesting comment on the availability of technically and economically feasible alternatives that are comparably beneficial to health or the environment for CTC.

NIOSH should conduct research to identify feasible alternatives for CTC.

46. EPA is requesting comment on the types and costs of technologies firms would adopt to comply with the prohibition on increased releases of CTC to outdoor air associated with engineering controls used in the implementation of the WCPP/ECEL.

To comply with the prohibition on increased releases of CTC to outdoor air associated with engineering controls used in the implementation of the WCPP/ECEL could be quite costly and could limit the use of CTC where possible.

[7] https://www.federalregister.gov/documents/2023/07/28/2023-15326/carbon-tetrachloride-ctc-regulation-under-the-toxic-substances-control-act-tsca

47. EPA requests comment on whether and to what extent these technologies would reduce CTC emissions at facilities that adopt them to or below emissions levels that existed prior to implementation of the WCPP/ECEL.

This could potentially be done through air emissions modeling to assist with determining effectiveness and feasibility. EPA would need to consider the cost-benefit of such an approach.

48. EPA is seeking comment on its conclusions that its proposed action in combination with the emissions standards resulting from existing NESHAP requirements would reduce risk sufficiently to the general population and fenceline communities, and whether, consistent with TSCA section 9(b), any other statutory authorities administered by EPA should be used to take additional regulatory action identified as necessary to protect against such risk.

EPA should consider AIHA ERPGs, which would reduce risk sufficiently to the general population and fenceline communities consistent with TSCA section 9(b). ERPGs are guidelines based on current knowledge to evaluate possible health effects to the public or emergency response personnel. ERPG 1 is the maximum airborne concentration below which it is believed nearly all individuals could be exposed up to one hour without experiencing other than mild transient adverse health effects or perceiving a clearly defined objectionable odor; ERPG 2 is the maximum airborne concentration below which it is believed nearly all individuals could be exposed up to one hour without experiencing or developing irreversible or other serious health effects. ERPG-3 is the maximum airborne concentration below which nearly all individuals could be exposed for up to one hour without experiencing or developing life-threatening health effects.[8]

49. EPA is soliciting comment on whether EPA should require ambient air monitoring at fenceline locations or facility emissions source monitoring to demonstrate compliance with the proposed requirement that engineering controls that are implemented as part of a WCPP/ECEL under this rule would not result in the ventilation of more CTC outside.

Fenceline ambient air monitoring is not effective for episodic CTC emissions. However, source sampling, although costly, may be effective for monitoring emissions.

[8] https://www.aiha.org/get-involved/aiha-guideline-foundation/erpgs

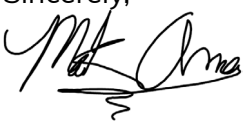
50. EPA is soliciting comment on the need for and associated costs of ambient air monitoring at fenceline locations or facility emissions source monitoring, as well as information on the frequency and nature of air monitoring EPA should consider including as requirements in the final rule (such as a detection limit for CTC).

EPA should identify specific proposed environmental monitoring requirements. Environmental monitoring may include fenceline locations, although possibly ineffective for facility emissions source monitoring. EPA should consider including any such requirements in the proposed rule.

Conclusion

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

Sincerely,



Mark Ames
Director, Government Relations
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.