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December 5, 2023

Michael S. Regan
Administrator
United States Environmental Protection Agency

AIHA's Recommendations on EPA's Proposed Rule on Trichloroethylene (TCE)

Agency/Docket Numbers: EPA-HQ-OPPT-2020-0642 / FRL-8317-01-OCSP
RIN: 2070-AK83

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 trichloroethylene (TCE). 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 primary alternative regulatory action.

EPA's approach to risk management mirrors the approach used for other recently proposed rules (e.g., perchloroethylene, carbon tetrachloride). Specifically, the approach requires regulated entities to develop a Workplace Chemical Protection Plan (WCPP) that includes compliance with an inhalation occupational exposure limit referred to by EPA as the existing chemical exposure limit (ECEL). This approach might be suitable for entities that currently do not have occupational safety and health programs, exposure controls and administrative controls to limit exposure. However, it ignores those entities that do have such exposures and controls in place, particularly those that are required to comply with and do comply with regulations from the Occupational Safety and Health Administration (OSHA).

In contemplating the management of risks to chemical exposures, EPA should consider current standard practices and best practices. The AIHA Guideline Foundation¹ is developing Principles of Good Practice that are practical, proven, and available practices that provide robust and reliable performance to effectively protect workers and communities

¹ <https://www.aiha.org/get-involved/aiha-guideline-foundation>

from unacceptable risks. To the extent EPA is prescribing risk management action, they should be consistent with current industrial hygiene practices and existing OSHA regulations so as not to create unnecessary burdens and confusing or conflicting requirements.

With respect to the ECEs proposed, whether for TCE or other chemicals, EPA should consider current occupational exposure limits used globally and the level of risk mitigation afforded. Moreover, EPA should acknowledge that even at the high end of the occupational exposure limit (OEL) range, there are a number of industrial hygiene practices that are necessary in order to comply with an OEL that bolster exposure control when compared to a workplace with no exposure controls. In addition, EPA should consider the range of current OELs and the motivations of various authoritative bodies in setting their limits. For TCE, the range is approximately 1 ppm to 100 ppm as an 8-hour time-weighted average (TWA).

Finally, the ECEL as developed by EPA appears to be a health-protective standard below which there is no unreasonable risk for all potentially exposed or susceptible subpopulations (PESS), and in cases where a substance has a threshold effect, is a level where there is no risk. In potentially setting an OEL for regulatory compliance, EPA should focus on eliminating unreasonable risk, not all risk, in a manner consistent with the particular condition of use and the associated employed subpopulation, rather than all PESS.

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

EPA proposes several time-limited Section 6(g) exemptions from prohibition; however, the conditions of those exemptions require a WCPP and compliance with the proposed ECEL. According to EPA's approach, if an entity has a WCPP and can meet the ECEL then it has mitigated the unreasonable risk. Therefore, a Section 6(g) exemption shouldn't be necessary. Those exemptions should be granted for situations where existing unreasonable risk remains uncontrolled. A risk management rule must include a de minimis threshold. It is impossible to demonstrate the absolute absence of a substance.

7. EPA requests comment on whether it should consider a *de minimis* level of TCE in formulations to account for impurities (e.g., 0.1% or 0.5%) when finalizing the prohibitions described in Units V.A.1.b. and c., and, if so, information on and rationale for any level that should be considered *de minimis*.

It is critical that EPA include a *de minimis* level of TCE in formulations to account for impurities. It will not be possible to achieve a “zero” (undetectable) level in every instance and trivial quantities will pose negligible risk.

14. EPA is requesting comment on the selection of the fetal cardiac defects endpoint for the ECEL of 0.0011 ppm in the proposed regulatory action, rather than the immunotoxicity endpoint on which the unreasonable risk determination is based, which would result in an ECEL of 0.0040 ppm, as further detailed in Unit IV.A.

EPA indicates that their OEL of 0.0011 ppm is based upon one day of exposure (page 74721 of the proposed rule), however, that goes against how OELs are created since OELs are based on chronic exposure.

15. EPA is requesting comment on personal air sampling devices that are capable of detecting indoor air TCE concentrations at or below the proposed ECEL action level of 0.00055 ppm (0.0029 mg/m³) with the requisite precision and accuracy.

To improve compliance with the WCPP, industrial hygiene methods will need to detect below the ECEL-Action Level, not simply at the ECEL. That means methods will need to focus on detection limits below half the ECEL, in the part per trillion (ppt) range. According to the WCPP, if you are not below the ECEL-Action Level, monitoring must continue every six months.

Detection limits are typically set at a fraction of the OEL. Current practices for OSHA and the National Institute for Occupational Safety and Health (NIOSH) require laboratories to quantify results by at least 10% of the exposure limit. As such, when a chemical has an ECEL that is much lower than the OEL, labs may not be capable of quantifying results below the ECEL. As a result, current non-detect results above the ECEL create a challenge for analysts trying to select the best statistical approach to translate those non-detect values into usable values that can be compared against the ECEL, and ECEL Action Level. Conversely, if EPA were to set an interim ECEL for TCE based on the limit of detection associated OSHA Method 1001, it should set the proposed action level at 10X the limit of detection, that is, 180 ppb (0.180 ppm), and the ECEL at 360 ppb (0.360 ppm).

Labs will need to switch from typical methods that use sorbent tubes and sample media solvent desorption (OSHA Method 1001) to a more sensitive method that may involve a completely different approach. EPA's Office of Research and Development (ORD) maintains a Compendium of Methods for determination of toxic organic compounds in ambient air. EPA Compendium Method TO-14 and TO-15 use canister-based sampling and gas chromatographic analysis that can be used for ambient concentrations of volatile organic compounds. However, Method TO-14 appears to have a similar limit of detection as OSHA Method 1001 though TO-15 "applies to ambient concentrations of VOCs above 0.5 ppbv."

EPA TO-17 Method uses a sorbent tube/thermal desorption/gas chromatographic-based monitoring method for VOCs in ambient air at 0.5 to 25 parts per billion (ppbv) concentration levels. However, the vast majority of industrial hygiene samples collected across industry use solvent desorption methods. The use of thermal desorption is not common across industry, as a result very few labs have this analytical capability. Thermal desorption technology can detect chemicals at much lower concentrations but the changeover to this new technology can be difficult, expensive, and take a long time. Very few labs have the capability to analyze industrial hygiene samples using thermal desorption. First, it will require labs to purchase new thermal desorption analytical equipment. Second, this will require equipment set-up and testing validation. Third, as this is not common technology, additional training and expertise will be needed to reliably utilize this equipment. Additionally, most thermal desorption methods are active, requiring a sampling pump, which increases the complexity of the collection process. This change is going to take a lot of investment and time before it will be widely available for use by industry.

16. EPA is requesting comment on using OSHA Method 1001, which has a personal breathing zone limit of detection for TCE of 18 ppb, or 0.018 ppm, to set an interim exposure limit of 0.036 ppm, with an action level of 0.018 ppm, as described further in Unit V.A.2.b.i.

Using the industrial hygiene convention of being able to detect 10% of the occupational exposure limit would lead to an interim exposure limit of 0.360 ppm, with an action level of 0.180 ppm.

The maximum sampling time is 240 minutes, so an occupational hygienist (or occupational health technician) would have to collect two samples for the eight hour shift. This is doable, however, it would take longer to assess the different similar exposure groups and the high risk tasks within each of those groups. Because of this, more time to meet compliance would be required.

Since the NIOSH 1022 method (as indicated in an earlier comment) has 0.026 ppm for a passive badge over eight hours, it may be better to follow that method since it is passive and since the badge would not need to be changed out.

17. EPA requests comments regarding replacing the proposed prohibitions with compliance with the WCPP, in the instance that regulated entities are able to consistently demonstrate compliance with an ECEL through effective controls.

EPA has indicated that exposures below the ECEL do not represent an unreasonable risk. Therefore, if an entity is compliant with the WCPP requirements including the ECEL, then they have mitigated risk to below the threshold of unreasonable and prohibition is unnecessary if not unlawful under TSCA. Moreover, the ECEL currently is designed to mitigate all risk (a level below which there is no adverse health effects). However, the TSCA standard is mitigation of unreasonable risk. This allows for some acceptable risk to remain but the ECEL removes all risk and thus does not fit TSCA's clear purposes.

22. EPA requests comment on how owners and operators should identify the lowest achievable exposure level, what documentation would be needed to support that further reductions are not possible, and whether EPA should provide a definition of meeting the ECEL to the extent possible. Additionally, EPA requests comment on whether current monitoring methods are able to detect airborne concentrations at the ECEL and action level values. EPA expects that detection and adherence to extremely low-ppm levels of TCE may present challenges to some in the regulated community; therefore, EPA is also requesting comment on whether EPA should propose specific requirements following results indicating non-detectable concentrations of TCE (non-detects), or a requirement that a specific monitoring method be used.

The proposed requirement in 40 CFR 751.707(b)(3)(i)(E) to re-monitor within 15 working days when results indicate non-detect is unnecessary. Additionally, incorporating a six-sample rolling average as the statistical evaluation would incorporate ongoing validation of exposure levels for a particular task thus removing any potential need for resampling based on a non-detect result.

26. EPA requests comment on the timeframes for periodic monitoring outlined in Table 1 of Unit V.A.2.

EPA requested comment on the timeframes for periodic monitoring outlined in Table 1 of the proposed regulation. EPA has proposed that periodic exposure monitoring be required at least once every five years when all initial exposure monitoring is below the ECEL action level (<0.00055 ppm 8-hour TWA). This requirement for initial monitoring every five years is unnecessary and overly burdensome for firms that have demonstrated compliance and whose processes have not changed in five years or more. It also deviates from the

monitoring frequencies in the OSHA Substance Specific Regulated Chemicals Standards. A lack of alignment between regulatory programs can create confusion for regulated entities resulting in possible compliance gaps. Additional monitoring should be based on local risk assessment reviews and management of change practices that seek to understand where changes have occurred so monitoring can be conducted to quantify changes in exposure risk. The other Periodic Monitoring Requirements proposed are appropriate, because the three-month/six-month strategy aligns with other OSHA practices with which regulated entities will be familiar.

In the Proposed Risk Management Rule for Methylene Chloride (88 FR 28303), EPA proposed the five-year data refresh because of fatalities:

“Given the steep dose response for methylene chloride that may lead up to and include fatalities as a result of inhalation exposure, EPA is instead proposing to require that a minimum initial monitoring frequency be established at 5-year intervals.”

There is no similar concern for fatalities from (acute) trichloroethylene exposure. As such, recurring five-year initial monitoring is not warranted.

27. 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.

EPA should defer to, and incorporate as necessary, existing performance-based programs for exposure reduction rather than enumerating specific elements in its regulations.

Although EPA notes that some of these requirements might be similar to prescriptive requirements in existing OSHA Standards for Toxic and Hazardous Substances (29 CFR § 1910 Subpart Z), we encourage EPA to cite the following OSHA requirements as more appropriate:

- Occupational Health and Environmental Control (29 CFR § 1910 Subpart G)
- Personal Protective Equipment (29 CFR § 1910 Subpart I)
- General Environmental Controls (29 CFR § 1910 Subpart J)

Prescriptive standards with respect to respirator cartridge replacement are inadvisable as the cartridge technology may change over time, resulting in an outdated regulatory requirement. A cross-reference to the Subpart I provision for Personal Protective Equipment, specifically 29 CFR § 1910.134 – Respiratory Protection, would be more appropriate with respect to the requirements for a Respiratory Protection Program that would adapt over time to new technology and situations.

31. EPA requests comment on the degree to which additional guidance related to use of gloves might be necessary. Additionally, EPA requests comment on whether EPA should incorporate additional dermal protection requirements into the exposure control plan or require consideration of the hierarchy of controls for dermal exposures.

AIHA concurs with EPA's proposal to require dermal protection for tasks where dermal exposure can be expected to occur. However, the text proposed for 40 CFR 751.311(e)(4) should reflect the preamble of the proposed rule. That is, the text should be changed to remove "is possible" to read: where dermal contact with TCE can be expected to occur.

We encourage EPA to follow recommendations from OSHA and the US Navy regarding how to determine glove assessments for mixtures that contain TCE. This includes assessing all of the components within the mixture and selecting the component's permeation rate that has the fastest permeation rate to represent the entire mixture's permeation rate.^{2,3}

33. EPA requests comment relative to the ability of owners or operators to conduct initial monitoring within 6 months after date of publication of the final rule in the Federal Register, and anticipated timeframes for any procedural adjustments (i.e., use of new technologies for personal breathing zone monitoring at extremely low-ppm levels of TCE) needed to comply with the requirements outlined in Unit V.A.2., including establishment of a respiratory protection program and development of an exposure plan.

It is important to ensure that sufficient lab capacity is available for compliance with the ECEL. It may not be feasible to comply with requirements to conduct initial monitoring within six months after the rule is final due to a lack of laboratory capacity. A large number of entities will be required to comply with a new exposure limit that necessitates a new, lower detection limit. This will stress the workers and laboratories that analyze the samples. EPA should confirm that there is sufficient capacity for companies to comply with the proposed requirements. If there currently is not sufficient capacity among firms that would support those regulated entities who need to satisfy the requirements of the proposed rule, EPA must ensure there is adequate time for such capacity to be established as part of the timeline for compliance with the rule.

² Navy and Marine Corps Public Health Center. "Industrial Hygiene Field Operations Manual: Technical Manual NMCPHC-TM6290.91-2 22. November 2019.

https://www.med.navy.mil/Portals/62/Documents/NMFA/NMCPHC/root/IndustrialHygiene/12IHFOM_CH10.pdf?ver=0bNK2nGTOvPn4aIGHBzLoQ%3d%3d

³ Occupational Safety and Health Administration. "OSHA Technical Manual (OTM) Section II: Chapter 2". <https://www.osha.gov/otm/section-2-health-hazards/chapter-2>

A complicating factor is EPA's proposal that "Exposure samples must be analyzed using an appropriate analytical method by a laboratory that complies with the Good Laboratory Practice Standards (GLPS) in 40 CFR part 792." The scope of the EPA GLPS is described as follows:

"This part prescribes good laboratory practices for conducting studies relating to health effects, environmental effects, and chemical fate testing."

Monitoring does not fall into these three categories. While it is appropriate that industrial hygiene compliance monitoring include protocols and practices to ensure the quality and integrity of the data, EPA should follow practices currently used by industrial hygiene practitioners.

Application of GLPS is not a current practice of industrial hygiene practitioners, consultants, and laboratories and will result in significant delays in processing samples as the current capacity is not sufficient to meet EPA's requirements. Furthermore, the collection of occupational monitoring samples need not be conducted under GLPS regulations where planning and collection is overseen by a Certified Industrial Hygienist or Environmental Professional as defined at 40 C.F.R. § 312.10.

EPA should apply the policy described in its New Chemicals Exposure Limits section 5(e) in the TSCA New Chemicals Program. Namely, that compliance with TSCA GLPS is not required where exposure monitoring samples are analyzed by a laboratory accredited by either: (A) the AIHA Industrial Hygiene Laboratory Accreditation Program (IHLAP); or (B) another comparable program approved in advance in writing by EPA.

Similarly, EPA has accepted AIHA IHLAP accredited laboratories associated with study plans in response to test orders for occupational monitoring data.

44. EPA requests comment on the ability of regulated entities to conduct initial monitoring within 12 months, anticipated timeframes for any procedural adjustments needed to comply with the requirements, and the extent to which this option could result in additional exposure, compared to the proposed regulatory option as described in Unit V.A.

It is important to ensure that sufficient lab capacity is available for compliance with the ECEL. It may not be feasible to comply with requirements to conduct initial monitoring within 12 months after the rule is final due to a lack of laboratory capacity. A large number of entities will be required to comply with a new exposure limit that necessitates a new, lower detection limit. This will stress the workers and laboratories that analyze the samples. EPA should confirm that there is sufficient capacity for companies to comply with the proposed requirements. If there currently is not sufficient capacity among firms that would support those regulated entities who need to satisfy the requirements of the proposed rule, EPA

must ensure there is adequate time for such capacity to be established as part of the timeline for compliance with the rule.

49. EPA requests comment on whether 50 years is a reasonable timeframe for a TSCA section 6(g)(1)(A) exemption for the cleanup of TCE-contaminated water and groundwater sites. Specifically, EPA requests comment on the anticipated duration of TCE cleanup projects, and whether there will be projects that may continue and require the disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works beyond 25 years.

EPA and the Superfund office in particular are already well aware that difficult cleanups involving TCE have continued far beyond the 25-year discharge prohibition proposal, particularly where difficult geology and/or DNAPL containing chlorinated solvents (such as PCE and TCE) are encountered. If EPA desires the removal of TCE from groundwater and other contaminated water sources, it does not make sense to limit the exemption at all.

50. EPA requests comment on whether industry anticipates increased releases of TCE to outdoor air associated with the implementation of the WCPP. EPA requests comment on whether owners and operators should be required to attest in their exposure control plan that engineering controls selected do not increase emissions of TCE to ambient air outside of the workplace and document in their exposure control plan whether additional equipment was installed to capture emissions of TCE to ambient air. EPA requests comment on how such a requirement could impact the availability, feasibility, or cost of engineering controls as a means to reduce workplace exposures to or below the proposed ECEL. EPA is also soliciting comment on the frequency and nature of air monitoring EPA should consider including as requirements in the final rule.

EPA requested comment on whether owners and operators should be required to attest in their exposure control plan that engineering controls selected do not increase emissions of TCE to ambient air outside of the workplace and document in their exposure control plan whether additional equipment was installed to capture emissions of TCE to ambient air. EPA states that the proposed requirement is intended to avoid unintended increases in exposure to people (presumably the general population) from TCE emissions to ambient air. EPA also requested comment on how this proposed requirement may impact the availability,

feasibility, or cost of engineering controls as a means to reduce workplace exposures to or below the proposed ECEL.

This proposal seems at odds with reasoning that is articulated later in the proposed rule:

“In the instances where efforts to reduce exposures in the workplace to levels below the ECEL could lead to adoption of engineering controls that ventilate more TCE outside, EPA believes this potential exposure would be limited as a result of the existing NESHAP for TCE for these conditions of use under the CAA.”

AIHA agrees with EPA’s premise that NESHAPs for TCE will mitigate potential general population exposures that could occur as a result of greater workplace controls ventilating TCE outside of facilities. As such, EPA should not implement additional requirements that owners and operators attest in their WCPP/ECEL exposure control plan that engineering controls selected do not increase emissions of TCE to ambient air outside of the workplace.

Additional Feedback on Proposed ECEs

AIHA members who assisted in drafting these comments believe that EPA has failed to appreciate the disconnect being introduced by the proposed ECEL in juxtaposition with the EPA Risk-Based Screening Levels for Air being used under the Superfund RAGS program and other (e.g., RCRA) programs that determine step-wise investigation and remediation limits needed in the CERCLA and RCRA (e.g., Environmental Indicators) programs. The cascading effect of a TSCA determination of ECEL at the 0.0011 or 0.004 ppm levels will now warrant revisiting the Records of Decision (ROD) at Superfund sites with TCE vapor intrusion in commercial/industrial settings and might trigger “Environmental Indicators” out of limits in future RCRA corrective action or Superfund Five-Year Reviews of remedy protectiveness because the limit of TCE in air at those sites for continuous commercial/industrial use was far higher.

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,



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.