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Nancy B. Beck, PhD
Principal Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency

Recommendations from AIHA on EPA's Draft Risk Evaluation for 1,2-Dichloroethane Under the Toxic Substances Control Act (TSCA)

Agency/Docket Numbers: EPA–HQ–OPPT–2018–0427; FRL–11809–06–OCSPP

Dear Principal Deputy Assistant Administrator Beck:

The American Industrial Hygiene Association, AIHA, is an association for scientists and professionals committed to preserving and ensuring occupational and environmental health and safety. We appreciate the opportunity to provide feedback on EPA's draft risk evaluation for 1,2-dichloroethane under TSCA. We hope you find our feedback useful and are happy to answer any questions you may have.

In the EPA document titled "1,2-Dichloroethane; Draft Risk Evaluation Under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comment" (EPA 2025a), EPA requests comments and specific feedback on the following items. AIHA is pleased to provide guidance, tools, and resources that may assist EPA with these specific requests.

1. **EPA solicits comment on "Whether and how exposure controls and personal protective equipment (PPE) are used during the manufacture, processing, and use of 1,2-dichloroethane for each of the COUs. Although EPA has test order data, additional information on when and where exposure controls and PPE are used would be informative" (EPA 2025a).**

AIHA encourages EPA to better understand the context in which the material/chemical is used to better control exposures. In real-world exposure scenarios, often industrial hygiene professionals will be controlling exposures to a number of chemicals being handled at the same time. Thus, evaluations of single chemical exposures (i.e., in a vacuum without consideration of any other exposure conditions), is not preferrable when evaluating chemical exposures and evaluating risk.

AIHA recommends performance based vs. prescriptive measures. AIHA's approach to workplace risk mitigation is through a holistic approach involving a variety of OSHA standards and other workplace measures that, among other things, considers Total Worker Health (a NIOSH program that AIHA supports). For this reason, prescriptive risk management measures are not recommended. Instead, risk management should be performance based and multifaceted. This is an important point since overly prescriptive

measures can lead to unintended adverse consequences to worker health such as heat stress, loss of dexterity, tripping hazards, ergonomic issues, and others.

2. **EPA solicits comment on "Information to help clarify the approach EPA used to analyze OSHA CEHD, specifically the step of removing data in which all measurements taken at the site were recorded as ''0'' or below the limit of detection and there was no evidence such as a bulk sample that shows the presence of the chemical at the site as EPA assumed that the chemical of interest may not have been at the site at the time of sampling" (EPA 2025a)**

Industrial hygiene professionals often encounter exposure data reported by laboratories as "0", non-detect (ND) or as below the limit of detection (LOD). These data are also often referred to as censored data, or left-censored data. For decades, the industrial hygiene profession has researched and discussed how to handle censored data in order to make judgments about exposure scenarios to protect worker health and safety. AIHA has a number of resources to assist the industrial hygiene professional for how to handle censored IH data. First, the AIHA book "A Strategy for Assessing and Managing Occupational Exposures: 4th Edition" has an extensive discussion for how to handle these types of data (Hewett, 2015). This document can be purchased on the AIHA website https://www.aiha.org/education/marketplace/strategy-book-4th-edition).

Additionally, industrial hygiene professionals know that accurate exposure risk decisions are critical to risk management programs that protect workers and optimize the use of limited resources. AIHA exposure decision registry (EDA) (both a training and registry program) teaches industrial hygiene professionals how to make accurate risk predictions based on limited data, in addition to how to handle left-censored data. These are freely available tools and resources on the AIHA website (https://www.aiha.org/education/elearning/online-courses/making-accurate-exposure-risk-decisions). These are resources IH professionals use for training/reference on how to handle this type of censored data. Additional resources for dealing with censored data are listed below.

- Hewett, P., and G. Ganser. 2007. A Comparison of Several Methods for Analyzing Censored Data. Annals Occup Hyg 51:7, 611–632.
- Ganser, G. and P. Hewett. 2010. An Accurate Substitution Method for Analyzing Censored Data. Journal of Occupational and Environmental Hygiene, 7:4, 233-244.
- Huynh, T., H. Quick, G. Ramachandran, S. Banerjee, M. Stenzel, D.P. Sandler, L.S. Engel, R.K. Kwok, A. Blair, and P.A. Stewart. 2016. A Comparison of the β-Substitution Method and a Bayesian Method for Analyzing Left-Censored Data. Annals Occup Hyg 60:1. 56–73.

In general, it is typically not the preferred practice in industrial hygiene and IH data analysis to remove those data with results reported as "0", non-detect, or below the limit of detection from a dataset. This can lead to biased judgments and decisions about exposure conditions in the workplace. Industrial hygiene data collection takes time/resources. Thus, if data is collected at a particular site, for a particular chemical of interest, it is reasonable to assume that that chemical is present at the site/in the process being sampled.

3. **EPA solicits comment on "Information on OESs for which EPA has slight confidence on exposures to workers and ONUs (Repackaging, Industrial and commercial aerosol products, and Waste handling, treatment, and disposal [landfills]), including on the degree to which 1,2-dichloroethane is used in Industrial and commercial aerosol products" (EPA 2025a)**

Many TSCA risk evaluations include the exposure potential of so called "occupational non-users" (ONUs). The exposure of ONUs is generally less than that of workers directly handling the substance whose risk is being evaluated. In most high-end scenarios and some central tendency scenarios, EPA has estimated lower exposures for ONUs than for "average workers." While this may be true of many ONUs, such as office workers who venture on to the shop floor only occasionally, or production workers in a nearby operation, other ONUs may have higher peak or average exposures than production workers. Workers engaged in maintenance, repair and/or cleaning of machines and/or containers with the substance being evaluated are likely (at least for purposes of risk evaluation which should not take controls such as PPE into account) to have higher peak or even average exposures than production workers who work directly with the substance under evaluation.

Regardless of whether EPA calls these workers ONUs, their exposures need to be analyzed separately from both production workers and from those whose exposures are merely incidental. One example of elevated exposures among workers engaged in these activities can be found in a study of urinary Bisphenol A as a marker of exposure (Hines et al. 2017). This study found that the geometric mean level of BPA in the urine of maintenance workers was 156 µg/g. This was higher than such occupational users as flaker operators and kettle operators (Hines et al. 2017). These data show that, in some cases, maintenance, repair and cleaning workers have higher average exposures than occupational users. EPA should obtain, examine, and present data related to the occupational exposures of workers engaged in maintenance, cleaning, and/or repair.

4. **EPA solicits comment on "Information (*e.g.,* SDS documents) to inform the level of 1,2-dichloroethane in adhesives. The concentration evaluated for the dermal exposure for the Industrial application of adhesives and sealants OES is 91.8 percent based on an SDS for an adhesive containing 1,2-dichloroethane" (EPA 2025)**

Industrial hygiene professionals often use SDSs to train their workers about how to work with and handle a chemical that may come in contact with over the course of their normal job duties. SDSs include important information (such as the properties of each chemical; the physical, health, and environmental health hazards; protective measures; and safety precautions for handling, storing, and transporting the chemical) that industrial hygienists consider when selecting appropriate personal protective equipment, developing safety protocols, implementing suitable exposure controls, and communicating hazard information to the worker population.

Additionally, in the DRAFT Risk Evaluation for 1,2-Dichloroethane EPA noted "Dermal exposure data were not reasonably available for the conditions of use in the assessment. Because 1,2-dichloroethane is a volatile liquid that readily evaporates from the skin, EPA estimated dermal exposures using the Dermal Exposure to Volatile Liquids Model. This model determines an APDR [acute potential dermal dose rate] based on an assumed amount of liquid on skin during one contact event per day and the theoretical steady-state fractional absorption for 1,2-dichloroethane." (EPA 2025b: p. 29).

AIHA has several resources that provide guidance on estimating dermal exposures. AIHA's *Mathematical Models for Estimating Occupational Exposure to Chemicals, 2nd Edition* specifically addresses dermal exposure modeling. It notes "[t]he U.S. EPA in the Risk Assessment Guidance for Superfund (RAGS) Supplemental Guidance for Dermal Risk Assessment...describes a dermal exposure estimation model in which the absorbed dose can be derived using either a permeability coefficient (for aqueous solutions) or a fraction of absorbed dose (for non-aqueous and non-steady state conditions such as exposure to soil." (Keil et al. 2009). In prior risk evaluations, a fractional absorption approach was used more frequently by

EPA for estimation of dermal exposure. However, with regards to the fractional absorption approach, Frasch et al. (2014) identified several potential limitations that should be considered when applying a fractional absorption approach (effects of loading, effects of evaporation, duration of experimentation to derive percent absorbed, and consideration of absorption that may occur following the exposure time). Lynch et al. (2023) compared results of the fractional absorption modeling approach to a flux-based approach for three chlorinated organic chemicals with high rates of volatilization and found 2- to 20-fold higher estimates of exposure with the fractional absorption approach.

The AIHA dermal absorption model IH SkinPerm uses a permeability coefficient approach (Tibaldi et al. 2014). IH SkinPerm is designed for three types of occupational skin exposures found in work environments. The assessment scenarios include instantaneous deposition, such as from a splash; deposition over time, such as from repeated or continuous emission; and skin absorption from airborne vapors.

AIHA also notes the EPA's Consumer Exposure Model (CEM) includes a number of approaches for estimating dermal exposure to chemicals in consumer products whether an article or a formulated product (U.S. EPA 2023):

- Formulated Products
  - Dermal Dose from Direct Transfer from Vapor Phase to Skin (P_DER1)
  - Dermal Dose from Product Applied to Skin, Fraction Absorbed Model (P_DER2a)
  - Dermal Dose from Product Applied to Skin, Permeability Model (P_DER2b)
  - Dermal Dose from Soil where Skin Contact with Soil, Dust, or Powder Occurs (P_DER3)
- Articles
  - Dermal Dose from Direct Transfer from Vapor Phase to Skin (Article Model) (A_DER1)
  - Dermal Dose from Article where Skin Contact Occurs (A_DER2)
  - Dermal Dose from Skin Contact with Dust (A_DER3)

AIHA would encourage EPA to better characterize those exposure determinants that may dictate which dermal exposure estimation approach is preferred (fit for purpose) for a given chemical and its conditions of use.

Additional Comments

In general, when evaluating the exposure potential of any chemical it is important to consider how the "bioavailability" of that chemical can change based on how it is used, handled or processed. In a chemical's "neat" state it could pose a completely different exposure risk than when it is heated, aerosolized, or is involved in an exothermic reaction or subject to a physical stressor such as high velocity air, or high pressure. For example, a low vapor pressure chemical may not present an inhalation exposure risk until it is heated, aerosolized, or severely agitated. Another example would be, a highly reactive monomer that once polymerized presents less of an exposure risk. These are important considerations of how industrial hygiene professionals evaluate different exposure risks, based on different applications, uses or different chemical characteristics.

Conclusion
If you have any questions about AIHA's comments on this proposed rulemaking or other matters, please contact me at mtwilley@aiha.org or (703) 846-0745. Thank you for your time and consideration.

Sincerely,
AIHA

Michele Twilley, DrPH, CIH
Chief Science Officer

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.

References
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