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Principal Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency

Recommendations from AIHA on EPA's Updated Draft Risk Calculation and Other Related Documents for Formaldehyde Under the Toxic Substances Control Act (TSCA)

Agency/Docket Numbers: EPA–HQ–OPPT–2018–0438; FRL–11608–05–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 updated draft risk calculation and other related documents for formaldehyde under TSCA. We hope you find our feedback useful and are happy to answer any questions you may have.

1. **AIHA Encourages EPA to Consider Workplace Variability in the Data Received/Reviewed**

AIHA encourages EPA to consider that the data they are reviewing in the risk evaluation phase, takes into account various exposure controls in place in the workplace. It may not be appropriate to assume every workplace is OSHA compliant, as the degree of compliance across industry and within sectors is a continuum. The variability in the data may reflect different workplace scenarios and exposure controls in place. EPA is encouraged to fully understand the holistic nature of the data in the risk evaluation phase better, and contextualize the data to help inform the results in the risk evaluation. EPA can leverage AIHA's knowledge about the range of typical IH practices associated with the data collection. This information will better support the conclusion in the risk management phase.

2. **AIHA's Recommendations Regarding EPA's Dermal Exposure Approach**

EPA used a screening level approach to dermal exposure assessment that resulted in conclusions of unreasonable risk of injury to workers based on those exposures. AIHA recommends that EPA incorporate higher tier dermal exposure assessment techniques in its risk evaluations. 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 depositions, such as from a splash; deposition over time, such as from repeated or continuous emission; and skin absorption from airborne vapors.

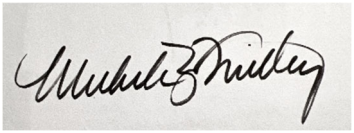
3. **AIHA Supports the General Approach that Sensory Irritation (as an Endpoint) is Protective for Chronic Exposures**

AIHA, in general, supports EPA's application of the recommendations of federal advisory committees in using sensory irritation as an endpoint that is protective of chronic exposures. Sensory irritation is a sensitive and relevant end point in human risk assessment, for many chemicals. By one estimate, 40 % of the occupational exposure limit values (OELs) are based on the avoidance of sensory irritation (Brüning et al. 2014). Such an approach is appropriate for substances/substance classes for which sensory or tissue irritation of the eyes and/or of the upper respiratory tract has been identified as the most sensitive end points (EPA 2025). Moreover, there are a number of published approaches for setting exposure limits for sensory irritants (Gunnar et al. 2017). In many cases, sensory irritation is protective of chronic exposures, but should be evaluated on a chemical by chemical basis. One cannot always assume that it is always protective for chronic exposures.

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



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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.

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