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August 4, 2025

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Recommendations from AIHA on EPA's Proposed Rule on DBP and DEHP Under the Toxic Substances Control Act (TSCA)

Agency/Docket Numbers: EPA-HQ-OPPT-2018-0433-0117/ EPA-HQ-OPPT-2018-0503-0111

Dear Dr. Beck:

AIHA, the association for scientists and professionals committed to preserving and ensuring occupational and environmental health and safety, appreciates the opportunity to provide feedback on EPA's draft risk evaluations for DEHP and DBP. We hope you find our feedback useful and are happy to answer any questions you may have.

EPA is soliciting comments/peer-review from the TSCA Science Advisory Committee on Chemicals (SACC) on a variety of charge questions (U.S. EPA 2025, Charge to SACC Peer Review). AIHA has reviewed these charge questions and has included commentary regarding occupational exposure to these specific chemistries. We have also included comments on industrial hygiene (IH) best practices.

Summary of Comments

EPA is requesting public comment on the use of a flux-based approach for estimating dermal exposure to materials with low volatility and low rates of absorption (Charge Question #13).

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. Moreover, the model is described as most applicable to substances with a log octanol/water partition coefficient (Log Kow) -3 to 6 and molecular weight (MW) < 600, and the maximum absorption rate is limited by the maximum solubility of the pure compound in water. Among the three phthalates, DEHP has a LogKow outside of this range (7.6) and very low water solubility (0.003 mg/L) according to the draft risk evaluation. Therefore, the absorption rate and Kp permeation coefficient might be difficult to measure.

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.

EPA is requesting public comment on the possibility and likelihood that a non-volatile chemical with low absorption may be contacted multiple times during a work shift (i.e., the worker is handling the chemical intermittently throughout the work shift) and may exist on the skin surface for a total of 8 hours (or until the material on the skin surface is depleted), including the representativeness of this exposure scenario to the COUs (Charge Question #16).

Charge Question 16 highlights the importance of quantifying exposure assessment parameters, such as contact frequency in the appropriate parameterization of dermal exposure models. Moreover, the EPA Office of Research and Development discusses additional critical parameters such as dermal loading (and skin loading adherence factors) and transfer coefficients in estimation of dermal exposures to chemicals in environmental and occupational media (U.S. EPA 2007). AIHA recommends that EPA focus less on "the possibility and likelihood that a non-volatile chemical with low absorption may be contacted multiple times during a work shift" (i.e., it is possible and likely) and more on the contact frequency, dermal loading and transfer efficiency of a particular condition of use. To answer these questions, EPA needs to work with industries and companies where the condition of use is relevant. AIHA encourages EPA to foster such partnerships so that it has the necessary information to develop high quality risk evaluations.

<u>Additional Feedback Regarding Industrial Hygiene (IH) Best Practices</u>

AIHA appreciates the opportunity to provide comments on the use of IH current/standard and best practices in risk evaluations. The AIHA Guideline Foundation has been developing its Principles of Good Practice (PGPs); which are practical, proven, and available practices that are effective in protecting workers and communities from unacceptable risks. To the extent EPA is prescribing risk management action, consistency with current IH practices and existing OSHA regulations is encouraged, so as not to create unnecessary burdens and confusing or conflicting requirements. PGPs could be included in the EPA risk evaluations as a baseline recommendation. These Principles of Good Practice for Exposure Assessment can be accessed here: https://aiha-

assets.sfo2.digitaloceanspaces.com/AIHA/resources/Get-Involved/Pages-from-AIHA-Guideline-Foundation-Principles-of-Good-Practice_Section2.pdf

In addition to the comments below, AIHA has also prepared and shared with EPA a separate repository of key IH terminologies. This document provides a map of key terms used by EPA in their risk evaluation process and the corresponding or related terms (when available) used by the IH profession. We consider this document to be another tool to effectively communicate IH best practices with EPA.

Need for Better Definition of Occupational Exposure Groups

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. EPA has made similar assumptions for DEHP.

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.

Availability of Sampling and Analytical Methods

EPA is encouraged to consider and assess the availability of the IH sampling and analytical methods and their respective Limit of Quantitation (LOQ) values relative to proposed

benchmarks in the risk evaluations. For example, if the current methods such as OSHA 104 yield too many sampling results below the LOQ and the OEV is also low, then the impact on using conservative assumptions for left censored data for the exposure assumptions justifies the need for detailed discussion.

Need for Public Comment on OEV and ECEL Derivations

Appendix F of the DBP draft risk evaluation regarding the occupational exposure value (OEV) states: "This calculated draft value for DBP represents the exposure concentration below which exposed workers and ONUs are not expected to exhibit any appreciable risk of adverse toxicological outcomes, accounting for PESS. It is derived based on the most sensitive human health effect (*i.e.*, decreased fetal testicular testosterone) and exposure duration (*i.e.*, acute) relative to benchmarks and a standard occupational scenario assumption of an 8-hour workday."

EPA has described the threshold for the OEV as “Any appreciable risk of adverse toxicological outcomes” in this and several other risk evaluations. It appears that EPA believes that “any appreciable risk of adverse toxicological outcomes” represents an unreasonable risk of injury to health under Section 6 of TSCA. Clearly, the statute does not contemplate that *the only reasonable risk is no risk*. Moreover, EPA’s approach to risk assessment includes several conservatisms to account for uncertainties in the available data.

EPA needs a clear and transparent process for developing OEVs and existing chemical exposure limits (ECELs) under TSCA that incorporates peer review of the approach and the ultimate outcome (value). While EPA has been making the draft OEV available as part of the draft risk evaluation, it has not sought public dialogue with stakeholders, experts, or the regulated community on OEV and ECEL derivations. The Fifth U.S. Open Government National Action Plan (https://open.usa.gov/national-action-plan/5/) states:

"Transparency is a cornerstone of open government and can be an important driver of more-equitable outcomes, innovation, and accountability. By making available information about the condition of society, the economy, and the environment, as well as government decisions, activities, data collections, and program outcomes, the public can hold the Federal Government accountable."

Public release of Federal Government research, information, and data can also enable greater evidence building, civic engagement, and public and private sector decision-making; accelerate private sector breakthroughs for scientific innovations; and identify novel business opportunities.

More meaningful engagement of the public in the work of government results in better policy design and program administration — as policies more closely reflect and respond to the needs of individual communities — and also builds virtuous cycles of public trust and confidence in the democratic institutions of the Federal Government.

EPA once maintained a detailed, transparent, and credible process for developing Acute Exposure Guideline Levels (AEGLs) (https://www.epa.gov/aegl/process-developing-acute-exposure-guideline-levels-aegls). In addition, a recent final rule from OSHA amending its existing standards for occupational exposure to beryllium and beryllium compounds evolved from a Notice of Proposed Rulemaking in August 2015 (80 Fed. Reg. 47565) to issuance of the final rule in January 2017 (82 Fed. Reg. 2470) and included a two-day public hearing in between. Similarly, the European Chemicals Agency mandates a detailed and robust process for the development of occupational exposure limits that involves engagement of a variety of experts and stakeholders with a resulting level of confidence in the ultimate outcome (See OEL Process, https://echa.europa.eu/oel-process). There are numerous other examples and approaches EPA could and should use to inform the public and regulated industry of its proposed ECELs. Accordingly, the agency has the responsibility to solicit public feedback regarding the technical aspects of their derivation, and the benefits and costs associated with implementation.

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.

Additional References

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