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November 6, 2025

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

Recommendations from AIHA on EPA's Proposed Rule on Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)

Agency/Docket Numbers: EPA–HQ–OPPT–2025–0260; FRL–8529.1–01–OCSPP

Dear Principal Deputy Assistant Administrator 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 proposed rule on procedures for chemical risk evaluation under TSCA. AIHA members bring significant expertise and experience to represent in working within a nexus of organizations. These include federal agencies, such as NIOSH, MSHA, OSHA and of course EPA, as well as chemical trade associations, and dozens of allied associations in the broader public health space.

AIHA's goal is to continue to foster a partnership with EPA to capitalize on AIHA's networks, expertise and experience regarding TSCA to increase efficiency, decrease administrative and regulatory burden, decrease redundancy, and decrease costs, all while protecting worker health and safety. The following comments are aligned with this goal. We hope you find our feedback useful and are happy to answer any questions you may have.

Need for Consideration of Controls and PPE in Risk Determinations

EPA proposes to amend the language in 40 CFR 702.39(f)(2) to say "In determining whether unreasonable risk is presented, EPA's consideration of occupational exposure scenarios will take into account reasonably available information, including known and reasonably foreseen circumstances where subpopulations of workers are exposed due to the absence or ineffective use of personal protective equipment. EPA will not consider exposure reduction based on assumed use of personal protective equipment as part of the risk determination".

AIHA encourages EPA to utilize realistic assumptions about industrial hygiene (IH) programs and the use of exposure controls, including engineering controls, administrative controls and the use of personal protective equipment (PPE) in real-world settings. EPA has used a baseline assumption for worker exposure in TSCA risk evaluations for occupational settings where hazardous chemicals are present that there is no industrial hygiene program, occupational exposure controls or risk management procedures

in the workplace. This is an unrealistic assumption, and if this were the case, then this would create a very dangerous and hazardous workplace for workers. There is no clear precedent in regulatory risk assessment processes for such an approach during the risk evaluation phase, and there is no question that there is unreasonable risk of injury in such a situation. Instead, we know that OSHA regulated workplaces are mandated to evaluate chemical exposures, record keeping, training, PPE, etc.

AIHA encourages EPA to consider risk mitigation measurers, such as the proper use of PPE, in the risk management phase consistent with the hierarchy of controls. Several OSHA standards already require the evaluation and effective use of PPE, which should be strictly enforced. Personal air sampling should be conducted when exposures remain uncertain and should adhere to a published exposure assessment strategy such as AIHA Strategy for Assessing and Managing Occupational Exposures, the DoD Exposure Assessment Model, or a similar industry or corporate-developed formalized exposure assessment strategies where personal sampling is not necessary unless exposure is deemed uncertain.

The concern with the current EPA TSCA process (i.e., excluding PPE) is that it likely results in the identification of conditions of use (COUs) as risks, in workplaces with a baseline IH program are not likely risks. The result is we waste time and valuable resources on detailed evaluations for low-risk scenarios. The real concern from an EPA TSCA perspective (which is aligned with AIHA's mission and vision) seems to be the need to ensure that all workplaces have a well-functioning IH program. This could be accomplished with a "rigorously enforced" version of the OSHA general duty clause or general EPA chemical exposure management program requirement. This would allow the agency and stakeholder community to dig into solutions for the most problematic exposure scenarios and develop exposure control strategies, where they will really make a difference.

The EPA TSCA framework rule should complement and align with other agencies that evaluate/regulate occupational exposures. Industrial hygienists have decades of experience studying various chemicals that are on the high priority list such as asbestos, TCE, perchloroethylene, and phthalates. Additionally, there are other agencies (both regulatory and advisory) that have studied occupational exposures of these chemicals in various contexts. EPA is encouraged to revisit the TSCA framework to see how it can better compliment and align, and not overlap, with current occupational regulations from OSHA, or guidance from ACGIH, ANSI, ASHRAE or NIOSH. For example, with regards to perchloroethylene, companies that use or manufacture the chemical already follow strict regulatory actions regarding exposure controls, recordkeeping, etc.

Consideration of Likely Exposure in Risk Determinations

EPA proposes to amend 40 CFR 702.39(f)(3) to include a number of "risk-related factors included in the risk evaluation…In determining whether unreasonable risk is presented". Those factors include:

> "(i) The severity of the hazard (e.g., the nature of the hazard and irreversibility of the hazard);
> (ii) Exposure-related considerations (e.g., duration, intensity, and frequency of exposure);
> (iii) The population exposed (including any potentially exposed or susceptible subpopulations (PESS)); and
> (iv) The confidence in the information used to inform the hazard and exposure values, including an evaluation of the strengths, limitations, and uncertainties associated with the information used to inform the risk estimate and the risk characterization."

It is notable that these factors are nearly identical to those proposed in EPA's June 2017 Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under the Toxic Substances Control Act (available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/guidance-

assist-interested-persons-developing-and-1). These concepts align with the statutory language of TSCA. However, AIHA recommends two amendments to the language proposed, consistent with industry best practices:

1. In proposed 40 CFR 702.39(f)(3), revise the text to read "In determining whether unreasonable risk is presented, EPA will take into account …". It is our understanding that "take into account" comes with greater obligation than "consider".
2. In proposed 40 CFR 702.39(f)(3)(ii), add "likely" so the text reads "Exposure-related considerations (e.g., likely duration, intensity, and frequency of exposure)".

We note that the statute states that among the requirements of a risk determination are that the Administrator shall "take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance" [15 U.S.C. § 2605 (b)(2)(F)(iv)]. In addition, it has been the Agency's practice to conduct its screening assessment by starting with conservative estimates of exposure such as a sentinel exposure (i.e., "…the plausible upper bound of exposure relative to all other exposures…" [40 CFR § 702.33]. While upper bound exposures assumptions may be suitable in a screening-level risk assessment, especially for screening out exposure scenarios where the exposure estimate does not exceed the hazard benchmark, they are not appropriate for making findings that a COU presents an unreasonable risk of injury to health. These bounding estimates while plausible and possible, are not likely.

Setting a Hazard Benchmark

The preamble to the proposed rule discusses EPA's recent policy of developing an "occupational exposure value" and asks whether it should continue this practice (90 Fed. Reg. 45690 at 45707): "EPA requests comment on whether EPA should establish occupational exposure values, and, if so, whether EPA should do so as part of the risk evaluation for a chemical substance, or in the subsequent risk management rule, or both. If both, EPA requests comments on what considerations should be taken into account in moving from the value established as part of the risk evaluation to the value established during risk management".

The occupational exposure value is not a benchmark of "unreasonable risk of injury", it is a benchmark of "no appreciable risk of adverse toxicological outcomes" as noted by several recent risk evaluations where an occupational exposure value is proposed (see the recent Draft Risk Evaluation for Octamethyl-cyclotetrasiloxane, Appendix F). These are not equivalent. Moreover, when establishing a hazard benchmark for the determination of unreasonable risk, AIHA encourages EPA comply with the statutory requirement to "integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health…" [15 U.S.C. § 2605 (b)(2)(F)(i)]. AIHA believes that such information includes published regulatory/public health agency OELs such in the United States NIOSH RELs, OARS WEELs, AIHA OELs, ACGIH TLVs, and outside the United States, sources such as MAK values (Germany), recommendations of the European Commission Scientific Committee on Occupational Exposure Limit Values and recommendations from the Japan Society for Occupational Health.

Revisions to EPA "One Chemical at a Time" Policy

AIHA supports EPA's mission to protect worker and community health, but the 'one chemical at a time' framework creates unnecessary delays and burdens without improving worker protection. AIHA encourages EPA to adopt class- or category-based evaluations where scientifically justified. These categories could be use-based categories rather than chemical-based categories, or sector based categories. Making this change will streamline reviews, reduce redundancy, and accelerate protective action. Evaluating structurally or toxicologically similar chemicals together can better reflect real-world

exposures, since workers and communities are rarely exposed to one chemical in isolation.

Industrial hygienists in workplaces must interpret and implement TSCA decisions. Multiple, duplicative single-chemical rules impose unnecessary complexity and unnecessary burdens without added worker protection. Thus, implementing class- or category-based risk evaluations will create a streamlined and efficient process for both EPA and industry. OSHA and NIOSH often address chemical categories (e.g., particulates not otherwise regulated, isocyanates)—to show that a category-based approach is consistent with occupational health best practice. This change again, ensures alignment with sound scientific principles and best practices in the field of occupational safety and health. AIHA encourages EPA to weigh regulatory costs against actual risk-reduction benefits, ensuring resources are targeted to the chemicals/uses posing the highest risks**.** This type of regulatory balance is critical.

Need For Holistic Approach to Worker Health and Safety

A single whole chemical unreasonable risk determination per chemical, instead of a determination for each COU, is not scientifically supported and should be re-considered. Risk should be assessed by COU, using defensible exposure reconstruction approaches to characterize exposures. 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 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.

AIHA Education and Training Resources

AIHA maintains a robust library of resources for practitioners. Among these, our Principles of Good Practice (free publication), documents vital professional practices that reliably and effectively protect workers and communities from unacceptable risks. It provides a common vision of effective risk management practices for OEHS professionals, and it elevates the performance of all OEHS programs by providing a set of uniform program and performance targets that can be used in continuous improvement activities.

Most relevant to the work of TSCA, the Principles of Good Practice offers detailed guidance to protect workers from hazardous airborne chemical exposures (available on the AIHA website). This includes information which assists companies in creating written occupational exposure assessment and control program and specifies whether practices are considered "good" vs "enhanced" (better in class). As an example, chemical exposures are judged acceptable if the estimated 95% percentile for the exposure profile is less than the Occupational Exposure Level with at least 70% confidence; an "enhanced" performance level would be 95% confidence.

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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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.