Dear Assistant Administrator Freedhoff:

AIHA is the association for scientists and professionals committed to preserving and ensuring occupational and environmental health and safety (OEHS). AIHA’s members work in the United States and around the world to anticipate, recognize, evaluate, and control occupational and environmental health and safety hazards in workplaces and communities. We appreciate the opportunity to provide feedback on the United States Environmental Protection Agency’s (EPA) procedural framework rule for conducting risk evaluations under the Toxic Substances Control Act (TSCA). We hope you find our feedback useful and are happy to answer any questions you may have.

**General Comments**

AIHA members include persons from Canada and persons working internationally who may be covered under the European regulation akin to TSCA for the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH). The main tasks for REACH are to provide a high protective level for human health and the environment. At the same time, this regulatory requirement is intended to ensure the free and safe movement of chemicals. REACH addresses risk assessment of highly hazardous chemicals to human health. REACH “has been in force since 2007 and is considered one of the strictest chemical laws in the world.” REACH addresses
the assessment of potential risks from highly hazardous industrial chemicals and their safe use. Currently, approximately 23,000 single chemicals are registered within REACH.

AIHA recommends that EPA provide global coordination of the European Chemicals Agency:

“The REACH Regulation requires registrants to prepare a registration dossier. This is composed of a technical dossier and, where relevant, a chemical safety report, which summarizes the results of a chemical safety assessment. A chemical safety report is only required if the registrant manufactures or imports a substance in quantities of 10 tonnes or more a year.”

AIHA suggests that EPA provide more clarity regarding proposed TSCA-related regulations, including by adding a summary of key points and rules with justification after every section for easier understanding.

AIHA recommends that EPA take a global approach to TSCA regulations and follow the lead of the United States Occupational Safety and Health Administration (OSHA). For example, the Globally Harmonized System of Classification and Labeling of Chemicals (GHS), is the internationally-accepted system that standardizes chemical hazard labels and chemical hazard communication.

These proposed TSCA regulations demonstrate a misunderstanding of workplace safety and health. For example, one issue of concern is the use of personal protective equipment (PPE) which requires a site assessment and continuing vigilance and considerations for training, fit, comfort, contaminant removal efficiency, permeation, or penetration data, etc., and a comprehensive written respiratory protection program for the use of respirators prepared by a qualified individual. EPA does not address the need for PPE evaluation, assessments, or the need for PPE oversight, but states that

“data on violations of PPE use suggest that assumptions that PPE is always provided to workers, worn properly, and effective at eliminating exposures are not justified. In addition, TSCA requires that risk evaluations consider the known, intended, or foreseen circumstances associated with the chemical substance—including circumstances that result or could result in exposures to workers. For the reasons described further in Unit III.E.1., EPA believes that circumstances that result in occupational exposures to chemicals are reasonable to foresee, and, in many cases, known. As such, continued

---

1 https://echa.europa.eu/regulations/reach/registration/information-requirements
2 https://www.osha.gov/hazcom/global
application of this general assumption could result in risk evaluations that underestimate risks, and in turn, prevent risk management rules from affording necessary protections.”

**1. EPA requests comment on how the Agency could consider potential climate-related risks in a risk evaluation.**
AIHA believes the regulation of greenhouse gases through TSCA may be problematic. AIHA believes, however, that the serious nature of global warming must lead to government action. Coordination with the global community is necessary, for example with the European Environment Agency.³

**2. EPA requests comment on the proposed approach of publishing a draft scoped during the prioritization process when it is clear that the chemical undergoing the prioritization process will be designated as a high-priority chemical.**
AIHA recommends that EPA develop a preliminary list of “high priority” chemicals, with the knowledge much of this work has already been developed and implemented by REACH.

**3. EPA requests public comment on the proposed elimination of the definitions of best available science and weight of scientific evidence, the need for such definitions, and the utility of definitions as the state of science evolves.**
AIHA does not agree with the proposed elimination of the definitions of best available science and weight of scientific evidence. Instead, AIHA recommends that EPA clarify the meaning of the “best available science” and “weight of scientific evidence” by providing appropriate definitions that can be revised later.

---

5. EPA requests comment on general approaches or best practices for improving engagement with small entities. Early engagement with and feedback from all those who manufacture, process, distribute, use or dispose of a chemical is critical for the Agency to be able to accurately identify and characterize that chemical's conditions of use for consideration in the risk evaluation, EPA is seeking comment on how to improve its outreach to the stakeholder community, including education on the TSCA risk evaluation process for small entities.

AIHA recommends that EPA support grants for research or teaching universities and colleges to improve its outreach to the stakeholder community, including education on the TSCA risk evaluation process for small entities, like the OSHA Susan Harwood Training Grant Program.4 A methodology should be implemented to ensure interactive sessions (webinars, face-to-face forums, etc.) are scheduled and these stakeholders are invited to participate.

AIHA suggests that EPA generate a list of the impacted entities (e.g., contractors who work at the sites where the chemicals will continue to be used). Sites that manufacture or produce these chemicals may be able to assist by providing listings of their contractors who may interact with the chemicals of interest.

AIHA recommends that EPA reach out to laboratories to generate new analytical methodologies to meet the lower Existing Chemical Exposure Limits (ECELs), etc.

AIHA suggests creating a platform that consolidates all ECELs and workplace chemical protection programs (WCPPs) that will be implemented to facilitate stakeholder understanding of what they will be expected to do regarding compliance.

AIHA recommends that EPA include OSHA in the communication of the TSCA ECELs and WCPPs to the health and safety community to increase awareness with health and safety professionals. The target audience should include health and safety personnel who typically manage workplace exposure.

4 https://www.osha.gov/harwoodgrants
6. EPA requests public comment on how the Agency can provide a transparent and detailed basis for the proposed unreasonable risk determination and existing chemical exposure limits derived from the risk evaluation process.

AIHA recommends that EPA provide operational definitions for “transparent and detailed basis” and “unreasonable risk” with supporting documentation and coordination with the REACH regulations.

OSHA has an existing process for chemical-specific requirements that follows a standard format. The standards set action levels and Permissible Exposure Limits (PELs) which must be complied with, and in some cases, like with silica, has a list of restricted tasks that must be eliminated. If EPA intends to increase the regulations affecting the workplace, they must explain how ECELs are related to PELs, contain information for hazard communication about why the material is considered more hazardous, and explain their conclusions in light of overlapping requirements. If EPA intends to propose restricting or eliminating certain substances in the workplace, EPA must help industry reformulate, and move away from chemicals EPA is proposing to restrict.

AIHA recommends that EPA reconsider the population included in their definition of unreasonable risk in the workplace. Including the most susceptible individuals EPA has identified (infants, older retired populations, etc.) as part of the workplace is inappropriate. AIHA recommends that the current application of the most susceptible individual being considered as part of the workplace be reviewed for more realistic scenarios.

**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.

References