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Michal Freedhoff
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency

Recommendations from AIHA on EPA's Proposed Requirement for Certain Manufacturers to Submit Unpublished Health and Safety Data Under the Toxic Substances Control Act

Agency/Docket Numbers: EPA-HQ-OPPT-2023-0360 / FRL-11164-01-OCSPP
RIN: 2070-AL15

Dear Assistant Administrator Freedhoff:

AIHA, the association for scientists and professionals committed to preserving and ensuring occupational and environmental health and safety (OEHS), appreciates the opportunity to provide feedback on the Environmental Protection Agency's (EPA) proposed rule to require manufacturers (including importers) of 16 chemical substances to submit copies and lists of certain unpublished health and safety studies to EPA. We hope you find our feedback useful and are happy to answer any questions you may have.

Support (with Caveats) for the Proposed Rule

AIHA mostly supports, with caveats, EPA's proposal to require manufacturers (including importers) of 16 chemical substances to submit copies and lists of certain unpublished health and safety studies to EPA. AIHA recognizes that unpublished health and safety information and data sought by this action may help inform EPA's responsibilities pursuant to TSCA, including prioritization, risk evaluation, and risk management. However, AIHA believes an unpublished study and its associated data may have limited value and validity if it has not undergone proper review and evaluation.

Although TSCA § 716.20(a)(1) states that studies which have been published in the scientific literature are exempt from the copy and list submission requirements of §§ 716.30 and 716.35, EPA should seek health and safety studies, information and other international

regulatory actions from valid pertinent sources, including international journals and other international sources, such as the World Health Organization (WHO), the International Agency for Research on Cancer (IARC), the European Chemicals Agency (ECHA), and other relevant European, Asian and international chemical regulatory agencies. For example, EPA should consider the database of information published by ECHA for chemicals submitted under the European Union's regulations for the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) with the identification of chemicals of "very high concern" and the harmonized classification and labeling process.

Ealy collection of information will be useful for EPA to carry out their assessments in a more informed manner. It would also allow manufacturers and importers (and the value chain) to identify data gaps prior to the risk evaluation process so that they can be fulfilled in a timely manner. However, a clear understanding of the objective and potential use and interpretation of this data is needed to help identify the relevant pieces of information for the agency and streamline the collation of information for decision-making.

Feedback on the Degree to Which Unpublished Health and Safety Studies May Help EPA Prioritize, Evaluate, and Manage Chemical Risks Under TSCA

AIHA urges EPA to consider studies that fall under other international government regulatory authorities and health and safety studies and peer-reviewed research published in recognized U.S. arenas for example, the American College of Environmental and Occupational Medicine, the American Industrial Hygiene Association Guideline Foundation, the American Conference of Governmental Industrial Hygienists (ACGIH) *Documentation of Threshold Limit Values (TLVs®)*, American Chemical Society, American Cancer Society, and the Society of Toxicology.

Scope of Chemicals Included

AIHA believes that EPA should take the lead of REACH by identifying "substances of very high concern" first. For example, from the U.K. Health and Safety Executive:

> "SVHCs are substances that have hazards with serious consequences. They cause cancer, or they have other hazardous properties and/or remain in the environment for a long time with their amounts in animals gradually building up.
>
> Substances with the following properties may be identified as SVHCs:
>
> - Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1A or 1B in accordance with the GB CLP regulation.
> - Substances which are persistent, bio-accumulative and toxic (PBT).

- Substances which are very persistent and very bio-accumulative (vPvB).
- Substances giving rise to an equivalent level of concern to substances meeting the above criteria. Such substances may have endocrine disrupting properties or have properties, that although not meeting the criteria for being a CMR, PBT or vPvB, there is scientific evidence of probable serious effects to human health or the environment. Such substances will be identified on a case-by-case basis."[1]

Occupational exposure assessment, albeit following quality control criteria, does not follow a specific protocol like toxicity or ecotoxicity tests, and therefore, there is no standard way to report results. Contrary to hazard characterization studies, these assessments are done on a routine basis that can vary in frequency depending on changes in the process, validation needs, etc., and thus likely to be numerous, particularly for substances of high production volume or manufactured or used by a large number of industries or companies (especially if there is already an OSHA standard mandating monitoring). Unpublished results without data aggregation or interpretation are unlikely to be useful for EPA to prioritize, evaluate, and manage chemical risks under TSCA.

On the other hand, recent risk evaluations have shown that EPA's expectations of the occupational exposure data are unlikely to be fulfilled by current analytical methodologies, as detection limits are sometimes orders of magnitude greater than EPA's ECEL. If the EPA makes determinations of unreasonable risk because the data is below the detection limit, even though professionals have already identified these situations as unlikely to be exposed, then this data will be uninformative for the agency.

A simplified approach could be to obtain information on the determinants of exposure and the controls in place and use models to estimate exposures. EPA may then wish to only require exposure characterization for the few scenarios in which safe use cannot be asserted with models.

Reporting Requirements and Timelines

Requirement to Report All Unpublished Exposure Assessments

The original definition in § 716.3(2)(iv) is "Monitoring data, when they have been aggregated and analyzed to measure the exposure of humans or the environment to a chemical substance or mixture." However, in the proposed rule EPA states:

> "All unpublished studies on occupational, general population, consumer, and environmental exposure, such as: unpublished studies on inhalation and dermal exposure, human biomonitoring, environmental monitoring of indoor and outdoor air, soil, water, and household dust, chamber emission rates from products or polymeric matrices, and unpublished modeling studies that estimate environmental concentrations or human exposures**."**

[1] https://www.hse.gov.uk/reach/svhc-overview.htm

It would be helpful if EPA could specify the types of studies it is requesting and limit it to the original definition in § 716.3.

Occupational Exposure Assessments and Formal Studies

Occupational exposure assessments are typically carried out to answer specific questions that may or may not need the writing of a report. Only rarely are occupational exposure assessments treated as "studies". Although there is likely to be a plan to characterize exposures in the workplace, it is unlikely to be a formal protocol as a toxicological or ecotoxicological study carried out under controlled conditions. Collecting all historical laboratory analysis reports and associated information is a labor-intensive task that will take likely thousands of person-hours (depending on the span of historical data to be retrieved) per chemical, per site. **This is likely to take much longer than the 90-day period EPA is proposing to provide and the final rule should be updated with these comments in mind.**

Proposed Requirement to Use OECD Harmonized Templates

EPA is requesting data to be submitted using harmonized templates "where such templates exist". Although there are such templates, they are not typically used by U.S. industrial hygienists, as they are mostly used for European Chemical Management regulation, using concepts such as "PROCs", "Conditions of Use", etc., that are not used in the United States. As similarly noted above, it would take hundreds of person-hours to convert unpublished and non-aggregated studies into these formats. Furthermore, there is no standardized approach in the U.S. to map the exposure scenarios to the European PROCs. As a result, industrial hygienists would have to first understand these concepts before data can be aggregated and presented in such a way.

It would be helpful if EPA could specify the types of templates to be used and provide guidance on the types of data to report, how to report them, and how will they be used.

Proposed Requirement to Report the Composition or Purity of the Substance is Not Applicable to Occupational Exposures

In general, occupational exposures are assessed in a workplace that handles a variety of substances, and only very rarely do these reports reference the composition or purity of a substance as part of the study. This adds to the complexity of the interpretation of the occupational exposure data, especially without a clear understanding of the industry and/or the operational conditions at the time the sample was collected.

Proposed Requirements Regarding Biomonitoring Data

The proposed requirements regarding biomonitoring data are unclear. Biomonitoring measurements are done for different objectives in the population and the workplace. In the occupational health arena, some substances might have a biological monitoring reference value, but that must be interpreted holistically. It would be helpful for EPA to better define the types of studies and type of information it wants to use, what for, and how it will use them.

Suggestions for the Type and Format of Information EPA is Requesting

If EPA wants to obtain information from manufacturers or importers on the conditions of use and exposure scenarios in the workplace, it would be beneficial to have a standard format to collate information and build a system to allow manufacturers and users of the substance to provide information so that EPA can easily identify what the potential activities are that may give rise to an exposure and the controls already in place (similar to the structure already implemented in Europe).

Understanding the type of information requested, the objectives, and the ultimate purpose will yield more informative communications which may lead to faster aggregation and interpretation of the results, and thus, more efficient risk evaluation and risk management processes.

Exemptions

AIHA recommends that EPA ensure the exemptions proposed by this rule agree and coordinate with the current Globally Harmonized System for Hazard Communication.

Estimated Impacts and Burdens

The collection of all the unpublished information EPA is asking for is likely to demand an enormous amount of time from manufacturers and importers. Occupational exposure data is typically collected for many different objectives and does not necessarily follow a specific format. Occupational health programs and exposure assessments are typically site-specific and address specific questions (e.g., regulatory compliance, exposure characterization, selection or validation of controls). These reports, without thorough interpretation by an industrial hygienist familiar with the scenario in question, might lead to misinterpretation of the data. Without a clear understanding of the potential use of this data, the collection and interpretation of these studies might yield less than useful information for EPA.

In addition to retrieving the raw studies, there is a need to interpret the results prior to submission to the agency. Since these studies are unlikely to be digitized, there is also a significant burden in retrieving the information.

Confidentiality Procedures

AIHA recognizes that some or a substantial portion of unpublished data, not related to human health and welfare may be company confidential. EPA access should be limited to unpublished health and safety data alone, where this data is needed to assist EPA with making judgments regarding setting priorities, risk evaluation, and risk assessment.

Electronic Reporting and Submission Formats

Experience with help desks indicates long telephone waits and unproductive time with often an inability to promptly answer relevant submission questions. AIHA suggests EPA also allow for the manual submission of reporting requirements directly to an EPA U.S. postal service mailing address with clear instruction for a mailing option provided.

Other Comments

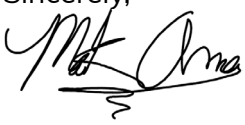
Exposure assessment strategies lead to the identification of the groups of workers or activities with the greatest potential for exposure. In many cases, qualitative assessments and professional judgment are used to identify the groups of workers or activities with little potential for exposure. These groups are seldom characterized with quantitative assessments, especially if early assessment corroborated the OHS professional assessment.

It should be noted that a lack of quantitative assessment does not mean a lack of assessment. As a result, additional requests for data on these groups will likely yield still very low (if any) levels of exposure but will require significant investments of time and resources that will yield little or no valuable information to the agency.

Conclusion

If you have any questions about AIHA's comments on EPA's proposed rule to require manufacturers (including importers) of 16 chemical substances to submit copies and lists of certain unpublished health and safety studies to EPA please contact me at mames@aiha.org or (703) 846-0730. Thank you for your time and consideration.

Sincerely,



Mark Ames
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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.