



May 2, 2016

Docket Office
Occupational Safety and Health Administration
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

RE: Docket Number OSHA-2016-0004
OSHA Guidance on Data Evaluation for Weight of Evidence Determination

Docket Officer:

The American Industrial Hygiene Association (AIHA) expresses its appreciation to the Occupational Safety and Health Administration (OSHA) for the opportunity to comment on OSHA's Guidance on Data Evaluation for Weight of Evidence Determination

AIHA is the premier association serving the needs of professionals practicing industrial hygiene in industry, government, labor, academic institutions, and independent organizations. The AIHA mission is to promote healthy and safe working environments by advancing the science, principles, practice, and value of industrial hygiene. A healthy workforce is essential to the success of American industry, our economic recovery, and our future position in the global economy.

As stated in OSHA's announcement, the guidance document has been developed to assist manufacturers, importers and employers on how to evaluate scientific studies under a Weight of Evidence (WoE) approach for hazard communication purposes. This guidance outlines the types of information to consider in the process of classification of a substance for health hazards, how to evaluate the strength of evidence in classification, the scope and use of WoE, and detailed considerations in the use of WoE as per the Hazard Communications Standard.

AIHA's attached comments on the WoE were developed by the AIHA Management Committee Standards Advisory team.

AIHA thanks OSHA for this opportunity to provide comments. If AIHA can be of any further assistance, please contact me. Thank you.

Sincerely,

Daniel H. Anna, PhD, CIH, CSP
AIHA President

cc: AIHA Board of Directors

AIHA Comments on OSHA Draft Guidance on Evaluation for Weight of Evidence

Application to the 2012 Hazard Communication Standard

AIHA Management Committee - Standards Advisory Team

Section	Page	Paragraph	Reference Text	Comments
1.0	2	1	In 2012, OSHA modified its HCS to conform to the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS).	Include a link to the UN GHS System for convenient reference
1.1	3	1	Most of the hazard definitions under the original rule simply led to a conclusion that the chemical involved presents that hazard or it does not.	Suggest rewording to "Most of the hazard definitions under the original rule simply led to a conclusion as to whether or not the chemical involved presents the particular hazard."
1.1	3	1	Thus, even though positive results from one study may have been used to determine initially whether a chemical was to be considered a hazard under HCS, there was a consideration of the weight of evidence when deciding what to include on a label.	Should the highlighted section read "...there was minimal guidance for consideration of the weight of evidence..."
1.2	4	2	Although OSHA does not expect a major shift in the determination of health effects of chemicals under the new GHS-aligned HCS, it anticipates that hazard classification will be more structured, organized and transparent.	Suggest adding 'consistent' to highlighted section, i.e., 'structured, organized, transparent and consistent.'
2.2	7	1	Krauth et al., (<i>Environ. Hlth. Perspec.</i> 121:985-992, 2013) presents systematic assessment criteria for bias, methodology, and reporting of studies in laboratory animals. Another tool that some evaluators have used in the evaluation of a particular set of experimental data involves criteria	Is this paragraph meant to represent OSHA's recommended references for systemic assessment? If so, that should be more clearly stated. Suggest that the last sentence of the paragraph (highlighted) be expanded to state that other 'peer reviewed or internationally recognized methods' are also considered as acceptable alternatives to the methodology presented by Krauth, et al and Klimiscb et al.

			<p>developed by Klimisch et al. (<i>Regul. Toxicol. Pharmacol.</i> 25:1-5; 1997). Scores for reliability of the data can be assigned using these criteria and then used to help judge the relative weight to give to various studies on the same substance or its analogs in the overall weight of evidence. However, this method must be used judiciously. The assessment is subjective and only oriented to an evaluation of the quality of the study—it does not assess bias or validity of the study. In addition, its criteria have an inherent preference for standardized studies, which is not employed under the HCS WoE approach. Other methods for judging the acceptability of studies may be used together with or separate from those in these publications.</p>	
2.4	11	3	<p>The positive study would take precedence in classification unless there were compelling reasons not to do so, such as fundamental flaws in the positive study or data that clearly established that positive results are not relevant to humans.</p>	<p>Should this statement also include relevance to the workplace?</p>
General Comments				
<p>The examples 3.2.3.4, 3.3 and 3.4 offer excellent guidance on hazard classification decision making. Suggest additional examples be included for 1A classifications.</p>				
<p>As a general comment, should there be some guidance here on frequency to review available data for updating classifications? Is that to be concurrent with the SDS update requirements? I believe some mention of update requirements in this document is warranted.</p>				
<p>As a general comment, suggest OSHA compile a summary list of all references noted in the guidance document along with other credible resources that could be considered in developing credible classifications.</p>				
<p>In several places OSHA indicates that information not sufficient for classification purposes should be included in Section 11 of the SDS. This needs to be limited to high order data that is perhaps not yet shown to be reproducible. Including data that does not provide direction is the quickest way to ensure that section is ignored.</p>				
<p>There is no mention of what to do if a study's protocols or findings come into question at a later time. There were not any recommendations for the frequency of review.</p>				