

## Science Based Decisions Must be Based on Weight of the Evidence

- Weight of the evidence has a discrete meaning for scientific risk assessment. (This is not to be confused with “weight of the evidence” as a concept in US courtrooms.)
- WoE is important because risk assessments must rely on the best available scientific information, and they must employ consistent, objective methods and models to derive realistic determinations of hazards and risks at environmentally relevant levels of exposure.
  - Scientifically valid, up-to-date data and knowledge of possible hazards and risks of substances should be used. All assessments must be based on a framework that takes into account – and integrates – all relevant studies, while giving the greatest weight to information from the most relevant and highest quality studies.
- WoE foundational concepts and approaches are well established in chemical risk assessment. They have been in use (and refined, improved, and integrated) over decades.
  - Douglas Weed, then with the National Cancer Institute, said “[f]or at least 50 years, the phrase “weight of evidence” (WOE) has appeared in the scientific literature, most often in the context of risk assessment (RA). In the National Research Council’s 1983 “red book,” for example, the concept played an important role in describing key components of RA.” (Weed 2005.)
  - EPA’s guidelines for cancer assessment were incorporating weight of the evidence review as early as 1986 (“In the 1986 guidelines, hazard identification and the weight-of-evidence process focused on tumor findings.” <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/evaluating-pesticides-carcinogenic-potential>)
  - Another commentator notes that the WOE approach was introduced into “ecological risk assessment since the early 1990s in response to the need for better risk analyses of Superfund sites and impacted natural ecosystems.” (Krimsky)
  - The EU recently evaluated nine regulatory frameworks set out by the European Commission and implemented by the European Chemicals Agency (ECHA), the European Food Safety Authority (EFSA), and the European Medicines Agency. 7 of 9 frameworks promote weight of the evidence/systematic review approaches.<sup>1</sup>
- US EPA has established weight of the evidence guidelines.<sup>2</sup> Example:

“Because of the importance of WoE in the U.S. Environmental Protection Agency’s assessments, the Agency has developed WoE guidelines. Their purpose is to make inferences by WoE more transparent and defensible by standardizing a formal framework and associated processes.”

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<sup>1</sup> European Commission, Chemicals risk assessment: evidence-evaluation methods analysed for nine EU regulations, 2016 citing Ågerstrand, M & Beronius, A. (2015). Weight of evidence evaluation and systematic review in EU chemical risk assessment: Foundation is laid but guidance is needed. Environment International. DOI: 10.1016/j.envint.2015.10.008 available at [http://ec.europa.eu/environment/integration/research/newsalert/pdf/chemicals\\_risk\\_assessment\\_evidence\\_evaluation\\_methods\\_nine\\_eu\\_regulations\\_460nal\\_en.pdf](http://ec.europa.eu/environment/integration/research/newsalert/pdf/chemicals_risk_assessment_evidence_evaluation_methods_nine_eu_regulations_460nal_en.pdf)

<sup>2</sup> EPA, Weight of the Evidence for Ecological Assessment, Suter G. Weight of Evidence for Ecological Assessment. International Conference of the Collaboration for Environmental Evidence, Paris, FRANCE, April 16 - 20, 2018 (at [https://cfpub.epa.gov/si/si\\_public\\_record\\_Report.cfm?dirEntryId=339391](https://cfpub.epa.gov/si/si_public_record_Report.cfm?dirEntryId=339391))

“WoE-related concepts. The three basic steps of the framework are: assemble evidence, weight the evidence, and weigh the body of evidence.”

“The assemble evidence step includes the literature search, screening, and evidence derivation processes that also occur in SRs.”

“The weight evidence step assigns scores to each piece or category of evidence and derives a combined weight. Weights are assigned to each of three major properties: relevance, strength and reliability.”

“The third step, weigh the body of evidence is the inferential step. It integrates the evidence for each alternative hypothesis, and then interprets the resulting bodies of evidence (BoE).”

- For any decision based on science – which includes chemical safety determinations) under TSCA, the 2016 amendments now require EPA to apply best available science and weight of the scientific evidence.
- This is set out in the law in an actual scientific standard – a standard for making decisions based on science. (i.e., failure to make decisions based on weight of the evidence does not meet the standard).
  - EPA defined the term in the final risk evaluation rule published on July 20, 2017: “Weight of the scientific evidence means a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.”
- But WoE does not have to be complex or time consuming. It is fit-for-purpose. EPA explains in the preamble to the final rule from 2017:
  - “As explained in the proposed rule at 82 FR 7566, all conditions of use will not warrant the same level of evaluation, and EPA expects that it may, in some cases, be able to reach conclusions without extensive or quantitative evaluations of risk. The addition of this phrase to the definition is intended to clarify that different weight of the scientific evidence review methods may be appropriate for different information, types of evaluations, or decisions. Specifically, fit-for-purpose means that while **EPA will always apply the principles contained in the definition, the depth or extent of the analysis will be commensurate with the nature and significance of the decision.**”