

Special Series

Advancing the weight of evidence approach to enable chemical environmental risk assessment for decision-making and achieving protection goals

Kuan-Chun Lee,¹ Patrick D. Guiney,² Charles A. Menzie,³ and Scott E. Belanger⁴

¹Procter & Gamble International Operations (SA) Singapore Branch, Singapore, Singapore

²University of Wisconsin-Madison, Madison, Wisconsin, USA

³Exponent Inc., Alexandria, Virginia, USA

⁴Procter & Gamble Company (retired), Cincinnati, Ohio, USA

EDITOR'S NOTE:

This article is part of the special series “Practical Considerations for Application of Weight of Evidence in Chemical Evaluations” and benefited from discussions at several symposia organized between 2015–2019 in conjunction with SETAC meetings in SETAC's Geographic Units. This series aims to reflect the broad applicability of Weight of Evidence (WoE) methodology in environmental risk assessment for chemical evaluations when combined with a classic tiered assessment approach, applicable regardless of regulatory structures. The articles discuss transparent mechanisms for communicating decision-making processes and critically examine case studies that lay out a guide for implementing WoE for improving chemical evaluations to increase their acceptability by all affected parties for desired protection goals.

Abstract

The weight of evidence (WoE) approach conflates the aspects of quality, reliability, relevance, and consistency of data and information to systematically strengthen the body of evidence and enable credible communication and decision-making on chemical risk assessment. Between 2015 and 2019, the Society of Environmental Toxicology and Chemistry (SETAC) held several workshops in all the geographical units with scientists and managers from academia, government, and business sectors focusing on the chemical risk-assessment approach. This article summarizes the knowledge that informs the needs concerning application of WoE, especially in the context of developing countries. This effort supports the use of existing data and test strategies for assessing chemical toxicity, exposure, and risk, and highlights the critical process for risk assessors to convey and discuss information sufficiency and uncertainty mitigation strategy with risk managers. This article complements the four articles in the special series that provide a critical review of existing frameworks for chemical risk screening and management, and applications of the WoE approach for assessing exposure in the aquatic environment, prediction of fish toxicity, and bioaccumulation. Collectively, the articles exemplify the use of WoE approaches to evaluate chemicals that are data rich and/or data poor for decision-making. They integrate the WoE concepts and approaches into practical considerations and guidance, and help to scale the value of WoE in supporting sound chemical risk assessment and science-based policy implementation. *Integr Environ Assess Manag* 2023;19:1188–1191. © 2023 The Authors. *Integrated Environmental Assessment and Management* published by Wiley Periodicals LLC on behalf of Society of Environmental Toxicology & Chemistry (SETAC).

KEYWORDS: Chemical management; Developing country; Risk assessment; Risk communication; Weight of evidence

This article contains online-only Supporting Information.

Address correspondence to lee.kc@pg.com

Published 8 July 2023 on [wileyonlinelibrary.com/journal/ieam](https://onlinelibrary.wiley.com/journal/ieam).

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

INTRODUCTION

This special series includes four articles that demonstrate practical aspects for the application of weight of evidence (WoE) in chemical evaluations and risk management. The articles stem from the Society of Environmental Toxicology and Chemistry (SETAC) workshops held between 2015 and 2019 in North America, Europe, Asia, Latin America, and Africa on chemical risk-assessment approaches and WoE (refer to the List of Workshops in the Supporting Information). The effort was initiated in 2014 by the SETAC International Programs Committee working with governance leadership in

the various SETAC Geographic Units (GUs). The workshop series began in 2015; the last workshop in 2019 occurred before the coronavirus pandemic forced SETAC to place face-to-face meetings on hold. Chemical management considerations addressed at the workshops entailed all life cycle aspects of chemicals including development, production, regulation, use, and eventual disposal and remediation where necessary. Although risk-assessment workshops were held in all SETAC GUs, GUs with low- and middle-income countries and resource-limited regions were emphasized: Asia-Pacific (two workshops), Latin America (three workshops), and Africa (one workshop). The workshops brought together scientists and managers from academia, government, and business to collectively achieve a diverse perspective aligned with SETAC's tripartite philosophy.

KNOWLEDGE AND PERSPECTIVES FROM SETAC WORKSHOPS

We view the workshop efforts and the four articles in this special series as complementary to and examples of the basic WoE principles outlined by the Organization for Economic Co-operation and Development (OECD, 2019). The OECD underscored the importance of flexible approaches to applying WoE concepts and noted that guiding principles and key elements can be employed to develop frameworks that range from simple and pragmatic approaches to more elaborate systems, depending on the context. Our collective experience from the workshops is that those recommendations are especially valuable. In particular, developing countries are challenged when considering the reliability and relevance of available information at early stages of the risk-assessment and risk-management process. The workshops held by SETAC on WoE revealed that developing countries were particularly interested in the reliability of toxicity, exposure, and derived benchmark values published by other countries for screening or regulating chemicals. There was also strong interest in the applicability of testing strategies being developed in their academic and governmental institutions for assessing toxicity, exposure, and risk. Over the past several decades, developed countries such as those in North America and Europe and Japan and Australia have developed testing- and risk-assessment strategies for chemicals. These strategies were based on experience and with consideration of the types of environments where chemical exposure might occur and for model organisms reflective of ecological receptors common to these environments. Common questions raised at the workshops by scientists and regulators from developing countries concerned how evaluations of new chemicals or use in specific environments and exposures to receptors will differ from those used to develop data within the various developed countries. These questions point to the value of an approach for the risk assessors involving a review of the technical factors and assumptions underlying existing data and chemical benchmarks to judge the reliability and identify data gaps. The same thoughtful consideration is valuable for judging the applicability and usefulness of testing and assessment strategies being developed by the countries' academic and

governmental institutions for assessing exposure, effects, and risks. These questions about data reliability and appropriate testing procedures underscore the importance of considering WoE at the earliest stages of an assessment process to ensure information is reliable and relevant. With that in mind and presuming formal systems are not fully developed, we recommend that countries, governmental agencies, and technical advisory groups consider incorporating WoE at early stages (e.g., even at screening levels stages) and then use a tiered approach as necessary to acquire and evaluate additional information.

Another key outcome of the workshop discussions is recognition of the importance of communication between the risk assessors and risk managers. From a technical and decision standpoint, a central question raised by discussants regards the sufficiency of information. We considered this and offer our thoughts on this important aspect of the process (Figure 1).

SPECIAL SERIES ARTICLES

The four articles in this special series illustrate the use of WoE approaches to evaluate chemicals that are data rich and/or data poor and inform decision-making even based on limited information. It should be noted that the application of a WoE approach does not increase or decrease the risk of the chemical but rather improves the quality of an assessment by reducing uncertainty surrounding the likelihood that existing conditions can or cannot cause an adverse effect or that a hypothetical future action (or condition) will cause an adverse effect. The context and objectives for the four articles are outlined below.

- Moore et al. (2023): "Frameworks for screening and risk management of chemicals and advanced materials: A critical review" provides a comprehensive review and critical comparison of 12 existing frameworks on the evaluation and management of chemical or material risk encompassing regional, national, and international authorities and purposes. The article discusses and summarizes issues, and provides recommendations to improve data transparency and accessibility, and communication of evaluation. It also outlines a risk-management framework and process, thus providing a foundational relevance to stage the articles in the special series for enabling and supporting chemical management and policy implementation.
- Miglino and Holmes (2023): "Applying weight of evidence methods to assessing exposure in aquatic environments: Comparing lines of evidence" delineates and strengthens the less examined application of WoE to exposure assessment via two case studies of aquatic exposure assessment. The process and analysis of the quality and reliability of the exposure data and lines of evidence (LoEs) illustrate the relevance of the WoE approach and how it can be applied to reduce uncertainty in the prediction of and decision-making on exposure concentrations.

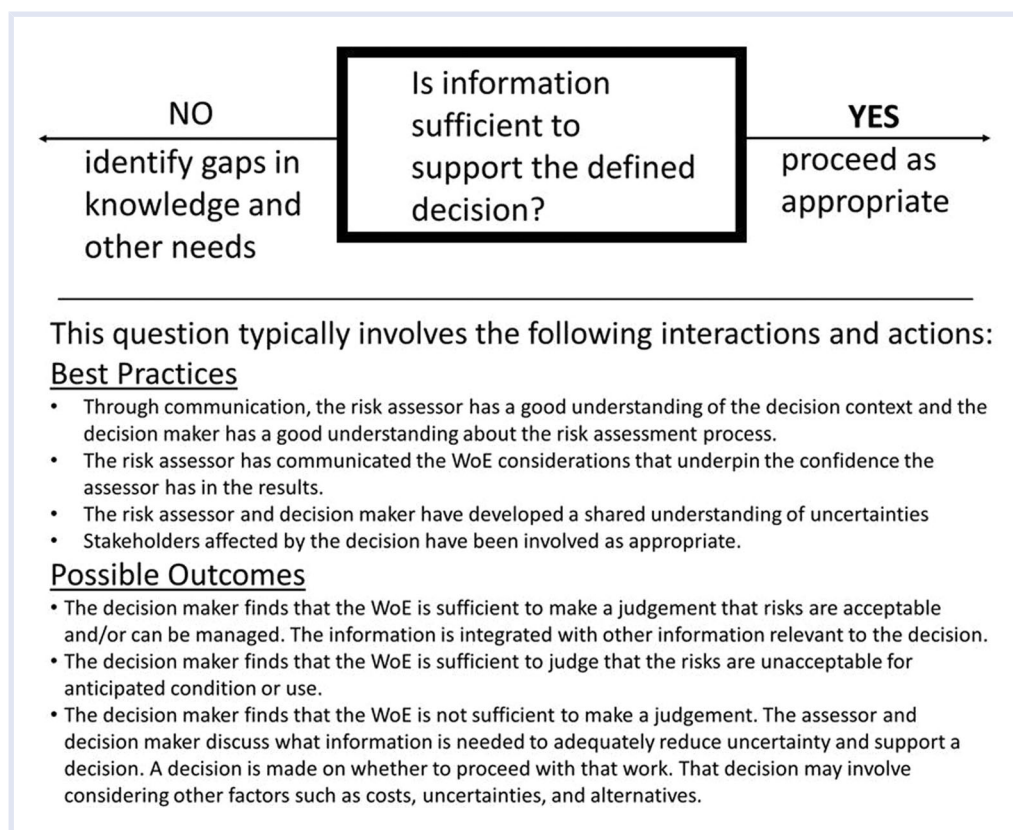


FIGURE 1 What is involved in answering the question: Is information sufficient to support the defined decision?

- Belanger et al. (2023): "Weight of evidence tools in the prediction of acute fish toxicity" focuses on thorough and practical aspects of applying WoE to acute fish toxicity (AFT), one of the most common regulatory environmental hazard assessment endpoints. It provides an in-depth discussion of how WoE contributes to assessing AFT with animal alternative assays including various LoEs and a statistical approach to support estimation of AFT that replaces or reduces animal use as well as delineating the important attributes for a successful WoE for AFT.
- Arnot et al. (2023): "A weight of evidence approach for bioaccumulation assessment" discusses the aspect of how the Bioaccumulation Assessment Tool (BAT), which illustrates an iterative and tiered organizational framework for integrating various LoE, supports a consistent and transparent WoE framework to address uncertainty challenges of measured or model-predicted data (data-poor chemicals) for bioaccumulation assessment and regulatory decision-making.

CONCLUSION

This article and the others in the special series are intended to serve as a bridge between integration of the WoE concepts and approaches into practical considerations and guidance and scaling the value in enabling

sound chemical risk assessment and science-based policy implementation, especially for developing countries. As a leading scientific global society, SETAC can and should continue to play a key role in providing training and workshops to advance application of WoE in chemical management and allow the exchange of experiences and new, emerging knowledge from the tripartite community to refine and broaden the reach of the approach.

ACKNOWLEDGMENT

We thank the authors of the four articles in the special series for their insights and knowledge in articulating the applications of WoE within a guidance framework. Appreciation also goes to all the participants in the WoE workshops for contributing to the valuable views and considerations that enabled this endeavor. We thank the Procter & Gamble Company for sponsoring Open Access of this article.

AUTHOR CONTRIBUTION

Kuan-Chun Lee: Conceptualization; data curation; investigation; project administration; resources; validation; visualization; writing—original draft; writing—review and editing. **Patrick D. Guiney:** Conceptualization; data curation; methodology; project administration; resources; validation; writing—review and editing. **Charles A. Menzie:** Conceptualization; data curation; methodology; resources;

validation; writing—original draft; writing—review and editing. **Scott E. Belanger:** Conceptualization; data curation; methodology; resources; writing—review and editing.

DATA AVAILABILITY STATEMENT

No data were generated for this article.

ORCID

Scott E. Belanger  <http://orcid.org/0000-0003-0369-9673>

SUPPORTING INFORMATION

The Supporting Information provides a list of SETAC Workshops, programs, and learnings that inform and support the content of this article.

REFERENCES

- Arnot, J. A., Toose, L., Armitage, J. M., Embry, M., Sangion, A., & Hughes, L. (2023). A weight of evidence approach for bioaccumulation assessment. *Integrated Environmental Assessment and Management*, 19(5). <https://doi.org/10.1002/ieam.4583>
- Belanger, S. E., Lillicrap, A. D., Moe, S. J., Wolf, R., Connors, K., & Embry, M. R. (2023). Weight of evidence tools in the prediction of acute fish toxicity. *Integrated Environmental Assessment and Management*, 19(5). <https://doi.org/10.1002/ieam.4581>
- Miglino, A. N., & Holmes, C. M. (2023). Applying weight of evidence methods to assessing exposure in aquatic environments: Comparing lines of evidence. *Integrated Environmental Assessment and Management*, 19(5). <https://doi.org/10.1002/ieam.4602>
- Moore, D. W., Ruffle, B., McQueen, A., Thakali, S., & Deborah Edwards, D. (2023). Frameworks for screening and risk management of chemicals and advanced materials: A critical review. *Integrated Environmental Assessment and Management*, 19(5). <https://doi.org/10.1002/ieam.4590>
- Organization for Economic Co-operation and Development (OECD). (2019). *Guiding principles and key elements for establishing a weight of evidence for chemical assessment* (Series on Testing and Assessment No. 311, ENV/JM/MONO(2019)31). Environment, Health and Safety Division, Environment Directorate.