

Improving the usability of ecotoxicology in regulatory decision-making



Executive Summary from a SETAC Pellston Workshop®

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The SETAC Pellston Workshop® “Improving the usability of ecotoxicology in regulatory decision-making” was held from 30 August to 4 September 2015 at the U.S. Fish and Wildlife Service National Conservation Training Center in Shepherdstown, West Virginia.

The aim of the workshop was to develop guidance on steps that can be taken to improve the use of all ecotoxicity data in prospective risk assessments, whether the data are from guideline studies conducted under Good Laboratory Practices regulations or from research studies published in the peer-reviewed literature. The goal was to increase understanding between those conducting studies to be published in the peer-reviewed literature and regulatory institutions assessing those studies. This includes an understanding of the advantages and limitations of guideline studies.

The workshop was attended by 38 experts from four continents representing academia, business, government and NGOs. Three students were also invited and contributed substantially. Expertise of the attendees spanned agricultural chemicals, industrial chemicals, metals, pharmaceuticals and consumer products.

The workshop addressed the following processes:

- Improving the reliability and reproducibility of ecotoxicity studies
- Improving the use of peer-reviewed studies in regulatory risk assessment of chemicals
- Improving the methods used in risk assessments when evaluating single pieces of evidence or lines of evidence

The focus of the workshop was on prospective ecological risk assessment (e.g., evaluation of chemicals, pesticide registration, etc.) versus retrospective risk assessment. In addition, the focus was on ecotoxicity testing; evaluating exposure was not part of the scope, although we recognize that risk assessment requires evaluation of both effects and exposure.

Recommendations on good practices for study design, establishment of minimum requirements for reporting the methodology, performance and results, and proposals for improving consistent use of the information during the regulatory processes were discussed. Other issues of importance were regulators’ view of academic research, the role of scientific journals in promoting reliability and reproducibility of studies, actions industry can take to increase the transparency of studies, methods for enabling transfer of knowledge between stakeholders, and tools for improved risk assessment.

The outcome from the workshop was a mix of peer-reviewed papers, which primarily will target the SETAC journal IEAM, and other actions to promote understanding and collaboration between stakeholders.

The following papers have been, or are in the process of being, published:

1. Hanson ML, Wolff BA, Green JW, Kivi M, Panter GH, Warne M St J, Ågerstrand M, Sumpter JP. 2016. How we can make ecotoxicology more valuable to environmental protection. *Science of The Total Environment*. 578:228-235.
2. Moermond CTA, Beasley A, Breton R, Junghans M, Laskowski R, Solomon K, Zahner H. 2017. Assessing the reliability of ecotoxicological studies: An overview of current needs and approaches. *Integrated Environmental Assessment and Management*. DOI: 10.1002/ieam.1870.
3. Ruden C, Adams J, Ågerstrand M, Brock T, Poulsen V, Schlekot C, Wheeler J, Henry T. 2017. Assessing the relevance of ecotoxicological studies for regulatory decision-making. *Integrated Environmental Assessment and Management*. DOI: 10.1002/ieam.1846.
4. Harris MJ, Huggett DB, Staveley JP, Sumpter JP. 2017. What training and skills will the ecotoxicologists of the future require? *Integrated Environmental Assessment and Management*. DOI: 10.1002/ieam.1877.
5. Hall AT, Martin O, Belanger SE, Galay-Burgos M, Guiney PD, Maack G, Stubblefield B. Weight-of-Evidence for Ecotoxicological Effects in Regulatory Decision-Making. Manuscript.

At the SETAC North America annual meeting in 2015 in Salt Lake City, a [session](#) discussing the initial workshop outcomes was held. Topics included recommendations for improving academic research papers, development of criteria for evaluating reliability, assessment of relevance, use of weight-of-evidence approaches, suggestions for increasing regulatory impact, and statistical considerations.

During the SETAC Europe annual meeting in Nantes in 2016 a special session was organized. Similar to the Salt Lake City session, participants from the Pellston Workshop presented their findings. However, at this meeting a panel of invited stakeholders, representing industry, journal editors, and national and European agencies, gave their view on the workshop findings. The session was well attended and resulted in fruitful discussion regarding possible ways forward.

This topic continued to be of interest at the SETAC 7th World Congress in Orlando in 2016, with a session on “Making your research relevant to regulatory science and supportive of decision-making,” which included presentations on environmental fate studies, exposure assessment and water quality criteria development, among other topics.

In our view, SETAC Pellston Workshops provide a platform for discussions and collaborations between academia, business, government and NGOs. They give different stakeholders opportunity to meet and find solutions to common problems, try new ideas and promote understanding of the various views. For this workshop, positive feedback has been received from participants representing all sectors. Highlights include the open discussion climate, the chance to meet new people and to gain new perspectives, and the beautiful environment in which the workshop was held.

During the workshop, a number of follow-up activities were identified for potential consideration. Some of these include:

- Draft letters to the editors of non-SETAC journals
- Conduct short courses at SETAC meetings or via online webinars
- Work with OECD's Working Party on Hazard Assessment to explore development of a project to develop an open literature screening and review guidance
- Provide student training and guidance for academic departments on research quality and regulatory processes
- Hold briefings with regulators and give presentations to other organizations
- Convene a panel on data quality among publishing companies

We would like to thank all the participants for their excellent contributions, the steering committee for their hard work organizing the workshop, and the SETAC North America office for their support.

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* steering committee members | # steering committee members unable to attend the workshop

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