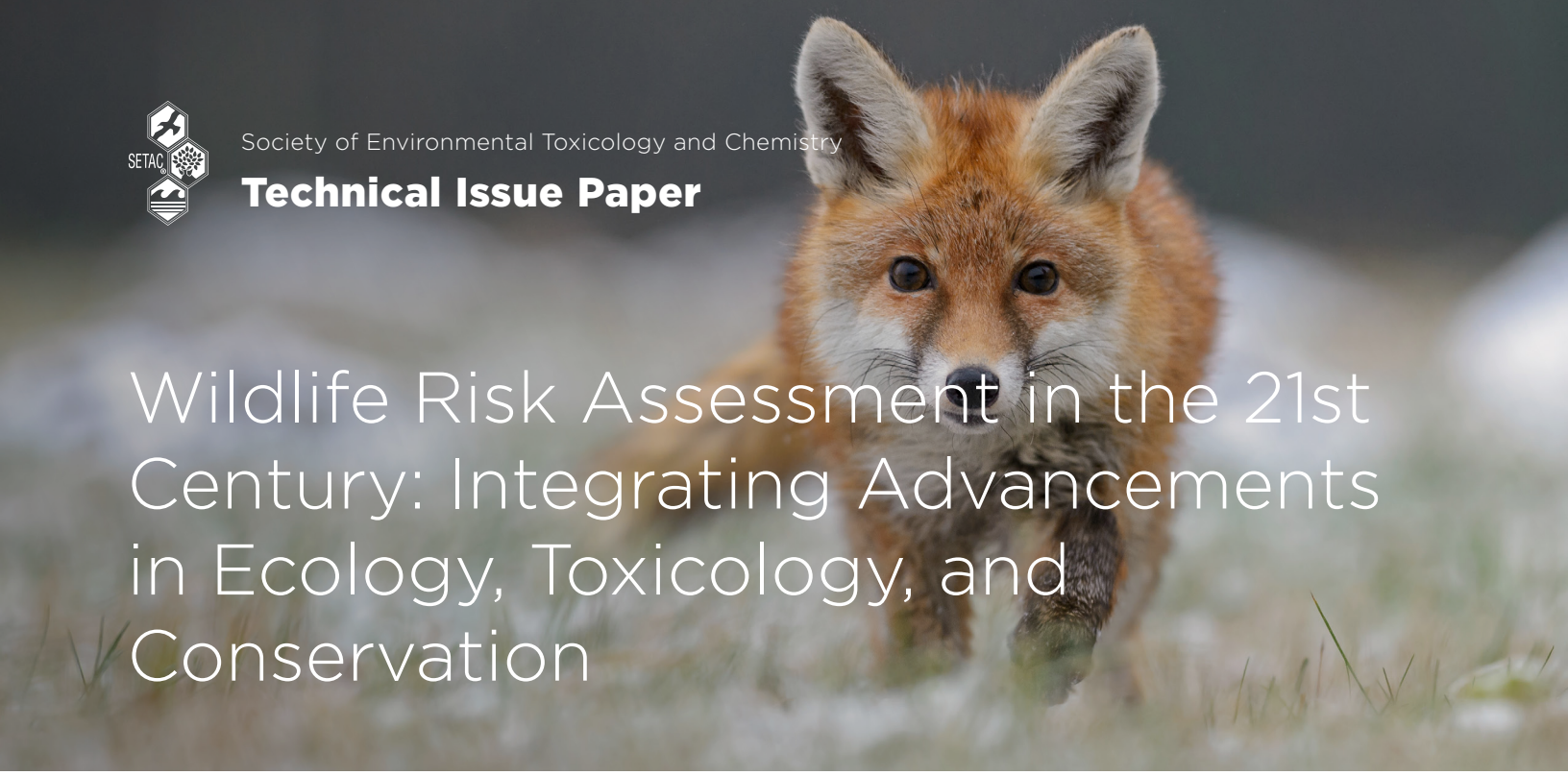

Society of Environmental Toxicology and Chemistry

Technical Issue Paper

Wildlife Risk Assessment in the 21st Century: Integrating Advancements in Ecology, Toxicology, and Conservation

Wildlife Risk Assessment in the 21st Century

Chemical management schemes around the world rely on wildlife risk assessment, which in turn rely on scientific advancements in the fields of biology, ecology, and toxicology. Subsequently, as science advances within these disciplines, so should the field of wildlife toxicology and the methods of wildlife ecological and environmental risk assessment (WERA). However, guidance to evaluate risk to wildlife from chemical exposure has not advanced in decades, despite the availability of new scientific tools and approaches. A group formed the WERA Team and hosted a SETAC workshop to improve methods for characterizing exposure, toxicity, and estimating risk of chemical exposures for terrestrial wildlife. The team aimed to trigger changes in practice, guidance, policy, and regulation related to WERA and to encourage risk assessors and regulatory agencies to consider how emerging science can increase the reliability of risk estimates and, ultimately, improve decision-making. The workshop output has now been published in a series of seven articles in IEAM titled: "Wildlife Risk Assessment in the 21st Century: Integrating Advancements in Ecology, Toxicology, and Conservation."

Integrating Advancements in Ecology, Toxicology, and Conservation

Wildlife risk assessment is applied in various regulatory environments. Most of such regulations and guidance are applied broadly to many organisms including plants, invertebrates, and fish. The WERA Workshop Team focused on regulations for Canada, the European Union (EU), and the United States (US), to identify challenges that risk assessor and managers encounter while applying them to wildlife. The team then developed recommendations to address these challenges, which provide the essence of this Technical Issue Paper. The team organized the challenges and recommendations based upon foundational components of WERA: problem formulation, exposure assessment, effects assessment, and risk characterization.

Challenges

Challenges in WERA begin in the first component of the process (problem formulation) and then are encountered throughout. The first and most important component in the risk assessment process is to define the scope of the problem correctly and there are several challenges related to this undertaking. In the toxicity and effects assessment components of WERA, there are gaps in both data and methods that need to be addressed to allow for better use of advanced WERA

techniques. Finally in the last component of a WERA, risk characterization, jurisdictions and legislation vary in their flexibility to incorporate data from new and emerging science in risk assessments for wildlife.

Challenges in wildlife ecological risk assessment

Problem formulation

- Ensuring that risk management goals are protective, reliable, and reflect ecological and social values.
- Incorporating improved methods in exposure and assessments during problem formulation.
- Using rudimentary toxicity information to evaluate adverse effects (e.g., use of no observed-adverse-effect levels [NOAELs] or Lowest observed- adverse-effect levels [LOAELs] instead of preferred dose–response [DR] relationships).
- Working within constrained regulatory frameworks and mindsets.

Toxicity assessment

- Employing alternative methods in place of live animal experimentation while recognizing that much valuable information may be lost.
- Increasing the use of omics and other technologies while recognizing there will be a continuing need for in vivo studies.
- Increasing the use of New Approach Methods (NAMs) as tools in addressing assumptions and data gaps in laboratory and field studies.
- Reducing use of animals in toxicity testing while maintaining relevance of the WERA.
- Considering use of adverse outcome pathways and key events in extrapolating effects between species without losing relevance to wildlife.
- Minimizing duration between registration and detection of ecologically relevant adverse effects in the field.
- Improving sophistication of population models and linkage to organism-level responses.

Exposure assessment

- Including environmental and interspecies complexity.
- Including chemical and species-specific routes of exposure and absorption, distribution, metabolism, and excretion.
- Considering spatial and temporal exposure patterns with behavioral contexts.
- Addressing uncertainty and assumptions.
- Applying animal-friendly techniques and relying less on in vivo tests.

Risk characterization within current regulatory frameworks

- Varying flexibility by jurisdictions and legislation to incorporate data from new and emerging science in risk assessments for wildlife.
- Considering risk assessments for wildlife species for new chemical production.
- Harmonizing methods for understanding toxicity from candidate pesticides and biocides do not allow for deviations or even interpretation of results.

Recommendations

Recommendations to integrate scientific advances into wildlife risk assessment are provided for each component of the process. Some of these recommendations identified by the WERA Team can immediately be deployed by risk assessors and risk managers, while others require advancement in knowledge through further development and refinement of the science.

Specifically, advancements in ecotoxicology are required to enable improvements in the exposure and effects assessments components of the WERA process. The key recommendations from the workgroup manuscripts, that is, for problem formulation, exposure assessment, effect assessment, and risk characterization, follow:

Problem Formulation

During problem formulation, conceptualizing the problem relative to regulatory statutes and management goals is paramount. In nearly all cases, decision criteria must be explicit and outlined before data are collected. Alternative lines of evidence can be used to help reduce uncertainty associated with traditional approaches, and new methods and tools can have direct applicability to them.

Specific recommendations to risk assessors to improve problem formulation:

- Identify protection goals and decision criteria clearly.
- Define data collection procedures.
- Consider ecological effects to wildlife and ecological services to inform protection goals.
- Work toward comprehensive conceptual site models.
- Consider indirect effects and multiple stressors relative to actual or expected chemical exposure.
- Incorporate methods to reduce or inform uncertainties during problem formulation and the selection of data collection procedures.

Exposure Assessment

Exposure assessment will never be able to envelop all potential cases under field conditions, which potentially results in increased uncertainty and even blind spots in WERA. However, certain improvements in ecotoxicology could enable better handling of some of the challenges faced in the exposure assessment component of wildlife risk assessment.

Conceptual recommendations to ecotoxicologists to improve exposure assessment:

- Develop and use standardized environmentally relevant scenario-based approaches, focusing on specific (focal) species and habitats, instead of the currently used tiered approaches, and thus provide a better balance between realism and uncertainty.
- Establish and implement post-registration, remediation, and/or restoration monitoring guidance.
- Operationalize and utilize animal-friendly techniques to compare exposure predictions.

Effects Assessment

Ecological risk assessments for wildlife would benefit greatly from including new approaches and methods for measuring the effects of chemicals. While the characterization of adverse effects in WERA has relied principally on data for survival, growth, and reproduction, endpoints at many other levels of biological organization could improve efficiency, reliability, and realism in estimating exposure–response relationships, providing basis for species extrapolation, and informing ecological significance. Such data would therefore be a valuable addition to WERA through a weight-of-evidence approach.

Conceptual recommendations to ecotoxicologists to improve effects assessment are organized into two sets of recommendations, namely a suite of recommendations for traditional toxicology studies (e.g., controlled laboratory animal studies or standard in vivo methods) and another suite for NAMs including in vitro omics and other methods that provide useful information on biological mode of action or mechanism.

Recommendation for Traditional Toxicology Studies

- Update standard test protocols to optimize data quality and ensure the biological relevance of test.
- Fill critical knowledge gaps on the sensitivity of amphibians, reptiles, and bats compared with current animal models.
- Reduce uncertainty in extrapolation from model species to more diverse wildlife species.
- Develop and validate modeling approaches to individual and population level effects (e.g., behavioral effects).
- Obtain clear regulatory guidance on field study design.
- Validate in vitro omics and other NAMs against data from in vivo omics, tissue, organismal, and population studies for both legacy contaminants and newer chemistries.
- Employ a holistic approach and develop a framework that builds on existing knowledge and integrates all lines of evidence from validated and soon-to be validated techniques.

Recommendation for New Approach Methods

- Conduct and document systematic reviews of all types of effects data, including data from traditional toxicology studies (e.g., controlled laboratory

animal studies) and from NAMs, and from all levels of biological organization and improved evidence-integration techniques.

- Develop and grow the adverse outcome pathway knowledgebase (i.e., more research and knowledge at higher levels of organization, particularly populations).
- Generate meta-analyses and dose-response relationships and for preferential use over NOAELs and LOAELs.
- Utilize probabilistic approaches even if only for exposure estimation.
- Encourage use of population modeling for local species-specific factors most responsible for metapopulation regulation protection goals and capitalize on their utility in incorporating uncertainty.
- Develop ecosystem service models and frameworks and integrate them into the WERA process.

Risk characterization in wildlife risk assessment

Regulatory guidance on WERA is relatively standardized in Canada, the EU, and the US, and has not been explicitly revised to reflect new approaches. While the review of regulatory guidance found that many jurisdictions have flexibility to include new methods, risk managers entrusted with overseeing such risk assessments may not embrace using these data if they are uncomfortable with the scientific foundation or demonstration of the method. Therefore, it is recommended that both risk assessors and risk managers develop and utilize weight-of-evidence integration approaches that can consider data from new methods developed from scientific advancements in the areas of biology, ecology, and toxicology to increase the reliability of risk estimates and, ultimately, to improve evidence-based decision-making.

Path Forward

Risk assessors in all sectors are encouraged to embrace these recommendations and update the methods used in wildlife risk assessment to advance chemical management that will likely improve environmental health on a global scale. The environmental professional community is called upon to continually evaluate wildlife risk assessment methods and incorporate improvements based on developments whether they be societal, scientific, climatic, or other. For example, changes in the societal contexts of chemical use may necessitate consideration of new routes of exposure and advances in niche area of ecotoxicology such as immunotoxicology or epigenetics. Moreover, integrate climate change models into wildlife risk assessment, and consider wildlife risk assessment in the context of One Health.

Resources

Johnson, M., van den Brink, N., Power, B., Elliott, J. (2024). Special Series: Wildlife Risk Assessment in the 21st Century: Integrating Advancements in Ecology, Toxicology, and Conservation. Integrated Environmental Assessment and Management: 20 (3), 645–779.

Environmental Risk Assessment of Chemicals

Weight of Evidence in Environmental Risk Assessment of Chemicals

Acknowledgements

SETAC appreciates the contributions of the whole Wildlife Team especially the Steering Committee (Mark Johnson, Nico van den Brink, John Elliott, Beth Power), Barnett Rattner, and Tamar Schlekat to this document. Financial support for the workshop was provided by the United States Department of the Interior, United States Geological Survey, Teck Resources Ltd., and SETAC.

Copyright