Presentation Abstracts and Background Materials

SCIENTIFIC ADVISORY COMMITTEE ON ALTERNATIVE TOXICOLOGICAL METHODS

Session 2a: Ecotoxicology Testing: Regulatory Needs
Tuesday, September 28, 2021

Current Ecotoxicity Testing Needs Among Selected U.S. Federal Agencies

Presenter: Dr. Jessica Leet, U.S. Department of the Interior

U.S. regulatory and research agencies use ecotoxicity test data to assess the hazards associated with substances that may be released into the environment, including but not limited to industrial chemicals, pharmaceuticals, pesticides, food additives, and cosmetics. These data are used to conduct hazard assessments and evaluate potential risks to aquatic life (e.g., algae, invertebrates, fish), birds, wildlife species, or the environment. The aim of this review was to identify opportunities for the replacement of tests relied upon by U.S. federal agencies that use animals with alternative non-animal methods. The review discusses challenges presented by current use of cross-taxa extrapolation and outlines points for consideration in the context of their application to decision-making. Testing and information use, needs, and/or requirements relevant to the regulatory or programmatic mandates of the agencies taking part in the ecotoxicity workgroup (EcoWG) of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) EcoWG are specifically captured. This information will be useful for coordinating efforts within the U.S. and international communities to develop and implement alternative test methods to reduce, refine, or replace animal use in chemical safety evaluations.

Background

- Alternative Approaches to Vertebrate Ecotoxicity Tests

Alternate Models for Acute Fish Toxicity Testing: A Survey

Presenter: Dr. Natalia Garcia-Reyero, U.S. Department of Defense

Aquatic toxicity testing assesses the adverse effects of chemicals and other environmental stressors on aquatic organisms. It involves different media or environments (i.e., marine, freshwater), and a large number of species. Common tests include acute and chronic exposures and are often standardized by agencies and international bodies such as the US EPA or the Organisation for Economic Co-operation and Development. Nevertheless, there is interest and social pressure worldwide to develop alternative methods. Here, we summarize the use of the Acute Fish Toxicity Test, which is often requested as part of the registration of new substances and has lethality as an endpoint. We then explore the potential of alternate models that could provide hazard information and potentially replace the above-mentioned test.

Background

- OECD Test Guideline No. 203: Fish, Acute Toxicity Test
- Key Opportunities to Replace, Reduce, and Refine Regulatory Fish Acute Toxicity Tests

Reduction of Animal Use Through Using Fewer Species

Presenter: Dr. William P. Eckel, U.S. Environmental Protection Agency

EPA's Office of Pesticide Programs has been working on several projects to reduce the number of animals used in toxicology testing for ecological risk assessment. To date, these projects have considered either using fewer test guidelines per taxon or reducing the number of species tested for a particular guideline ("retrospective" studies) or quantitative structure-activity relationship (QSAR) methods.

Retrospective Studies.

- *Avian Acute Toxicity*. Collaborator: People for the Ethical Treatment of Animals (PETA). Our retrospective analysis found that the five-day avian dietary acute test does not contribute to bottom-line risk conclusions beyond the single oral dose study except for highly bioaccumulative chemicals.
- *Avian Reproduction*. Collaborator: PETA. We are conducting a retrospective comparison of mallard duck and bobwhite quail studies to determine if both are required to characterize chronic risk.
- *Fish Bio-Concentration Factor*. Collaborator: National Centre for the Replacement, Refinement and Reduction of Animals in Research. We determined that the BCF test may be reduced to one dose level except when the BCF is expected to approach 1,000.
- *Fish Acute LC50*. Collaborator: National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM). We are conducting a retrospective comparison of the three routinely tested species to determine if one is consistently more sensitive and whether fewer than three will suffice for assessing acute risk.
- *Fish Reproduction*. Collaborator: NICEATM. We are in the early stages of a retrospective study to evaluate if an acute to chronic toxicity ratio (ACR) can be used to estimate chronic toxicity to fish instead of early-life stage and full life-cycle studies.

QSAR Studies.

- *Fish Acute QSAR*. Collaborator: EPA Office of Research & Development. We are working to construct regression equations, based on OPP's data holdings, that expand pesticide-specific modes of action and structural classes.
- *Rat Oral LD50*. Collaborators: NICEATM and Humane Society. This study seeks to determine if the CATMoS acute mammalian toxicity prediction model can replace the rat acute oral toxicity study.

Background

- EPA: Strategic Vision for Adopting New Approach Methodologies
- EPA: Adopting 21st-Century Science Methodologies – Metrics
- Retrospective Evaluation of the Acute Fish Toxicity Test for Pesticide Registration
- Fish Bioconcentration Data Requirement: Guidance for Selection of Number of Treatment Concentrations
- Evaluation of the Avian Acute Oral and Sub-acute Dietary Toxicity Test for Pesticide Registration
- Final Guidance for Waiving Sub-Acute Avian Dietary Tests for Pesticide Registration and Supporting Retrospective Analysis