

# Next Generation Ecological Risk Assessment

Note: As of 2022, the former Animal Alternatives in ERA and Bioaccumulation Committees have merged to form the Next Generation ERA Committee



## Our Mission

To develop, refine, and communicate the scientific tools and approaches needed to support ecological risk assessment around the globe, with a focus on alternative, non-animal testing methods.

## HESI Staff

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## Webpage

<https://hesiglobal.org/ecorisk/>

## 2021 Committee Highlights

### Participating Organizations



8 government/regulatory agencies, 6 academic/research institutes, 7 industry, 3 others, and 4 consulting

### Publications



4 published, 1 accepted, and 9 in progress

### Web Tools and Assays



- 1 web tool
- EnviroTox ([envirotoxdatabase.org](http://envirotoxdatabase.org)), a curated, publicly available aquatic toxicity database that includes several analysis tools

### Outreach



- 1 poster presentation, 7 oral presentations, 1 guest lecture, 1 webinar, 1 webinar series and 1 survey
- 1 poster presentation and 2 oral presentations at the Society of Environmental Toxicology and Chemistry (SETAC) Europe 31<sup>st</sup> Annual Meeting (May 2021, virtual)

### Outreach



- 1 oral presentation at the "1<sup>st</sup> Workshop for Risk Assessment: Successes and Challenges for Safety Assessment" organized by the Federal University of Paraná (Brazil), University of São Paulo (Brazil), and University of Washington (January 2021, virtual)
- 1 oral presentation at the 11<sup>th</sup> World Congress on Alternatives and Animal Use in the Life Sciences (August 2021, virtual)
- 2 oral presentations at the SETAC Latin America 14<sup>th</sup> Biennial Meeting (September 2021, virtual)
- 1 guest lecture for the George Mason University Environmental Toxicology Course on "ecoTTC and the EnviroTox Database and Tools: Applications for Ecological Risk Assessment" (March 2021, virtual)
- 1 webinar co-organized by HESI, Eawag, and AquaTox Solutions on "New OECD Test No. 249: Fish Cell Line Acute Toxicity - The RTgill-W1 Cell Line Assay" (September 2021, virtual)
- 1 oral presentation at the "1<sup>st</sup> Workshop for Risk Assessment: Successes and Challenges for Safety Assessment" organized by the Federal University of Paraná (Brazil), University of São Paulo (Brazil), and University of Washington (January 2021, virtual)
- A monthly webinar series was initiated in 2021 with presentations related to the advancement of toxicokinetics and bioaccumulation science to aid ecological and human health risk assessment
- A survey was distributed to identify critical scientific needs, as well as data and knowledge gaps which, if addressed, could considerably advance the field of ecological risk assessment

### Collaborations



- 1 external
- Co-project with NC3Rs on endocrine disruption

### Geographic Representation



Canada, China, Denmark, Finland, France, Germany, Italy, Netherlands, Norway, Portugal, Switzerland, United Kingdom, and United States

## Working Groups

- **Alternatives to Chronic Fish Testing**

Building from previous committee work, a new scoping group will be formed 2Q 2022 to explore recent challenges and opportunities related to alternatives for chronic fish tests (e.g., OECD TG 210).

- **Bioaccumulation and Toxicokinetics**

This working group is focused on understanding the processes that impact the behavior of contaminants within an organism in order to refine ecological risk assessment. Though much of the initial work was focused specifically on bioaccumulation metrics, the group has expanded to consider how toxicokinetics can help inform interpretation of toxicity data, study design, cross-species extrapolations, and species sensitivity. The group has 3 sub-groups that are each focusing on various taxa important for ecological risk assessment: birds, invertebrates, and fish.

- **Ecotoxicology Endocrine Toolbox**

This team, a collaboration between HESI and NC3Rs, is focused on assessing available in vitro/in silico methods (new approach methodologies [NAMs]) to evaluate chemicals that may act via an endocrine pathway in fish and amphibians. Within this effort, several sub-groups focus on related supporting topics:

- NAM evaluation & case study development
- *in vivo* endocrine disrupting chemical (EDC) tests in fish and amphibians, focusing on analysis of historical control data (HCD)
  - *Smaller working group focused on HCD and histopathology of the amphibian metamorphosis assay (AMA)*
- Maximum Tolerated Dose (MTD) project

- **Effluent Assessment**

This team is working to engage with various stakeholders about current effluent testing approaches and needs within North America, to identify the opportunities and limitations related to alternative methods. A small group is working on a scoping document on harnessing existing data to inform best practices for effluent assessment with a fit for purpose approach. The goal is to broaden the discussion beyond alternative methods specifically and talk about some of the needs more broadly related to effluent data and methods.

- **EnviroTox Database and Tools / Ecological Threshold of Toxicological Concern (ecoTTC)**

This group is tasked with developing a strategy to update and augment the EnviroTox database (<https://envirotoxdatabase.org>) and refine and further develop applicable tools. Case studies to illustrate the use and application of the database and tools are ongoing.

## Areas of Focus for 2022:

- **Merger.** This year the merger of the Bioaccumulation and Animal Alternatives Committees created the Next Generation Ecological Risk Assessment Committee. This committee will address (but is not necessarily restricted to) the following topical areas: (a) explore the use of toxicokinetics in various species and taxa to better understand chemical exposure, and help refine ecological risk assessment and (b) the use and development of new approach methodologies (NAMs) and animal alternative methods for ecological risk assessment in various contexts (e.g., screening, prioritization in risk assessment) sectors (e.g., pharmaceutical, agrochemical, chemical, personal care/cosmetics), and regulatory jurisdictions.
- **EnviroTox Database and Tools/ecoTTC.** Work will continue to identify a sustainable process to augment and update the EnviroTox database on a yearly basis. A case study on "Exploring conservatism in ecoTTC and CTD: case study of chemicals with regulatory water quality values" is nearing completion. This example was presented at the 2020 SETAC Europe Virtual Annual Meeting and includes neurotoxicants, benzenes, and phthalates as examples. It is anticipated that this case study will be completed in late 2021, with journal submission in 1Q 2022.
- **Effluent Assessment.** The working group will work to expand an outline of a short overview communication and highlight some recent applications / analysis of effluent data. An abstract on this group's work was submitted for the 2022 SETAC North America Meeting.
- **Ecotoxicology Endocrine Toolbox.** The two major working groups (alternatives and in vivo) are completing several manuscripts to be submitted in mid-2022. These include (a) NAMs in the ecological endocrine activity toolbox, (b) Analysis of amphibian metamorphosis assay data, (c) Dose setting in in vivo endocrine assays, and (d) Analysis of historical control data from existing in vivo tests to evaluate endocrine disruption.
- **Weight-of-Evidence in Acute Fish Toxicity Assessment (SWIFT).** The project is continuing to pull together data sources and refine the Bayesian network.
- **Manuscripts.** Publish the state of the science on invertebrate bioaccumulation and biotransformation and the output from the fish biotransformation workshop

## Strategic Impact Areas

### Enhanced Efficiency and Accuracy in Safety Assessment Practice

The EnviroTox database has pulled together a curated resource of existing information that will facilitate development and evaluation of new methods in a more straight-forward manner. The tools associated with the database allow for novel analysis approaches, particularly with regard to risk-based prioritization. The committee's database and tools were recently highlighted in a [European Commission Report](#), and the ecoTTC concept was invited to be part of a special issue of *Frontiers in Toxicology* dedicated to the TTC concept more broadly ([Barron et al., 2021](#)).



The bioaccumulation subgroup aims to provide a better understanding of bioaccumulation, biotransformation, and toxicokinetics in various organisms, such as birds, invertebrates, and fish. It will help determine how to use various metrics in a weight-of-evidence approach, and ultimately allow for a refinement of the way ecological risk assessments are conducted.

### Catalysis of New Science

The initial work of this committee was focused on the Fish Embryo Toxicity (FET) test, which has led to various initiatives, including the recently funded CEFIC-LRI SWIFT project. SWIFT is working to develop qualitative and quantitative weight-of-evidence frameworks for assessment of acute fish toxicity using a wide range of lines of evidence. This project will develop a Bayesian network model with collaboration from HESI and various committee members and is led by researchers at the Norwegian Institute for Water Research (NIVA).



### Enhancement of the Societal Knowledge Base on Environmental or Ecological Processes of Relevance for Protecting the Health of the Environment

The totality of this committee's work is dedicated to environmental protection. It focuses on developing and evaluating alternative strategies that can maximize resource use while providing sufficient levels of protection. The working groups are identifying approaches and strategies to reduce the use of *in vivo* fish tests, while coupling scientific advancements with considerations and needs of various stakeholders at the national, state/provincial, and local levels. The bioaccumulation working group focuses on the characterization of biotransformation in different taxa to better predict the potential ecological impact of environmental contaminants.



### Increasing the Audiences for Collaborative Safety Science

This committee continually engages a variety of groups involved in Bioaccumulation research, as well as modeling and improvements of assessment methods (US EPA, Environment and Climate Change Canada, European Commission Joint Research Centre, CEFIC, etc.). In addition, the group has maintained strong ties with the SETAC Bioaccumulation Scientific Interest Group (BSIG) through which scientific sessions, training opportunities, and presentations have been organized at all the SETAC annual meetings. At these meetings, HESI has presented overviews of ongoing research activities to better forge ties with other interested research and regulatory groups. HESI is regularly invited to present the work of this committee at other stakeholder events and meetings.



## 2021 Awards, Grants and Recognition

HESI was awarded \$20,000 over two years from Cefic-LRI to support staff time for the Weightof-Evidence in Acute Fish Toxicity (SWIFT) program.

The manuscript "Recommendations for improving methods and models for aquatic hazard assessment of ionizable organic chemicals" (Escher et al., 2020) was recently recognized as one of Environmental Toxicology and Chemistry's Top 10 Exceptional Papers of 2020. The concepts for the publication were initiated in an "Experts Workshop on the Ecological Risk Assessment of Ionizable Organic Chemicals" that was co-sponsored by HESI, Environment and Climate Change Canada, Cefic, and SETAC.

## Publications

### Published

Brill JL, Belanger SE, Barron MG, Beasley A, Connors KA, Embry M, Carr GJ (2021) Derivation of algal acute to chronic ratios for use in chemical toxicity extrapolations. *Chemosphere*. doi: 10.1016/j.chemosphere.2020.127804.

Barron MG, Otter RR, Connors KA, Kienzler A, Embry MR (2021) Ecological thresholds of toxicological concern: a review. *Frontiers in Toxicology*. doi: 10.3389/ftox.2021.640183.

Belanger SE, Beasley A, Brill JL, Krailler J, Connors KA, Carr GJ, Embry M, Barron MG, Otter R, Kienzler A (2021) Comparisons of PNEC derivation logic flows under example regulatory schemes and implications for ecoTTC. *Regulatory Toxicology and Pharmacology*. doi: 10.1016/j.yrtph.2021.104933.

Burden N, Embry MR, Hutchinson TH, Lynn SG, Maynard SK, Mitchell CA, Pellizzato F, Sewell F, Thrope KL, Weltje L, Wheeler JR (2021). Investigating endocrine disrupting properties of chemicals in fish and amphibians: opportunities to apply the 3Rs. Integrated Environmental Assessment and Management. doi: 10.1002/ieam.4497

Kuo DTF, Rattner BA, Marteinson SC, Letcher RJ, Fernie KJ, Treu G, Deutsch M, Johnson M, Deglin S, Embry M (2021) A review on bioaccumulation and biotransformation of organic chemicals in birds. Reviews of Environmental Contamination and Toxicology.

### In Progress

Mitchell CA et al. New approach methodologies (NAMs) in the endocrine activity toolbox: environmental assessment for fish and amphibians.

Authors TBD. Critical evaluation of existing in vivo tests for endocrine modes of action. Wheeler et al. Control of performance of amphibian metamorphosis assays with xenopus laevis.

Authors TBD. Concentration setting for in vivo ecotoxicology studies.

Embry MR, Barron MG, Bejarano A, Connors KA, Fay K, Kienzler A, Mitchell CA et al. Quantifying conservatism in ecoTTC and CTD: case study of chemicals with regulatory water quality criteria values.

Authors TBD. Analysis of amphibian metamorphosis assay data. In preparation. Anticipated submission mid-2022.

Authors TBD. Existing in vivo tests to evaluate endocrine disruption. In preparation. Anticipated submission mid-2022.

Authors TBD. Application of the OECD 319 Test Guidelines for bioaccumulation assessment: opportunities, challenges, and next steps. In preparation

## Participating Organizations

### Government/Regulatory Agencies

Environment and Climate Change Canada  
 European Commission, Joint Research Centre  
 German Environment Agency (UBA)  
 National Institute for Public Health and the Environment (RIVM, The Netherlands)  
 Norwegian Institute for Water Research (NIVA)  
 Ontario Ministry of the Environment, Conservation, and Parks  
 Swiss Federal Institute of Aquatic Science and Technology (Eawag)  
 UK Environment Agency  
 US Army Corps of Engineers  
 US Department of Agriculture  
 US Environmental Protection Agency  
 US Geological Survey

### Academic/Research Institutes

University of Bern	University of Aarhus
University of Coimbra	University of Bern
Ecole Polytechnique Federale de Lausanne	University of Guelph
Fraunhofer Institute	University of Heidelberg
George Mason	University of Oslo
Helmholtz Centre for Environmental Research (UFZ)	University of Pittsburgh
Institutes City University of Hong Kong	University of Plymouth
McGill University	University of Saskatchewan
Middle Tennessee State University	University of Windsor
National Institute for Basic Biology (Japan)	Utrecht University
Roskilde University	Wageningen University
Simon Fraser University	
St. Cloud State University	
Texas Christian University	
University Helmholtz Centre for Environmental Research (UFZ)	

**Industry**

Bayer AG  
Chevron  
Corteva  
DuPont  
Enko  
FMC Corporation  
Givaudan  
L'Oréal Corporation  
Procter & Gamble Company  
S.C. Johnson & Son, Inc.  
Sanofi  
Shell Chemicals, Ltd.  
Syngenta  
The Dow Chemical Company

**Others**

National Centre for the Replacement, Refinement, and Reduction of Animals in Research (NC3Rs, UK)  
Research Institute for Fragrance Materials (RIFM)  
National Research Institute of Science and Technology for Environment and Agriculture (IRSTEA, France)  
Watchfrog (France)

**Consulting**

Arnot Research and Consulting  
KJ Scientific  
Kuo Research and Consulting