

# Risk Assessment in the 21st Century (RISK21)



## Our Mission

The committee's mission is to promote a transparent, structured approach to risk assessment based on key principles, including problem formulation, tiered integration of both hazard and exposure at each step, and fit for purpose.

## Science Advisory Board

### Public Science Advisory Board Members

Dr. Angelika Zidek (Health Canada)  
 Dr. Angelo Moretto (University of Padua)  
 Dr. Camila Moreira (Brazilian Health Regulatory Agency, ANVISA)  
 Dr. Eliana Munarriz (University of Buenos Aires)  
 Dr. Gino Scarano (US Environmental Protection Agency)  
 Dr. Jon Arnot (Arnot Research and Consulting)  
 Dr. Juliana Braz (Brazilian Health Regulatory Agency, ANVISA)  
 Dr. Maria Trainer (Australian Pesticides and Veterinary Medicines Authority)  
 Dr. Marcelo Wolansky (University of Buenos Aires)  
 Dr. Tara Barton-McClaren (Health Canada)

### Private Science Advisory Board Members

Dr. Shadia Catalano (Corteva Agriscience)  
 Dr. Edward Chikwana (Corteva Agriscience)  
 Dr. Haitian Lu (Syngenta)  
 Dr. Steven Zou (ExxonMobil Biomedical Sciences, Inc.)  
 Dr. John Norman (ExxonMobil Biomedical Sciences, Inc.)

## HESI Staff

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## Webpage

<https://hesiglobal.org/risk-assessment-in-the-21st-century-risk21/>

## 2021 Committee Highlights



### Participating Organizations

**8** government/regulatory agencies, **2** academic/research institutes, **5** industry, **1** other, and **2** consulting



### Scientific Meetings and Trainings

**2** workshops and **2** training courses

- **1** RISK21 module at the "1st Workshop for Risk Assessment: Successes and Challenges for Safety Assessment" organized by the Federal University of Paraná, University of São Paulo, and University of Washington to focus on alternative methods of safety assessment (January 2021, virtual; 21 attendees)
- **1** workshop held with the Colombian Ministry of Health to provide attendees with the basics of risk assessment as well as an introduction to the RISK21 approach and tools (October 2021, virtual; 30 attendees)
- **1** training course held at the National University of San Martín in Buenos Aires, Argentina, and presented in Spanish by Dr. Eliana Munarriz (University of Buenos Aires, HESI Board of Trustees). Attendees were students in a Toxicological Risk and Environmental Pollution Assessment Postgraduate Specialization and were from both the government and private sectors (August 2021, virtual; 20 attendees)
- **1** training course held at the University of Panama and presented in Spanish by Dr. Eliana Munarriz (University of Buenos Aires, HESI Board of Trustees) (September 2021, virtual; 18 attendees)



### Web Tools and Assays

**1** web tool

- The RISK21 web tool (<https://risk21.org/webtool/>) supports a problem formulation-based, exposure-driven, tiered data acquisition approach that leads to an informed decision



### Outreach

**1** oral presentation



- Presentation to members of the Association of International Chemical Manufacturers (AICM) on the RISK21 approach and a case study (June 2021, virtual; 70 attendees)



### Geographic Representation

Argentina, Australia, Brazil, Canada, Finland, France, Italy, and United States

## Working Groups

- **Exposure Group.** This group initiated a conversation around the development of a strategic plan that links to ongoing RISK21 and other efforts, with an eye toward the integration of state-of-the-art science in exposure assessments.
- **Brazil Pesticide Prioritization Work.** The committee contracted out the development of a database of information necessary to estimate pesticide exposure (and obtain parameters for exposure models) in Brazil. Pesticide use and application information are being extracted from the Brazilian Health Regulatory Agency (ANVISA) monographs and from Agrofit, Brazil's pesticide registration tool, and pulled into an easily searchable, publicly accessible database. A project advisory team is monitoring and supporting the project, which is expected to be completed in 1Q 2022.
-  **South America Outreach.** An informal team, focused on developing outreach in Colombia and Argentina. This team is exploring opportunities to:
  - Collaborate with the Colombian Ministry of Health to prioritize contaminants in drinking water using the RISK21 approach, and
  - Help the National Food Safety and Quality Service (SENASA) in Argentina with the development of an exposure database similar to the one being developed in Brazil.
-  **Asia Outreach.** A committee member has been facilitating outreach with China, with the goal of presenting the RISK21 approach to the Chinese Ministry of Ecology and the Environment (MEE).
- **Problem Formulation Group.** This group initiated a conversation to formalize the problem formulation process on an international scale and provide guidance to help the more consistent application of problem formulation for risk assessment.

## Areas of Focus for 2022

- **Problem Formulation.** The problem formulation group will pursue the development of practical problem formulation guidance that can be broadly applied to risk assessment. This work will be based on a broad approach considering how problem formulation is conducted in various international regulatory agencies.
- **Exposure Evaluation.** The exposure evaluation subgroup will focus on identifying the needs, gaps, and challenges in the exposure evaluation field, as well as opportunities for improvement and tool development.
- **Colombian Drinking Water.** A team will be convened to identify the right partners and explore how to best approach the prioritization of contaminants in drinking water in Colombia, using the RISK21 approach.
- **SENASA Exposure Database.** The committee will collaborate with SENASA to identify sources of pesticide exposure information, as well as the relevant partners/contractors who could assist with the development of an exposure data repository similar to what is being created in Brazil, for ANVISA.
- **China Outreach.** The committee will pursue outreach with China with the goal of introducing the approach to MEE to assist them with the screening of 40,000+ chemicals to prioritize the risk assessment.

## Strategic Impact Areas

### Enhanced Efficiency and Accuracy in Safety Assessment Practice

The RISK21 Committee is promoting problem formulation-based, risk-based, transparent, and fit for purpose risk assessment, hence making risk assessments more relevant and efficient.



### Increasing the Audiences for Collaborative Safety Science

The RISK21 community of practice has been growing internationally (e.g., posters presented at international conferences, training given in South America, and development of outreach in Argentina and Colombia), demonstrating an encouraging uptake of the principles underpinning the framework.



### Development of Scientists Skilled in Translational Science

RISK21 training programs have reached people worldwide via >10 hands-on workshops in seven countries around the world.





## Participating Organizations

### Government/Regulatory Agencies

Australian Pesticides and Veterinary Medicines Authority  
Brazilian Health Regulatory Agency (ANVISA)  
European Chemicals Agency  
European Commission, Joint Research Centre  
Health Canada  
Organisation for Economic Cooperation and Development (OECD)  
Pacific Northwest National Laboratory  
US Environmental Protection Agency

### Academic/Research Institutes

University of Buenos Aires  
University of Padua

### Industry

BASF  
Bayer  
Corteva Agriscience  
ExxonMobil Biomedical Sciences, Inc.  
Syngenta

### Other

American Chemistry Council

### Consulting

Arnot Research and Consulting  
Summit Toxicology