Session 4 speaker:

New approaches in regulatory assessment of chemicals

Anna Beronius, Associate Professor, Karolinska Institutet, Sweden

Anna Beronius is Associate Professor and researcher at the Institute of Environmental Medicine, Karolinska Institutet, Sweden. Her research aims to minimize risks to human health from endocrine disrupting chemicals, focusing mainly on methods for hazard and risk assessment. Her work centers on structured evaluation and integration of toxicity data in assessments of chemicals, especially working towards maximizing the use of mechanistic non-animal data in the assessment and identification of endocrine disruptors. This includes for example development and application of Adverse Outcome Pathway (AOP) methodology and systematic methods for toxicity data evaluation and weight of evidence (WoE) assessment. She is one of the initiators and developers of the Science in Risk Assessment and Policy (SciRAP) web-based platform that provides tools for evaluation of toxicity data for use in chemical assessments. Beronius is also involved in various expert assignments and training to support national and international agencies in the areas of endocrine disruptors and risk assessment methodologies, for example at the Swedish national agencies, EFSA and ECHA. She is also deeply engaged in education and is deputy programme director of KI's master programme in Toxicology.

Short abstract

Health risk assessment of chemicals traditionally relies on toxicity data from *in vivo* tests in animals. However, in recent decades there has been increased focus on reducing animal testing for research and regulatory purposes, primarily based on ethical considerations. Several European legislations, including REACH, promote the implementation of the 3R principles (to refine, reduce and replace animal testing) in the regulatory setting. It has also been acknowledged that animals used in toxicity tests, commonly rodents, are not the most relevant and sensitive model for many toxic effects in humans. Importantly, there is a need to develop fast and resource-efficient screening and test methods to keep up with assessing hazards and risks from the large, and increasing, number of chemicals on the market.

In parallel, there is a rapid global development of non-animal (e.g. *in silico*, *in chemico* and *in vitro*) methods for testing chemicals driven by regulatory and stakeholder needs, as well as academic research and innovation. Implementation of these novel methods in the regulatory setting faces a number of possibilities and challenges. A major challenge is to reliably connect data on molecular and cellular mechanisms generated from such methods to adverse health effects of regulatory relevance.

This presentation will provide an introduction to new approach methodologies (NAM), Adverse outcome pathways (AOP), Defined Approaches (DA) and Integrated Approaches to Testing and Assessment (IATA), give examples of their use to advance regulatory assessment of chemicals, and highlight some future development and research needs.