

Alternative approaches to animal testing for (eco)toxicity, and the regulatory application of the 3Rs in chemical risk assessments

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Within this session, new and novel approaches to the use of vertebrate species (e.g. fish, amphibians, and birds) for (eco)toxicity tests will be explored, with a focus on understanding the role that animal alternatives have in supporting environmental hazard and risk assessments of chemicals. Numerous technical and regulatory challenges need to be considered during the future integration of the traditional 3Rs (reduction, refinement, and replacement of animal tests). These challenges include consideration of the additional 3Rs (6Rs), which requires that any alternative approach is robust/reliable, repeatable and most importantly gains regulatory acceptance. In Europe, the need for alternative approaches has been primarily driven by certain legislations such as the EU Directive on the protection of animals used for scientific purposes, the UK Animals (Scientific Procedures) Act, the 7th Amendment to the EU Cosmetics Directive, selected legislation in Germany and the European chemical legislation REACH. As an example, in REACH it is possible in principle to fulfil so-called 'standard information requirements' by other means than new experimental studies by using existing non-GLP and non-guideline data; weight of evidence (WoE); (Q)SAR predictions; in vitro methods; grouping of substances and read-across approaches. Some of the adaptations may also be based on novel approach methodologies such as Adverse Outcome Pathways (AOPs) and/or OMICs. This session will explore new approaches towards developing and adopting efficient chemical assessments and also the hazard assessments of effluents for both acute and chronic ecotoxicity endpoints. Advances in read-across, enhanced predictive models (e.g. QSARs) and new developments for in vitro and in vivo models to support environmental risk assessments are encouraged. Additionally, progress relating to the generation of new bioaccumulation data using alternative approaches, particularly for PBT assessments, or how the various approaches or methods could be accepted into a regulatory framework and/or integrated test strategy are also encouraged. Furthermore, we welcome discussions on how to address uncertainties, challenges, advances and needs for further development for alternative approaches, particularly in support of understanding potential limitations/advantages. This session is organised by the SETAC Animal Alternatives in Environmental Science Advisory Group (AAAG) and the European Chemicals Agency (ECHA).