

Recent developments in regulatory science and environmental risk assessment of nanomaterials

Co-chairs: Laurence Deydier Stephan, Doris Völker, Edward Salinas

The manufacture, import and use of nanomaterials are regulated by a broad range of regulatory frameworks such as REACH, the Biocidal Products Regulation, the Cosmetic Products Regulation (within the EU) and other chemical management schemes (outside the EU). Taking into account the specificities of nanomaterials in the context of risk assessment, additional guidance is needed to ensure a robust fate and ecotoxicological assessment and improve the adequacy of the assessment within a regulatory context. Recently, progress has been made in the development of multiple tools to support regulatory implementation and safe use of nanomaterials together with a transparent communication. The need for new or updated standardised methods, guidance and grouping approaches has been recognised by regulators. ECHA, for example, has provided specific guidance for the safety assessment of nanomaterials. These guidance documents now provide advice on sample preparation, recommendations on how to perform and interpret aquatic, sediment, terrestrial toxicity tests and the bioaccumulation and degradation/transformation testing. While both ECHA and OECD have made progress on updating the relevant frameworks, certain fundamental regulatory risk assessment challenges remain. In this regard, effective communication between scientists, regulators and other stakeholders is crucial to enable continued progress. Communication tools are also needed which reach beyond the scientific and regulatory communities. For example, ECHA has launched the European Union Observatory on Nanomaterials (EUON), aimed at providing factual and reliable information on nanomaterials on the EU market and their safety. Increased transparency has also been driven by EU member states establishing national nanomaterial registries. This session aims to bring scientists, regulators and industry together to discuss recent developments in the regulatory science and risk assessment of nanomaterials. It is acknowledged that, besides the existing and applicable testing and assessment approaches on nanomaterials, there are still knowledge gaps in many areas of environmental hazard, fate and exposure assessment. Therefore, the session focuses on how to produce adequate and reliable information suitable for regulatory purposes and on innovative approaches to communicate the risks and benefits of nanomaterials beyond the scientific community. To support the session abstracts are welcome on experience gained in environmental hazard and risk assessment of nanomaterials illustrated by case studies. Presentations may also cover the implementation of existing (or new) test methods, grouping and read-across approaches specific to nanomaterials, discussion on the further needs for guidance and standard methods in relation to the regulatory needs, and available or innovative communication tools.