Regulatory Best Practices for Assessment of Endocrine Active Substances

Ellen Mihaich, Gerd Maack, Katherine Coady

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Regulatory assessment and proposed management of endocrine active substances (EAS) varies in different jurisdictions across the globe. Irrespective of the regulatory process, most jurisdictions use the World Health Organization International Programme on Chemical Safety definition of an endocrine disruptor requiring that a substance is demonstrated to cause a change in endocrine function that consequently leads to an adverse effect in an intact organism. Based on this common understanding of what constitutes an endocrine disruptor, harmonization of best practices for the assessment of endocrine active substances should be promoted where possible. This session will discuss various aspects of endocrine active substance assessments including data quality and relevance of various endocrine endpoints for hazard and risk assessment. Additionally, tools and approaches that can be used to help identify endocrine activity and disruption will be discussed. Topics may also include: use of emerging high through-put tools related to endocrine pathways, methodologies for deciphering systemic toxicity from endocrine activity, and weight of evidence approaches that include both exposure and potency of endocrine active substances. To illustrate best practices in endocrine assessments, case studies of endocrine active substances in different regulatory programs may be presented.