Recent examples of implementation of science into regulation- Combining exposure assessment and effect assessment by TK-TD models

Ecotoxicological experiments are most often performed under a static or semi-static exposure. In contrast, pesticide concentrations in water bodies adjacent to agricultural fields show highly variable dynamics, which depend chiefly on chemical application schemes, entry pathways and dissipation rates. Therefore, one refinement option in environmental risk assessment for pesticides is to consider time-variable exposure profiles. In addition to experiments using refined exposure, also model calculations of the expected risk under time-variable exposure can be calculated. For that aim, a scientific opinion on the state of the art of Toxicokinetic-Toxicodynamic (TKTD) models and their use in prospective Environmental Risk Assessment (ERA) for pesticides and aquatic organisms has been developed by an EFSA working group. TKTD models are species- and compound-specific and can be used to predict (sub)lethal effects of pesticides under untested (time-variable) exposure conditions. This presentation will focus on the ‘General Unified Threshold models of Survival’ (GUTS), and show principles of model calibration, validation and application within Tier 2 refinement. Special attention is given to the way the model was tied to the existing risk assessment procedures. In addition, short views on DEBtox and primary producer models are given.