

FRAUNHOFER INSTITUTE FOR TOXICOLOGY AND EXPERIMENTAL MEDICINE ITEM

PLANT PROTECTION PRODUCTS – ASSESSMENT AND AUTHORIZATION



Plant protection products are widely used to protect plants and plant products from harmful organisms. According to the Plant Protection Products Regulation (EC) No. 1107/2009, a complex assessment involving comprehensive data is required for the authorization of active substances and plant protection products. In a two-stage process, active substances

are first thoroughly evaluated and assessed by the European Commission (EFSA). In a second step, the active substance-containing products are examined and evaluated by the national authorities of the EU to ensure sufficient effectiveness on the one hand and protection of human and animal health and the environment on the other hand.

Based on our cross-disciplinary, in-depth expertise and many years of experience, we support you in all scientific and regulatory issues. In addition to analyzing data gaps and evaluating all data, we assess potential substances of concern, residues and metabolites, prepare dossiers including risk assessments and expert statements, and submit and defend dossiers. Our aim is to identify risks to health and the environment and to reduce these, while not losing sight of the desired efficacy.

Fraunhofer Institute for Toxicology and Experimental Medicine ITEM

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Our services

- Scientific and regulatory support
 - Development of an authorization strategy
 - Support in the implementation of regulatory requirements
 - Communicating with competent authorities
 - Letter of access (LoA) negotiations
 - Submission of MRL (maximum residue levels) applications
 - Support with the new application rules, e.g. with regard to biodiversity
- Data collection and study monitoring
 - Identification of data gaps
 - Commissioning and monitoring of required experimental studies in the fields of specification, analytics, physicochemical properties, efficacy (in compliance with the EPPO guidelines), toxicology and ecotoxicology (in vitro, in vivo)
 - Development of testing strategies and use of (Q)SAR models
- Risk assessment of plant-protecting active substances and plant protection products
 - Assessment of the potential hazard including classification and labeling
 - Identification and assessment of potential substances of concern, endocrine-disrupting properties, residues and metabolites according to (EC) No. 396/2005
 - Exposure assessment and risk assessment for humans and the environment
 - In-house exposure measurements and analytics
- Dossier preparation and submission
 - Dossier preparation for the authorization of plant-protecting active substances and plant protection products, including CADDY, GHSTS, draft Registration Report (dRR) incl. GAP table, draft assessment reports (DAR) or renewal assessment reports (RAR), and IUCLID (in the future)
 - Support in simplified authorization procedures for adjuvants, plant strengtheners, and basic substances
 - Dossier submission, e.g. via the BVL portal (BVL = German Federal Office of Consumer Protection and Food Safety) or the Plant Protection Products Application Management System (PPPAMS)
 - Support in the MRL procedure
 - Response to additional data requests by the authorities
- Miscellaneous services
 - Training courses
 - Development of models for exposure and emission evaluation
 - Assistance with strategic decisions and product development
 - In-house exposure measurements and analytics

Expertise

- Long-term experience in regulatory research and practice (dossier preparation, communication with authorities, dossier defense)
- Exposure and emission evaluation and risk assessment
- Consulting in related regulatory areas including biocides, REACH, veterinary medicinal products, foods, medical devices, and cosmetics
- Development and evaluation of concepts and methods for chemical risk assessment including development of quantitative structure-activity relationships ((Q)SAR), read-across and bridging principles, and integrated testing strategies or exposure models