

AUTHORIZATION OF FOOD AND FEED PRODUCTS



The safety of food and feed products is top priority to sustain and improve human health and animal well-being. In collaboration with the European Commission, the European Food Safety Authority (EFSA) assesses these products before they can be authorized for the European market. Authorizations in the context of food and animal feed require dossiers to be sub-

mitted to the competent authority. Comprehensive data is required for the preparation of substance and product dossiers and their assessment in accordance with the relevant regulation is complex. Based on our cross-disciplinary, in-depth expertise and many years of experience, we support you with all scientific and regulatory issues. In addition to evaluating available data, we cooperate with you to develop a tailor-made regulatory strategy, assess potential residues and metabolites of concern, 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.

Fraunhofer Institute for Toxicology and Experimental Medicine ITEM

Nikolai-Fuchs-Strasse 1
30625 Hannover, Germany

Contact

Ariane Zwintscher
Phone +49 511 5350-312
ariane.zwintscher@item.fraunhofer.de
www.item.fraunhofer.de

Overview of our services

We support you in the authorization of food and feed ingredients and products.

Scientific and regulatory advice:

- Evaluation and assessment of available data and data requirements
- Development of regulatory strategies and support in the implementation of regulatory requirements
- Development of testing strategies and commissioning and monitoring of required experimental studies
- Toxicological and ecotoxicological assessment based on experimental data, quantitative structure-activity relationships ((Q)SAR) and read-across of the substances including GMOs, production processes, and all by-products and residues
- Exposure assessment and risk assessment with regard to consumers
- Dossier preparation and submission
- Communication with the authorities

Additional specific services in the different product categories:

- Food ingredients: food additives, food enzymes, flavorings, smoke flavorings, or vitamin and mineral resources added to food products
 - Study monitoring (e.g. analyses in the food product, storage stability)
- Additives in animal feed:
 - Exposure assessment and risk assessment with respect to animal health
- Food contact materials:
 - Assessment of migrating substances
- Nutrition: nutrition and health claims, novel foods, baby foods, and food allergies
 - Research of the history of a food/distinction of a novel food
 - Scientific evidence of nutrition and health claims
 - Evaluation of the production process including all by-products and residues
- Biological hazards: Processing of animal by-products, decontaminators for animal products
 - Scientific evidence of sufficient efficacy
 - Assessment of potential development of resistance
 - Risk assessment of animal by-product processing
- Processing aids:
 - Identification of processing aids and differentiation from food additives
- 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