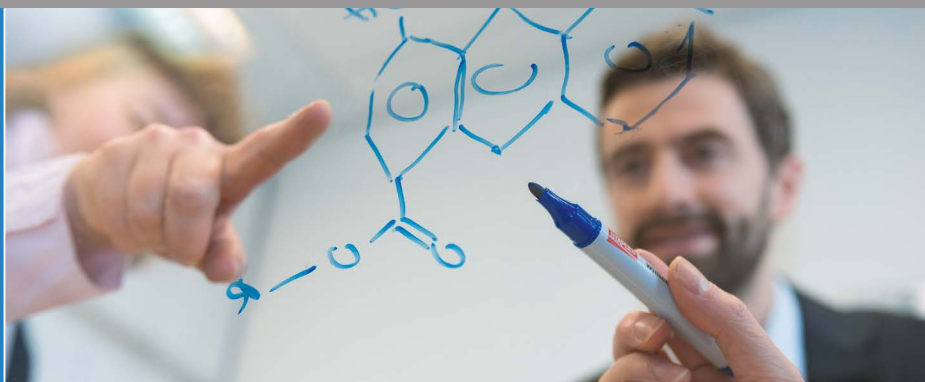


## CHEMICAL SAFETY AND ASSESSMENT



## REGULATORY RESEARCH AND RISK ASSESSMENT OF CHEMICALS

Facilitating safe products by advanced risk assessment strategies

Our commitment is to assess the potential risk from chemical substances, including their specific use in very different products. For this purpose, we use tiered approaches as described by the term "integrated approaches to testing and assessment" (IATA).

We offer the studies and services required to assess the potential risks from chemicals to human health and the environment and to register these substances for the intended use. Our portfolio includes industrial chemicals, biocides, food additives, and both human and veterinary medicinal products. In close collaboration with our clients, we gather the data required for substance registration to comply with legal requirements, and we take care of regulatory issues.

With our research projects, we contribute to the development of novel assessment strategies to help improve and refine existing risk assessment methods and ultimately to minimize the need for experimental studies, in particular animal studies. Examples of such projects are elucidation of structure-activity relationships ((Q)SAR), category approaches such as read-across, the setting up of databases, and further development of the TTC concept.

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### Key topic

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We are committed to bringing safe products to the market and to protecting public health and the environment.

### Contact

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*Risk assessment of the ingredients of chemical products facilitates safe products for consumers.*

## Our services and expertise

- **Data gap analysis and literature search:** We determine what data are already available and whether additional studies are required, and we check whether there is information publicly available about the substance in question. We have special experience in the use of category approaches and read-across.
- **Dossier preparation:** We prepare IUCLID datasets for the studies, perform exposure and risk assessments, and prepare a chemical safety report (CSR) and the registration dossier.
- **Counseling and support:** We provide comprehensive consulting and develop custom-tailored registration strategies.
- **Study design and monitoring:** Experimental investigations, e.g. for toxicology testing, can be performed directly at Fraunhofer ITEM or are subcontracted to preferred testing institutes. If an external partner is needed, we can assist you in selecting an appropriate partner and in the monitoring of your studies.
- **Risk assessment and expert reports:** In the form of expert reports, we document the (eco)toxicological properties of substances and assess their risks to human health and the environment, for example for biocides under REACH and for contaminants or chemical residues in foods and products.

## Your benefits

- Synergies between experimental toxicology, advanced analytical methods, and regulatory knowledge.
- Interface to regulatory authorities, facilitated by our active participation in panels preparing legislation and our collaboration with national and international scientific organizations.
- Analysis of existing data for gaps, which can then be closed by using structure-activity relationships ((Q)SAR models), read-across or waiving; whenever required, development of an optimized testing strategy.
- Access to our toxicological databases (RepDose, FeDTeX, PaFTox), which we can customize, whenever needed, to meet a client's specific requirements. Query of other public databases, if necessary.

## Fraunhofer ITEM

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The Fraunhofer Institute for Toxicology and Experimental Medicine ITEM is one of about 70 institutions of the Fraunhofer-Gesellschaft, Europe's leading organization for applied research. Protecting man from health hazards in our industrialized world and contributing to the development of novel therapeutic approaches are the aims Fraunhofer ITEM is pursuing with its contract research, with a focus on airway research.

In the area of chemical safety we assess the risks from potentially harmful substances and support the development of novel products with an eye on human health and the environment. We can draw upon a broad spectrum of expertise, covering toxicology testing, exposure assessment, analytical methods, regulatory research, and chemical risk assessment.

## From compound to safe products

Development of test and analytical methods

Toxicology testing

Exposure characterization

Regulatory research and risk assessment