

One-stop service - world-class, worldwide



## ERA (Environmental Risk Assessment) of Human Pharmaceuticals

### Welcome to Eurofins Agroscience Services

We are a leading provider of product development consultancy and technical support to the crop protection industry. Our technical activities involve conducting field and laboratory studies to determine the safety and efficacy of new agrochemicals and crop varieties. With over 30 years of experience, Eurofins Agroscience Services offers outstanding technical knowledge and project management skills. By acquiring a carefully selected range of CRO's, we have created a unique portfolio of expertise that provides analytical, regulatory and field support to plant breeders, agrochemical, biopesticide, biocide and fine chemical manufacturers.

### ERA (Environmental Risk Assessment) of Human Pharmaceuticals

For the marketing authorization of Human Medicinal Products, the European Medicines Agency (EMA) requires an Environmental Risk Assessment (ERA) and the U.S. Food and Drug Administration (FDA) requires an Environmental Assessment (EA).

Eurofins can provide the full range of services required, performing the environmental studies and offering necessary consultancy services, including the environmental risk assessment, for the pharmaceutical industry.



## Eurofins Regulatory AG

### Our dedicated, in-house regulatory service includes:

- Consulting regarding requirements and design of environmental studies
- Cost and time analysis of the regulatory program
- Peer review and gap analysis of existing data sets
- Literature search and compilation of published data including quality evaluation
- Study monitoring, i.e. discussion of the study setup and performance with the study directors, check of draft study plans, evaluation of study results, review of draft reports
- Project management, i.e. study coordination, interim status reports, communication focus between client and laboratory, trouble shooting
- Environmental risk assessment (ERA / EA) including refinements
- ERA expert report preparation
- PBT assessment
- Expert assessments, e.g. for potential endocrine disrupting activity
- Pharmaceuticals in the Environment (PIE) assessment of potential impacts

## Eurofins Agroscience Services (EAS)

The Eurofins Agroscience Services portfolio includes all the required studies for the environmental risk assessment Phase I & Phase II Tier A and B according to GLP.

### Eurofins Agroscience Services (EAS)

- Physical-chemical properties
- Environmental fate studies
- Aquatic and terrestrial ecotoxicological studies

## Eurofins Agroscience Services Group

[easinfo@eurofins.com](mailto:easinfo@eurofins.com)  
[www.eurofins.com/agroscienceservices](http://www.eurofins.com/agroscienceservices)

## Our Assurance,

- GLP Certification since 1990
- Membership of GDCh, SETAC

## Our Promise

As a global service provider, Eurofins Regulatory AG and Eurofins Agroscience Services Group offers unparalleled expertise and a commitment to excellence.

## You can expect,

- Integrated, fluid services for trouble free solutions
- Project management from the industry's most respected individuals
- Experienced and dedicated professionals with specific areas of expertise

## Eurofins Scientific Group

Eurofins Scientific is a life sciences company that serves a wide range of industries including the pharmaceutical, agricultural, food and environmental sectors.

**Today the Eurofins Group is a leading provider of analytical services.**

