



# International reach through local focus

**Ecotoxicology** is a key element of environmental risk assessment for chemicals whether plant protection products, biocides or general chemicals governed by REACH legislation.

APC associate ecotoxicologists have a wealth of knowledge, gained over many years, through hands on experience conducting laboratory and field studies, interpretation of data and its use in risk assessment, and management of regulatory ecotoxicological programmes. Our ecotoxicologists are well known experts within the scientific and regulatory community and maintain close contact with influential ecotoxicology experts in government agencies within Europe.



## Impact of changing legislation

Ecotoxicology, and its role in environmental risk assessment, is continuously developing as a consequence of changes in European legislation. The mechanism of risk assessment and consequent ecotoxicological data requirements under 91/414/EEC and its revision remain different from and generally more complex than requirements under the Biocidal Products Directive and REACH. The Revision of Directive 91/414/EEC will result in changes to some current ecotoxicology data requirements and endpoints.

APC ecotoxicologists keep abreast of such developments and are members of working groups involved with the development of several European regulatory ecotoxicological guidance documents.

## Client support

We have wide experience in preparing and managing a portfolio of ecotoxicology studies for the client. Our strengths are in identifying data gaps followed up by effective study placement, monitoring and delivery of a range of aquatic and terrestrial studies to fulfil registration requirements. Where appropriate, we communicate directly with government regulatory experts on study requirements and study design. For Plant Protection Products we identify what needs to be done on the active substance for Annex II and whether or not specific additional ecotoxicology studies are required for Member State registration at Annex III.



our team provides a complete service for the plant protection, biocide & chemical industries

## Aquatic ecotoxicology

APC experts have wide experience with aquatic studies ranging from single species and multispecies tests in the laboratory to outdoor population, community and model ecosystem (mesocosm) studies. We place studies with trusted contract research organisations with specific expertise in handling cold and warm water fish, aquatic invertebrates such as *Daphnia* and *Chironomus*, and aquatic plants (macrophytes) such as *Lemna* and *Myriophyllum*. Where higher tier studies are required these are specially designed to meet the regulatory endpoints of concern and include modified exposure/effects studies using one or more species in laboratory microcosms, and outdoor mesocosm studies using replicated pond enclosures with several dose rates. Key changes to data requirements under the revision of 91/414 will be the introduction of a fish early life stage test as a core data requirement for hydrolytically stable substances and a mysid shrimp study for insecticidal compounds.



## Terrestrial ecotoxicology

APC experts are experienced in key areas of terrestrial ecotoxicology having had hands-on experience with non-target arthropod laboratory and field tests, earthworm laboratory and field studies, insect residue studies for avian and small mammal dietary risk assessment, small mammal field studies and honeybee laboratory and field studies. Key changes to 91/414 will see the elimination of the litterbag study and its replacement with tests on *Collembola* and soil mites, where triggered. The acute earthworm toxicity test with *Eisenia* will be withdrawn and replaced with the 28-day reproduction test. The soil microbial respiration study will be withdrawn. Unless exposure can be discounted, studies on the effects of active substances on the brood of honeybees will be required. Higher-tier tests using terrestrial model ecosystems (TMEs) are being considered.

## Risk assessment

The purpose of ecotoxicological studies is to provide endpoints to compare with exposure concentrations (PECs) for use in risk assessment. Considerable developments are currently underway both in aquatic and terrestrial risk assessments of Plant Protection Products. For example, proposed changes to the design of aquatic effects studies are likely to come into effect to better account for different types of FOCUS surface water PEC profiles and the revised bird and small mammal risk assessment document from EFSA will change the way dietary exposure concentrations are calculated.

In the light of these changes APC will continue to provide the client with informed opinion on the selection and development of relevant study designs to ensure the generation of appropriate data for use in risk assessment.



Please contact us at [enquiries@apc.eu.com](mailto:enquiries@apc.eu.com)  
or find our nearest office on [www.apc.eu.com](http://www.apc.eu.com)