

## International reach through local focus

Consumer safety is a key issue when a new chemical product is to be put on the market. Plant protection products are often sprayed on food crops and thus it is necessary to assess the potential risk of foodstuffs intended for human or animal consumption.

The general framework for these assessments is specified by the regulatory institutions and includes the following steps:



- ◆ **Residue definition**

It is critical to identify the relevant compound to be taken into account during the subsequent steps. This generally includes **metabolism studies** using radio-labelled material specifically for new active ingredients.

- ◆ **Residue field trials, livestock feeding studies, processed commodity studies**

The field studies are carried out to check the real residue content in raw agricultural commodity and foodstuffs after application of the plant protection product. This step permits to establish the so called Maximum Residue Limits (**MRLs**) and also the Pre Harvest Interval (**PHI**).

- ◆ **Consumer risk assessment**

After the MRLs are established, **diet consumption** data is used to assess the potential intake of the observed chemicals by consumers. The risk is then defined as acceptable or not, by comparison with toxicological reference values such as the Acceptable Daily Intake (**ADI**) and the Acute Reference Dose (**ARfD**).

APC has broad experience of residue management and can assist in either full development or intervene at any step of your project, at European or national level. APC will liaise with local country experts and use their specialist knowledge in order to determine the best strategy in conducting local crop residue trials for each country.



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

APC offers a complete **data gap analysis**, quality checks and a review of the DAR, to give you expert advice and the best regulatory strategy. This is an important step to define the safe uses and the critical Good Agricultural Practices for residues (**critical GAPs**). According to the project and objective agreed, APC experts are available to provide the following services:



- ▶ Expert consideration on residue definition, including relevant metabolite and metabolic pathway identification. Our team helps initiate and manage metabolism studies, working as monitoring scientists and selecting the most suitable GLP laboratories and testing facilities.
- ▶ Design and management of residue trial programs, animal feeding studies, processing and crop rotation studies. This can include MRL definition for new substances or for an active to be reviewed in the framework of the Regulation 396/2005 for the harmonization of MRLs in Europe. APC experts have extensive experience of managing complex multi-site trial programs and can undertake both the field and analytical phases.
- ▶ Evaluation of chronic and acute consumer risk assessments using the latest guidelines and various models available from EFSA, other international and national regulatory bodies. APC can provide expert opinion in cases of refinement.
- ▶ APC provides the essential support for all aspects of residue field testing tailored to suit the client's need. Our consultants also meet the increasing demands for new actives, as well as for re-registration and new formulations of more established products.



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or find our nearest office on [www.apc.eu.com](http://www.apc.eu.com)