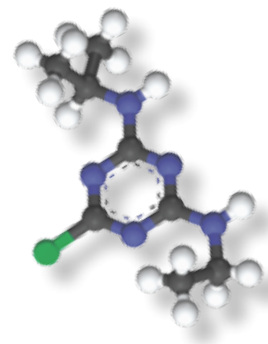




International reach through local focus

Determining the physical and chemical properties of products is a basic requirement for registration of any chemical. APC's chemists have extensive experience in physicochemical requirements for pesticides according to European directive 91/414/EEC. In addition, APC has a dedicated team of experts for the registration of general chemicals under the REACH regulation and for biocides under directive 98/8/EC.

APC is an independent consultancy that has excellent contacts with many leading laboratories. This gives APC the freedom to commission studies at the best laboratory and the best price. APC provides assistance in all aspects of the registration process, including data gap analysis, the commissioning and monitoring of studies, plus the preparation and submission of a summary dossier.



DATA REQUIREMENTS	
Pesticides and Biocides	<i>Physicochemical data must be provided in accordance with Annex II and III of Directive 91/414/EEC for pesticides and Annexes II to IV of Directive 98/8/EC for Biocides.</i>
REACH	<i>For general chemicals, the REACH regulation (EC) No. 1907/2006 requires a Chemical Safety Report to assess physicochemical hazards plus information on physicochemical properties according to tonnage produced. The ECHA give detailed criteria for acceptable data in Chapter R.7a of their guidance for REACH implementation.</i>



The wide variety of active ingredients and formulation types require an equivalent variety of physicochemical studies. Failure to provide the correct studies will halt the regulatory approval process until new studies are generated. APC experts are skilled in identifying data gaps and ensuring they are filled.

APC will commission and monitor studies to regulatory requirements using EEC, OECD or CIPAC methods and Good Laboratory Practice (GLP) standards as appropriate. APC are also skilled at writing waivers and literature searches to meet registration requirements without the need for additional studies.

Because national authorities may interpret EU directives in different ways, APC has a network of experts covering over 40 countries to ensure compliance with any specific local requirements.

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



Accurate, precise and robust analytical methods form the foundation for data used in chemical registration dossiers. Poorly validated methods can result in the rejection of the studies and product registrations that rely on them. APC's experts in product registration will ensure that studies comply with regulatory guidelines.

APC has extensive experience in preparing dossiers to establish a technical specification for pesticide and biocide active ingredients. A high quality dossier is particularly important for establishing equivalence with the original source of active ingredient approved on Annex I of Directive 91/414/EEC or 98/8/EC. This requires validated methods for determining the active ingredient concentration, any impurities present at >0.1%, and toxicologically significant impurities at even lower levels.

Validated methods are required for determining residues of the active ingredient, plus any relevant metabolites and impurities. Depending on the nature of the residue and method, additional confirmatory studies or an Independent Laboratory Validation (ILV) may be required. APC specialists will identify where additional validation work is needed and can commission and monitor any necessary studies.

Regulatory authorities are placing increasing demands upon applicants in order to ensure that methods are fit for purpose. Existing pesticide guidelines such as SANCO/3029/99 and 3030/99 are being rigorously enforced and it is highly likely that there will be more stringent guidelines in the forthcoming revision of directive 91/414/EEC. For biocides, technical notes for guidance on analytical requirements were recently issued in May 2008 after the 29th Competent Authority Meeting.

As requirements evolve, APC's network of experts will ensure that data packages remain up to date with requirements at both national and international levels.



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