

## International reach through local focus



▶ APC has an extensive team of experts with consultancy, CRO, industry and government backgrounds. This coupled with a network of consultants covering over 40 countries means we have excellent relationships with many of the regulators throughout Europe and are well placed to provide up to date advice on new guidance initiatives.

▶ The revision to 91/414 is expected to be published in Q2 2009. This will mean re-registration according to revised criteria and many new requirements, such as registration of safeners being necessary. APC's regulatory team keeps a close eye on all developments in this area and is able to advise on the implications of the revised data requirements of your dossier.

▶ APC experts have many years of practical experience in conducting and managing a wide range of studies. Their experience ranges from laboratory to field based studies for a wide variety of products in the agrochemical industry.

▶ Risk assessment forms a critical part of the dossier and our experienced scientists have the knowledge to interpret exposure and effects assessment and apply refinement where possible. Refinement can also take the form of higher tier testing for which APC can offer advice on planning and where appropriate, regulatory consultation.



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



The current EU review of all existing active substances must be completed by the end of 2009. For list 3 and 4 substances, with outstanding issues that cannot be resolved during this time, it is possible to voluntarily withdraw substances within 2 months of the publication of the DAR. Re-submission of any additional data required to complete the dossier is then possible 6 months after date of entry into force of the withdrawal decision. APC has extensive experience in dealing with the complex regulatory issues arising from the review process and can help you assess what additional information will be required for a successful Annex I listing.

In order to support existing products in Europe at re-registration, it is necessary to have access to the Annex II data required for Annex I listing of the active substance. For companies who have not supported an active substance, it is possible to generate an equivalent Annex II data package to protect your product registrations. The above-mentioned voluntary withdrawal procedure effectively lengthens the time to Annex I listing allowing additional time for data generation for certain active substances.

APC's team of experts can scientifically review the DAR to determine which studies will be required. Our extensive experience means we are able to assess which studies are unnecessary, thereby saving you money. We also take our review one step further and check whether necessary protected studies have been submitted to other EU member states, meaning data protection cannot actually be claimed. We aim to develop the most cost effective regulatory strategy for our clients.



APC can also help with registration of new active substances in Europe. We are able to recommend and initiate dialogue with an RMS to complete the assessment of your substance. Our team of experts can conduct a data gap analysis to determine which studies will be necessary at the first tier of testing. We can also place and monitor studies on your behalf and compile these into a dossier for submission. We offer post-submission support to answer any questions that arise during the review of your active.



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