

## International reach through local focus

- ▶ APC has a team of experts in all specialist areas across the biocides regulation, who can assess the need for product registration under **BPD** and advise on a regulatory strategy. Our personnel has many years of experience in negotiations with regulatory agencies and can represent the client in discussions with the competent authority.
- ▶ APC will help perform a **data gap analysis** on active substances and products and then place and monitor studies on the client's behalf. Alternatively we can assist with negotiating access to existing studies. We also have extensive experience in literature searching, which can help produce an economical dossier.



- ▶ **Mutual recognition** will be a key route to gaining national registrations for biocidal products following Annex I listing of the active substance. APC has extensive experience of the mutual recognition process from the related directive on plant protection products 91/414.
- ▶ APC helps identify companies with similar products and advise on data sharing. We also have experience of working in task forces for joint generation of data for submission.

- ▶ Our team can prepare and deliver all required complete dossiers to the relevant regulatory authorities in the most appropriate format. We have wide experience of using **IUCLID** and can manage the entry of data into IUCLID 5.
- ▶ **Modelling and risk assessment** form a key part of a biocide dossier. Our team are experienced in applying appropriate modelling and refining scenarios to result in an acceptable risk assessment. We can also conduct relevant risk assessment appraisal for all exposure groups and propose appropriate risk management strategies.



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



The EU Biocidal Products Directive (BPD) (98/8/EC) aims to harmonise the regulation of all biocides across the EU, remove trade barriers and ensure high levels of health and environmental protection. It was implemented by all member states on 14 May 2000 and applies to both new and existing active substances and their associated products.

Biocides are divided into 23 product types (PTs), which are sub-divided into 4 priority lists. All active substances are being reviewed at EU level according to the priority lists. The review dossiers contain detailed information on efficacy, physical chemical properties, analytical methods, mammalian toxicology, ecotoxicology, environmental fate, exposure assessments, risk assessments and risk management measures. Those active substances deemed to be sufficiently efficacious and having an acceptable risk profile are included in Annex 1, 1A or 1B of the directive.

Products containing active substances included in the review programme can continue to be marketed under existing national schemes while the active substance is reviewed at EU level. Once an active substance is included in Annex 1 of the directive, products belonging to the product type reviewed containing that active substance have to be authorised nationally.

Active substances not included in the review programme are deemed to be new active substances and must be approved at EU level. Associated products containing that active must be approved at national level before they can be placed on the market. Substances which were not notified or supported by a dossier by the submission deadline are no longer included in the review programme and as such are treated as new active substances.

<b>Main group - 1 Disinfectants &amp; general biocides</b>	PT1 Human hygiene products
	PT2 Private and public health disinfectants
	PT3 Veterinary hygiene biocides
	PT4 Food and feed area disinfectants
	PT5 Drinking water disinfectants

<b>Main group - 2 Preservatives</b>	PT6 In-can preservatives
	PT7 Film preservatives
	PT8 Wood preservatives
	PT9 Fibre, leather and polymerised materials preservatives
	PT10 Masonry preservatives
	PT11 Preservatives for liquid cooling and processing systems
	PT12 Slimicides
	PT13 Metal working fluid preservatives

<b>Main group - 3 Pest control</b>	PT14 Rodenticides
	PT15 Avicides
	PT16 Molluscicides
	PT17 Piscicides
	PT18 Insecticides, acaricides and arthropod control products
	PT19 Repellents and attractants

<b>Main group - 4 Other biocide products</b>	PT20 Preservatives for food or feedstocks
	PT21 Anti-fouling products
	PT22 Embalming and taxidermy fluids
	PT23 Control of other vertebrates



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)