

## International reach through local focus



▶ APC has a dedicated REACH team with an extensive background in the chemical industry coupled with the expertise to support clients with the management of substances within REACH legislation. APC provides both advice and technical/regulatory support for all levels of registration needs for REACH whether you are a substance manufacturer, importer or a downstream user of the substance in a preparation or article.

▶ APC's experience of negotiation within task forces will be applied to supporting your interests in Substance Information Exchange Forums (SIEFs), whether for data sharing, cost sharing or compensation issues.

▶ APC technical experts are skilled in literature searches, analysis of data sets, identifying data gaps, and gap filling such as read-across. APC will conduct safety assessments and prepare the Chemical Safety Report for substances greater than 10 tonnes. For substances above 1000 tonnes and SVHC's, APC can conduct the ECHA required Chemicals testing and prepare environmental exposure assessments with the client to finalize on time exposure scenarios with appropriate risk management measures.

▶ APC has internationally recognised regulatory scientists who will negotiate, place and monitor necessary studies on the client's behalf. Where possible, (Q)SARs and read-across will be used to fill information gaps in lieu of studies.

▶ APC has wide experience of using IUCLID and will manage the entry of data (including the pre-registration of substances) into IUCLID 5. APC has many years of experience in negotiations with regulatory agencies and will represent the client in discussions with the ECHA and specific Member States when required.



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

The REACH (Registration, Evaluation and Authorisation of Chemicals) regulation entered into force in June 2007. This regulation imposes new requirements on manufacturers, importers and downstream users of chemicals and will affect both new and existing compounds.



The key aim of REACH is to protect human health and the environment while maintaining competitiveness and enhancing the innovative capacity of the EU chemical industry. REACH intends to achieve this goal by requiring all companies that manufacture or import a chemical in quantities greater than 1 tonne per

year to register it in a central database administered by the European Chemicals Agency (ECHA). Downstream users must ensure that any substances in their products will be registered to cover those uses.

The first phase is pre-registration of substances. For existing manufacturers and importers in the EU, who meet REACH registration criteria, this phase is now complete. For substances that now meet registration criteria, but didn't before 1 December 2008, it is possible to complete a late pre-registration. Pre-registration is followed by a phase-in

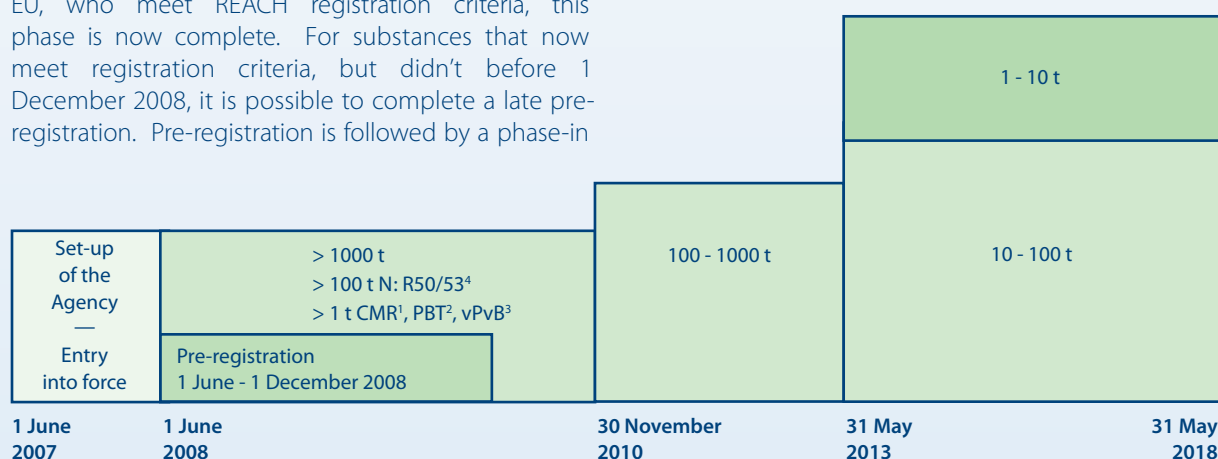
registration process, which will last for up to 10 years. If a manufacturer or importer fails to pre-register a phase-in substance it will need to be registered before continuing to manufacture or import into the EU.

Higher tonnage substances or substances of very high concern (SVHCs) will have to be registered first. SVHCs are CMRs<sup>1</sup>, PBTs<sup>2</sup> and vPvBs<sup>3</sup>. Registration requires a dossier or information on the substance, a key element of which, for many substances, will be the Chemical Safety Assessment and Chemical Safety Report. The amount of information included in the dossier will depend upon substance tonnage and classification.

Substances of very high concern to human health or the environment will only be allowed to be used if authorised by ECHA. Such substances will also be candidates for substitution with safer alternatives.

Further information on REACH can be found on the ECHA website: [http://echa.europa.eu/reach\\_en.asp](http://echa.europa.eu/reach_en.asp)

1. CMRs : carcinogens, mutagens and reprotoxins.
2. PBTs : persistent, bioaccumulative and toxic substances.
3. vPvBs : very persistent and very bioaccumulative substances.
4. R50/53 : very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.



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