

New EU rules on Chemical Registration

Since 1 June 2008, EU legislation has been in force to control the importation and manufacture of chemical substances and preparations. It governs 'Registration, Evaluation, Authorisation and Restriction of Chemicals' (REACH) in all EU Member States. The legislation is a cornerstone of the EU Commission's policy to protect the health of its citizens and the environment.

The key points are:

- Companies must register chemical substances with a new agency (European Chemicals Agency)
- Information pertaining to the composition and effects of these chemical substances must be made available, subject to commercial sensitivities, to the general public

This legislation has profound long term implications not only for the chemical and pharmaceutical industries in Europe but also many downstream users of chemicals and preparations such as manufacturers of paint, adhesives, lubricants, plastics and detergents and many other industries which use chemicals in their production processes. The pervasive nature of REACH means that many industries who would consider their activities to be unrelated to 'chemicals' will need to take account of this legislation.

We set out below an overview of the key aspects of the legislation.

However, we stress that each manufacturer and importer should review their chemical usage in light of the legislation, as the requirements vary depending on the chemical and tonnage involved.

The Regulation complements existing requirements relating to:

- substances in medicinal products for human and veterinary use
- substances in food and feeding stuffs.

Exemption from REACH does not apply to raw materials and isolated intermediates used in the manufacture of the medicinal and veterinary products. The tonnage rule (please see below) also applies to these materials and intermediates.

Overview

The new legislation requires virtually all "substances" including "preparations" (and "articles" containing substances or preparations) to be registered with the Agency appointed to monitor such goods. In order to satisfy itself as to the possible affects of each chemical, the party registering the chemical must supply very detailed information.

"Substance" means a chemical element and its compounds (the legislation contains additional qualifying information on the meaning of a substance). A "preparation" is a mixture of two or more "substances".

"Articles" are objects intended to release one or more substances during normal usage (e.g. a sponge impregnated with soap).

Polymers are exempt from the requirement to register though monomers imported or manufactured in amounts greater than one tonne are required to be registered.

Registration Key Points

- A limited number of substances are already considered registered and others are exempted from REACH.
- Substances and preparations currently on the market must be pre-registered by 1 December 2008 ("Phase-in" substances) to avail of extended timelines for full registration.
- Since 1 June 2008, "non phase-in" substances (or preparations containing them), cannot be manufactured in the EU or imported, unless those substances have been registered. While "phase-in" substances which miss the pre-registration opportunity (outlined below) will undergo full registration from 1 December 2008

- Manufacturers and importers are not required to register a substance if its annual imports or manufacture amounts are less than one tonne.
- Non-EU parties can appoint a single EU Representative to act on their behalf to meet the legal obligations of importers and registrants under this legislation.
- Substances manufactured or imported for R&D may be exempt from this legislation until June 2012 (and possibly longer) provided certain specified details are supplied to the Agency.
- The Irish Health & Safety Authority (HSA) is the Competent Authority (CA) for enforcing REACH in Ireland. Legislation (The Chemical Act 2008) has been put in place that will allow the CA to impose a system of penalties for infringements against REACH requirements. The penalties for those found guilty of a summary offence under Irish Legislation are up to €5K and or up to six months imprisonment while those guilty under indictment could be penalised up to €3M and or up to two years in prison.

Pre-Registered of “Phase-in” Substances

To facilitate the existing activities, a registration “phase-in” period will apply for current European manufacturers and Importers:

- Substances already on the EU market will be able to avail of “phase in” periods provided the substances are pre-registered before 1 December 2008. The time periods for completing the full registration process will depend on the annual tonnage of the substance used and range from 2 years to 10 years.
- Since 1 June 2008, all “non phase-in” substances and preparations must be registered before they can be imported or manufactured in any EU Member State. In addition, from 1 December 2008, those “phase-in” substances that did not avail of the prior registration window will require full registration.
- Each potential registrant of these new substances must make an initial enquiry as to the registration status of the substance. The result of this enquiry will dictate the level of information gathering and testing that will be required for registration.

Registration Process

- In order to submit a registration application, very extensive information per substance must be supplied including: a ‘technical’ dossier and possibly a chemical safety report. The contents of both of these data sets are defined in the legislation and may, subject to the hazardous nature of the product, require inclusion of all physiochemical, toxicological and ecotoxicological information.
- The information requirements for registration may be considered as commercially sensitive. Details, such as the full composition of a mixture, the precise usage of the registered material and the relationship between an importer and its distributor, for example, will not be made publicly available. However, they will be required to be submitted with the application.
- It will be possible for several parties to jointly submit data relating to a substance where this is practical and does not lead to the pooling of commercially sensitive information.
- Unless there is an indication to the contrary, within three weeks of submission of the application, a manufacturer or importer may proceed with their activities in regard to the substance in question.
- Certain substances are considered to be of “high concern” to public health and safety and the registration process will be more stringent for them. The legislation gives further details of this matter, but they can be summarised as being substances with known harmful effect to health and the environment such as carcinogens and toxins.
- Once satisfied, the Agency will supply a registration number which must be used and state any conditions associated with the usage of the chemical in question.
- The period of registration of any given substance will be subject to a time-limited review depending on the nature of the substance concerned.

Sharing of Information

A central theme of REACH is to ensure that all appropriate health and safety information is shared between parties in the supply chain. For example:

- For certain dangerous substances, any supplier will be required to give their customers a ‘Safety Data Sheet’ (SDS).



Where an SDS is not required, the supplier must provide the registration number of the substance and any other relevant information concerning authorisations or restrictions.

- A Downstream User (DU, i.e. a substance user other than the registrant) may provide information to the registrant to assist in the preparation of a registration. The DU will be required to supply appropriate information where for example the substance is used in a novel manner, as its usage will need to be understood to define the exposure category of the substance concerned.
- By pre-registering, companies will be able to exchange or sell test results required for registration. For certain test results, there will be a legal requirement that such results must be made available (with suitable compensation) to other potential registrants.

Therefore, it is critically important that each "actor" in the supply chain clearly understand the REACH implications of their substance(s) and share information as required.

How can PwC Help?

PwC has a multi-disciplined team of specialists, including chemists, which can assist clients to assess the impact of REACH on their business. We can:

Evaluate your materials and products to determine if they are within the scope of REACH

- Advise on how REACH will impact on your role as an importer
- Determine if you can benefit from any exemptions including usage threshold relief
- Assess what pre-registration and registration deadlines must be met
- Assist with registration application and the set-up of internal controls
- Provide support to implement any new internal or external information requirements needed to meet ongoing REACH obligations.

If you would like further information on REACH or assistance in determining the effects of REACH, we would be delighted to assist.

If you require help please contact a member of our team:



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