REACH

REGISTRATION, EVALUATION, AUTHORIZATION (AND RESTRICTION) OF CHEMICALS



A GUIDE FOR API MEMBERS

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REACH—A Guide for API Members

What is REACH?

REACH[1] is the new European Union (EU) legislation concerning the Registration, Evaluation, Authorization (and Restriction) of Chemicals, which came into force on June 1, 2007. The regulation sets out new requirements for chemicals and substances manufactured within or imported into the EU to ensure that substances (including refinery streams and substances used to produce them in the EU) can continue to be used. Each substance, along with every identified use, will need to be registered with the newly formed European Chemicals Agency (ECHA). If a use is not registered, then the substance cannot be employed in that application within the EU unless the user takes the responsibility for conducting a risk assessment and ensuring safe use.

Registration

Evaluation

Authorization of CHemicals

The introduction of the legislation has a phased approach, starting this year (2008), through to final submission in 2018. For those in commerce with substances in the higher tonnage bands, the effective first major deadline is 2010.

REACH is the most comprehensive chemicals legislation in the world, and is also likely to become one of the most complicated to comply with—at all levels from the technical to managerial and business challenges. It will also have global implications. Even those not immediately involved in the EU market are in the supply chain of others who are, and will be asked for information and support by those formulators who do, or whose customers decide not to, support substances that are currently exported to the EU.

The newly formed European Chemicals Agency (ECHA) will administer REACH. Because the legislation is so complex, the EU Commission, through ECHA, has issued, or will be issuing, guidance in various aspects of the legislation and its implementation. A list of this guidance and a link to the source is given in Appendix 1.

This guide does not seek to replace the official EU guidance, but rather to provide an overview and to highlight the main issues and places to go to for help.

[1] *Regulation (EC) No. 1907/2006 of the European Parliament and of the Council concerning Registration, Evaluation and Authorization of Chemicals.*

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Is our Business Affected by REACH?

We export catalysts to the EU through a series of business partners and distributors. We have no EU presence ourselves—it has always been handled by our distributors.

You will be affected.

Under REACH it is the responsibility of your importers to comply and register your substances.

However, if they do not comply, you will not be able to distribute directly into the EU. By leaving this activity to importers you have diminished control of your future business activities as the importers will have the registration.

Consider working though an "only representative" or a company with whom you have a firm long lasting partnership agreement.

There will inevitably be a cost associated with all the work that is required

We sell product to a formulator who then imports final product into the EU—sometimes the product goes through other regions first.

You will be affected.

Unless someone does a registration of your substance and its use within the EU then it cannot be supplied.

It is likely that the formulator will want an assurance from you that you will support the registration-information, costs, and time. However, you may not want to give the confidential information that this may require.

The rules on how to register in this case are complex and still being formally adopted. You may need to obtain specialist advice on the best way for you to proceed, in order to protect your business activities.

We do not sell to the EU, but we do buy critical substances for our manufacturing process and product line.

You could be affected.

Registration will have a cost implication for any company manufacturing in the EU.

It is possible that because of these costs the EU manufacturer decides not to continue a substance that is critical to your business continuation.

You may want to contact your supplier to ensure that the substances you buy will be supported by your supply chain.

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REACH Timeline

June 1 2007	REACH Came into Force
2008 1st June to 1st December 2008	Pre-registration >1 tonne
3.5 Years 30th November	Registration 1,000 tonnes/yr + CMRs[1] (Category 1 & 2) ≥ 1 tonne/yr + very toxic[2] ≥100 tonnes/yr
6 Years 31st May	Registration 100 – <1,000 tonnes/yr
11 Years 30th November	Registration 1 – <10 tonnes/yr 10 – <100 tonnes/yr

[1]CMRs—Carcinogens Mutagens Reprotoxins following current EU classification scheme

[2]EU Environmental classification

What Does REACH Try to Do?

The stated goals of REACH are to improve scientific knowledge about environmental and health impacts of substances and to encourage their safe use. REACH was specifically designed to place the responsibility with the industry to demonstrate safe use and show why hazardous substances should continue to be used. Through the provisions of authorization and restrictions, REACH will also allow regulators to act to limit the use of hazardous substances. There has been some criticism of the regulation because it is all-encompassing, ambitious and complex.

However, despite many attempts to change the legislation, it is now on the European statute and its progress is firmly under way.

The Business Impact of REACH

Because REACH may cause the withdrawal of a substance from the EU market, it has immediately gained the attention of management within companies. But, this is not the only threat that makes REACH a major business process issue requiring management attention. REACH easily translates into "No registration—no global market" in today's economy, where materials are supplied on a worldwide basis, rather than a regional one.

There is also the potential for the loss of production of certain chemicals if a supplier does not register for reasons of cost or complexity.

Notwithstanding the potential loss of chemistry or uses through restriction, authorization, or costs, the registration process will also have significant resource and organizational implications—both technical and managerial—in almost all areas of the business.

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