



REACH Update

Described as "one of the most complex pieces of legislation to ever come out of Europe", the Regulation for the Registration, Evaluation, Authorisation and Restriction of Chemicals, or more commonly known as REACH, entered into force on June 1st 2007.

AN UPDATE

The Regulation will drive major changes in the global chemicals industry most significantly for manufacturers and importers of substances and preparations into the EU. However, considerable implications will also exist for companies that either use or process chemicals to manufacture products in the EU particularly the electronics, automotive and textile sectors.

Also affected by the REACH Regulation are: manufacturers of goods that are designed to emit chemicals such as printer cartridges, pens, fade-out clothing, adhesive tape; also products which have an unintentional release of chemicals due to their properties such as furniture and clothing.

The REACH Regulation, which implements the EU's New Chemicals Policy replaces four major existing EU laws controlling chemicals. This single uniform system will make chemical manufacturers and importers responsible for 'Registering' substances manufactured or imported into EU Member States (in volumes greater than 1 tonne per manufacturer/importer per year). Registration timelines have been prioritised according to volume and hazard and will be "phased in" over time.

Failure to register a substance with the newly established European Chemicals Agency (ECHA) will make it unlawful to manufacture or import a substance into the European Union.

PRE-REGISTRATION

As a first requirement for manufacturers and importers of chemicals, careful consideration should be given to 'Pre-Registering' substances during the Pre-Registration window, which extends from 1st June 2008 to 1st December 2008.

The Pre-Registration process is straightforward comparative to full Registration, and will require the submission of a limited amount of information such as contact details and estimated tonnage band. Pre-Registration is designed to enable the authorities to calculate the number and volumes of chemicals on the market and to ease the formation of Substance Information Exchange Fora (SIEFs) whereby manufacturers and importers will be able to work together to compile the necessary information and to share the costs to fully register chemicals.

Failure to Pre-Register chemicals will exclude manufacturers and importers from taking advantage of the 'phase in' arrangements, forcing Registration to begin from June 2008.

REGISTRATION DEADLINES

- December 2010 - substances imported or manufactured in volumes greater than 1,000 tonnes or more per year and substances of very high concern such as: mutagens, carcinogens and reproductive toxins (CMR substances)
- June 2013 - substances in the volume bracket of 100-1000 tonnes per year
- June 2018 - substances placed on the market in volumes greater than 1 tonne per year

REGISTRATION

During the Registration process, manufacturers and importers of chemicals will have to compile and submit a Registration Dossier that should prove they are managing their chemicals safely. This will involve gathering and assessing hazard data on the physiochemical, toxicological and eco-toxicological properties of a substance. For substances manufactured or imported in volumes greater than 10 tonnes/year, a Chemical Safety Report (CSR) will also have to be submitted to the European Chemicals Agency.

In addition to reporting the hazard data associated with a substance, the intended uses and associated risks and proposed risk management measures, in the form of 'exposure scenarios' for each substance, will also have to be detailed. These exposure scenarios will eventually be communicated to the 'down stream users' of the substance as annexes in Safety Data Sheets.

Registration requirements also exist where a substance in an 'article' (very simplistically, a manufactured product) is designed to be emitted during normal and foreseeable conditions of use, for example, a pen or printer cartridge. Additionally, 'Notification' to the ECHA may also be required in some circumstances, where the article contains a 'substance of very high concern' above a 1 tonne per year threshold.

Manufacturers of articles should now be determining if chemicals in their products are designed for release under normal foreseeable conditions. In looking ahead, manufacturers may face requests from their downstream users seeking exposure information. Additionally, it would be advisable for manufacturers to begin considering the properties of the process chemicals used to manufacture products to assess whether they are likely to become 'authorised substances' under REACH.

COMPANIES BASED OUTSIDE THE EU

Companies based outside the EU can also register substances imported in quantities over one tonne per year, by appointing an 'only representative' to act on their behalf. Despite the costs and resources involved, registering a substance will ensure that non-EU manufacturers will be able to continue to export freely to the EU and will prevent their individual EU customers having to register the substance independently.

To ensure continued access to chemicals it is critical that downstream users ensure that their use of a substance is registered by manufacturers/importers. Whilst, it is probably still too early to begin approaching suppliers to enquire about their registration plans, early preparation is essential. As a first step, downstream users should now be:

- reviewing their product portfolios
- identifying their suppliers per product
- identifying the quantities purchased of each substance
- determining their own position in the supply chain i.e. manufacturer, importer or downstream user

In the years ahead, downstream users should be aware that they will eventually be called upon by their suppliers to provide 'use' and 'exposure' information and to comment on risk management measures as well as passing any new hazard information to their supplier.

EVALUATION

Once the Registration Dossiers have been received by the ECHA they will be evaluated for completeness. A more detailed evaluation will be undertaken by the Competent Authorities in Member States countries, which may result in a request for further testing.

AUTHORISATION

For substances of high concern such as carcinogenic, mutagenic and reproductive toxic substances (CMRs) and chemicals that are persistent, bio-accumulative and toxic in the environment, Authorisation will be required before use. Industry will be able to continue to manufacture and use such chemicals if the risks can be adequately controlled or there is a strong socio-economic argument for doing so. Such chemicals will however need to be substituted if safer alternatives are available and are technically and economically viable. The initial list of chemicals that meet the criteria for 'substances of very high concern' will be issued in 2009.

OUR SERVICES

WSP Environmental Ltd is a leading global environmental consultancy and we are already advising companies to assess the impact of the new REACH Regulation on their operations. This process includes mapping out their responsibilities under the Regulation in order to minimise business risks.

WSP Environmental has a range of services to assist companies with compliance with the REACH Regulations. These include:

REACH Vulnerability Assessment

Suitable for manufacturers, importers and downstream users, a vulnerability assessment is undertaken by an experienced consultant at a company's premises. It is an evaluation of the product portfolio to detect substances at risk. The output from the assessment will enable companies to prioritise their actions and to implement an action plan of bite-sized, manageable tasks within a defined timetable, to meet their REACH obligations over the coming years. These outputs are also an excellent start for REACH data collection and communication tasks.

Advising Suppliers

It is essential that businesses communicate with their suppliers to ensure they are aware of the implications of REACH and their obligations. Downstream users need reassurance that the chemicals they purchase and their intended uses, will be registered by manufacturers and importers. Similarly, importers may request their non-EU suppliers, to take on the registration obligations for imported substances. WSP Environmental is assisting companies in communicating with suppliers; providing advice on compliance and maintaining regular dialogue to ensure substances will be registered.

Advising Customers

REACH also requires companies to have effective communication with downstream users. As well as the supply of Safety Data Sheets and Chemical Safety Reports, downstream users will need to pass information on the use and exposure of the chemicals back up the supply chain. WSP Environmental can assist in the implementation of effective Product Stewardship programmes to achieve these downstream user obligations.

Data Gathering and Gap Analysis

WSP Environmental's highly qualified REACH experts and in-house toxicologists and eco-toxicologists, can help companies gather the necessary data for REACH and to identify any gaps in this data. Where data is missing, they can assess the likely costs to gain the appropriate information and also position any case for waiving tests as well as compiling the reports and paperwork necessary at various stages of REACH. This may include; Dossier preparation, Risk assessments, Chemical Safety Reports, Exposure Scenarios and Safety Data sheets.

Consortia Management

REACH requires that the level of toxicity testing is minimised through shared testing of substances by the different producers. Chemical manufacturers and importers, involved with the same chemicals, can become part of a consortium enabling them to share information and carry out tests together in a more cost effective manner. WSP Environmental can facilitate consortia formation and operations, establish the necessary agreements and assist in compiling the Chemical Safety Assessment Report and Registration Dossier.

REACH Training

WSP Environmental hold open REACH training courses throughout the year or can develop a course tailored to a specific organisation to support REACH awareness and compliance.



PREPARING FOR PRE-REGISTRATION AND REGISTRATION

In order to pre-register and register under REACH, many companies will need to complete a dossier. Therefore, companies should now be developing implementation plans which address:

■ Project Management

- Strategic approach to implementation
- Internal organisational responsibilities for managing REACH implementation
- Co-ordination of registration(s) and resources
- Action tracking
- Monitoring and reporting progress on implementation

■ Technical Issues

- Legal identity status for registration
- Role(s) in REACH
- Collation of uses to be registered
- Scientific data searching
- Substance grouping, (Q)SARs and read-across
- Physico-chemical testing
- Chemical identification and characterisation
- Toxicological testing
- Testing environmental effects and fate
- Assessing and compiling environmental effects and fate data packages
- Performing and reviewing environmental exposure modelling and monitoring
- Reviewing epidemiological data and health monitoring studies
- Assessing and compiling human health and exposure data
- Evaluating hazard classification and labelling
- Preparing Chemical Safety Reports
- Devising and evaluating Exposure Scenarios
- Preparing Safety Data Sheets
- Validating Registration dossier prior to Agency submission

■ Training

- Awareness of requirements
- Roles of Business functions under REACH
- UCLID software use

CONTACT US

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