

REACH will have major global impact

REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals. It is the most onerous single piece of legislation to hit the European chemicals industry ever. Furthermore, this legislation's far-reaching effect will have a major impact on the global chemical industry.

All chemical manufacturers, distributors and downstream users within the EU (European Union) will need to be REACH compliant. It is also a requirement that all substances imported into the EU (individually or as part of a preparation or article) must be REACH compliant. This effectively means that non-EU manufacturers and traders must ensure compliance if they intend to continue supplying the EU market. REACH affects the entire supply chain. Downstream users will be required to supply information regarding exposure scenarios and applications back up the supply chain.

The legislation was finally ratified at the end of 2006 and came into force on 1 June 2007 as Regulation (EC) No. 1907/2006. The compromises and changes which have blighted its course to the statute books have made REACH an extremely cumbersome piece of legislation. Although REACH has been ratified and is now "in place" there are still a number of issues which need substantial clarification before we know the full effect this will have on industry.

The new European Chemical Agency (ECHA), based in Helsinki, Finland will be responsible for managing the technical and administrative aspects of REACH although, it must be made clear, REACH will be in part self-regulating with industry itself being responsible for ensuring compliance. The ECHA will work in cooperation with the Competent Authorities (CAs) in each EU member state. The Health & Safety Executive (HSE) is the UK's CA.

This article outlines the main facts and gives advice on how to negotiate the legislation and what help is available.

Background

In 1979, the 6th Amendment to the Dangerous Substances Directive was adopted (79/831/EEC). This introduced a notification system for new substances placed on the EU market. This was later superseded by the 7th Amendment (92/32/EEC) which amended the requirements. The notification requirements of the Directive were implemented into the legislation of the member states, e.g. in the UK as the Notification of New Substances Regulations. The notification scheme includes mandatory data requirements such as toxicology and environmental testing which increase with increasing supply volume. Once a substance is notified it is placed on the ELINCS list. The approximate 100,000 substances already listed in the EINECS inventory were much less rigorously regulated and did not require any kind of registration. The Existing Substances Regulation (No.793/93) did address existing substances. However, it was felt that progress was too slow and there remained a concern that too little was known about existing substances.

REACH introduces a single legislative regime for both new and existing substances.

How will it work?

The extraordinary costs involved in registering substances as well as the huge workload which will be required have resulted in a "phase in" period being instigated for those existing substances which have been pre-registered. REACH has allowed for a volume dependent, 11 year "phase in" period whereby parties registering the same substances can share data to mitigate testing costs and avoid unnecessary use of animals.

Registration will be preceded by a pre-registration period starting on 1 June 2008. This pre-registration will last for six months up until 31 November 2008. Pre-registration will be free and will require very basic identity information such as: chemical name, CAS number, EINECS



number etc. The pre-registration will essentially allow for all potential registrants to register an interest in specific substances. At the time of writing it is not known exactly what the mechanism for pre-registrations will be. However, at least one option will be on-line. Since pre-registration will be a comparatively simple process and will allow for delayed registration deadlines it is recommended that potential registrants take advantage of this opportunity. Downstream users should be checking with their suppliers that substances are going to be pre-registered or else there is a danger that substances could suddenly disappear from the market.

Once pre-registration has taken place, the ECHA will facilitate the formation of a SIEF (Substance Information Exchange Forum). A lead registrant will be nominated and parties will then share what relevant test data they have in order to select the best data and identify any data gaps. Ultimately, financial negotiations will take place to compensate parties holding relevant data which is utilised by the other members of the SIEF. This will require formal agreements between the members which may be complex and expensive to

achieve. The SIEF should effectively work as a democratic consortia although the ECHA will assist in resolution by means of an Ombudsman should negotiations fail. There is a guidance document on data sharing available.

The registration of existing substances which have been pre-registered will take place based on an individual registrant's volumes and hazard classification as shown in Table 1.

All substances with a volume of less than one tonne per annum will be exempt from registration. Other exemptions include: polymers (however, constituent monomers may have to be registered); substances listed in Annex IV and substance types as described in Annex V. Substances used in pharmaceuticals and food are also exempt although it must be noted that these substances will require registration if used in non-exempted applications.

Information on substances which are Carcinogenic, Mutagenic and Toxic to Reproduction can be found in Annex XVII of REACH.

Volume is used as a general indicator of risk so the amount of data required is dependent on the volume band. A full list of data requirements can be found in Annex VII (1-10 tpa); Annex VIII (10-100 tpa); Annex IX (100-1000 tpa) and Annex X (>1000 tpa). The requirements are cumulative, i.e. for a substance at >1000 tpa the endpoints given in Annexes VII, VIII, IX and X all need to be addressed.

There are various opportunities to avoid conducting new studies such as use of existing data, alternative methods, read-across from structurally related compounds and exposure based waiving.

A Chemical Safety Report (CSR) is also required as part of a registration submission at >10 tpa. This is essentially a risk assessment. If the substance is classified as dangerous or is a PBT (Persistent, Bioaccumulative, Toxic) or vPvB (very Persistent and very Bioaccumulative) then a formal exposure assessment and risk characterisation is required. It is essential that downstream users communicate with their suppliers to ensure that their particular use of a substance is included in the CSR.

Authority fees are also volume dependent and are thought, at this time, to range from €500 to €24,000 depending on whether a registrant is part of a SIEF, the volume band and whether the registrant meets the definition of an SME (Small/ Medium Enterprise). The final fees are due to be published in March 2008.

The EU Commission estimates that 30,000 substances will need registration.

Table 1.

1 Tonne per annum and classified as Carcinogenic, Mutagenic or Toxic to Reproduction (CMR), Category 1 or 2	By 1 December 2010
100 Tonnes per annum and classified as very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment (R50/53)	By 1 December 2010
1,000 Tonnes per annum	By 1 December 2010
100-1,000 Tonnes per annum	By 1 June 2013
1-100 Tonnes per annum	By 1 June 2018

However, this figure excludes intermediates so will ultimately be significantly higher. The regulation also effectively requires multiple registrations for a single substance so there could easily be as many as 150,000 registrations.

Dossier evaluation – the ECHA will assess all testing proposals submitted with a registration dossier (principally to ensure that no unnecessary animal testing is carried out). Also the agency will conduct a compliance check on approx 5% of registration submissions.

Substance evaluation – the ECHA will compile a draft Community rolling action plan which will cover a period of three years and will specify substances to be evaluated each year. The substances will be selected on the basis of hazard, exposure and tonnage. This may result in requests for further information/data or for new control measures.

Running alongside registration will be the authorisation process. This focuses on ensuring that the risks from substances of very high concern are adequately controlled and that where possible the substances are replaced. Substitution is a key element of REACH. Typically this would cover Category 1 and 2 CMR, PBT and vPvB substances as well as any other substances of equivalent concern. ECHA will add substances to Annex XIV. Any substance on that list will require

authorisation from the Commission before it may continue to be used. The authorisation will define specific use(s) and will be time limited.

If adequate control is not possible then authorisation may be granted if it is shown that the socio-economic benefits outweigh the risks to human health and the environment and that there are no suitable replacements. It is thought that approx 1,500 substances will come under the scope of authorisation.

Restriction

Any substance for which Annex XVII contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of the restriction.

Annex XVII will replace the Marketing and Use Directive (76/769/EEC) on 1 June 2009. However, it should be noted that the scope includes manufacture.

What does this mean to non-EU manufacturers and exporters?

REACH is European Union legislation and has no jurisdiction outside of the EU. Consequently, non-European parties cannot pre-register and register from outside of the EU. Parties with European importers will be able to register through those importers.

Parties who do not wish to use their importers can pre-register and register through an "Only Representative" as described in Article 8 of the legislation. This could be a party's European office. Alternatively, there are many consultants offering their services as an "Only Representative". It would be prudent to be familiar with the requirements laid out in Article 8 and be satisfied that the "consultant" is indeed adequately qualified to carry out this important role. Once an "Only Representative" has been agreed on, it is vital to establish which substances will be pre-registered and registered well before the actual pre-registration period starts. At this point it is advisable to bear in mind that pre-registration is free and does not require a great deal of information or, indeed, effort. Furthermore, pre-registration does not make registration



mandatory. It may be that when the time comes for registration it is not considered cost-effective to register. It is also important to understand which “phase in” period a particular substance is in. It may be that the substance does not require registration until 2018!

There are other things that can be done in preparation for REACH. Any physical, toxicological or environmental test data available should be checked against the various volume band requirements of the legislation. This data could be used advantageously during the SIEF negotiations and possibly even have a financial value.

The scope of REACH is such that non-EU customers may request the materials they purchase to be “REACH compliant”. Many multinational companies which operate throughout the world are already requesting this and many more may follow suit. In addition, it does not follow that substances not currently exported directly to the EU should not be considered for pre-registration since they may ultimately be exported to the EU in preparations, products or articles. It is important that companies are aware of the entire supply chain in which they operate so that they are ready for any REACH issues which may arise.

REACH is, effectively, a global issue!



Compliance solutions

There is a shortage of personnel with the genuine experience and expertise in chemical regulation to help guide companies through the challenge of REACH. One response to this skills shortage is the REACH Facilitation Company (ReFaC) which is an independent company that has been set up by the industry for the industry. It has two simple objectives: to provide its members with cost-effective compliance and, wherever possible, reduce the burden

of administration imposed by REACH. It aims to provide a secure, cost-effective and confidential route to REACH compliance, from pre-registration and consortia formation through to final registration. Its services include:

- Only Representative.
- Third Party Representative.
- Pre-registration.
- Consortia formation.
- Registration.
- Testing.
- Evaluation.
- Authorisation.

ReFaC helps all companies, large or small based inside or outside the EU. For more information on ReFaC visit www.refac.eu or e-mail info@refac.eu

Conclusion

REACH is here to stay. It is vital that chemical manufacturers, importers and companies outside the EU understand the importance of REACH and, if intending to export into the EU, directly or indirectly, they must ensure full compliance of their substances. PC

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