Your REACH Basics summary

Introduction

The **R**egistration, **E**valuation, **A**uthorisation and restriction of **Ch**emicals (REACH) Regulation entered into force in 2007. Since its inception, manufacturers and importers have registered more than 21,000 unique substances; over 190 substances have been added to the Candidate List, and many amendments to the lists of restrictions and substances subject to Authorisation have been made. Although we have seen progress in terms of the tightening chemical legislation to regulate the manufacture and importation of chemical substances to the EU, there is still a lot more to be done.

Evolving from a European Commission draft with inputs from industry, Member States, the European Parliament and environmental organisations, REACH has become one of the most complex and far-reaching pieces of legislation to ever originate from Brussels. It is a Regulation, rather than a directive, meaning that it acts directly in each Member State without the need for national implementation.

REACH aims to protect human health and the environment from the risks arising from the use of chemicals whilst maintaining the free movement of goods on the EU market and enhancing competitiveness and innovation. It intends to achieve its goal by requiring industry to determine and make public the risks posed by the use of chemicals, according to the precautionary principle. Unlike prior legislation which placed the onus on the regulatory authorities to ensure the safe use of chemicals, REACH places the burden on EU substance manufacturers, EU importers (if you buy substances from non-EU suppliers, you are an importer), and downstream users (if you buy from EU suppliers but your use is not supported by your supplier) to ensure the responsible supply and use of substances.

As part of their registration, manufacturers and importers must define the uses in their supply chain which they can support, and detail the specific conditions of use which allow for safe handling. For hazardous substances which are manufactured or imported at 10 tonnes or more per year, the manufacturer or importer must extend their safety data sheet, using “exposure scenarios” setting out the appropriate operational conditions and risk management measures to be employed.

REACH Registration

For many companies REACH registration will be the most costly and time-consuming part of compliance. Generally, anyone that makes or imports a chemical into the EU above 1 tonne per year will need to register it with ECHA; there are exemptions to REACH Registration and our REACHScope tool can help identify them. Exemptions might apply where more demanding legislation already exists.

The third and final phase in registration deadline was on 31st May 2018. This now means that if you are manufacturing or importing a substance at 1 tonne or greater per year you require a valid registration before it is placed on the EU market.

Inquiry Process

Article 26 of REACH states that all potential registrants of non- phase in substances have to submit an inquiry dossier to ECHA before they can begin the registration process. The dossier should clearly identify the substance that is being manufactured or imported. Potential registrants must wait for ECHA to respond to their inquiry before they can submit the registration dossier. This is because ECHA checks to see if the substance the registrant is inquiring about has already been registered by other registrants. If this is the case ECHA will put you in contact with the lead registrant so you can join the already existing joint registration. If the substance hasn't been previously registered, you will become the lead registrant and are able to undertake any necessary animal testing required to complete the registration dossier.

REACH Evaluation

Under evaluation, the authorities examine information submitted by companies during registration. Evaluation focuses on three key areas: dossier evaluation, substance evaluation, and examination of testing proposals.

Dossier evaluation is carried out by ECHA; it is a compliance check of the registration dossier, and is based on scientific judgement. It assesses whether the information needed for the registration is present in the dossier and is adequate to meet the requirements under REACH. ECHA can, within 12 months of starting this compliance check, prepare a draft decision requiring the registrant to submit further information for the application by a set deadline. Any testing proposals for substances manufactured or imported in quantities of 100 tonnes or more submitted by registrants are also examined. From January 2019 all registrants that are part of the registration are now included in the communication rather than just the lead registrant.

Substance evaluation is carried out by Member States. It assesses whether the risk to human health or the environment of a given substance is such that additional controls, for example Authorisation or Restriction, are required.

ECHA adopted its first Community Rolling Action plan (CoRAP) in February 2012 to further investigate any potential risks posed by substances to human health and the environment. This substance evaluation is carried out by Member States and will address issues such as regional risks, potential additional risk caused by aggregated exposures of a (sub) population or releases into the environment, and the prediction of cumulative effects, all of which go beyond the standard information requirements of REACH. Registrants may also be asked to submit additional information for substance evaluation.

Testing proposals are published by ECHA if they involve vertebrate animal studies. Stakeholders can provide scientifically valid information or studies addressing the hazard end points in question. ECHA then uses this information when preparing their decision on the testing proposal

REACH Authorisation

Another of REACH's mechanisms is an authorisation process for chemicals identified as being a substance of very high concern (SVHC) to human health or the environment. SVHCs are first included on a "Candidate List" and may subsequently be included in Annex XIV – the Authorisation list – meaning they cannot be placed on the EU market or used after a given date unless the specific use of the substance is exempted or is authorised by ECHA. Annex XIV substances are also

considered candidates for substitution with 'safer' alternatives. Manufacturers, importers or downstream users can apply for authorisation for the use of a substance on the list. There are now more than 40 substances on Annex XIV.

Producers, importers and suppliers of finished products (articles) such as laptops, shoes, items of clothing and furniture may be affected by the authorisation process, even though they may have no registration obligations. Suppliers of such articles containing SVHCs listed on the Candidate List above 0.1% by weight must communicate relevant, available safety information about the substance to the recipients of these articles and the component articles they are composed of.

Furthermore, where the total tonnage of that SVHC in those articles reaches 1 tonne or more per year the producer/importer may be required to notify ECHA if the substance has no registration for that use. ECHA can then request a registration dossier for the specific use(s) of the SVHC present in the article.

REACH Restriction

The restriction process is used under REACH to limit or ban the manufacture, supply or use of substances when an unacceptable level of risk exists. A substance does not need to meet the SVHC criteria associated with the authorisation process to be restricted and, once adopted, a restriction affects all manufacturers, importers, distributors, downstream users and retailers. The restriction relates to substances on their own, in mixtures and in articles, and it can affect the import of finished goods as well as EU uses. All substances that have a restriction in place are listed in Annex XVII

The process to restrict a substance is complicated, and involves public consultations as well as preparation of a socio-economic analysis by the regulators.

In conclusion…

Everyone involved in manufacturing a product within the EU, along with their supply chain, is likely to be affected by REACH to some extent; if you make or import a chemical substance, **REACH is likely to be one of the biggest programmes of work your company will have to undertake and continue to maintain your compliance.**

Worried? No need to be! If you think any of the above processes may affect you or your business REACHReady is here to help.

REACHReady can provide tools and personal technical support to ensure you're well on your way to being REACH compliant as well as helping you develop management strategies that save you time, trouble and money.

www.reachready.co.uk enquiries@reachready.co.uk