Simple guide to REACH

Introduction

On 1 June 2007 a new EU Regulation (EC) No. 1907/2006 came into force concerning the **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals (REACH). This was the most significant piece of legislation on control and management of chemicals since the introduction of the Dangerous Substances Directive (67/548/EEC) in 1967. REACH replaced some 40 pieces of existing legislation and has a significant impact on all manufacturers, importers and users of chemicals in the EU.

The fundamental requirement of REACH is that EU businesses that manufacture or import chemical substances whether on their own or in a preparation (or in some cases in an article) into the EU in tonnages in excess of 1 tonne/year must register those substances with the European Chemicals Agency (ECHA), based in Helsinki. In addition, businesses other than manufacturers or importers may also have a number of other obligations under REACH.

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Registration

There is a general obligation for manufacturers and importers (M/I) of substances to submit a registration to the European Chemicals Agency (ECHA) for each substance manufactured in, or imported into, the EU in quantities of ≥ 1 tonne/year per M/I. Failure to register means that the substance is not allowed to be manufactured or imported by the M/I in question. All M/I of the same substance are required to cooperate to provide a single hazard dataset per substance, therefore reducing costs and avoiding unnecessary animal testing. This is achieved through the formation of SIEFs (Substance Information Exchange Forums), whose principal aims are to facilitate data sharing for the purposes of registration and to agree on the classification and labelling of the substance where there is a difference of interpretation between the potential registrants.

SIEF members need to appoint a lead registrant (LR) who must act with the agreement of the other co-registrants and submit the lead dossier of the joint submission. A lead dossier is a complete dossier that includes the classification and labelling of the substance, (robust) study summaries and proposals for further testing, if applicable. All other M/I of the same substance are known as joint registrants and must submit a joint registration dossier. The information requirements for the preparation of a joint registration dossier are largely reduced when compared to those of the lead dossier. Joint registrants must buy a Letter of Access (LoA) from the LR - a document that grants them the right to:

- refer to the LR REACH registration dossier
- participate in the joint submission

Substances fall into one of two categories. Phase-in substances are broadly speaking substances that were listed on EINECS (the European Inventory of Existing Commercial Chemical Substances - a list of over 100,000 substances that

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were on the EU market in 1981). Non-phase-in substances are those that are not phase-in substances and are often referred to as 'new' substances.

Potential registrants of phase-in substances can take advantage of the phase-in deadlines (see Table 1) as long as they are pre-registered by the M/I. Pre-registration required M/I of phase-in substances to submit some basic information to ECHA and the window for pre-registration closed on 30 November 2008. Non-phase-in substances and phase-in substances that are not pre-registered are subject to immediate registration (from 1 June 2008) otherwise they should be withdrawn from the market. A manufacturer or importer of a phase-in substance who enters the EU market for the first time after 1 June 2008 can still use the phase-in periods for registration. This is known as a late pre-registration.

Table 1: Timings for Registration

Substance group	**Registration deadline**
Non-phase-in (new) substance	Prior to M/I from 1 June 2008
Non-pre-registered phase-in substance	
Pre-registered phase-in substance M/I ≥ 1000 tpa	30 November 2010
Pre-registered phase-in R50/53 (very toxic to aquatic organisms) substance M/I ≥ 100 tpa	
Pre-registered phase-in CMR (carcinogens, mutagens and reproductive toxicants) substance M/I ≥ 1 tpa	
Pre-registered phase-in substance M/I ≥ 100 tpa	31 May 2013
Pre-registered phase-in substance M/I ≥ 1 tpa	31 May 2018

Non-EU manufacturers and Only Representatives (ORs)

Under REACH, a non-EU manufacturer cannot submit a registration to the European Chemicals Agency (ECHA) themselves. According to Article 8 of the Regulation, a natural or legal person established outside the EU who manufactures a substance on its own or in preparations, formulates a preparation or produces an articles imported into the EU may by mutual agreement appoint a natural or legal person established in the EU to fulfill, as his Only Representative (OR), the obligations on importers regarding the registration of substances. In simple terms, the non-EU manufacturer must appoint an EU-based representative (an OR) to fulfill all the obligations of an importer under REACH.

Registration exemptions

The Regulation exempts certain uses of substances that are adequately regulated under other legislation, such as medicinal products, or that generally present such low risks as not to require registration (set-out in REACH Annexes IV and V).

Polymers are also exempted from the requirement to register because of the large number of polymers and the limited risk posed by the vast majority of them. Monomers and other starting materials or additives will however normally need to be registered. The provisions for polymers will be subject to a review in due course and may be required to be registered in the future.

The following substance categories are exempt from registration:

- The specific substances listed in Annex IV of the Regulation
- Substances covered by Annex V of the Regulation, including:
    - Degradation products from environmental factors
    - Chemical degradation products from storage
    - Products from use
    - Products from reaction with additives
    - By-products

    - Hydrates, providing the anhydrous form is registered
    - Non-dangerous natural substances
    - Hydrogen, oxygen, nitrogen and the noble gases
    - Minerals, ores and ore concentrates, cement clinker, natural gas, liquid petroleum gas, natural gas, condensate process gases, crude oil, coal and coke
- Monomers bound into polymers, but note that registration is required if the monomer is present at ≥ 2% (w/w) in the polymer and is at ≥ 1 tonne/year
- Polymers
- Certain uses of substances addressed in 'equivalent' sectoral legislation
- Food and food ingredients
- Certain recycled materials
- Waste (exempt from REACH)
- Substances needed in the interests of defence (exempt from REACH)

Substances in articles

An Article is defined under REACH as 'an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition' (Article 3.3).

Substances intended to be released from articles, and present above 1 tonne/year per M/I, are subject to the same registration requirements and deadlines as for substances on their own or in preparations. Substances not intended to be released from articles need not be registered.

Notification to ECHA of substances in articles is required when all conditions of Article 7(2) are met:

- The substance is included in the Candidate List for Authorisation (Article 59(1))
- The substance is present in all articles produced or imported by one actor in an amount totalling over 1 tonne per year (per producer or importer)
- The substance is present in articles above a concentration of 0.1% weight by weight (w/w)

ECHA may request the registration of a notified substance in an article if it poses a risk to human health or the environment.

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PPORD (product and process oriented research and development)

In order to promote innovation, Article 9 of REACH specifies that substances manufactured or imported on their own or in preparation, as well as substances incorporated in articles or imported in articles for the purpose of product and process oriented research and development (PPORD) can be exempted from the duty to register for a period of 5 years. To be exempted a company needs to submit a PPORD Notification to the Agency.

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Evaluation

There are two types of evaluation with different aims:

1. Dossier evaluation (i.e. per individual registration dossier):

Registration dossier evaluation concerns the checking of testing proposals to prevent unnecessary animal testing, i.e. the repetition of existing tests, and poor quality or unnecessary tests. ECHA must check the compliance of a minimum of 5% registration dossiers with the registration requirements. National enforcement action is possible as a result.

2. Substance evaluation (i.e. per substance):

The Community Rolling Action Plan (CoRAP) introduces a list of substances that are proposed for review by the EU Member States Competent Authorities under the substance evaluation process of REACH (Articles 44 to 48). The plan contains substances for which there is a suspicion that their use could pose a risk to human health or the environment. ECHA will publish a new CoRAP list once a year, which will contain substances distributed for evaluation in the following 3 years. Following the evaluation by Member States, further information may be requested from the registrants of these substances if additional data is considered necessary to clarify the suspected risk. Alternatively, it may be concluded that

the substance does not constitute a risk based on the available knowledge at the time and no further data is needed with respect to the evaluation activity.

Authorisation

The Authorisation system (REACH Title VII) addresses 'Substances of Very High Concern' (SVHCs) with the aim of ensuring they are properly controlled and progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. SVHCs are considered to have hazardous properties of such high concern that it is necessary to regulate them centrally through a mechanism that ensures that the risks related to their actual uses are assessed, considered and then decided upon on an EU-wide basis. The justification is that the effects on humans and the environment of these substances are very serious and normally irreversible.

SVHCs are firstly identified and put on a so-called 'Candidate List'. Candidate List substances are then gradually included in Annex XIV of the REACH Regulation, the 'List of Substances Subject to Authorisation'. Once included in that Annex, substances cannot be placed on the market or used after a date to be set (the so-called 'sunset date'), unless the company has been granted an authorisation. There is no tonnage trigger for this requirement. Note that Authorised uses are specific to a supply chain.

If a substance is an authorised substance then you can only use that substance if either:

- You have successfully applied for an authorised use, or
- You have been named as a user in the authorised use dossier submission of a party up the supply chain.

One way of gaining an authorisation is to demonstrate 'adequate control' per use as part of any application for authorisation. However it may not be possible to demonstrate adequate control because:

a threshold limit value (TLV) cannot be established (for example for substances which are PBTs (persistent, bioaccumulative and toxic), vPvBs (very persistent and very bioaccumulative), non-threshold CMRs (carcinogens, mutagens or reproductive toxicants), or non-threshold endocrine disruptors) or;

the exposure cannot be kept below an identified TLV.

If 'adequate control' cannot be demonstrated, or the 'adequate control' route is not available, then an alternative is to seek an authorisation per use taking into account the risks posed by the substance, the socio-economic impacts of authorising or not the use, and possible alternatives and substitutes (substances and processes). Regardless of whether 'adequate control' is demonstrated or not, for SVHC the user has a duty to keep exposure to the minimum technically and practically possible.

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Restrictions

Restrictions were taken over from the old 'Restrictions on the marketing and use of certain dangerous substances and preparations' Directive (76/769/EEC). The substances restricted under REACH and the conditions of their restrictions are included in Annex XVII of the Regulation. The restriction process aims to regulate the manufacture, placing on the market or use of certain substances if they pose an unacceptable risk to health or the environment. The restriction is designed as a 'safety net' to manage risks that are not addressed by the other REACH processes. Restrictions are generally specific to one or more particular uses i.e. the same substance can still be used in other applications. If restrictions apply to a substance that you use, either on its own or in a preparation or article, you may only continue to use it if you comply with the restrictions.