The regulation of chemicals in the European Union (REACH)

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In the past, the regulation of chemical substances fell under the European Commission (EC) inventory, grouping them into new and existing chemicals based on the safety information available for each chemical substance. However, REACH adopts a single regulation system that places the responsibility for the safe use of chemical substances on the manufacturers and importers, and aims to seek out information on chemicals that has previously been lacking.

Which chemical substances apply to REACH?
In relation to REACH, chemical substances are defined as ‘compounds that are obtained by any manufacturing process, including any component to preserve its stability and any impurity derived from the manufacturing process’. Chemical substances that are manufactured alone, in formulation (preparation) or as an article product (chemical substances given a shape that determines its function) are applicable to REACH. All chemical substances manufactured or imported within the EU in quantities of more than one tonne per year must be registered. Some chemical substances are exempt from REACH (detailed in Annex IV and V of the regulation) either because they display a low hazard risk and therefore pose minimal threat to human health and the environment, or that they are regulated under separate legislation. Radioactive substances, transportation of dangerous goods by air or road and non-isolated intermediates are examples of chemicals exempt from REACH.

REACH objectives
REACH was primarily introduced to replace most of the existing EU framework including the European Inventory of Existing Commercial Chemical Substances (EINECS). It aims to put the responsibility of handling chemical substances solely on the industry, ensuring risks associated with the chemical substances are assessed adequately and are communicated throughout the entire supply chain, from the manufacturer or importer right through to the downstream user. All chemical substances applicable to REACH have to be registered and evaluated on the basis of toxicological data with regards to their intended uses. Chemical substances identified as high risk substances are subject to authorisation, which results in restriction and banning for particular identified uses where the risks cannot be adequately controlled. The aim of this process of authorisation and restriction is to encourage manufacturers and importers to substitute chemicals of high concern with a safer alternative, and in doing so to increase the competitiveness of the chemical industry within the EU.

The REACH process is a five-step process (see Figure 1) that starts off with pre-registration, moves into registration, evaluation and authorisation, and ends with restriction. Each step is further discussed in detail below.

Step 1: Pre-registration
The pre-registration phase of REACH took place between 1 June 2008 and 1 December 2008, and involved the registration of those chemicals already marketed and imported in quantities of more than one tonne per year. Pre-registration involved registering the name of manufacturer/importer, identity of the substance, and the annual tonnage manufactured or imported annually.

Step 2: Registration
The registration stage involves EU manufacturers or importers of all chemical substances, both new (non-phase in, as described by REACH) and existing (phase in), to submit a technical dossier outlining the potential risks, uses, applications and risk management measures for chemical substances to the newly formed chemical agency, the European Chemical Agency (ECHA). Registration began
on 1 January 2009 and involves staggered deadlines where the higher volumes of chemicals manufactured/imported are required to be registered sooner than those of a lower volume, in accordance with requirements. Chemical substances of more than 10 tonnes per year require additional safety information to be submitted (in the form of a Chemical Safety Report) that outlines in depth hazard and risk information for all intended uses. All registration documents must be submitted by the applicant electronically via the REACH-IT portal, found on the agency website (HYPERLINK "http://www.echa.europa.eu/reachit_en.asp"www.echa.europa.eu/reachit_en.asp).

REACH encourages applicants to share safety-related information concerning their chemicals. It is mandatory to share information related to animal testing proposals. The Substance Information Exchange Forum (SIEF) is used for data sharing and voluntary consortia used for registration. In many cases, a manufacturer producing a low volume of a chemical will often find that it has already been registered by the higher volume producer by the time the lower volume deadline has been reached. Another potential advantage is that several manufacturers/importers of the same chemical substances might submit a joint application and benefit from a reduced application fee.

**Step 3: Evaluation**

During the evaluation phase, ECHA will carry out a dossier check to ensure the registration is compliant with legal requirements. At this stage of the process, all animal testing proposals will be scrutinised in order to limit them to a minimum. Further in-depth evaluation will be performed on any substances that display a high risk and, if used, are prioritised for further action. This substance evaluation is carried out by the competent member state authorities in coordination with the agency. All decisions (requests for safety data) must be approved via the European process, through which either all member states must agree with the proposals, or the Commission takes the decision in the absences of a unanimous decision.

**Step 4: Authorisation**

Authorisation encourages substitution of dangerous chemical substances with safer alternatives. However, in cases where no viable alternatives are available, companies can apply for authorisation to use the chemical substance by showing that the risks are adequately controlled and that the benefits considerably outweigh the risk.

**Step 5: Restriction**

The restriction process is a safety net that deals with chemicals that display properties of concern, to control their use. Chemicals that have an unacceptable risk to human health and the environment are dealt with by restricting their manufacture and usage.

The difference between authorisation and restriction of chemicals is that authorisation bans all use of a chemical except those that the industry comes forward to defend. However, during the restriction phase, authorities provide justification for banning specific uses. The regulator should investigate which uses exist and which should be restricted, while considering whether safer alternatives are available. This differs from the authorisation phase, where the industry itself will choose and make a case for those intended uses it wishes to continue. In addition, authorisation encourages producers of alternative substances to bring forward information, and in some cases will force the applicant to prepare a substitution plan.

**Summary**

We have entered the registration phase of the REACH process. All manufacturers and importers within the EU that produce or import chemical substances in quantities of more than one tonne per year should have pre-registered by 1 December 2008. Manufacturers and importers have until 1 June, 2018, to register all their chemical substances that comply with the REACH regulation.

**Bibliography**