



REACH INFORMATION SHEET

What is REACH?

REACH is the EU's New Chemical Policy and entered into force on 1st June 2007. REACH stands for the *Registration Evaluation Authorisation and restriction of Chemicals* and will affect all producers, manufacturers, importers and downstream users of chemicals in the EU.

Why is REACH needed?

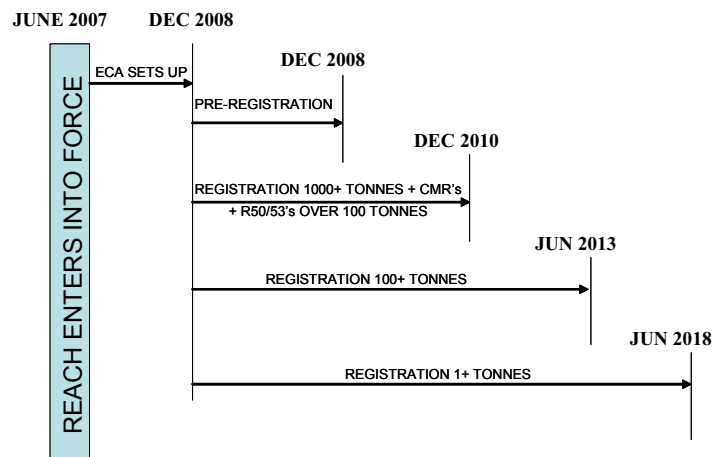
The EU believe that their current chemicals legislation - especially the comprehensive risk assessment foreseen by the Existing Substances Regulation - is not achieving the appropriate limitation of the potential risk posed by chemicals to man and the environment in an adequate time. REACH aims to gather the required information for each of the substances manufactured and sold within the EU to ensure that workers and the public are not at risk. Other priorities of the regulation include promoting non-animal testing, giving consumers better access to information on the risks associated with substances.

The REACH proposal consists of three main stages:

- Registration - Importers, manufacturers and some downstream users of substances in quantities over 1 tonne per year must register their substance with a new European Chemicals Agency
- Evaluation – Member State competent authorities will review registration packages and request further information / testing to determine the impact of the substance on human health and the environment
- Authorisation / Restriction – Decisions regarding which substances require an authorisation or restriction will be carried out at EU level by the Commission for substances that pose the most concern, such as carcinogens and mutagens

Registration is proposed to take place in three stages based on production / usage tonnage:

- 1000 tonnes / year, CMR's (Carcinogens, Mutagens, Reproductive Toxins) and R50/53's (Substances classified as very toxic to the aquatic environment, may cause long term adverse effects in aquatic environment) over 100 Tonnes – must be registered within three and a half years
- 100 – 1000 tonnes / year – must be registered within six years
- 1 – 100 tonnes / year – must be registered within eleven years



Substances Vs Preparations

The definitions of substance and preparation are very important in the REACH framework, as they determine the duties of the potential registrant. A **substance** is defined as "a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition" whilst a **preparation** is "a mixture or solution composed of two or more substances". Unless otherwise excluded substances made by a company in volumes over 1 tonne per year are always



REACH INFORMATION SHEET

registered, with the information needed dependent on the tonnage. Alloys are counted as special preparations as it is realised that their properties are altered from the sum of their parts, however the guidance and handling of alloys within REACH is still under development. Preparations have a number of obligations such as their own SDS's

What is Pre-registration?

The Pre-registration period occurs 12 – 18 months after legislation comes into force. During this time companies will pre-register on-line with the European Chemical Agency (ECA), submitting basic information on substance identity and the company. All companies who are liable to register have to pre-register in this period.

What is Registration?

For all substances produced or imported by a company in quantities of 1 tonne or more per year, manufacturers and importers must prepare a registration dossier which will be submitted to the European Chemicals Agency. It is industry's task to gather and assess the required information (the information needs are mainly based on company tonnage, comprises data on physicochemical, toxicological and eco-toxicological properties). In addition to the data on the substance, individual identified uses of downstream users throughout the supply chain as well as assessments of the associated risks and safety measures derived from these must be specified.

For substances with annual volumes of more than 10 tonnes per company, the assessment of the safe handling (Chemical Safety Assessment) must be documented in a Chemical Safety Report.

What is Authorisation?

Authorisation is for CMR's Cat 1 &2, respiratory sensitisers, PBT, vPvB, equivalent level of concern e.g. endocrine disruptors. So it will include Cobalt Chloride, Sulphate, Carbonate, Nitrate, Acetate. However prioritisation is likely to be focussed on PBT's and vPvB before the CMR's are considered.

Authorisation is both SUBSTANCE and USE specific, meaning that each use of an authorised substance has to be authorised separately. The authorisation process ensures risks of substance are adequately controlled, if not that they can be justified on Socio-Economic Grounds. Failure to gain authorisation could lead to the restriction of that use for the specific compound within the EU.

What are my Downstream User Obligations?

Amongst a Downstream Users obligations are that they should

- Communicate their usage to their supplier
- Ensure that the Chemical Safety Assessment covers their use
- Implement Risk Management Measures suggested by Supplier
- Prepare a chemical safety report if they do not wish to tell their supplier about a certain use
- Ensure good communication up and down supply chain

What can I do?

How a company prepares for REACH will depend on its commercial activities. Examples of preparatory activities that companies are currently taking include:

- Setting-up administrative and product management systems to facilitate complying with REACH when it enters into force
- Developing portfolios of substances affected by REACH and identifying gaps in the information currently available and that likely to be needed
- Reviewing and improving available data (e.g. contained in Safety Data Sheets)
- Communicating the potential business impact of REACH with suppliers and customers.

Where Can I find more information?

There are a number of available sources including Cobalt News – the CDI's quarterly on-line magazine is running a series on REACH, the EU on their REACH site (<http://ecb.jrc.it/REACH>), for information on different substances the ESIS section of the ECB website is useful (<http://ecb.jrc.it/ESIS>). As well as specialised helpdesks such as www.reachready.com

What is the CDI doing for REACH?

Currently the CDI has set up a Task Force charged with ascertaining the best way for the cobalt industry as a whole to prepare and organise itself for REACH. We are running two, six month projects examining the substances which will be registered and their uses. The outcome of these projects will indicate the best way forward for CDI members and allow further advance preparations to be made.

For further information please contact David Weight (david.weight@thecdi.com)