

Introduction

This guide provides a background to REACH, and gives a statement of Holchem's current compliance position.

Registration, Evaluation, Authorisation and Restriction of Chemicals

REACH is an EU regulation (EC 1907/2006) that places responsibility on industry to manage the risks from [chemical substances](#) and to provide sufficiently detailed safety information to allow safe use of chemical substances. Since its introduction there have been a number of amendments to the original text. However the broad aims remain the same:-

- To provide a high level of protection to human health and the environment from the use of chemicals.
- To make the people who place chemicals on the market responsible for understanding and managing the risks associated with their use.
- To allow the free movement of chemical substances within the EU market.
- To enhance innovation in and the competitiveness of the EU chemicals industry.
- To promote the use of alternative methods for the assessment of the hazardous properties of substances.

It is expected that the EU chemical industry will benefit from enhanced competitiveness and innovation.

To achieve the aims of REACH, companies manufacturing or importing [chemical substances](#) (*that is individual single component chemicals*), in quantities greater than 1 tonne per year, will be required to gather information on the properties, uses, and classification of those [chemical substances](#). This information will then form part of the registration dossier, which must include information on safe usage. For [chemical substances](#) produced or imported in quantities greater than 10 tonne per year, a chemical safety report will also be required. For quantities above 100 tonne per year further information will be required.

It is important to note that REACH applies to [chemical substances](#), that is, a single chemical in its 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. **REACH only requires registration of [Chemical Substances](#)**; Preparations, Mixtures, and Formulations are not required to be registered under REACH, only each of their component substances. Most of the products supplied by Holchem are not substances; instead they are mixtures of substances and as such are not required to be registered under REACH.

Products such as medicines, biocides, radioactive materials and wastes will not be covered by REACH; these are covered by other legislation.

How will REACH work?

For REACH to work, manufacturers of [chemical substances](#) need to know how their products are used. Without this information it would be impossible to provide the correct and appropriate safety information. This means that in the early stages of registration and dossier generation, downstream users were required to provide information on how substances were used. A downstream user is defined as any natural or legal person established within the community, other than the manufacturer or the importer, who uses a substance, either on its own, or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. Most of the activity in this part of the REACH process was carried out several years ago and Holchem was engaged in discussions with producers and importers of substances to ensure that they were aware of the intended use of those substances both in our own processing plant and ultimately in the factories of our customers using formulated products.

How will REACH affect Holchem Customers?

Most large suppliers of formulated chemicals (for example; hygiene products, food processing aids, effluent treatments, corrosion inhibitors, etc) will be well aware of REACH and how it affects products supplied to their customers. However, it is advisable for users of chemical based products to produce an inventory of all chemicals used on site and contact the suppliers to confirm their position. When thinking about chemicals, remember to include less obvious things such as paints, effluent processing aids, lubricants, articles impregnated with chemicals that could be released to the environment etc. In reality; if you are using Holchem products in the way that is expected, then REACH should have little impact on your business. However, it is advisable to be aware of exposure scenarios. An exposure scenario describes the operating conditions and risk management measures that have been identified by the supplier as necessary to use a substance safely. REACH requires you to follow the advice on risk management measures given in an exposure scenario. For substances; a large number of exposure scenarios can be attached to the safety data sheet. For mixtures; there is no requirement to produce exposure scenarios. However, Holchem will examine a formulation and determine from exposure scenarios for each substance, an overall risk management measure, details of this will be included in the traditional 16 chapter safety data sheet, typically in section 8. It is advisable that information included here is considered as part of any COSHH or risk assessment.

Who is the Competent Authority for REACH

A European Chemicals Agency has been formed to act as the central point of reference and will be responsible for managing REACH and providing a database from which consumers and professionals can find hazard information.

In the UK the competent authority is the HSE.

What are the time scales for REACH?

- The EU regulatory framework for REACH was introduced on 29 October 2003.
- First Reading: European Parliament Reading – 2005.
- Second Reading: European Parliament Reading – 2006.
- Regulation in force mid-2007.
- July to November 2008 Pre-registration of substances.
- 2008 – 2010 Registration of substances produced or imported >1000 tonne.
- 2010 – 2013 Registration of substances produced or imported in the range 100 – 1000 tonne.
- 2018 – Registration of substances in the range 1- 100 tonne.

Compliance Certificates

There is no such thing as a certificate of REACH compliance for either substances or mixtures! However, once a substance has gained REACH registration, it will be assigned a REACH registration number; this will appear against the entry for that substance on a safety data sheet. In the example below, the registration number for Sodium Hydroxide can be seen. There is no registration number for the Glycoside. This simply means that at the time of producing the safety data sheet no registration number had been received for the substance. However, as part of Holchem's raw material approval process we have checked that the material has been pre-registered in REACH for the uses appropriate to our product, a registration number will eventually be granted; this however may take many more years to occur.

SODIUM HYDROXIDE		30-60%
CAS-No.: 1310-73-2	EC No.: 215-185-5	Registration Number: 01-2119457892-27
Classification (EC 1272/2008) Skin Corr. 1A - H314		Classification (67/548/EEC) C;R35
D-GLUCOPYRANOSE OILGOMERIC DECYL OCTYL GLYCOSIDE		5-10%
CAS-No.: 68515-73-1	EC No.: 500-220-1	
Classification (EC 1272/2008) Eye Dam. 1 - H318		Classification (67/548/EEC) Xi;R41.

Statement of Holchem's Compliance

Holchem mainly produces formulated products (mixtures) by blending [chemical substances](#). Formulated products do not need to be registered in REACH; hence there are no REACH compliance certificates.

All of Holchem's suppliers have confirmed that they are pre-registering the substances used in our formulations. As new raw materials are utilised their REACH status is confirmed as part of the approval process.

The combination of the Biocidal Products Regulation and REACH resulted in a few raw materials being withdrawn by suppliers. We were given plenty of warning and were able to formulate around the problem. We suspect that a few more materials will disappear over the next few years, but this is unlikely to be an overnight occurrence and again we will be able to formulate around the problem.

Overall, we do not anticipate REACH resulting in the withdrawal of any Holchem products.

Additional Information

More information on REACH is available from the HSE <http://www.hse.gov.uk/reach/index.htm>

Legislation

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).