



REACH is Here

The Politics are Over, Now the Hard Work Starts

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This report briefly explains the Regulatory process that was followed towards the final adoption by the European Union (EU) of the REACH Regulation. More importantly it sets out its key elements as contained in the final and agreed REACH Regulation adopted on 19 December 2006.

Summary

The European Commission published on 29 October 2003 a proposal for a new Regulation setting out the strategy for the management of chemicals in the European Union (EU). This Regulation is known as REACH (Registration, Evaluation and Authorisation of Chemicals) and will bring about the biggest change to the management of chemicals in the EU since the Dangerous Substance Directive (67/548/EEC) was first introduced in 1967. REACH will impact all sectors of industry along the length and breadth of the supply chain in the EU as well as importers into the EU; this will have a direct effect on those companies outside the EU who export their products into the EU. REACH will come into force on 1 June 2007. It is therefore important that all those affected understand what REACH will mean for them. Decisions are already being taken by some companies on the assumption that REACH will bring about major changes in the way chemicals are managed both in a regulatory sense and also in terms of health, safety and the environment.

This report sets out why REACH is needed, outlines the major provisions in REACH, explains the impact on supply chain information (including classification and labelling), and the timing of its introduction.

REACH replaces over 40 existing Directives and Regulations (most are updates and amendments to existing legislation which are notoriously difficult to track down and keep track of) and at over 800 pages contains far more than can be fully explained in this report.

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The Regulatory Process

History

The REACH proposal was considered by the European institutions through the 'Co-decision Process'. Co-decision means that the European Parliament and the Council of Ministers of the European Union (referred to as "the Council") have to agree on the text of the legislation. The European Parliament completed its 'First Reading' of REACH on 17 November 2005, and proposed a number of amendments to the European Commission legislative proposal of October 2003; these amendments were largely, but not wholly, accepted by the European Commission. The Council completed its deliberations on the Commission's proposal on 13 December 2005 and reached **political agreement** on a revised text. This revised text was not identical to the text agreed by the European Parliament at its first reading. Following its verification by linguistic and legal experts the formal '**Common Position**' text was agreed by the Council on 27 June 2006 and subsequently published. The 'Common Position' text was the formal, agreed position of all the EU Member State Governments and was the version of REACH considered by the European Parliament in a 'Second Reading'. The 'Second Reading' started officially in September 2006 but the EP had already made considerable progress in its deliberations. During the 'Second Reading', the European Parliament proposed amendments from its 'First Reading' that the Council had not taken on board.

The last 6 months of 2006 were taken up in negotiations on the shape and detail of the final REACH text. The Second Reading requires the three EU institutions (the Council, the EP and the European Commission) in effect to agree on the final text before it can be finally adopted and agreed.

These negotiations were particularly difficult for a number of reasons. First, because of the sheer size, complexity and technical/ scientific detail that is contained in REACH. Second, the EP found it difficult to agree on its position because of the competing interests of the various political groups and national interests. Third, although the Common Position was agreed by all the EU MS there were considerable differences between them on the extent of any further possible changes in order to reach an agreement with the other institutions. Fourth, the two responsible DGs of the European Commission (ENV and ENTR) had significantly diverging views. And fifth, the timescales for reaching a deal under the Second Reading were extremely tight for something as politically and technically and scientifically challenging as REACH.

How REACH was agreed

After almost 8 years of discussions, deliberations, negotiations and often fierce arguments the REACH Regulation has finally arrived. Final political agreement was reached at the Environment Council on 18 December 2006 after a fraught and difficult period of negotiations between the key stakeholders (the European Union (EU) Member States (MS) represented by Finland as holder of the Presidency of the EU, the European Parliament (EP) and in particular the rapporteur and Chair of its Environment Committee, Directorates-General (DG) Environment (ENV) and Enterprise (ENTR) of the European Commission (COM), and others (e.g. industry, NGOs) who were lobbying the various EU Institutions right up until the end) during the Finnish Presidency of the EU in the second half of 2006. Much of the credit for agreement being reached by the end of

2006 must go to the Government of Finland in its role as President of the EU for the second half of 2006. The final REACH text was published in the Official Journal of the European Union on 30 December 2006 and can be found at:

<http://europa.eu.int/eur-lex/lex/JOHtml.do?uri=OJ:L:2006:396:SOM:EN:HTML>

Fundamental Change

The EU is in the process of making the most fundamental changes to its legislation on the management of chemicals for over 30 years. Not only has the EU developed and put in place a new chemicals strategy (**REACH** – **R**egistration, **E**valuation and **A**uthorisation of **C**hemicals) but it is also planning to implement the globally harmonised system for the classification and labelling of chemicals (**GHS**) in the very near future (see below). **REACH entered into force on 1 June 2007**. A process that started in earnest in 1999 during a UK Presidency of the EU is now completed.

Why is REACH needed?

Until now EU legislative framework for chemical substances was a patchwork of many different Directives and Regulations which has developed since 1967 when the first Dangerous Substances Directive was introduced. There were different rules for “existing” and “new” substances. However, this system did not produced sufficient information about the effects of the majority of existing substances on human health and the environment. The identification and assessment of risks - covering the hazard of a substance as well as exposure of humans and the environment to it – have proved to be slow, as have been the subsequent introduction of risk management measures. The system, in particular for new substances, has hampered research and innovation, causing the EU chemicals industry to lag behind its counterparts in the US and Japan in this regard.

The distinction between so-called “existing” and “new” substances is based on the cut-off date of 1981. All substances that were put on the market before 1981 were called “existing” substances. In 1981, they numbered 100,106 different substances (listed on EINECS – the European Inventory of Existing Chemical Substances). Substances introduced to the market after 1981 (about 3,000) are termed “new” substances.

Under the old regime new substances had to be tested extensively (and expensively) before they were placed on the market, there were no such provisions for “existing” substances. As a result, although some information exists on the properties and uses of existing substances, there is generally a **lack of sufficient information** publicly available in order to assess and control these substances effectively.

The allocation of responsibilities was also considered, by the European Commission and others, to be inappropriate. Public authorities were responsible for undertaking risk assessments of substances rather than the enterprises that manufacture, import or use the substances; and these risk assessments are required to be comprehensive, rather than targeted and use-specific. Since 1993, only 141 high-volume (existing) substances have been identified for risk assessment and possible recommendations for risk reduction, of which only a limited number (27) have completed the process.

Furthermore, the legislation required the manufacturers and importers of chemicals to provide information, but did not impose similar obligations on downstream users

(industrial users and formulators) unless the substance had to be classified and a safety data sheet (SDS) had to be supplied with it further down the supply chain. As a result, information on uses of substances may have been difficult to obtain and information about the exposure arising from downstream uses scarce.

On the other hand, new substances had to be notified and tested starting from volumes as low as 10 kg per year. This has been perceived as a **barrier to innovation** within the EU chemicals industry by discouraging research and invention of new substances and favouring the development and use of existing substances over new ones.

If EU-wide controls (e.g. bans and restrictions) were considered to be necessary, the process to restrict the marketing and use of substances had been slow. It started in 1976 (Directive 76/769/EEC – known as the Marketing and Use or Limitations Directive) and restricted the marketing or use of only about 100 substances, including the use of some of them in articles, as well as the marketing to the general public of about 900 substances classified as carcinogenic, mutagenic or toxic to reproduction (CMRs).

Globally Harmonised System for the classification and labelling of chemicals (GHS)

It is the intention of the European Commission to introduce the GHS at the same time as REACH as far as is possible. They published draft proposals to implement the GHS in the EU (http://ec.europa.eu/enterprise/reach/ghs_consultation_en.htm) and made a formal proposal in 2007 taking into account the comments received on the published draft. The GHS introduces classification criteria for substances and mixtures (preparations) and associated hazard communication elements. The GHS will, it is anticipated, be adopted globally so that exporters of chemicals will only need to perform a hazard assessment and produce a label once rather than for all importing countries with their own system as now. Translation will of course normally still be necessary. The current requirements for classifying substances and preparations in the EU will largely be replaced. This means that the classification and labelling elements of the Dangerous Substances Directive (67/548/EEC) and the Dangerous Preparations Directive (1999/45/EC) will be replaced.