

## REACH REGULATION: LAST DEVELOPMENTS

February 2006

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### Background

The EU Council of Ministers convened an extraordinary meeting on 13 December, 2005, to try and find a common position on the proposed REACH Regulation (Registration, Evaluation and Authorisation of Chemicals).

EU ministers had previously agreed on the aspects of REACH dealing with producers' obligation to register health and safety data about the chemicals they wish to (continue to) commercialise. The compromise closely matched the line adopted by the Parliament when it voted on REACH in first reading last November 2005.

According to the Commission, safety information is "sketchy for around 99%" of the 100,000 chemicals that were introduced before 1981. REACH proposes to assess about 30,000 of them since it leaves out substances produced or imported in quantities of less than one tonne per year. Under the current compromise on registration, it is estimated that about 12,000 will escape full safety data submission, mainly for substances produced or imported in small quantities (1-10 tonnes a year). The exemptions are said to concern only chemicals which do not raise particular concerns for human health and the environment.

### Issues

Ministers struck an agreement on the draft REACH Regulation on 13 December 2005, finding a compromise on how to authorise the most dangerous substances or replace them with safer alternatives. The vote paves the way for a second reading in Parliament and Council, aiming to reach a final agreement before the end of 2006.

However, more drama is expected at second reading in Parliament with the Greens group heavily criticising the agreement and the majority centre-right EPP-ED group calling for further concessions to industry.

### ***Authorisation of most dangerous chemicals***

The key remaining point EU ministers had to deal with concerned approval rules for those substances that cause cancer, genetic mutations or reproduction problems, as well as those that accumulate in human bodies and the environment.

Under the Council compromise, the future chemicals agency in Helsinki will grant authorisation for these dangerous chemicals only after companies can show that:

- "the risks are adequately controlled"
- "social and economic benefits outweigh the risks" or
- analysis has shown "suitable alternative substances do not exist"

In a statement, the EU said "authorisations should not be granted on the grounds of adequate control in the case of substances that are persistent, bioaccumulative and toxic (PBT) or very persistent, very bioaccumulative (vPvB)".

Precisely under which circumstances can toxic substances be considered to be "adequately controlled" will be defined by the Commission with help from member state experts, using a fast-track procedure ('comitology'). This will be decided within 12 months of REACH coming into force. According to the UK Presidency, the definition will only concern "substances where it is not possible to determine safe thresholds with current methods".

Once adopted, the definition will be inserted in Annex I of REACH which deals with general provisions on how to assess substances. The amendment has been added at the request of Commissioner Verheugen, according to French Industry Minister François Loos, who said the amendment extends the procedure to the revision of all other REACH annexes.

### ***Exemptions and time limitations to authorisation rules***

A number of exemptions have been granted, notably to chemicals used for R&D purposes, which are broadly unaffected by REACH. In what is perceived as a gesture to small businesses, SMEs can be exempted from registration tax if they show "a complete registration form".

Ministers also agreed that the length of time limitations to authorisations granted for the most dangerous substances - those which cannot be replaced under the above conditions - should be decided on a case by case basis. In plenary, Parliament had adopted a one-size-fits-all review for all products of major concern every five years.

### ***Data sharing (OSOR), 'duty of care' and 'right to know'***

Ministers have limited the opt-outs to rules obliging companies to share information when submitting group applications under the One Substance, One Registration rule (OSOR). But they dropped the 'duty of care' and 'right to know' principles which would have strengthened companies' responsibility to handle chemicals safely and allowed information to be communicated to consumers.

### ***Substitute fibres (chrysotile)***

Since no exemption appears for substitute fibres in the text of the draft Regulation (current copy) and based on the contacts held by Alonso&Asociados in Brussels, the producers and importers of chrysotile's substitute fibres should fully comply with the future Regulation REACH once it is approved.

### **Next steps**

- **March 2006:** Council common position (25 Ministers from Member States) to be finalised (including translations, legal clean-up, etc.)
- **Around July 2006:** second reading in Parliament
- **Autumn 2006:** second reading in Council (and possible final approval)
- **Spring 2007:** expected entry into force of REACH
- **Spring 2008:** expected time by which agency is operational
- **By 2008:** REACH expected to become operational.