Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

2003/0256(COD) - 18/12/2006 - Corrigendum to final act

CORRIGENDUM to 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), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

LEGISLATIVE ACT: Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

PURPOSE: to establish a regulatory framework for the management of chemicals at EU level and to establish a European Chemicals Agency.

CONTENT: the Regulation establishes **REACH** (**Registration, Evaluation, Authorisation and Restriction of Chemicals**). It provides for provisions for the manufacture, placing on the market or use of chemicals in the European Union.

The purpose of this Regulation is to ensure a high level of **protection of human health and the environment**, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. It is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the **precautionary principle**.

The Regulation applies to **all chemical substances manufactured, imported, marketed and used as such, in mixtures or products**. It shall not apply to certain types of substances, such as radioactive substances or waste that are already covered by other legislation.

The main elements of the Regulation are:

Registration: the Regulation obliges manufacturers and importers to **identify and manage the risks** associated with the substances they produce and market in the European Union by demonstrating the extent to which the substances in question may be used safely. This information must be transmitted to the European Chemicals Agency (ECHA) for **registration in a database**.

By 31 May 2018, all chemical products manufactured, imported or placed on the EU market in **excess of 1 tonne per year** must be registered. Without registration, chemicals may not be manufactured or imported into the EU.

Evaluation: the European Chemicals Agency (ECHA) is in charge of verifying the information submitted during registration. Member States shall evaluate substances in the light of specific concerns regarding human health and the environment. The Agency and the Member States may request from manufacturers, importers or downstream users further information on substances suspected of posing a risk to health or the environment.

Authorisation: the purpose of this procedure is to ensure that risks from substances of very high concern (for example, carcinogens, mutagens and reproductive toxins) are adequately controlled and that substances are **progressively replaced by less dangerous substances** or technologies where economically and technically viable alternatives are available. These substances shall be listed in Annex XIV of the REACH (List of substances subject to authorisation), in which case companies must obtain an authorisation to continue using them.

Restrictions: restrictions on the manufacture, use or placing on the market of certain substances are intended to **manage unacceptable risks** to human health or the environment that are not covered by other REACH processes or by other EU legislation. The European Commission or EU Member States may restrict the manufacture or use of certain substances if they consider that risk management is not appropriate.

Agency: the Regulation establishes a European Chemicals Agency for the management and, in some cases, the implementation of the technical, scientific and administrative aspects of the Regulation and to ensure a consist approach at EU level. It provides the Member States and the EU institutions with the best possible **scientific advice** on questions relating to chemicals which fall within its remit. It is responsible for setting up and maintaining one or more **databases** containing information on all registered substances, the classification and labelling inventory, and the harmonised list of classifications and labels.

The Agency's **revenue** shall consist of: (i) a subsidy from the Community, entered in the general budget; (ii) fees paid by the undertakings; (iii) any voluntary contribution from the Member States.

Reports: Member States, ECHA and the Commission are required to submit periodic reports on the operation of the Regulation. The Commission must also make a number of reviews by different deadlines.

Lastly, the competent authorities of the Member States shall **inform the general public** about the risks arising from substances where this is considered necessary for the protection of human health or the environment.

ENTRY INTO FORCE: 1.1.2007.