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

2003/0256(COD) - 13/12/2006 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a resolution based on the report by Guido **SACCONI** (PES, Italy) on the Council's common position. Parliament arrived at an agreement with Council on outstanding issues a few days before the vote in plenary. The compromise package agreed with the Council and tabled by 4 political groups (EPP-ED, PES, ALDE and UEN), was approved with 529 in favour, 98 against and 24 abstentions. The key points are as follows:

Registration of substances: REACH will require manufacturers and importers to gather information on the properties of all substances produced or imported in quantities higher than 1 ton per year and to submit the necessary information to demonstrate their safe use in a registration dossier to the European Chemicals Agency (the Agency). Failure to register will mean the substance cannot be manufactured or imported into the EU market. Currently about 30,000 substances are in the EU market in volumes above one tonne.

Quantities above 10 tonnes per year additionally require the submission of a Chemical Safety Report (CSR) to document the safety assessment of the substance. Accordingly, substances imported in low volumes (below ten tonnes per year) will not require the submission of a Chemical Safety Report.

The Commission must decide in 12 years' time whether or not to recommend extending the requirement for chemical safety reports to substances produced or imported in amounts of less than 10 tonnes per year. This deadline was shortened to seven years for cancerous or mutagenic substances or those toxic to reproduction.

Substitution: substitution plans - or at least an analysis of possible alternatives - aiming to replace the most dangerous substances where a safer alternative is available, must be submitted to the Agency by producers alongside authorisation applications. The Economic and Social Committee, scientific committees and interested third parties will be able to intervene to submit additional (and/or contradictory) information. Where an alternative product exists, substitution is compulsory on the basis of a precise timetable outlined in the substitution plan. If, on the contrary, no substitute product exists, producers should present a research plan with a view to developing such a product. There are exceptions to this rule based on the criteria of adequate control.

Provisions relative to 'high-concern' chemicals: around 1500 substances of very high concern may become subject to authorisation, including:

- CMRs (substances that are carcinogenic, mutagenic or toxic to reproduction), category 1 and 2;
- PBTs (substances with persistent, bio-accumulative and toxic properties);
- vPvBs (substances that are very persistent, very bio-accumulative).

Substances identified from scientific evidence as causing probable serious effects to human health and the environment equivalent to those of the other categories mentioned above, for example certain endocrine disrupting substances (substances disturbing the body's hormone system). These will be identified on a case by case basis.

For certain substances that are carcinogenic, mutagenic or toxic to the reproductive system (CMR substances), an authorisation will be granted if the producer or importer can show that risks from the use in question can be adequately controlled. This means that scientists can agree on a "safe threshold" below which a substance does not create negative effects to the human body or the environment. Endocrine disrupters will be subject to the 'adequate control' criteria. A review clause nevertheless provides scope for looking into their possible inclusion among the substances subject to specific authorisation (see below) six years after the entry into force of the regulation on the basis of the latest available scientific data and in view of the results of a cost/socioeconomic benefits analysis of their use.

The agreement does not enforce mandatory substitution of substances of high concern in all consumer products.

For other CMR substances and substances with persistent, bio-accumulative or toxic properties (PBT, vPvB substances), where adequate control is not possible, a specific authorisation will be granted if no safer alternative exists and if the socio-economic benefits of the use of the substance outweigh the risks.

Burden of proof: instead of national authorities having to justify concern about particular chemicals, the responsibility for proving that their products are safe will now rest with the manufacturers. The industry will have to prove the safety of chemicals produced or imported in large volumes (above 10 tonnes a year).

Duty of care: The agreement of Council and Parliament clarifies in two recitals the general responsibility of industry to avoid adverse effects on health and environment when manufacturing, importing, using or placing on the market chemicals.

Animal welfare: the promotion of alternatives to the animal testing of chemicals is now included among the goals of REACH. To avoid duplication of animal testing, interested parties will have 45 days to state their views before each new plan for animal tests. Information on toxicity to human beings should if possible be discovered using means other than tests on vertebrate animals, through alternative methods such as in vivo procedures. These alternative methods must be validated by the Commission, once recognised by the agency, or international institutions. The Commission will submit a report every three years on the use of alternative tests and, if necessary, bring forward fresh legislative proposals.

European Chemicals Agency: Parliament will appoint two members of the Helsinki-based European Chemicals Agency and the text also specifies the agency's responsibilities and its role in relation to the relevant national authorities. The Board of Administration will comprise one delegate per member state, two members appointed by the European Parliament and six by the Commission (including three non-voting stakeholder representatives). The Executive Director will have to undergo a hearing with MEPs before his/her appointment is confirmed. However, Parliament's demands for guarantees of the independence of the agency's members vis-à-vis industry and the publication of declarations of interest were not accepted. The agency will have one year (until 1 June 2008) to be fully operational (staff recruitment and training, establishment of various committees, etc). It should present its first recommendations on dangerous substances two years after the entry into force of the regulation, i.e. after 1 June 2009.

Communication of information: a clause was added on the duty to inform the public about dangerous substances contained in products. The distribution chain, including consumers who request it, must be informed of the presence of any chemical in an amount greater than 0.1% of the total product weight. The Commission must consider the possibility of establishing a European quality mark for chemical products.

Comitology: the Council accepted a number of amendments bringing REACH into line with the new comitology provisions, which give the EP a right of scrutiny over certain Commission decisions.

Timeline for the implementation of REACH:

- June 2007: entry into force of REACH.

- June 2008: European Chemicals Agency becomes operational.

- June 2008 to November 2008: pre-registration of so-called phase-in substances.

- November 2010: registration deadline for substances in quantities of 1000 tonnes and above as well as carcinogens, mutagens and substances toxic to reproduction (CMR category 1 and 2) above 1 tonne/year and substances classified as very toxic to aquatic organisms (R50/53) above 100 tonnes.

- June 2013: registration deadline for substances in quantities of 100 tonnes and more.

- June 2018: registration deadline for substances in quantities of 1 tonne and more.

- Voluntary registration prior to the deadline is of course possible. Registration dossiers can be submitted as of 1 June 2008.

- New substances need to be registered before they are placed on the market. Their registration will start on 1 June 2008.

- June 2018: Registration phase closes with substances produced in smaller quantities (1-10 tonnes).