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

2003/0256(COD) - 17/11/2005 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution based on the draft by Guido **SACCONI** (PES, IT) and approved a large number of amendments to the REACH (Registration, Evaluation and Authorisation of Chemicals) proposal. The main elements of the position of the European Parliament were adopted by 398 votes in favour, 148 against and 36 abstentions. The actual vote on the report was 407 in favour, 155 against with 41 abstentions. Parliament sought to achieve balance between the need to protect public health and the environment on the one hand, while safeguarding the chemicals industry's interests in terms of competitiveness, on the other. It was necessary to draw up composite amendments on different aspects of the proposal, notably on authorisation, as a means of ring-fencing the vote.

On registration: This was one of the most controversial areas. The compromise reached by the PES, the EPP-ED and the ALDE groups was endorsed by plenary by 438 votes in favour, 144 against and 15 abstentions. French socialists refused to back the compromise. The provisions on registration were diluted: obligations regarding the quantity and quality of information to be provided, tests to be undertaken and the number of substances covered are significantly reduced. The compromise is based on the following elements:

-A single pre-registration phase has been introduced to simplify the procedure. The time for pre-registration has been increased to 18 months to take into account the time needed for the Agency to become operational.

-Registration will be staggered: within three years for the most dangerous chemicals and those produced in volumes of more than 1,000 tonnes a year; within six years for substances produced in volumes of 100 tonnes per year and more; and within 11 years for substances produced in volumes of between 1 and 100 tonnes per year.

-the introduction of a targeted approach on data requirements for 1-10 tonnes chemicals (those having been identified by the impact assessment studies as being the ones for which costs of REACH implementation would be higher)

- Parliament introduced scope in the proposal for requesting additional testing where necessary;

-it also introduced scope for companies to avoid the need to make certain tests on substances produced or imported in volumes of between 10 and 100 tonnes/year provided due justification is provided on the basis of criteria defined by the Commission.

-the scope of the Regulation is expanded by the addition of several substances to Annex II;

-on the issue of the burden of proof, it is the responsibility on industry to make available information on the hazards, risks, and risk reduction measures for chemicals. These provisions apply to existing chemicals. Safety data on new substances should be submitted in accordance with existing legislation. The most dangerous substances and those contained in everyday consumer goods that are harmful to human health or the environment will also be subject to comprehensive information requirements regarding safety data.

-Parliament confirmed the "One Substance, One Registration" (OSOR) principle. This requires companies to share data (notably on animal testing to reduce the numbers involved) and costs, which should be “proportionate” to the volumes produced/imported by each partner. A company can ask to dispense with this obligation provided it notifies and provides due justification to the Agency (“opt-out”). Both the sharing of data (notably regarding testing on animals) and the sharing of costs are provisions that respond directly to the concerns of SMEs.

On Authorisation: The issue of authorisation was one of the most controversial. This series of amendments, broadly rallying left-wing parties (PES, ALDE, Greens, European United Left) restores the environment and health protection to the heart of the system by strictly limiting the duration of authorisations and making substitution mandatory, whereas the compromise on registration leant heavily towards industry.

The European Parliament endorsed by 324 votes in favour, 263 against and 13 abstentions the approach of the Environment Committee which is based on the following elements:

- the granting of licences by the Agency following an evaluation of substances regarded as being dangerous for a limited duration of five years, with provision for a review at the end of this period. Where substances have not been modified and the producer provides evidence that efforts have been made to produce the substance in an environmentally-friendly manner, renewal procedure may be simplified;

-the introduction of the obligation to replace dangerous products with less harmful substances as soon as alternatives become available. These provisions are designed to encourage industry to invest in research and innovation. By extension, authorisation will only be granted for the most dangerous chemicals where there are no alternatives.

On Substances in Articles: Parliamentendorsed by 291 in favour, 290 against and 16 abstentions a slightly revised version of the approach adopted on this issue by the Environment Committee. The amendments provide notably for equal treatment of imported products and those produced in the EU through simple notification of substances contained in consumer goods, where they are already registered as being of grave concern, and the application of an equivalent authorisation procedure.

For SMEs: Parliament endorsed the approach of the Environment Committee (supported also by Internal Market and Industry Committees). It made provision for an aid mechanism (to be established notably by the member states local and/or regional authorities) in the form of an assistance and guidance bureau on implementation of the REACH system. The text also acknowledges that the system must not result in an increase in bureaucracy. Parliament clarified requirements and obligations regarding communication of risks and transparency on the part of large enterprises for the benefit of downstream users.

On the Agency: Parliament endorsed the approach of the Environment Committee (supported by Internal Market and Industry Committees). The amendments adopted enhance the role and powers of the Agency, specify its tasks and responsibilities and emphasise that it will be answerable to EU institutions for its management of chemicals policy. The responsibilities of the committee on risk assessment are extended. It is entrusted with the task of drawing up a research policy on alternative methods of evaluation. Parliament established a new committee charged with examining new alternative testing methods (alternatives to testing on animals). Parliament called for additional funding for research into alternative testing methods. It granted additional powers to the Agency by making existing provisions on the sharing of testing data mandatory: by refusing to provide such information a company runs the risk of seeing its request for registration and authorisation rejected.

On animal testing: The European Parliament endorsed the approach of the Environment Committee. It sought to minimise animal testing through regular adaptation of testing methods and avoidance of duplication of testing. Parliament gave priority to in vitro tests and extended the obligation to share data from tests on both vertebrates and invertebrates.