Placing of plant protection products on the market

2006/0136(COD) - 23/10/2007 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution drafted by Hiltrud **BREYER** (Greens/ALE, DE), and made some amendments to the proposal for a regulation concerning the placing of plant protection products on the market. With specific regard to the approval regime, the Commission's zone-based approach was rejected by Parliament, which preferred Member States to maintain national control over product approval.

The main points are as follows:

Objective and legal bases: Members specified that Articles 152 (4)(b) and 175(1) should be used as dual legal bases since the purpose of the Regulation is to ensure a high level of protection of both human and animal health and the environment. The purpose of the Regulation is furthermore to harmonise the rules on the placing on the market of plant protection products in order to harmonise the availability of plant protection products between farmers in different Member States. Member States may not be prevented from applying the precautionary principle in restricting or prohibiting pesticides. They may establish any pesticide-free zones they deem necessary in order to safeguard drinking water resources. Such pesticide-free zones may cover the entire Member State. Member States may impose a ban on the use and marketing of EU-authorised pesticides where they are found in measurable quantities outside the root zone.

Active substances: Members introduced a definition of 'active substances' as substances, including their metabolites present in the use phase, micro-organisms and viruses, having general or specific action against target organisms or on plants, parts of plants or plant products. They clarified that they must not have any harmful effects on human health, in particular that of users who are in direct contact with the products, residents, bystanders and vulnerable groups. Parliament accepted an amendment in plenary that such substances shall not have any unacceptable effect on the environment taking into account cumulative and synergistic effects and all relevant exposure routes to organisms in the environment. Methods to assess such effects will be presented by the European Food Safety Authority. A derogation will not apply to any active substance classified in accordance with Directive 67/548/EEC as: carcinogenic, mutagenic, toxic to reproduction, sensitising chemicals, or to substances that are qualified as: persistent with a half-life of more than 60 days; endocrine disrupters appearing on the EU list of suspected endocrine disrupters; toxic; bioaccumulative and non-readily degradable. On e year after entry into force of the legislation, the Commission must review and if necessary specify the criteria for treating an active substance as a low risk substance and, if appropriate, submit proposals. The Commission may review the approval of an active substance at any time and shall give due consideration to requests for review from a Member State, the European Parliament and other stakeholders, based on current scientific and technical knowledge and monitoring data.

Parliament added as part of the definition of “substance of concern” that any substance that has or potentially has either carcinogenic, mutagenic, endocrine disrupting, neurotoxic, immunotoxic, reprotoxic or genotoxic capabilities should be regarded as a substance of concern.

Zonal licensing: Parliament rejected the Commission’s proposal regarding the introduction of zones and corresponding zonal licensing of pesticidal products. It specified instead that authorisations granted by one Member State should be notified to other Member States. Member States should be entitled to confirm, reject or restrict the authorisation granted by another Member State on the basis of their specific

agricultural needs or to maintain a higher protection level in line with their National Pesticide Action Plan. A new recital states that good administrative co-operation between Member States should be increased during all steps of the authorisation procedure and should be facilitated by a European Helpdesk.

Approval procedure: Parliament stated that the Authority must be responsible for coordinating the approval procedure, and in doing so, the Authority will rely on the competent authorities of Member States. An application for the approval of an active substance or for an amendment to the conditions of an approval shall be submitted by the producer of the active substance to the Authority (rather than the 'rapporteur Member State '). The Authority shall inform the competent authorities of the Member States of the applications it has received. A Member State may choose an active substance for which an application for approval has been received by the Authority, with the aim of becoming the rapporteur Member State. Disagreement should be solved in comitology, on the basis of objective criteria, such as geographic, agricultural and climatic conditions, especially with regard to the target organisms, the performance and impartiality of the competent authority and the reference laboratory, and the absence of interests linked to the producing companies.

The authorisation setting out the requirements relating to the placing on the market and use of the plant protection product will include indications for proper use according to the principles of Integrated Pest Management as defined in the legislation, to apply from 2012 onwards.

Renewal of approval: whilst the Commission had specified that the renewal shall be for an unlimited period of time, Parliament endorsed the views of its competent committee and stated that the approval may be renewed once or repeatedly for a period not exceeding 10 years. The approval period should be proportional to the possible risks inherent in the use of such substances and should be limited to a maximum of 15 years for low risk substances, 5 years for candidates for substitution and 10 years for other substances. After the first renewal, a regular review of substances should take place.

Substitution principle and comparative assessment: Member States must not authorise for use in a given crop a plant protection product either containing a candidate for substitution or posing a higher risk where a comparative assessment weighing up the risks and benefits, as set out in Annex IV, shows that safer alternatives are available, as defined in the legislation. While Member States must not authorise any plant protection product where a comparative assessment shows the existence of safer alternatives, priority in comparative assessment and substitution shall be given to candidates for substitution.

Minor uses: Member States must establish a list of minor uses. This list shall be made available to the public through official websites of the Member State and of the Commission. Not later than one year after entry into force of the legislation, the Commission must present a proposal to the European Parliament and the Council for establishing a European promotion fund for minor uses. The Fund shall also be entitled to finance additional residue tests for minor uses. Comparative assessments shall take authorised minor uses into account.

Transparency and competition: Producers, suppliers, distributors and professional users of plant protection products must keep records of the plant protection products they produce, store or use for at least 10 years after the end of production or use. They shall make the information contained in these records available to the competent authority. They shall also keep this information available for neighbours and residents, retailers or the drinking water industry who request direct access to it. The information on all applications of plant protection products on a given agricultural product shall be provided to retailers and wholesalers in the form of a pesticide passport. In addition, the Commission must maintain an updated list of approved active substances in Annex IIa and publish this list on the Internet. Lastly, Members specified the need for a clear definition and a minimum set of community harmonized rules regulating the placing of products on the market through parallel trade, and inserted a new Article on the granting of parallel trade permits.

Animal testing: in order to avoid animal testing, testing on vertebrate animals for the purposes of the Regulation must be undertaken only as a last resort. The use of non-animal tests and intelligent testing strategies must be promoted, and duplicate vertebrate animal testing shall be prohibited. Dossiers for each test or study involving vertebrate animals must show a justification of the steps taken to avoid animal testing and duplicative testing on vertebrate animals.