

Placing of plant protection products on the market

2006/0136(COD) - 13/01/2009 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a legislative resolution amending the Council's common position for adopting a regulation of the European Parliament and of the Council on the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

The recommendation for second reading (under the codecision procedure) had been tabled for consideration in plenary by Hiltrud **BREYER** (Greens/ALE, DE), on behalf of the Committee on the Environment, Public Health and Food Safety.

The amendments were the result of a compromise between Parliament and Council. The main amendments were as follows:

Legal bases: the compromise text stated that the legal bases were Articles 37(2) (agriculture), 95 (internal market) and 152(4)(b) (health).

Precautionary principle: the provisions are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human health or the environment. Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human, animal health or the environment posed by the plant protection products to be authorised in their territory.

Active substances: Members dropped the definition of active substances that Parliament had proposed at 1st reading. The compromise text states that where an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, such active substance may be approved for a time limited period necessary to control that serious danger but not exceeding five years even if it does not satisfy the approval criteria. Member States may authorise plant protection products containing active substances approved in accordance with this derogation only when it is necessary to control that serious danger to plant health in their territory. At the same time, they shall elaborate a phasing out plan on how to control the serious danger by other means, including non-chemical methods, and shall forthwith transmit it to the Commission.

CMR and endocrine disruptors: with regard to the derogation from the approval criteria for active substances, the text provides that the derogation shall not apply to active substances which are or have to be classified in accordance with Directive 67/548/EEC, as carcinogenic category 1, carcinogenic category 2 without a threshold, or toxic for reproduction category An active substance must not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects. Those products that are affected will only be banned once their current approvals come up for renewal.

Zoning system: Parliament accepted that the three-zones division should be maintained.

Residents: residents should be taken into account for the authorisation of plant protection products

Honeybees: An active substance, safener or synergist shall be approved only if it is established that it will result in a negligible exposure of honeybees, or that there are no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour.

Application: assessment of an application may be performed by a number of Member States together under a co-rapporteur system. Scientific peer-reviewed open literature, as determined by the Authority, on the active substance and its relevant metabolites dealing with side-effects on health, the environment and non-target species and published within the last ten years before the date of dossier submission shall be added by the applicant to the dossier.

Animal testing: the summary dossier must include for each test or study involving vertebrate animals, a justification of the steps taken to avoid animal testing and duplicative testing on vertebrate animals. Furthermore, the Commission's work programme must include measures to minimise animal testing, in particular the use of non-animal test methods and intelligent testing strategies.

Testing on vertebrate animals: this may be undertaken only where no other methods are available. Repetition of tests and studies involving vertebrates shall be avoided. Seven years after entry into force of the regulation, the Commission shall report on the effects of the provisions concerning data protection of tests and studies involving vertebrate animals.

Comitology: the regulatory procedure with scrutiny will apply to harmonised methods to determine the nature and quantity of active substances, safeners and synergists as well as relevant impurities and coformulants. It will also apply to detailed rules for the maximum quantities of plant protection products which may be released during experiments.

Minor uses: 2 years after entry into force of the legislation, the Commission shall present a report to the European Parliament and the Council on the establishment of a European fund for minor uses, accompanied, if appropriate, by a legislative proposal.

Advertising: Member States may prohibit or restrict the advertising of plant protection products in certain media subject to Community law.

Record-keeping: records must be kept for at least five years. Professional users of plant protection products shall keep records of the plant protection products they use, containing the name of the plant protection product, the time and the dose of application, the area and the crop where the plant protection product was used, for at least three years. 3 years after entry into force of the legislation, the Commission shall present a report on costs and benefits of the traceability of the information from users to retailers concerning the plant protection products' applications on agricultural products accompanied, if necessary, with appropriate legislative proposals. Producers of plant protection products shall undertake post-authorisation monitoring on request of the competent authorities and notify the competent authorities of the relevant results.