Placing of plant protection products on the market

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The Committee on the Environment, Public Health and Food Safety adopted a report drafted by Hiltrud **BREYER** (Greens/ALE, DE), and recommended amendments to the Council 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. Most of the amendments were reinstatements of amendments from 1st reading. The main ones were as follows :

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 common position provides for Article 95 (internal market) and Article 37(2) (agriculture) to be used as legal bases.

Objective: the committee expanded considerably the purposes of the Regulation, stating that, in addition to autorisation and approval of active substances, purposes include: ensuring a high level of protection of both human and animal health and the environment; and harmonising 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.

Precautionary principle: the Regulation is based on the precautionary principle in order to ensure that substances or products placed on the market do not adversely affect human or animal health or the environment. Member States may not be prevented from applying the precautionary principle in restricting or prohibiting pesticides. Member States 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.

Active substances: Members re-introduced the definition of active substances that Parliament had proposed at 1st reading. With regard to the derogation from the criteria for the approval of a substance in case of a serious danger to plant health, the committee specified that there must be a public interest in controlling that danger. Such an active substance may be approved for a time-limited period necessary to control that serious danger but not exceeding 4 years (rather than 5 years) and a substitution plan on how to control the serious danger in two years' time by other means, including non-chemical methods, must be presented by the applicant. Regarding substances with endocrine-disrupting properties, the committee provides some examples of substances which may be considered as such. Further specific scientific criteria for the determination of endocrine disrupting properties shall be adopted in accordance with the regulatory procedure with scrutiny.

A new clause states that an active substance, safener or synergist shall only be approved if it is not considered to cause a significant risk (affecting at least one in a million citizens) of **developmental neurotoxic or immunotoxic** properties in humans, taking into account exposure during embryonic/foetal life and/or during childhood as well as likely combination effects, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, i.e. the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Regulation (EC) No 396/2005.

The committee also introduces in the criteria the consideration of **risk to honeybees**, honeybee larvae, honeybee behaviour, or colony survival and development.

Zoning: the committee deleted the proposed zoning system, since it felt that the latter undermines national authorisation and it is not in line with the EC principle of proportionality and subsidiarity because it is going beyond what is necessary to speeding up the decision making process. These objectives can be reached by amending the mutual recognition system without the concept of zoning. The committee proposes to keep the principle of compulsory mutual recognition of authorisations for plant protection products in the context of a one-zone system and introduces more flexibility for Member States to refuse mutual recognition. An amended recital states that authorisations granted by one Member State should be notified to other Member States in which the applicant wishes to put the product on the market. Those Member States should be entitled to recognise an authorisation issued by another Member State, amend it or refrain from authorising the plant protection product in their territory, if justified because of specific agricultural or environmental circumstances that may be, but do not need to be, limited to that Member State, or if the high level of protection of human or animal health or the environment set out in the Regulation cannot be achieved, or to maintain a higher protection level in their territory in line with their national action plan to reduce the risks associated with pesticides, adopted in accordance with Directive 2008/.../EC establishing a framework for Community action to achieve a sustainable use of pesticides.

Approval procedure: the committee insisted that the Authority (EFSA) shall be responsible for coordinating the approval procedure. In doing so, the Authority shall rely on the competent authorities of Member States. Upon being informed which Member State will examine the application, the applicant shall immediately forward to the Authority the complete and the summary dossiers. Within 180 days, the Member States concerned shall grant or refuse authorisations.

Substitution of dangerous substances with safer alternatives: the approval time of candidates for substitution should not be the same as the general approval period. To ensure regular comparative assessment of products containing such substances, the approval period should be limited to 5 years (renewable) rather than 10. Furthermore, any authorisation of plant protection products containing a candidate for substitution without comparative assessment should be limited to a maximum of 3 years. The adoption of the list of substances that are candidates for substitution should be done after 3 years at the latest, rather than 6.

Animal testing: Members specified that, in order to avoid animal testing, testing on vertebrate animals for the purposes of the Regulation shall be undertaken only as a last resort. The use of non-animal tests and intelligent testing strategies shall be promoted, and duplicate vertebrate animal testing shall be prohibited.

Standardised format for information: Members want records of plant protection products produced, imported, exported, stored, used or placed on the market to be kept for at least 10 years after the end of production or use, rather than for 3 years. This information must be 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 using a standardised format, which will be established in accordance with the advisory procedure.

Promotion fund for minor uses: not later than one year after entry into force of the legislation, the Commission shall present a proposal to the European Parliament and the Council for the establishment of a European promotion fund for minor uses. The Fund shall also be entitled to finance additional residue tests for minor uses.

Comitology: the Commission must be empowered to approve active substances, to renew or review their approval, to adopt harmonised methods to determine the nature and quantity of active substances, safeners and synergists, and where appropriate of relevant impurities and co-formulants, to adopt detailed rules for

allowing derogations from authorisation of plant protection products for research and development and the list of approved substances. Rules on these matters must be adopted in accordance with the regulatory procedure with scrutiny.