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 drawn up by Hiltrud BREYER (Greens/ALE, DE), and amended, in the first reading of the co-decision procedure, the proposal for a regulation concerning the placing of plant protection products on the market.

The main amendments 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.

Definitions: the Committee inserted and amended several definitions. It specified, particularly, that ?plant protection products? should be replaced with ?pesticides? and in the relevant places ?pesticide products'.

Zonal licensing: in view of the objectives of the regulation, the Committee did not consider the Commission?s proposed introduction of zones and corresponding zonal licensing of pesticidal products to be useful, since it felt that dividing the EU into arbitrary zones did not meet environmental or nature-conservancy criteria. Risk assessment and risk management should be set up in accordance with smaller, differentiated nature conservancy areas and soil-climate conditions. In addition, each Member State should retain the option of going beyond the Community standard in its fundamental standard of protection or of making decisions in product licensing in order to implement established objectives of national pesticide action plans, health programmes or environmental protection measures. Each Member State should also be allowed to decide to link licensing decisions to a test of usefulness based on specific national conditions. The Committee stipulated, instead of arbitrary zones, that the principle of mutual recognition of national licensings should be retained, but that the Member States should, in the spirit of the subsidiarity principle, be allowed to make national or regional specifications. 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.

Active substances: Members clarified that active substances that have no adverse effect on humans, animals or the environment can be considered as low-risk. The Commission may review the approval of an active substance at any time and will 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. The Committee made clear that a derogation will not apply to any active substance classified in accordance with Directive 67/548/EEC as: carcinogenic, mutagenic, toxic to reproduction, sensitising, 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.

Approval criteria for an active substance or a metabolite in the use-phase: the Committee stated that cut-off criteria will be used for the exclusion of active substances, in order to protect human health and the environment against intrinsic hazards of certain substances. 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, such as pregnant and nursing women, embryos and foetuses, infants and children. All testing and decision-making strategies must follow this principle, and current scientific knowledge must be borne in mind in the process. Furthermore, to prevent animal testing, tests on vertebrate animals should for the purposes of the Regulation be carried out 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. 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.

Substitution principle and comparative assessment: the Committee considered it important to follow the principles of the REACH and biocide directives, and to introduce the substitution principle and comparative assessment in order to reduce the risks and dangers of pesticides. Products that contain a candidate for substitution will not be approved by Member States if there are safer alternatives or methods available for a given crop. 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. In addition, the aims of the Thematic Strategy on the compulsory introduction of standards of integrated pest management and integrated plant protection into agriculture should be incorporated into the definitions and measures of ?good technical practice? and ?proper handling of pesticides? in the regulation. These conditions should become a compulsory component of the licensing process by 2012 instead of 2014.

Approval procedure: the Committee 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.

Renewal of approval: whilst the Commission had specified that the renewal shall be for an unlimited period of time, the Committee 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.

Transparency and competition: Members consider the greatest possible transparency in licensing and use, all the way through to the consumer, to be essential. For this reason information on permitted substances should be published on the Internet, and consumer-relevant information (e.g. eco-toxicological data) from the licensing procedure, as well as the results of residue monitoring, should be published. In addition to the proposed rule on keeping records on pesticide use, the Committee suggests a ?pesticide pass?, with which greater transparency and traceability in the food chain could be achieved. 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.