Placing of plant protection products on the market

2006/0136(COD) - 21/10/2009 - Final act

PURPOSE: to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production.

LEGISLATIVE ACT: Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117 /EEC and 91/414/EEC.

CONTENT: following an agreement reached at second reading of the codecision procedure, the Council adopted a regulation concerning the placing of plant protection products on the market.

The proposed Regulation would replace the existing legislation on the placing on the market of plant protection products (Council Directive 91/414/EEC), thoroughly revising the procedures for the safety evaluation of active substances and plant protection products. However, it keeps the two steps procedure of the Directive:

1. Approval of active substances at EU level;
2. Authorisation of plant protection products, containing approved substances, by Member States.

For simplification, it would also repeal Council Directive 79/117/EEC prohibiting the placing on the market and use of plant protection products containing certain active substances. The main aim of the proposal is to maintain a high level of protection for humans, animals and the environment; to reduce the administrative burdens of the present approval and authorisation procedures and to achieve a higher level of harmonization.

This proposal should be seen as part of a package together with the Thematic Strategy on the Sustainable Use of Pesticides and the proposal for a Framework Directive, which fills a legal gap in the use phase of pesticides, as well as a proposal for a Regulation on the collection of statistics regarding the placing on the market and the use of plant protection products.

The main elements of this new Regulation are as follows:

Subject matter and purpose: this Regulation lays down rules for the authorisation of plant protection products in commercial form and for their placing on the market, use and control within the Community. It lays down both rules for the approval of active substances, safeners and synergists, which plant protection products contain or consist of, and rules for adjuvants and co-formulants.

The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production. The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment. In particular, Member States shall not be prevented from applying the **precautionary principle** where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory.

Criteria: strict cut-off criteria for the approval at EU level of active substances are laid down in the new Regulation which will ban from the market the most toxic substances currently available. However, in exceptional cases, temporary derogations from these criteria could be granted in case of a serious threat to plant health. Under the new Regulation, a substance shall only be approved if, inter alia:

- **it has no immediate or delayed harmful effect on human health, including that of vulnerable groups, or animal health**. These include pregnant and nursing women, the unborn, infants and children, the elderly and workers and residents subject to high pesticide exposure over the long term;
- **it has no unacceptable effects on the environment**, having particular regard to the following considerations: (i) its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, groundwater, air and soil taking into account locations distant from its use following long-range environmental transportation; (ii) its impact on non-target species, including on the ongoing behaviour of those species; (iii) its impact on biodiversity and the ecosystem.

Derogations: where on the basis of documented evidence included in the application 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 limited period necessary to control that serious danger but not exceeding five years, provided that the use of the active substance is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised. This derogation shall not apply to active substances which are or have to be classified as carcinogenic category 1A, carcinogenic category 1B without a threshold, or toxic for reproduction category 1A.

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 draw up a phasing out plan concerning the control of the serious danger by other means, including non-chemical methods, and shall without delay transmit that plan to the Commission.

Procedures: the procedures for the approval of active substances and authorisation of plant protection products have been harmonised and simplified, deadlines have been tightened, and the roles of the Member States, the Commission, and European Food Safety Authority (EFSA) have been clarified. First approval shall be for a period not exceeding 10 years. 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 a Member State, (the rapporteur Member State), together with a summary and a complete dossier or a scientifically reasoned justification for not providing certain parts of those dossiers, demonstrating that the active substance fulfils the approval criteria provided for in this Regulation. A joint application may be submitted by an association of producers designated by the producers for the purpose of compliance with this Regulation. 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 10 years before the date of submission of the dossier shall be added by the applicant to the dossier. Member States should, within a delay of 120 days, decided on the mutual recognition. The renewal of the approval should be for a period not exceeding 15 years.

Regular examinations of products: under this Regulation Member States should regularly examine plant protection products containing substances which pose a high risk for human health or the environment with the aim of replacing them by plant protection products containing active substances which require less risk mitigation or by non-chemical control or prevention methods. In addition, incentives should be given for the placing on the market of low-risk plant protection products.

Definition of zones for the authorisation of plant protection products: the Regulation also sets out a system of three geographical zones (north, centre and south) for the mutual recognition of plant protection products which will increase the availability of plant protection products throughout the EU and reduce the workload for Member States. Nevertheless Member States will have the possibility to limit or reject the authorisations granted in another Member State in certain environmental or agricultural circumstances.

Animal testing: the Regulation stipulates that animal testing for the purposes of this Regulation should be minimised and tests on vertebrates should be undertaken as a last resort. Duplicative testing and duplication of tests and studies on vertebrates should be prohibited.

It should also be noted that an active substance, safener or synergist shall be approved only if it is established following an appropriate risk assessment on the basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist: (i) will result in a negligible exposure of **honeybees**, or (ii) has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour.

Candidates for substitution: an active substance complying with the criteria shall be approved, for a period not exceeding seven years, as a candidate for substitution if it meets one or more of the additional criteria laid down in the regulation. By way of derogation, the approval may be renewed once or more for periods not exceeding seven years.

Other provisions: the new regulation also includes, in particular, rules on data protection, classification, packaging and labelling, advertising, record-keeping, parallel trade and on seeds treated with plant protection products.

Review clause: by 14 December 2014, the Commission shall present a report to the European Parliament and the Council on the functioning of mutual recognition of authorisations and in particular on the the division of the Community into three zones and on the application of the criteria for the approval of active substances, safeners and synergists as set out in Annex II and the impact thereof on the diversification and competitiveness of agriculture as well as on human health and on the environment. The report may be accompanied, if necessary, by the appropriate legislative proposals to amend those provisions.

By 14 June 2011, the Commission shall adopt the following: (a) a Regulation containing the list of the active substances already approved at the moment of adoption of that Regulation; (b) a Regulation on data requirements for active substances; (c) a Regulation on data requirements for plant protection products; (d) a Regulation on uniform principles for risk assessment for plant protection products; (e) a Regulation containing the requirements of the labelling of plant protection products.

ENTRY INTO FORCE: 14.12.2009.

APPLICATION: from 14.06.2011.