Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 21 October 2009

concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37(2), Article 95 and Article 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee[(1)],

Having regard to the opinion of the Committee of the Regions[(2)],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(3)],

Whereas:

(1) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market[(4)] provides for rules governing plant protection products and the active substances contained in those products.

(2) Following the progress report presented by the Commission under Directive 91/414/EEC, the European Parliament by its Resolution of 30 May 2002[(5)] and the Council in its Conclusions of 12 December 2001 asked the Commission to review Directive 91/414/EEC and identified a number of issues for the Commission to address.

(3) In the light of the experience gained from the application of Directive 91/414/EEC and of recent scientific and technical developments, that Directive should be replaced.

(4) By way of simplification, the new act should also repeal Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances[(6)].

(5) To simplify application of the new act and to ensure consistency throughout the Member States, it should take the form of a Regulation.

(6) Plant production has a very important place in the Community. One of the most important ways of protecting plants and plant products against harmful organisms, including weeds, and of improving agricultural production is the use of plant protection products.

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(7) Plant protection products can however also have non-beneficial effects on plant production. Their use may involve risks and hazards for humans, animals and the environment, especially if placed on the market without having been officially tested and authorised and if incorrectly used.

(8) The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture. Particular attention should be paid to the protection of vulnerable groups of the population, including pregnant women, infants and children. The precautionary principle should be applied and this Regulation should ensure that industry demonstrates that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment.

(9) In order to remove as far as possible obstacles to trade in plant protection products existing due to the different levels of protection in the Member States, this Regulation should also lay down harmonised rules for the approval of active substances and the placing on the market of plant protection products, including the rules on the mutual recognition of authorisations and on parallel trade. The purpose of this Regulation is thus to increase the free movement of such products and availability of these products in the Member States.

(10) Substances should only be included in plant protection products where it has been demonstrated that they present a clear benefit for plant production and they are not expected to have any harmful effect on human or animal health or any unacceptable effects on the environment. In order to achieve the same level of protection in all Member States, the decision on acceptability or non-acceptability of such substances should be taken at Community level on the basis of harmonised criteria. These criteria should be applied for the first approval of an active substance under this Regulation. For active substances already approved, the criteria should be applied at the time of renewal or review of their approval.

(11) The development of non-animal test methods should be promoted in order to produce safety data relevant to humans and to replace animal studies currently in use.

(12) In the interest of predictability, efficiency and consistency, a detailed procedure should be laid down for assessing whether an active substance can be approved. The information to be submitted by interested parties for the purposes of approval of a substance should be specified. In view of the amount of work connected with the approval procedure, it is appropriate that the evaluation of such information be performed by a Member State acting as a rapporteur for the Community. To ensure consistency in evaluation, an independent scientific review should be performed by the European Food Safety Authority established by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[7] (the Authority). It should be clarified that the Authority performs a risk assessment whilst the Commission should perform the risk management role and take the final decision on an active

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substance. Provisions should be included to ensure the transparency of the evaluation process.

(13) For ethical reasons, the assessment of an active substance or a plant protection product should not be based on tests or studies involving the deliberate administration of the active substance or plant protection product to humans with the purpose of determining a human 'no observed effect level' of an active substance. Similarly, toxicological studies carried out on humans should not be used to lower the safety margins for active substances or plant protection products.

(14) To speed up the approval of active substances, strict deadlines should be established for the different procedural steps.

(15) In the interest of safety, the approval period for active substances should be limited in time. The approval period should be proportionate to the possible risks inherent in the use of such substances. Experience gained from the actual use of plant protection products containing the substances concerned and any developments in science and technology should be taken into account when any decision regarding the renewal of an approval is taken. The renewal of the approval should be for a period not exceeding 15 years.

(16) The possibility of amending or withdrawing the approval of an active substance in cases where the criteria for approval are no longer satisfied, or where compliance with Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy[(8)] is compromised, should be provided for under certain conditions.

(17) The evaluation of an active substance may reveal that it presents considerably less of a risk than other substances. In order to favour the inclusion of such a substance in plant protection products, it is appropriate to identify such substances and to facilitate the placing on the market of plant protection products containing them. Incentives should be given for the placing on the market of low-risk plant protection products.

(18) Certain substances which are not predominantly used as plant protection products may be of value for plant protection, but the economic interest of applying for approval may be limited. Therefore, specific provisions should ensure that such substances, as far as their risks are acceptable, may also be approved for plant protection use.

(19) Some active substances with certain properties should be identified at Community level as candidates for substitution. Member States should regularly examine plant protection products containing such active substances 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.

(20) In certain Member States non-chemical control or prevention methods, which are significantly safer for human and animal health and for the environment, have been established and generally applied for certain uses. In exceptional cases Member States should also be able to apply the comparative assessment when granting authorisation for plant protection products.

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(21) In addition to active substances, plant protection products may contain safeners or synergists for which similar rules should be provided. The technical rules necessary for the evaluation of such substances should be established. Substances currently on the market should only be evaluated after those rules have been established.

(22) Plant protection products may also contain co-formulants. It is appropriate to provide a list of co-formulants which should not be included in plant protection products.

(23) Plant protection products containing active substances can be formulated in many ways and used on a variety of plants and plant products, under different agricultural, plant health and environmental (including climatic) conditions. Authorisations for plant protection products should therefore be granted by Member States.

(24) The provisions governing authorisation must ensure a high standard of protection. In particular, when granting authorisations of plant protection products, the objective of protecting human and animal health and the environment should take priority over the objective of improving plant production. Therefore, it should be demonstrated, before plant protection products are placed on the market, that they present a clear benefit for plant production and do not have any harmful effect on human or animal health, including that of vulnerable groups, or any unacceptable effects on the environment.

(25) In the interest of predictability, efficiency and consistency, criteria, procedures and conditions for the authorisation of plant protection products should be harmonised, account being taken of the general principles of protection of human and animal health and the environment.

(26) Where the decision on approval cannot be finalised within the period provided for due to reasons not falling under the responsibility of the applicant, Member States should be able to grant the provisional authorisations for a limited period in order to facilitate the transition to the approval procedure provided for under this Regulation. In the light of the experience gained from the approval of the active substances under this Regulation, the provisions on provisional authorisations should cease to apply or be extended after the period of five years, if necessary.

(27) The active substances contained in a plant protection product can be produced by different manufacturing processes, leading to differences in specifications. Such differences may have safety implications. For efficiency reasons, a harmonised procedure at Community level should be provided for the assessment of those differences.

(28) Good administrative cooperation between Member States should be increased during all steps of the authorisation procedure.

(29) The principle of mutual recognition is one of the means of ensuring the free movement of goods within the Community. To avoid any duplication of work, to reduce the administrative burden for industry and for Member States and to provide for more harmonised availability of plant protection products, authorisations granted by one Member State should be accepted by other Member States where agricultural, plant health and environmental (including climatic) conditions are comparable. Therefore,

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the Community should be divided into zones with such comparable conditions in order to facilitate such mutual recognition. However, environmental or agricultural circumstances specific to the territory of one or more Member States might require that, on application, Member States recognise or amend an authorisation issued by another Member State, or refuse to authorise the plant protection product in their territory, where justified as a result of specific environmental or agricultural circumstances or where the high level of protection of both human and animal health and the environment required by this Regulation cannot be achieved. It should also be possible to impose appropriate conditions having regard to the objectives laid down in the National Action Plan adopted in accordance with Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve a sustainable use of pesticides[(9)].

(30) The economic incentive for industry to apply for an authorisation is limited for certain uses. In order to ensure that diversification of agriculture and horticulture is not jeopardised by the lack of availability of plant protection products, specific rules should be established for minor uses.

(31) Where identical plant protection products are authorised in different Member States, a simplified procedure for granting a parallel trade permit should be provided for in this Regulation, in order to facilitate the trade between Member States of such products.

(32) In exceptional cases, Member States should be permitted to authorise plant protection products not complying with the conditions provided for in this Regulation, where it is necessary to do so because of a danger or threat to plant production or ecosystems which cannot be contained by any other reasonable means. Such temporary authorisations should be reviewed at Community level.

(33) Community seeds legislation provides for free movement of seeds within the Community but does not contain a specific provision concerning seeds treated with plant protection products. Such a provision should therefore be included in this Regulation. If treated seeds constitute a serious risk to human or animal health or to the environment, Member States should have the possibility of taking protective measures.

(34) To promote innovation, special rules should be established permitting the use of plant protection products in experiments even where they have not yet been authorised.

(35) To ensure a high level of protection of human and animal health and the environment, plant protection products should be used properly, in accordance with their authorisation, having regard to the principles of integrated pest management and giving priority to non-chemical and natural alternatives wherever possible. The Council should include in the statutory management requirement referred to in Annex III to Council Regulation (EC) No 1782/2003 of 29 September 2003 establishing common rules for direct support schemes under the common agricultural policy and establishing certain support schemes for farmers[(10)], the principles of integrated pest management, including good plant protection practice and non-chemical methods of plant protection and pest and crop management.