# 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

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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.

(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

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.

(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,

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.

(36) In addition to this Regulation and Directive 2009/128/EC, a thematic strategy on the sustainable use of pesticides was adopted. In order to achieve coherence between these instruments, the user should know from the product label where, when and under what circumstances a plant protection product may be used.

(37) A system of exchange of information should be established. Member States should make available to each other, the Commission and the Authority the particulars and scientific documentation submitted in connection with applications for authorisation of plant protection products.

(38) Adjuvants may be used to increase the efficacy of a plant protection product. Their placing on the market or use should be forbidden where they contain a co-formulant which has been prohibited. The technical rules necessary for the authorisation should be established.

(39) Studies represent a major investment. This investment should be protected in order to stimulate research. For this reason, tests and studies, other than those involving vertebrate animals, which will be subject to obligatory data sharing, lodged by one applicant with a Member State should be protected against use by another applicant. This protection should, however, be limited in time in order to allow competition. It should also be limited to studies which are genuinely necessary for regulatory purposes, to avoid applicants artificially extending the period of protection by submitting new studies which are not necessary. Business operators, in particular small and medium sized enterprises, should have the same opportunities in respect of market access.

(40) The use of non-animal test methods and other risk assessment strategies should be promoted. Animal testing for the purposes of this Regulation should be minimised and tests on vertebrates should be undertaken as a last resort. In accordance with Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes[11], tests on vertebrate animals must be replaced, restricted or refined. Therefore, rules should be laid down to avoid duplicative testing and duplication of tests and studies on vertebrates should be prohibited. For the purpose of developing new plant protection products, there should be an obligation to allow access to studies on vertebrates on reasonable terms and the results and the costs of tests and studies on animals should be shared. In order to allow operators to know what studies have been carried out by others, Member States should keep a list of such studies even where they are not covered by the above system of compulsory access.

(41) As different rules are applied by Member States, the Commission and the Authority in relation to access to and confidentiality of documents, it is appropriate to clarify the provisions concerning access to information contained in the documents in the possession of these authorities and the confidentiality of these documents.

(42) Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous

preparations[12] applies to the classification, packaging and labelling of plant protection products. However, to improve further the protection of users of plant protection products, of consumers of plants and plant products and of the environment, further specific rules are appropriate which take account of the specific conditions of use of plant protection products.

(43) To ensure that advertisements do not mislead users of plant protection products or the public, it is appropriate to lay down rules on the advertising of those products.

(44) Provisions on record-keeping and information about the use of plant protection products should be established in order to raise the level of protection of human and animal health and the environment by ensuring the traceability of potential exposure, to increase the efficiency of monitoring and control and to reduce the costs of monitoring water quality.

(45) Provisions on control and inspection arrangements with regard to the marketing and use of plant protection products should ensure correct, safe and harmonised implementation of the requirements laid down in this Regulation in order to achieve a high level of protection of both human and animal health and the environment.

(46) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[13] provides for control measures for the use of plant protection products at all stages of the production of food, including record-keeping on the use of plant protection products. Similar rules on monitoring and controls relating to the storage and use of plant protection products not covered by Regulation (EC) No 882/2004 should be adopted by the Commission. The bureaucratic burden on farmers should be as limited as possible.

(47) The measures provided for in this Regulation should apply without prejudice to other Community legislation, in particular Directive 2009/128/EC, Directive 2000/60/EC, Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin[14] and Community legislation on the protection of workers and anyone concerned with the contained use and deliberate release of genetically modified organisms.

(48) It is necessary to establish procedures for the adoption of emergency measures in situations where an approved active substance, a safener, a synergist or a plant protection product is likely to constitute a serious risk to human or animal health or the environment.

(49) Member States should lay down rules on penalties applicable to infringements of this Regulation and should take the measures necessary to ensure that they are implemented.

(50) General civil and criminal liability in the Member States of the manufacturer and, where applicable, of the person responsible for placing the plant protection product on the market or using it should remain applicable.

(51) Member States should have the possibility of recovering the costs of the procedures associated with the application of this Regulation from those seeking to place, or

placing, plant protection products or adjuvants on the market and from those applying for the approval of active substances, safeners or synergists.

(52) Member States should designate the necessary national competent authorities.

(53) The Commission should facilitate the application of this Regulation. Therefore, it is appropriate to provide for the necessary financial resources and the possibility of amending certain provisions of this Regulation in the light of experience or of developing technical notes for guidance.

(54) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[(15)].

(55) In particular, the Commission should be empowered 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, and maximum quantities of plant protection products to be released, and to adopt Regulations concerning labelling requirements, controls and rules for adjuvants, establishing a work programme for safeners and synergists, including their data requirements, postponing the expiry of the approval period, extending the date for provisional authorisations, setting the information requirements for parallel trade and on inclusion of co-formulants, as well as amendments to the Regulations on data requirements and on uniform principles for evaluation and authorisation and to the Annexes. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(56) On grounds of efficiency, the normal time limits for the regulatory procedure with scrutiny should be curtailed for the adoption of a Regulation postponing the expiry of the approval period for a period sufficient to examine the application.

(57) Furthermore, it is appropriate to transfer certain current provisions set out in the Annexes to Directive 91/414/EEC into separate legal instruments to be adopted by the Commission within 18 months after the entry into force of this Regulation. Since these current provisions should be, as a first step, transferred into new legal instruments and thus be adopted without any substantial modification, the advisory procedure is the most appropriate.

(58) It is also appropriate to use the advisory procedure to adopt some purely technical measures, in particular technical guidelines in view of their non-binding character.

(59) Certain provisions of Directive 91/414/EEC should remain applicable during the transitional period,

HAVE ADOPTED THIS REGULATION:

(**1**) OJ C 175, 27.7.2007, p. 44.

(**2**) OJ C 146, 30.6.2007, p. 48.

(**3**) Opinion of the European Parliament of 23 October 2007 (OJ C 263 E, 16.10.2008, p. 181), Council Common Position of 15 September 2008 (OJ C 266 E, 21.10.2008, p. 1) and European Parliament Position of 13 January 2009 (not yet published in the Official Journal). Council Decision of 24 September 2009.

(**4**) OJ L 230, 19.8.1991, p. 1.

(**5**) OJ C 187 E, 7.8.2003, p. 173.

(**6**) OJ L 33, 8.2.1979, p. 36.

(**7**) OJ L 31, 1.2.2002, p. 1.

(**8**) OJ L 327, 22.12.2000, p. 1.

(**9**) See page 71 of this Official Journal.

(**10**) OJ L 270, 21.10.2003, p. 1.

(**11**) OJ L 358, 18.12.1986, p. 1.

(**12**) OJ L 200, 30.7.1999, p. 1.

(**13**) OJ L 165, 30.4.2004, p. 1.

(**14**) OJ L 70, 16.3.2005, p. 1.

(**15**) OJ L 184, 17.7.1999, p. 23.

**Status:**
Point in time view as at 31/12/2020.

**Changes to legislation:**
There are currently no known outstanding effects for the Regulation (EC) No 1107/2009 of the European Parliament and of the Council, Introductory Text.