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

CHAPTER II

ACTIVE SUBSTANCES, SAFENERS, SYNERGISTS AND CO-FORMULANTS

SECTION 1

Active substances

Subsection 1

Requirements and conditions for approval

Article 4

Approval criteria for active substances

1 An active substance shall be approved in accordance with Annex II if it may be expected, in the light of current scientific and technical knowledge, that, taking into account the approval criteria set out in points 2 and 3 of that Annex, plant protection products containing that active substance meet the requirements provided for in paragraphs 2 and 3.

The assessment of the active substance shall first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied. If these criteria are satisfied the assessment shall continue to establish whether the other approval criteria set out in points 2 and 3 of Annex II are satisfied.

2 The residues of the plant protection products, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements:

a they shall not have any harmful effects on human health, including that of vulnerable groups, or animal health, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available, or on groundwater;

b they shall not have any unacceptable effect on the environment.

For residues which are of toxicological, ecotoxicological, environmental or drinking water relevance, there shall be methods in general use for measuring them. Analytical standards shall be commonly available.

3 A plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements:

a it shall be sufficiently effective;

b it shall have no immediate or delayed harmful effect on human health, including that of vulnerable groups, or animal health, directly or through drinking water (taking into account substances resulting from water treatment), food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available; or on groundwater;

c it shall not have any unacceptable effects on plants or plant products;

d it shall not cause unnecessary suffering and pain to vertebrates to be controlled;

e it shall have no unacceptable effects on the environment, having particular regard to the following considerations where the scientific methods accepted by the Authority to assess such effects are available:

(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.

4 The requirements of paragraphs 2 and 3 shall be evaluated in the light of uniform principles as referred to in Article 29(6).

5 For approval of an active substance, paragraphs 1, 2 and 3 shall be deemed to be satisfied where this has been established with respect to one or more representative uses of at least one plant protection product containing that active substance.

6 In relation to human health, no data collected on humans shall be used to lower the safety margins resulting from tests or studies on animals.

7 By way of derogation from paragraph 1, 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 even if it does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II, 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. For such substances maximum residue levels shall be set in accordance with Regulation (EC) No 396/2005.

This derogation shall not apply to active substances which are or have to be classified in accordance with Regulation (EC) No 1272/2008, 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 paragraph 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.

Article 5

First approval

First approval shall be for a period not exceeding 10 years.

Article 6

Conditions and restrictions

Approval may be subject to conditions and restrictions including:

(a) the minimum degree of purity of the active substance;

(b) the nature and maximum content of certain impurities;

(c) restrictions arising from the evaluation of the information referred to in Article 8 taking account of the agricultural, plant health and environmental, including climatic, conditions in question;

(d) type of preparation;

(e) manner and conditions of application;

(f) submission of further confirmatory information to Member States, the Commission and the European Food Safety Authority, (the Authority), where new requirements are established during the evaluation process or as a result of new scientific and technical knowledge;

(g) designation of categories of users, such as professional and non-professional;

(h) designation of areas where the use of plant protection products, including soil treatment products, containing the active substance may not be authorised or where the use may be authorised under specific conditions;

(i) the need to impose risk mitigation measures and monitoring after use;

(j) any other particular conditions that result from the evaluation of information made available in the context of this Regulation.

Subsection 2

Approval procedure

Article 7

Application

1 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 as provided for in Article 8(1) and (2) 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 Article 4.

A joint application may be submitted by an association of producers designated by the producers for the purpose of compliance with this Regulation.

The application shall be examined by the Member State proposed by the applicant, unless another Member State agrees to examine it.

2 Assessment of an application may be performed by a number of Member States together under a co-rapporteur system.

3 When submitting the application, the applicant may pursuant to Article 63 request certain information, including certain parts of the dossier, to be kept confidential and shall physically separate that information.

Member States shall assess the confidentiality requests. Upon a request for access to information, the rapporteur Member State shall decide what information is to be kept confidential.

4 When submitting the application the applicant shall at the same time join a complete list of tests and studies submitted pursuant to Article 8(2) and a list of any claims for data protection pursuant to Article 59.

5 When assessing the application the rapporteur Member State may at any time consult the Authority.

Article 8

Dossiers

1 The summary dossier shall include the following:

a information with respect to one or more representative uses on a widely grown crop in each zone of at least one plant protection product containing the active substance, demonstrating that the approval criteria provided for in Article 4 are met; where the information submitted does not cover all zones or concern a crop which is not widely grown, justification for this approach;

b for each point of the data requirements for the active substance, the summaries and results of tests and studies, the name of their owner and of the person or institute that has carried out the tests and studies;

c for each point of the data requirements for the plant protection product, the summaries and results of tests and studies, the name of their owner and of the person or institute that carried out the tests and studies, relevant to the assessment of the criteria provided for in Article 4(2) and (3) for one or more plant protection products which are representative of the uses referred to in point (a), taking into account the fact that data gaps in the dossier, as provided for in paragraph 2 of this Article, resulting from the proposed limited range of representative uses of the active substance, may lead to restrictions in the approval;

d for each test or study involving vertebrate animals, a justification of the steps taken to avoid animal testing and duplication of tests and studies on vertebrate animals;

e a checklist demonstrating that the dossier provided for in paragraph 2 of this Article is complete in view of the uses applied for;

f the reasons why the test and study reports submitted are necessary for first approval of the active substance or for amendments to the conditions of the approval;

g where relevant, a copy of an application for a maximum residue level as referred to in Article 7 of Regulation (EC) No 396/2005 or a justification for not supplying such information;

h an assessment of all information submitted.

2 The complete dossier shall contain the full text of the individual test and study reports concerning all the information referred to in points (b) and (c) of paragraph 1. It shall not contain any reports of tests or studies involving the deliberate administration of the active substance or the plant protection product to humans.

3 The format of the summary dossier and the complete dossier shall be established in accordance with the advisory procedure referred to in Article 79(2).

4 The data requirements referred to in paragraphs 1 and 2 shall contain the requirements for active substances and plant protection products as set out in Annexes II and III to Directive 91/414/EEC and laid down in Regulations adopted in accordance with the advisory procedure referred to in Article 79(2) without any substantial modifications. Subsequent amendments to these Regulations shall be adopted in accordance with Article 78(1)(b).

5 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.

Article 9

Admissibility of the application

1 Within 45 days of receiving the application, the rapporteur Member State shall send the applicant a written acknowledgement, stating the date of receipt, and check whether the dossiers submitted with the application contain all the elements provided for in Article 8, using the checklist referred to in point (e) of Article 8(1). It shall also check the requests for confidentiality referred to in Article 7(3) and the complete lists of tests and studies submitted pursuant to Article 8(2).

2 Where one or more of the elements provided for in Article 8 are missing, the rapporteur Member State shall inform the applicant, setting a period for their submission. Such period shall be a maximum of 3 months.

Where at the end of that period, the applicant has not submitted the missing elements, the rapporteur Member State shall inform the applicant, the other Member States and the Commission that the application is inadmissible.

A new application for the same substance may be submitted at any time.

3 Where the dossiers submitted with the application contain all the elements provided for in Article 8, the rapporteur Member State shall notify the applicant, the other Member States, the Commission and the Authority of the admissibility of the application and start assessing the active substance.

After receiving that notification, the applicant shall immediately forward the dossiers as provided for in Article 8 to the other Member States, the Commission and the Authority, including the information about those parts of the dossiers in respect of which confidentiality has been requested as referred to in Article 7(3).

Article 10

Access to the summary dossier

The Authority shall without delay make the summary dossier referred to in Article 8(1) available to the public, excluding any information in respect of which confidential treatment has been requested and justified pursuant to Article 63, unless there is an overriding public interest in its disclosure.

Article 11

Draft assessment report

1 Within 12 months of the date of the notification provided for in the first subparagraph of Article 9(3), the rapporteur Member State shall prepare and submit to the Commission, with a copy to the Authority, a report, referred to as the 'draft assessment report', assessing whether the active substance can be expected to meet the approval criteria provided for in Article 4.

2 The draft assessment report shall also include where relevant, a proposal to set maximum residue levels.

The rapporteur Member State shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge.

Where, pursuant to Article 4(1), the assessment establishes that the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are not satisfied, the draft assessment report shall be limited to those parts of the assessment.

3 Where the rapporteur Member State needs additional studies or information, it shall set a period in which the applicant must supply those studies or that information. In that case, the 12-month period shall be extended by the additional period granted by the rapporteur Member State. The additional period shall be of a maximum of 6 months and shall cease at the moment when the additional information is received by the rapporteur Member State. It shall inform the Commission and the Authority accordingly.

Where at the end of the additional period, the applicant has not submitted the additional studies or information, the rapporteur Member State shall inform the applicant, the Commission and the Authority and shall state the missing elements in the assessment included in the draft assessment report.

4 The format of the draft assessment report shall be established in accordance with the advisory procedure referred to in Article 79(2).

Article 12

Conclusion by the Authority

1 The Authority shall circulate the draft assessment report received from the rapporteur Member State to the applicant and the other Member States at the latest 30 days after its receipt. It shall ask the applicant to circulate an update of the dossier where applicable to the Member States, the Commission and the Authority.

The Authority shall make the draft assessment report available to the public, after giving the applicant two weeks to request, pursuant to Article 63, that certain parts of the draft assessment report be kept confidential.

The Authority shall allow a period of 60 days for the submission of written comments.

2 The Authority, where appropriate shall organise a consultation of experts, including experts from the rapporteur Member State.

Within 120 days of the end of the period provided for the submission of written comments, the Authority shall adopt a conclusion in the light of current scientific and technical knowledge using guidance documents available at the time of application on whether the active substance can be expected to meet the approval criteria provided for in Article 4 and shall communicate it to the applicant, the Member States and the Commission and shall make it available to the public. In the event of a consultation as provided for in this paragraph, the 120-day period shall be extended by 30 days.

Where appropriate, the Authority shall address in its conclusion the risk mitigation options identified in the draft assessment report.

3 Where the Authority needs additional information, it shall set a period of a maximum of 90 days for the applicant to supply it to the Member States, the Commission and the Authority.

The rapporteur Member State shall assess the additional information and submit it to the Authority without delay and at the latest within 60 days after receipt of the additional information. In that case the 120-day period provided for in paragraph 2 shall be extended by a period which shall cease at the moment when the additional assessment is received by the Authority.

The Authority may ask the Commission to consult a Community reference laboratory, designated pursuant to Regulation (EC) No 882/2004 for the purposes of verifying whether the analytical method for the determination of the residues proposed by the applicant is satisfactory and meets the requirements in Article 29(1)(g) of this Regulation. The applicant shall, if requested by the Community reference laboratory, provide samples and analytical standards.

4 The conclusion of the Authority shall include details concerning the evaluation procedure and the properties of the active substance concerned.

5 The Authority shall establish the format for its conclusion which shall include details concerning the evaluation procedure and the properties of the active substance concerned.

6 The time limits for the Authority's opinion on applications concerning maximum residue levels set out in Article 11 and for decisions on applications concerning maximum residue levels set out in Article 14 of Regulation (EC) No 396/2005 shall be without prejudice to the time limits laid down in this Regulation.

7 Where the conclusion of the Authority is adopted within the time limit set out in paragraph 2 of this Article, extended by any additional period set in accordance with paragraph 3, the provisions of Article 11 of Regulation (EC) No 396/2005 shall not apply and the provisions of Article 14 of that Regulation shall apply without delay.

8 Where the conclusion of the Authority is not adopted within the time limit set out in paragraph 2 of this Article, extended by any additional period set in accordance with paragraph 3, the provisions of Articles 11 and 14 of Regulation (EC) No 396/2005 shall apply without delay.

Article 13

Approval Regulation

1 Within six months of receiving the conclusion from the Authority, the Commission shall present a report, referred to as 'the review report', and a draft Regulation to the Committee referred to in Article 79(1), taking into account the draft assessment report by the rapporteur Member State and the conclusion of the Authority.

The applicant shall be given the possibility to submit comments on the review report.

2 On the basis of the review report, other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) of Regulation (EC) No 178/2002 are relevant, a Regulation shall be adopted in accordance with the regulatory procedure referred to in Article 79(3), providing that:

a an active substance is approved, subject to conditions and restrictions, as referred to in Article 6, where appropriate;

b an active substance is not approved; or

c the conditions of the approval are amended.

3 Where the approval provides for the submission of further confirmatory information as referred to in Article 6(f), the Regulation shall provide the time limit to submit the information to the Member States, the Commission and the Authority.

The rapporteur Member State shall assess the additional information and submit its assessment to the other Member States, the Commission and the Authority without delay and at the latest six months after the receipt of the additional information.

4 Approved active substances shall be included in the Regulation referred to in Article 78(3) containing the list of active substances already approved. The Commission shall maintain a list of approved active substances electronically available to the public.

Subsection 3

Renewal and review

Article 14

Renewal of approval

1 On application the approval of an active substance shall be renewed where it is established that the approval criteria provided for in Article 4 are satisfied.

Article 4 shall be deemed to be satisfied where this has been established with respect to one or more representative uses of at least one plant protection product containing that active substance.

Such renewal of the approval may include conditions and restrictions, as referred to in Article 6.

2 The renewal of the approval shall be for a period not exceeding 15 years. The renewal of approval of active substances covered by Article 4(7) shall be for a period not exceeding five years.

Article 15

Application for renewal

1 The application provided for in Article 14 shall be submitted by a producer of the active substance to a Member State, with a copy to the other Member States, the Commission and the Authority, no later than three years before the expiry of the approval.

2 When applying for renewal, the applicant shall identify new data he intends to submit and demonstrate that they are necessary, because of data requirements or criteria which were not applicable at the time of the last approval of the active substance or because his request is for an amended approval. The applicant shall at the same time submit a timetable of any new and ongoing studies.

The applicant shall identify, giving reasons, the parts of the information submitted that he requests to be kept confidential in accordance with Article 63 and at the same time any data protection claims pursuant to Article 59.

Article 16

Access to the information for renewal

The Authority shall, without delay, make available to the public the information provided by the applicant under Article 15, excluding any information in respect of which confidential treatment has been requested and justified pursuant to Article 63, unless there is an overriding public interest in its disclosure.

Article 17

Extension of approval period for the duration of the procedure

Where for reasons beyond the control of the applicant it appears that the approval is likely to expire before a decision has been taken on renewal, a decision shall be adopted in accordance with the regulatory procedure referred to in Article 79(3), postponing the expiry of the approval period for that applicant for a period sufficient to examine the application.

A Regulation postponing the expiry for a period sufficient to examine the application shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(5) where an applicant could not give the three years' notice required under Article 15(1) because the active substance was included in Annex I to Directive 91/414/EEC for a duration which expired before 14 June 2014.

The length of that period shall be established on the basis of the following:

(a) the time needed to provide the information requested;

(b) the time needed to complete the procedure;

(c) where appropriate, the need to ensure the establishment of a coherent work programme, as provided for in Article 18.

Article 18

Work programme

The Commission may establish a work programme grouping together similar active substances setting priorities on the basis of safety concerns for human and animal health or the environment and taking into account, as far as possible, the need for an effective control and resistance management of target pest. The programme may require interested parties to submit all the necessary data to the Member States, the Commission and the Authority within a period provided for in the programme.

The programme shall include the following:

(a) the procedures concerning the submission and assessment of applications for renewal of approvals;

(b) the necessary data to be submitted, including measures to minimise animal testing, in particular the use of non-animal test methods and intelligent testing strategies;

(c) the periods for submission of such data;

(d) rules on the submission of new information;

(e) period for assessment and decision making;

(f) the allocation of evaluation of active substances to Member States, taking into account a balance in the responsibilities and work to be done among Member States acting as rapporteurs.

Article 19

Implementing measures

A Regulation, adopted in accordance with the regulatory procedure referred to in Article 79(3), shall set out the provisions necessary for the implementation of the renewal procedure, including, where relevant, the implementation of a work programme, as provided for in Article 18.

Article 20

Renewal Regulation

1 A Regulation shall be adopted in accordance with the regulatory procedure referred to in Article 79(3), providing that:

a the approval of an active substance is renewed, subject to conditions and restrictions where appropriate; or

b the approval of an active substance is not renewed.

2 Where the reasons for not renewing the approval do not concern the protection of health or the environment, the Regulation referred to in paragraph 1 shall provide for a grace period not exceeding six months for the sale and distribution, and in addition a maximum of

one year for the disposal, storage, and use of existing stocks of the plant protection products concerned. The grace period for the sale and distribution shall take into account the normal period of use of the plant protection product but the total grace period shall not exceed 18 months.

In the case of a withdrawal of the approval or if the approval is not renewed because of the immediate concerns for human health or animal health or the environment, the plant protection products concerned shall be withdrawn from the market immediately.

3 Article 13(4) shall apply.

Article 21

Review of approval

1 The Commission may review the approval of an active substance at any time. It shall take into account the request of a Member State to review, in the light of new scientific and technical knowledge and monitoring data, the approval of an active substance, including where, after the review of the authorisations pursuant to Article 44(1), there are indications that the achievement of the objectives established in accordance with Article 4(1)(a)(iv) and (b)(i) and Article 7(2) and (3) of Directive 2000/60/EC is compromised.

Where, in the light of new scientific and technical knowledge it considers that there are indications that the substance no longer satisfies the approval criteria provided for in Article 4, or further information required in accordance with Article 6(f) has not been provided, it shall inform the Member States, the Authority and the producer of the active substance, setting a period for the producer to submit its comments.

2 The Commission may ask the Member States and the Authority for an opinion, or for scientific or technical assistance. The Member States may provide their comments to the Commission within three months from the date of the request. The Authority shall provide its opinion or the results of its work to the Commission within three months of the date of the request.

3 Where the Commission concludes that the approval criteria provided for in Article 4 are no longer satisfied, or the further information required in accordance with Article 6(f) has not been provided, a Regulation to withdraw or amend the approval shall be adopted in accordance with the regulatory procedure referred to in Article 79(3).

Article 13(4) and Article 20(2) shall apply.

Subsection 4

Derogations

Article 22

Low-risk active substances

1 An active substance complying with the criteria provided for in Article 4 shall be approved for a period not exceeding 15 years by way of derogation from Article 5, where it is considered a low-risk active substance and where it may be expected that plant protection

products containing that substance will pose only a low risk to human and animal health and the environment as provided for in Article 47(1).

2 Articles 4 and 6 to 21 and point 5 of Annex II shall apply. Low-risk active substances shall be listed separately in the Regulation referred to in Article 13(4).

3 The Commission may review and if necessary specify new criteria for approving an active substance as low-risk active substance in accordance with Article 78(1)(a).

Article 23

Approval criteria for basic substances

1 Basic substances shall be approved in accordance with paragraphs 2 to 6. By way of derogation from Article 5, the approval shall be for an unlimited period.

For the purpose of paragraphs 2 to 6, a basic substance is an active substance which:

a is not a substance of concern; and

b does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects; and

c is not predominantly used for plant protection purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent; and

d is not placed on the market as a plant protection product.

For the purpose of this Regulation, an active substance which fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002 shall be considered as a basic substance.

2 By way of derogation from Article 4, a basic substance shall be approved where any relevant evaluations, carried out in accordance with other Community legislation regulating the use of that substance for purposes other than for a plant protection product, show that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment.

3 By way of derogation from Article 7 an application for the approval of a basic substance shall be submitted by a Member State or by any interested party to the Commission.

The application shall be accompanied by the following information:

a any evaluations of its possible effects on human or animal health or the environment carried out in accordance with other Community legislation regulating the use of the substance; and

b other relevant information on its possible effects on human or animal health or the environment.

4 The Commission shall ask the Authority for an opinion, or for scientific or technical assistance. The Authority shall provide its opinion or the results of its work to the Commission within 3 months of the date of the request.

5 Articles 6 and 13 shall apply. Basic substances shall be listed separately in the Regulation referred to in Article 13(4).

6 The Commission may review the approval of a basic substance at any time. It may take into account the request of a Member State to review the approval.

Where the Commission considers that there are indications that the substance no longer satisfies the criteria provided for in paragraphs 1 to 3 it shall inform the Member States, the Authority and the interested party, setting a period for their comments to be submitted.

The Commission shall ask the Authority for an opinion, or for scientific or technical assistance. The Authority shall provide its opinion or the results of its work to the Commission within three months of the date of the request.

Where the Commission concludes that the criteria referred to in paragraph 1 are no longer satisfied, a Regulation to withdraw or amend the approval shall be adopted in accordance with the regulatory procedure referred to in Article 79(3).

Article 24

Candidates for substitution

1 An active substance complying with the criteria provided for in Article 4 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 point 4 of Annex II. By way of derogation from Article 14(2), the approval may be renewed once or more for periods not exceeding seven years.

2 Without prejudice to paragraph 1, Articles 4 to 21 shall apply. Candidates for substitution shall be listed separately in the Regulation referred to in Article 13(4).

SECTION 2

Safeners and synergists

Article 25

Approval of safeners and synergists

1 A safener or synergist shall be approved, where it complies with Article 4.

2 Articles 5 to 21 shall apply.

3 Similar data requirements to those referred to in Article 8(4) shall be defined for safeners and synergists in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

Article 26

Safeners and synergists already on the market

By 14 December 2014, a Regulation shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4) establishing a work programme for the gradual review of synergists and safeners on the market when that Regulation enters into force. The Regulation shall include the establishment of data requirements, including measures to minimise animal testing, notification, evaluation, assessment and decision-making procedures. It shall require interested parties to submit all the necessary data to the Member States, the Commission and the Authority within a specified period.

SECTION 3

Unacceptable co-formulants

Article 27

Co-formulants

1 A co-formulant shall not be accepted for inclusion in a plant protection product where it has been established that:

a its residues, consequent on application consistent with good plant protection practice, and having regard to realistic conditions of use, have a harmful effect on human or animal health or on groundwater or an unacceptable effect on the environment; or

b its use, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, has a harmful effect on human or animal health or an unacceptable effect on plants, plant products or the environment.

2 Co-formulants which are not accepted for inclusion in a plant protection product pursuant to paragraph 1 shall be included in Annex III in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

3 The Commission may review co-formulants at any time. It may take into account relevant information provided by Member States.

4 Article 81(2) shall apply.

5 Detailed rules for the implementation of this Article may be established in accordance with the regulatory procedure referred to in Article 79(3).

Status:
Point in time view as at 21/10/2009.

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, CHAPTER II.