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 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.

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, Subsection 2.