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 III

PLANT PROTECTION PRODUCTS

SECTION 1

Authorisation

Subsection 2

Procedure

Article 33

Application for authorisation or amendment of an authorisation

1 An applicant who wishes to place a plant protection product on the market shall apply for an authorisation or amendment of an authorisation himself, or through a representative, to each Member State where the plant protection product is intended to be placed on the market.

2 The application shall include the following:

a a list of intended uses in each zone as indicated in Annex I and the Member States where the applicant has made or intends to make an application;

b a proposal as to which Member State the applicant expects to evaluate the application in the zone concerned. In the case of an application for use in greenhouses, as post-harvest treatment, for treatment of empty storage rooms and for seed treatment, only one Member State shall be proposed, which evaluates the application taking account of all zones. In this case the applicant shall send the summary or complete dossier as referred to in Article 8 to other Member States on request;

c where relevant, a copy of any authorisations already granted for that plant protection product in a Member State;

d where relevant, a copy of any conclusion of the Member State assessing equivalence as referred to in Article 38(2).

3 The application shall be accompanied by the following:

a for the plant protection product concerned, a complete and a summary dossier for each point of the data requirements of the plant protection product;

b for each active substance, safener and synergist contained in the plant protection product, a complete and a summary dossier for each point of the data requirements of the active substance, safener and synergist;

c 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;

d the reasons why the test and study reports submitted are necessary for first authorisation or for amendments to the conditions of the authorisation;

e where relevant a copy of the 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;

f where relevant for an amendment of an authorisation an assessment of all information submitted in accordance with point (h) of Article 8(1);

g a draft label.

4 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.

The applicant shall at the same time submit the complete list of studies submitted pursuant to Article 8(2) and a list of test and study reports for which any claims for data protection pursuant to Article 59 are requested.

Upon a request for access to information the Member State examining the application shall decide what information is to be kept confidential.

5 Where requested by the Member State the applicant shall submit his application in the national or official languages of that Member State or one of those languages.

6 On request, the applicant shall provide the Member State with samples of the plant protection product and analytical standards of its ingredients.

Article 34

Exemption from the submission of studies

1 Applicants shall be exempted from supplying the test and study reports referred to in Article 33(3) where the Member State to which an application is made has the test and study reports concerned and the applicants demonstrate that they have been granted access in accordance with Article 59, 61 or 62 or that any data protection period has expired.

2 However, applicants to whom paragraph 1 applies shall provide the following information:

a all necessary data for the identification of the plant protection product including its complete composition as well as a declaration that no unacceptable co-formulants are used;

b the information needed to identify the active substance, safener or synergist, where they have been approved, and to establish whether the conditions for approval are met and comply with point (b) of Article 29(1), where appropriate;

c on the request of the concerned Member State, the data needed to demonstrate that the plant protection product has comparable effects to the plant protection product for which they show access to the protected data.

Article 35

Member State examining the application

The application shall be examined by the Member State proposed by the applicant, unless another Member State in the same zone agrees to examine it. The Member State which will examine the application shall inform the applicant.

At the request of the Member State examining the application, the other Member States in the same zone to which an application has been submitted shall cooperate to ensure a fair division of the workload.

The other Member States within the zone to which an application has been submitted shall refrain from proceeding with the file pending assessment by the Member State examining the application.

Where an application has been made in more than one zone, Member States evaluating the application shall agree on the evaluation of data which are not related to the environmental and agricultural conditions.

Article 36

Examination for authorisation

1 The Member State examining the application shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge using guidance documents available at the time of application. It shall give all Member States in the same zone the opportunity to submit comments to be considered in the assessment.

It shall apply the uniform principles for evaluation and authorisation of plant protection products, referred to in Article 29(6), to establish, as far as possible, whether the plant protection product meets the requirements provided for in Article 29 in the same zone, where used in accordance with Article 55, and under realistic conditions of use.

The Member State examining the application shall make available its assessment to the other Member States within the same zone. The format of the assessment report shall be established in accordance with the advisory procedure referred to in Article 79(2).

2 The Member States concerned shall grant or refuse authorisations accordingly on the basis of the conclusions of the assessment of the Member State examining the application as provided for in Articles 31 and 32.

3 By way of derogation from paragraph 2 and subject to Community law, appropriate conditions may be imposed with respect to the requirements referred to in Article 31(3) and (4) and other risk mitigation measures deriving from specific conditions of use.

Where the concerns of a Member State relating to human or animal health or the environment cannot be controlled by the establishment of the national risk mitigation measures referred to in the first subparagraph, a Member State may refuse authorisation of the plant protection product in its territory if, due to its specific environmental or agricultural circumstances, it has substantiated reasons to consider that the product in question still poses an unacceptable risk to human or animal health or the environment.

That Member State shall immediately inform the applicant and the Commission of its decision and provide a technical or scientific justification therefor.

Member States shall provide for the possibility of challenging a decision refusing the authorisation of such products before national courts or other instances of appeal.

Article 37

Period for examination

1 The Member State examining the application shall decide within 12 months of receiving it whether the requirements for authorisation are met.

Where the Member State needs additional information, it shall set a period for the applicant to supply it. In that case, the 12-month period shall be extended by the additional period granted by the Member State. That additional period shall be a maximum of 6 months and shall cease at the moment when the additional information is received by the Member State. Where at the end of that period the applicant has not submitted the missing elements, the Member State shall inform the applicant that the application is inadmissible.

2 The time limits provided for in paragraph 1 shall be suspended during the application of the procedure set out in Article 38.

3 For an application for authorisation of a plant protection product containing an active substance not yet approved, the Member State examining the application shall start the evaluation as soon as it has received the draft assessment report referred to in Article 12(1). In case the application concerns the same plant protection product and the same uses as contained in the dossier referred to in Article 8, the Member State shall decide on the application at the latest within six months of the active substance being approved.

4 The other Member States concerned shall at the latest within 120 days of the receipt of the assessment report and the copy of the authorisation of the Member State examining the application decide on the application as referred to in Article 36(2) and (3).

Article 38

Assessment of equivalence under point (b) of Article 29(1)

1 Where it is necessary to establish for an active substance, safener or synergist whether a different source or, for the same source a change of the manufacturing process and/or manufacturing location complies with point (b) of Article 29(1), this shall be assessed by the Member State which acted as rapporteur for the active substance, safener or synergist as referred to in Article 7(1) unless the Member State examining the application as referred to in Article 35 agrees to assess the equivalence. The applicant shall submit all necessary data to the Member State assessing equivalence.

2 After giving the applicant the opportunity to submit comments, which the applicant shall also communicate to the rapporteur Member State or the Member State examining the application as the case may be, the Member State assessing equivalence shall prepare a report on equivalence within 60 days from receiving the application and shall communicate the report to the Commission, the other Member States and the applicant.

3 In the case of a positive conclusion on equivalence and where no objection to this conclusion has been raised, point (b) of Article 29(1) shall be considered to be complied with. However, where a Member State examining the application does not agree with the conclusion of the rapporteur Member State or vice versa, it shall inform the applicant, the other Member States and the Commission stating its reasons.

The Member States concerned shall try to reach agreement on whether point (b) of Article 29(1) is complied with. They shall provide the applicant with an opportunity to submit comments.

4 Where the Member States concerned do not reach agreement within 45 days, the Member State assessing equivalence shall submit the matter to the Commission. A decision on whether the conditions referred to in point (b) of Article 29(1) are complied with shall be adopted in accordance with the regulatory procedure referred to in Article 79(3). The 45-day period begins on the date on which the Member State examining the application for authorisation informed the rapporteur Member State or vice versa that it does not agree with the conclusion of the latter, in accordance with paragraph 3.

Before such a decision is adopted, the Commission may ask the Authority for an opinion, or for scientific or technical assistance which shall be provided within 3 months of the request.

5 Detailed rules and procedures for the implementation of paragraphs 1 to 4 may be established in accordance with the regulatory procedure referred to in Article 79(3), after consultation of the Authority.

Article 39

Reporting and exchange of information on applications for authorisation

1 Member States shall compile a file on each application. Each file shall contain the following:

a a copy of the application;

b a report containing information on the evaluation of and decision on the plant protection product; the format of the report shall be established in accordance with the advisory procedure referred to in Article 79(2);

c a record of the administrative decisions taken by the Member State concerning the application and of the documentation provided for in Article 33(3) and Article 34 together with a summary of the latter;

d the approved label, where applicable.

2 On request, Member States shall, without delay, make available to the other Member States, the Commission and the Authority a file containing the documentation provided for in points (a) to (d) of paragraph 1.

3 On request, applicants shall provide a copy of the documentation to be submitted with an application pursuant to Article 33(3) and Article 34 to Member States, the Commission and the Authority.

4 Detailed rules for the implementation of paragraphs 2 and 3 may be established in accordance with the regulatory procedure referred to in Article 79(3).