Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (Text with EEA relevance)

CHAPTER 1

ADMISSIBILITY

SECTION 1

Application for renewal

Article 1

Submission of the application

1 An application for the renewal of an approval of an active substance shall be submitted by a producer of the active substance to the rapporteur Member State, as set out in the second column of the Annex to Commission Implementing Regulation (EU) No 686/2012[(1)] and to the co-rapporteur Member State, as set out in the third column of that Annex, no later than three years before the expiry of the approval.

When submitting an application, the applicant may, pursuant to Article 63 of Regulation (EC) No 1107/2009, request certain information to be kept confidential. In that event, the applicant shall present such parts of the application physically separated, setting out the reasons for requesting confidentiality.

At the same time, the applicant shall submit any data protection claims pursuant to Article 59 of Regulation (EC) No 1107/2009.

2 The applicant shall send a copy of the application to the Commission, the other Member States and to the European Food Safety Authority (‘the Authority’), including the information on those parts of the application in respect of which confidentiality has been requested as referred to in paragraph 1.

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

Article 2

Format and contents of the application

1 The application shall be submitted in the format set out in the Annex.

2 The application shall list the new information the applicant intends to submit. It shall demonstrate that such information is necessary in accordance with the first subparagraph of Article 15(2) of Regulation (EC) No 1107/2009.

The application shall list separately any new studies involving vertebrate animals that the applicant intends to submit.

Article 3

Checking of the application

1 Where the application has been submitted by the date provided for in the first subparagraph of Article 1(1) and contains all the elements provided for in Article 2, the rapporteur Member State shall, within one month of the date of receipt of the application, inform the applicant, the co-rapporteur Member State, the Commission and the Authority of the date of receipt of the application and the fact that it has been submitted by the date provided for in the first subparagraph of Article 1(1) and contains all the elements provided for in Article 2.

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

2 Where the application has been submitted by the date provided for in the first subparagraph of Article 1(1) but one or more elements provided for in Article 2 are missing, the rapporteur Member State shall, within one month of the date of receipt of the application, inform the applicant which elements are missing and set a period of 14 days for the submission of those elements to the Rapporteur Member State and to the co-rapporteur Member State.

Where the application contains all the elements provided for in Article 2 at the expiry of that period, the rapporteur Member State shall, without delay, proceed in accordance with paragraph 1.

3 Where the application has not been submitted by the date provided for in the first subparagraph of Article 1(1), or where the application still does not contain all the elements provided for in Article 2 at the expiry of the period set for the submission of the missing elements in accordance with paragraph 2, the rapporteur Member State shall, without delay, inform the applicant, the co-rapporteur Member State, the Commission, the other Member States and the Authority that the application is inadmissible and of the reasons why it is inadmissible.

4 Within 14 days from the date of receipt of the information that the application has been submitted by the date provided for in the first subparagraph of Article 1(1) and that it contains all the elements provided for in Article 2, the applicant shall submit to the Authority a copy of the application, including the information about those parts of the application in respect of which confidentiality has been requested and justified by the applicant pursuant to Article 63 of Regulation (EC) No 1107/2009.

At the same time, the applicant shall forward a copy of the application to the Authority, excluding any information in respect of which confidentiality has been requested and justified by the applicant pursuant to Article 63 of Regulation (EC) No 1107/2009.

5 Where, by the date provided for in the first subparagraph of Article 1(1), two or more applications for the same active substance have been submitted separately and each of them contains all the elements provided for in Article 2, the rapporteur Member State shall communicate the contact details of each applicant to the other applicant(s).

6 The Commission shall publish, for each active substance, the names and the addresses of the applicants whose applications have been submitted by the date provided for in the first subparagraph of Article 1(1) and contain all the elements provided for in Article 2.

Article 4

Contacts prior to submission of supplementary dossiers

The applicant may request a meeting with the rapporteur Member State and the co-rapporteur Member State to discuss the application.

If requested, such pre-submission contacts shall take place prior to the submission of supplementary dossiers, as provided for in Article 6.

Article 5

Access to the application

Upon receipt of the application, as provided for in Article 3(4), the Authority shall make it available to the public without delay, excluding any information in respect of which confidentiality has been requested and justified by the applicant pursuant to Article 63 of Regulation (EC) No 1107/2009, unless there is an overriding public interest in its disclosure.

SECTION 2

Supplementary dossiers

Article 6

Submission of supplementary dossiers

1 Where the rapporteur Member State has informed the applicant in accordance with Article 3(1) that its application has been submitted by the date provided for in the first subparagraph of Article 1(1) and that it contains all the elements provided for in Article 2, the applicant shall submit the supplementary dossiers to the rapporteur Member State, the co-rapporteur Member State, the Commission and the Authority.

2 The contents of the supplementary summary dossier and the supplementary complete dossier shall comply with Article 7.

3 The supplementary dossiers shall be submitted no later than 30 months before the expiry of the approval.

4 Where there is more than one applicant requesting renewal of the approval of the same active substance, those applicants shall take all reasonable steps to submit their dossiers jointly.

Where such dossiers are not submitted jointly by all the applicants concerned, the reasons shall be set out in the dossiers.

5 When submitting the supplementary dossiers, the applicant may pursuant to Article 63 of Regulation (EC) No 1107/2009 request certain information, including certain parts of the dossier, to be kept confidential and shall physically separate that information.

Article 7

Contents of supplementary dossiers

1 The supplementary summary dossier shall include the following:

a a copy of the application;

b where the applicant is joined or replaced by one or more other applicants, the name and address of that applicant or those other applicants and, if applicable, the name of the association of producers provided for in Article 1(3);

c 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 of Regulation (EC) No 1107/2009 are fulfilled; where the information submitted does not cover all zones or does not concern a widely grown crop, a justification shall be submitted;

d data and risk assessments which were not part of the approval dossier or subsequent renewal dossiers and which are necessary:

(i) to reflect changes in legal requirements which have occurred since the approval or last renewal of the approval of the active substance concerned;

(ii) to reflect changes in scientific and technical knowledge since the approval or last renewal of the approval of the active substance concerned;

(iii) to reflect changes to representative uses; or

(iv) because the application is for an amended renewal;

e for each point of the data requirements for the active substance, as set out in a Regulation setting out data requirements for active substances under Regulation (EC) No 1107/2009, for which new data are necessary in accordance with point (d), the summaries and results of tests and studies, the name of their owner and of the person or institute that has carried them out and the reason why each test or study is necessary;

f for each point of the data requirements for the plant protection product, as set out in a Regulation setting out data requirements for plant protection products under Regulation (EC) No 1107/2009, for which new data are necessary in accordance with point (d), 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, for one or more plant protection products which are representative of the supported uses, and the reason why each test or study is necessary;

g where relevant, documented evidence as referred to in Article 4(7) of Regulation (EC) No 1107/2009;

h for each test or study involving vertebrate animals, a description of the steps taken to avoid animal testing on vertebrate animals;

i where relevant, a copy of an application for maximum residue levels as referred to in Article 7 of Regulation (EC) No 396/2005 of the European Parliament and of the Council[(2)];

j where relevant, a copy of the proposal for classification where it is considered that the substance has to be classified or reclassified in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[(3)];

k an assessment of all information submitted;

l a checklist demonstrating that the supplementary dossier provided for in paragraph 3 is complete in view of the uses applied for and indicating which data are new;

m the summaries and results of scientific peer-reviewed open literature, as referred in Article 8(5) of Regulation (EC) No 1107/2009.

2 The uses referred to in paragraph 1(c) shall, where appropriate, include the uses evaluated for the approval or subsequent renewals. At least one plant protection product referred to in paragraph 1(c) shall contain no other active substance, where such a product exists for a representative use.

3 The supplementary complete dossier shall contain the full text of each test and study report referred to in paragraph 1(e), (f) and (m).

It shall not contain any reports of tests or studies involving the deliberate administration of the active substance or the plant protection product containing it to humans.

Article 8

Admissibility of the application

1 Where the supplementary dossiers have been submitted by the date provided for in Article 6(3) and contain all the elements provided for in Article 7, the rapporteur Member State shall, within a period of one month, inform the applicant, the co-rapporteur Member State, the Commission and the Authority of the date of receipt of the supplementary dossiers and of the admissibility of the application.

The rapporteur Member State shall assess any requests for confidentiality. In the event of a request for access to information, the rapporteur Member State shall decide what information is to be kept confidential.

2 Where the supplementary dossiers have been submitted by the date provided for in Article 6(3), but one or more elements provided for in Article 7 are missing, the rapporteur Member State shall, within a period of one month from the date of receipt of the supplementary dossiers, inform the applicant which elements are missing and set a period of 14 days for the submission of those elements to the rapporteur Member State and co-rapporteur Member State.

Where at the expiry of that period the supplementary dossiers contain all the elements provided for in Article 7, the rapporteur Member State shall, without delay, proceed in accordance with paragraph 1.

3 After receiving the information that the application is admissible, the applicant shall immediately forward the supplementary dossiers to the other Member States, the Commission and the Authority, including the information about those parts of the dossier in respect of which confidentiality has been requested and justified by the applicant pursuant to Article 63 of Regulation (EC) No 1107/2009.

At the same time, the applicant shall forward the supplementary summary dossiers to the Authority, excluding any information in respect of which confidentiality has been requested and justified by the applicant pursuant to Article 63 of Regulation (EC) No 1107/2009.

4 The Authority shall make the supplementary summary dossier available to the public, without delay, excluding any information in respect of which confidentiality has been requested and justified by the applicant pursuant to Article 63 of Regulation (EC) No 1107/2009, unless there is an overriding public interest in its disclosure.

5 At the request of the Authority or a Member State, the applicant shall make available the dossiers submitted for the approval and subsequent renewals of the approval, where it has access to them.

6 Where the supplementary dossiers have not been submitted by the date referred to in Article 6(3), or where at the end of the period set for the submission of the missing elements in accordance with paragraph 2 of this Article the supplementary dossiers still do not contain all the elements provided for in Article 7, the rapporteur Member State shall, without delay, inform the applicant, the co-rapporteur Member State, the Commission, the other Member States and the Authority that the application is inadmissible and of the reasons why it is inadmissible.

Article 9

Replacement of the applicant

An applicant may be replaced by another producer in respect of all of its rights and obligations under this Regulation by informing the rapporteur Member State, through a joint declaration by the applicant and the other producer. In that case, the applicant and the other producer shall, at the same time, inform the co-rapporteur Member State, the Commission, the other Member States, the Authority and any other applicants that have submitted an application for the same active substance of the replacement.

Article 10

Adoption of non-renewal Regulation

The Commission shall adopt a Regulation on the non-renewal of the approval of an active substance in accordance with Article 20(1)(b) of Regulation (EC) No 1107/2009 where all of the applications submitted for that active substance are inadmissible in accordance with Article 3(3) of this Regulation or Article 8(6) thereof.

(**1**) OJ L 200, 27.7.2012, p. 5.

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

(**3**) OJ L 353, 31.12.2008, p. 1.