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)

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)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[(1)], and in particular Article 19 thereof,

Whereas:

(1) Regulation (EC) No 1107/2009 provides that the approval of an active substance may be renewed upon expiry.

(2) It is appropriate to set out the provisions necessary for the implementation of the renewal procedure.

(3) In particular, periods should be set for the different steps of the renewal procedure to ensure that it functions properly.

(4) Rules should be set out as regards confidentiality and the publication of the application for renewal, the supplementary dossiers and their updates.

(5) Rules should also be set out as regards the submission of the application for renewal and its contents and format. The applicant should be obliged to justify the submission of new information and to list separately studies concerning vertebrate animals that they intend to submit.

(6) Rules should be set out as regards the checking of the application by the rapporteur Member State.

(7) In order to ensure the proper functioning of the renewal procedure, the rapporteur Member State should, at the applicant's request, organise prior to the submission of the supplementary dossier, a meeting to discuss the application.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) No 844/2012. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(8) The supplementary dossiers submitted for renewal should, in particular, include necessary new data and new risk assessments and demonstrate why such data and risk assessments are necessary.

(9) Rules should be set out as regards the establishment of the admissibility of the application by the rapporteur Member State.

(10) Where all applications submitted are inadmissible, the Commission should adopt a Regulation on the non-renewal of the active substance concerned.

(11) Rules should be set out to ensure an independent, objective and transparent assessment of the active substance.

(12) The applicant, the Member States, with the exception of the rapporteur Member State, and the public should be given the opportunity to submit comments on the draft renewal assessment report.

(13) The European Food Safety Authority should provide conclusions and organise consultations of experts, except where the Commission informs it that a conclusion is not necessary.

(14) Rules should be set out as regards the renewal report and the adoption of a regulation on the renewal of the approval of the active substance.

(15) Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances[(2)] should continue to apply with respect to the renewal of the approval of the active substances listed in Annex I thereto.

(16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

CHAPTER 1

ADMISSIBILITY

SECTION 1

Application for renewal

Article 1

Submission of the application

1 **[**[F1]Without prejudice to the fourth subparagraph, 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

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Implementing Regulation (EU) No 686/2012[(3)] and to the co-rapporteur Member State as set out in the third column of that Annex, or to each of the Member States in a group of Member States acting jointly as rapporteur Member State as set out in the fourth 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.

[[F2]Where a group of Member States jointly assumes the role of the rapporteur Member State as set out in the fourth column of the Annex to Implementing Regulation (EU) No 686/2012, no co-rapporteur Member State shall be appointed. In this case, all references to 'the rapporteur Member State' in this Regulation shall be deemed to be references to 'the group of Member States acting jointly as rapporteur Member State'.

Prior to the expiry of the deadline for submission of the application, the Member States acting jointly as rapporteur Member State shall agree on the repartition of all tasks and workload.

Member States forming part of the group of Member States acting jointly as rapporteur Member State shall endeavour to reach consensus during the evaluation.**]**

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.

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2019/724 of 10 May 2019 amending Implementing Regulation (EU) No 686/2012 as regards the nomination of rapporteur Member States and co-rapporteur Member States for the active substances glyphosate, lambda-cyhalothrin, imazamox and pendimethalin and amending Implementing Regulation (EU) No 844/2012 as regards the possibility that a group of Member States assumes jointly the role of the rapporteur Member State (Text with EEA relevance).

F2 Inserted by Commission Implementing Regulation (EU) 2019/724 of 10 May 2019 amending Implementing Regulation (EU) No 686/2012 as regards the nomination of rapporteur Member States and co-rapporteur Member States for the active substances glyphosate, lambda-cyhalothrin, imazamox and pendimethalin and amending Implementing Regulation (EU) No 844/2012 as regards the possibility that a group of Member States assumes jointly the role of the rapporteur Member State (Text with EEA relevance).

Article 2

Format and contents of the application

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

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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).

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) No 844/2012. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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.

[[F3]3 The supplementary dossiers shall be submitted no later than 33 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.