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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)

(OJ L 252, 19.9.2012, p. 26)

Amended by:

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►**M2**	Commission Implementing Regulation (EU) 2019/724 of 10 May 2019	L 124	32	13.5.2019
►**M3**	Commission Implementing Regulation (EU) 2020/103 of 17 January 2020	L 19	1	24.1.2020

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CHAPTER 1

ADMISSIBILITY

SECTION 1

Application for renewal

Article 1

Submission of the application

1. ►M2 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 Implementing Regulation (EU) No 686/2012 ([1]) 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.

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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.

([1]) Commission Implementing Regulation (EU) No 686/2012 of 26 July 2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of the active substances (OJ L 200, 27.7.2012, p. 5).

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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.

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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.

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

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3. The supplementary dossiers shall be submitted no later than 33 months before the expiry of the approval.

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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;

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(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 ([1]);

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(j) a 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 ([2]);

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(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).

([1]) OJ L 70, 16.3.2005, p. 1.

([2]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1.).

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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.

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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.

CHAPTER 2

ASSESSMENT

Article 11

Assessment by the rapporteur Member State and the co-rapporteur Member State

1. Where the application is admissible in accordance with Article 8(1), the rapporteur Member State shall, after consulting the co-rapporteur Member State, at the latest ►M3 13 months ◄ after the date referred to in Article 6(3), prepare and submit to the Commission, with a copy to the Authority, a report assessing whether the active substance can be expected to meet the approval criteria, as provided for in Article 4 of Regulation (EC) No 1107/2009 (‘the draft renewal assessment report’).

2. The draft renewal assessment report shall also include the following:

(a) a recommendation with regard to the renewal of the approval;

(b) a recommendation on whether the substance should be considered a ‘low-risk’ substance;

(c) a recommendation on whether the substance should be considered a candidate for substitution;

(d) where relevant, a proposal to set maximum residue levels;

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(e) a suggestion for the classification, or its confirmation, where applicable, or reclassification of the active substance in accordance with the criteria of Regulation (EC) No 1272/2008, as specified in and consistent with the dossier to be submitted pursuant to paragraph 9;

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(f) a conclusion on which of the new studies included in the supplementary dossiers are relevant for the assessment;

(g) a recommendation as to the parts of the report on which a consultation of experts is to be organised in accordance with Article 13(1);

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(h) the points on which the co-rapporteur Member State did not agree with the assessment by the rapporteur Member State, where relevant, or, where applicable, the points where there is no agreement between Member States forming a group of Member States acting jointly as rapporteur Member State.

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3. The rapporteur Member State shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge. It shall take into account the supplementary dossiers, and, where appropriate, the dossiers submitted for the approval and subsequent renewals of approval.

4. The rapporteur Member State shall first establish whether the approval criteria set out in points 3.6.2, 3.6.3, 3.6.4 and 3.7 of Annex II to Regulation (EC) No 1107/2009 are satisfied.

Where those criteria are not satisfied, the draft renewal assessment report shall be limited to those parts of the assessment, unless Article 4(7) of Regulation (EC) No 1107/2009 applies.

5. Where the rapporteur Member State requires additional information, it shall set a period for the applicant to supply that information. That period shall not lead to an extension of the period of ►M3 13 months ◄ provided for in paragraph 1. The applicant may, pursuant to Article 63 of Regulation (EC) No 1107/2009, request such information to be kept confidential.

6. The rapporteur Member State may consult the Authority and request additional technical or scientific information from other Member States. Such consultations and requests shall not lead to an extension of the period of ►M3 13 months ◄ provided for in paragraph 1.

7. Information submitted by the applicant without having been requested, or provided after the expiry of the period set for its submission in accordance with the first sentence of paragraph 5, shall not be taken into account, unless it is submitted in accordance with Article 56 of Regulation (EC) No 1107/2009.

8. When submitting the draft renewal assessment report to the Commission, the rapporteur Member State shall request the applicant to submit the supplementary summary dossiers, updated to include the additional information requested by the rapporteur Member State in accordance with paragraph 5 or submitted in accordance with Article 56 of Regulation (EC) No 1107/2009, to the co-rapporteur Member State, the Commission, the other Member States and to the Authority.

The applicant may pursuant to Article 63 of Regulation (EC) No 1107/2009 request such information to be kept confidential. Any such requests shall be addressed to the Authority.

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9. The rapporteur Member State shall at the latest at the time of submission of the draft renewal assessment report submit a proposal to the European Chemicals Agency ('the Agency') pursuant to Article 37(1) of Regulation (EC) No 1272/2008 and in accordance with the Agency's requirements to obtain an opinion on a harmonised classification of the active substance at least for the following hazard classes:

— explosives,

— acute toxicity,

— skin corrosion/irritation,

— serious eye damage/eye irritation,

— respiratory or skin sensitisation,

— germ cell mutagenicity,

— carcinogenicity,

— reproductive toxicity,

— specific target organ toxicity – single exposure,

— specific target organ toxicity – repeated exposure;

— hazardous to the aquatic environment.

The rapporteur Member State shall duly justify its view that the criteria for classification for one or more of these hazard classes are not fulfilled.

Where a proposal for classification of an active substance has already been submitted to the Agency and its assessment is ongoing, the rapporteur Member State shall submit an additional proposal for classification, limited to any hazard classes listed above that are not covered by the pending proposal unless new information has become available that was not part of the pending dossier as regards the hazard classes listed above.

For the hazard classes, which are already covered by an existing opinion of the Committee for Risk Assessment of the Agency set up pursuant to Article 76(1)(c) of Regulation (EC) No 1907/2006, whether or not this opinion has formed the basis of a decision concerning an entry for harmonised classification and labelling of a substance in Annex VI of Regulation (EC) No 1272/2008, it is sufficient that the rapporteur Member State duly justifies in its submission to the Agency that the existing opinion, or where it has already formed the basis of a decision concerning the inclusion in Annex VI, the existing classification remains valid as regards the hazard classes listed in the first subparagraph. The Agency may provide its views regarding the rapporteur Member State's submission.

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Article 11a

For the purposes of assessment of the approval criteria set out in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 as amended by Commission Regulation (EU) 2018/605 ([1]), in relation to applications submitted in accordance with Article 1 before 10 November 2018 for which the draft renewal assessment report has not been submitted by that date, where the information available in the supplementary dossiers is not sufficient for the rapporteur Member State to conclude the assessment on whether these approval criteria are met and, where applicable, whether application of Article 4(7) is justified, the rapporteur Member State shall specify in the draft renewal assessment report, in a detailed way, the additional information which is necessary in order to make the assessment concerned.

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Article 11b

The Committee for Risk Assessment shall endeavour to adopt the opinion referred to in Article 37(4) of Regulation (EC) No 1272/2008 within 13 months from the submission referred to in Article 11(9).

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Article 12

Comments on the draft renewal assessment report

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1. The Authority shall examine whether the draft renewal assessment report received from the rapporteur Member State contains all the relevant information in the agreed format and circulate it to the applicant and to the other Member States at the latest three months after its receipt.

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2. The Authority shall make the draft renewal assessment report available to the public, after giving the applicant two weeks to request, pursuant to Article 63 of Regulation (EC) No 1107/2009, that certain parts of the draft renewal assessment report are kept confidential.

3. The Authority shall allow a period of 60 days from the date the report is made available to the public for the submission of written comments. Such comments shall be communicated to the Authority, which shall collate and forward those comments, including its own comments, to the Commission.

4. The Authority shall make the updated supplementary summary dossiers available to the public, 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.

([1]) Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

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Article 13

Conclusion by the Authority

1. ►M3 Within five months from the expiry of the period referred to in Article 12(3), or within two weeks from the adoption of the opinion of the Committee for Risk Assessment referred to in Article 37(4) of Regulation (EC) No 1272/2008, if any adopted, whichever occurs later, the Authority shall adopt a conclusion in the light of current scientific and technical knowledge using guidance documents applicable at the date of the submission of the supplementary dossiers and in the light of the opinion of the Committee for Risk Assessment on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. ◄ The Authority shall, where appropriate, organise a consultation of experts, including experts from the rapporteur Member State and co-rapporteur Member State. The Authority shall communicate its conclusion to the applicant, the Member States and the Commission.

By way of derogation from the first subparagraph, the Commission may inform the Authority without delay after the period referred to in Article 12(3) has expired that a conclusion is not necessary.

2. After giving the applicant two weeks to request, pursuant to Article 63 of Regulation (EC) No 1107/2009, that certain parts of the conclusion be kept confidential, the Authority shall make its conclusion available to the public, excluding any information in respect of which confidentiality has been granted by the Authority, unless there is an overriding public interest in its disclosure.

3. Where the Authority considers that additional information from the applicant is necessary, it shall, in consultation with the rapporteur Member State, set a period not exceeding one month for the applicant to supply such information to the Member States, the Commission and the Authority. The rapporteur Member State shall, within 60 days from the date of receipt of the additional information evaluate the information received and send its evaluation to the Authority.

Where the first subparagraph applies, the period referred to in paragraph 1 shall be extended by the periods referred to in the first subparagraph of this paragraph.

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3a. For the purposes of assessment of the approval criteria set out in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 as amended by Commission Regulation (EU) 2018/605, in relation to applications submitted in accordance with Article 1 before 10 November 2018, for which the draft renewal assessment report has been submitted but the conclusion by the Authority is not yet adopted by that date, where the information available in the dossier is not sufficient for the Authority to conclude the assessment on whether these approval criteria are met, the Authority shall, in consultation with the Member States, request from the applicant the additional information to be submitted to the rapporteur Member State, the other Member States, the Commission, and the Authority in the form of an updated supplementary dossier including the additional information. The Authority shall, in consultation with the rapporteur Member State and the applicant, set a period for the submission of that information. Such period shall be at least of 3 months, shall not exceed 30 months, and shall be justified in relation to the type of information which has to be submitted.

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Within this period set by the Authority, the applicant may also submit where applicable, documentary evidence showing that the conditions for the application of the derogation under Article 4(7) of Regulation (EC) No 1107/2009 are met.

Where the Authority, in consultation with the Member States, is able to conclude without requesting additional information that the scientific criteria for the determination of endocrine disrupting properties set out in point 3.6.5 and/or point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 are met, it shall inform the applicant. Within 3 months after being informed by the Authority, the applicant may submit to the rapporteur Member State, the other Member States, the Commission, and the Authority, additional information to address the approval criteria set in point 3.6.5 and/or point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, and/or documentary evidence showing that the conditions for the application of the derogation under Article 4(7) of that Regulation are met.

Where the first or third subparagraphs apply, the period referred to in paragraph 1 shall be extended by the period set for submission of the additional information.

Where no additional information is submitted in accordance with the first, second or third subparagraph within the period set for its submission, the Authority shall, without delay, inform the applicant, the rapporteur Member State, the Commission and the other Member States and conclude the assessment based on the available information.

Where additional information is submitted in accordance with the first, second or third subparagraph within the period set for its submission, the rapporteur Member State shall, within 90 days from the date of receipt of the additional information evaluate the information received and send its evaluation to the Authority in the form of a revised draft renewal assessment report. The Authority shall conduct a consultation on the revised draft renewal assessment report with all the Member States and the applicant in accordance with Article 12. The Authority shall adopt the conclusion referred to in paragraph 1, within 120 days from the date of receipt of the revised draft renewal assessment report, using the guidance for identification of endocrine disruptors applicable at the date of the submission of the updated supplementary dossier referred to in the first subparagraph.

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4. The Authority may ask the Commission to consult a European Union reference laboratory designated, pursuant to Regulation (EC) No 882/2004 of the European Parliament and of the Council [1], for the purposes of verifying whether the analytical method for the determination of the residues proposed by the applicant is satisfactory and complies with the requirements in Article 29(1)(g) of Regulation (EC) No 1107/2009. The applicant shall, if requested by the European Union reference laboratory, provide samples and analytical standards.

[1] OJ L 165, 30.4.2004, p. 1.

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5. Information submitted by the applicant without having been requested, or provided after the expiry of the period set for its submission in accordance with the first subparagraph of paragraph 3 or in accordance with the first or third subparagraphs of paragraph 3a of this Article, shall not be taken into account, unless it is submitted in accordance with Article 56 of Regulation (EC) No 1107/2009.

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Article 13a

Fees and charges

Member States may require payment of fees and charges in accordance with Article 74 of Regulation (EC) No 1107/2009 to recover the costs associated with any work they carry out within the scope of this Regulation.

Article 14

Renewal report and renewal Regulation

1. The Commission shall present to the Committee referred to in Article 79(1) of Regulation (EC) No 1107/2009 a renewal report and a draft Regulation within six months from the date of receipt of the conclusion of the Authority or in cases where there is no such conclusion of the Authority, the expiry of the period referred to in Article 12(3) of this Regulation.

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The renewal report and the draft Regulation shall take into account the draft renewal assessment report of the rapporteur Member State, the comments referred to in Article 12(3) of this Regulation and the conclusion of the Authority, where such a conclusion has been submitted, and the opinion of the Committee for Risk Assessment, if any, referred to in Article 37(4) of Regulation (EC) No 1272/2008.

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The applicant shall be given the possibility to submit comments on the renewal report within a period of 14 days.

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1a. For the purposes of assessment of the approval criteria set out in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 as amended by Commission Regulation (EU) 2018/605, in relation to applications for which the conclusion by the Authority is adopted before 10 November 2018, and where the Committee referred to in Article 79(1) of Regulation (EC) No 1107/2009 has not yet voted on a draft Regulation concerning the renewal or non-renewal of that active substance by that date, the Commission may consider that additional information is necessary to assess whether these approval criteria are met. In such cases, the Commission shall request that the Authority reassesses within a reasonable time period the available information and shall inform the applicant of that request.

When requested by the Commission in accordance with the first subparagraph, the Authority may, in consultation with the rapporteur Member State, decide whether additional information is required and request the applicant to submit such information to the rapporteur

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Member State, the other Member States, the Commission and the Authority in the form of an updated supplementary dossier including the additional information. The Authority shall, in consultation with the rapporteur Member State and the applicant, set a period for the submission of that information. Such period shall be at least of 3 months, shall not exceed 30 months, and shall be justified in relation to the type of information which has to be submitted.

Within this period set by the Authority, the applicant may also submit where applicable, documentary evidence showing that the conditions for the application of the derogation under Article 4(7) of Regulation (EC) No 1107/2009 are met.

Where the Authority, in consultation with the Member States, is able to conclude without requesting additional information that the scientific criteria for the determination of endocrine disrupting properties set out in point 3.6.5 and/or point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 are met, it shall inform the applicant. Within 3 months after being informed by the Authority, the applicant may submit to the rapporteur Member State, the other Member States, the Commission, and the Authority, additional information to address the approval criteria set out in point 3.6.5 and/or point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, and/or documentary evidence showing that the conditions for the application of the derogation under Article 4(7) of that Regulation are met.

The rapporteur Member State shall, within 90 days from the date of receipt of the additional information evaluate the information received and send its evaluation to the Authority in the form of a revised draft renewal assessment report. The Authority shall conduct a consultation of the revised renewal assessment report with all the Member States and the applicant in accordance with Article 12.

The Authority shall adopt an addendum to the conclusion referred to in paragraph 1, within 120 days from the date of receipt of the revised draft renewal assessment report, using the guidance for identification of endocrine disruptors applicable at the date of the submission of the updated supplementary dossier referred to in the second subparagraph.

Where no additional information is submitted in accordance with the second, the third or the fourth subparagraph within the period set for its submission, the Authority shall, without delay, inform the applicant, the rapporteur Member State, the co-rapporteur Member State, the Commission and the other Member States and conclude the assessment based on the available information within 30 days from the expiry of the period referred to in the second or fourth subparagraph.

Information submitted by the applicant without having been requested, or provided after the expiry of the period set for its submission in accordance with the second or fourth subparagraph of this Article, shall not be taken into account, unless it is submitted in accordance with Article 56 of Regulation (EC) No 1107/2009.

▼B

2. On the basis of the renewal report and taking into account comments submitted by the applicant within the period referred to in the third subparagraph of paragraph 1, the Commission shall adopt a Regulation in accordance with Article 20(1) of Regulation (EC) No 1107/2009.

CHAPTER 3

TRANSITIONAL AND FINAL PROVISIONS

Article 15

Transitional provisions

Regulation (EU) No 1141/2010 shall continue to apply with respect to the renewal of the approval of active substances listed in Annex I thereto.

Article 16

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2013.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

▼B

ANNEX

Format for applications, as provided for in Article 2(1)

The application shall be in writing, signed by the applicant, and sent to the rapporteur Member State and to the co-rapporteur Member State.

A copy of the application shall be sent to the European Commission, DG Health and Consumers, 1049 Brussels, Belgium, to the European Food Safety Authority, Via Carlo Magno 1/A, 43126 Parma, Italy and to the other Member States.

MODEL

1. Information concerning the applicant

1.1. Name and address of the applicant including the name of the natural person responsible for the application and other obligations resulting from this Regulation:

1.1.1. (a) Telephone No:

(b) E-mail address:

1.1.2. (a) Contact:

(b) Alternative contact:

2. Information to facilitate identification

2.1. Common name (proposed or ISO-accepted) specifying, where relevant, any variants thereof such as salts, esters or amines manufactured by the producer.

2.2. Chemical name (IUPAC and CAS nomenclature).

2.3. CAS, CIPAC and EC numbers (if available).

2.4. Empirical and structural formula, molecular mass.

2.5. Specification of purity of the active substance in g/kg which must be, whenever possible, identical or already accepted as equivalent to the one listed in the Annex to Commission Implementing Regulation (EU) No 540/2011 ([1]).

2.6. Classification and labelling of the active substance in accordance with the provisions of Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([2]) (health and environment effects).

3. New information

3.1. List of new information intended to be submitted together with a justification showing that they are considered necessary, in accordance with Article 15(2) of Regulation (EC) No 1107/2009.

3.2. List of new studies intended to be submitted on vertebrate animals.

3.3. Timetable of any new and ongoing studies.

The applicant confirms that the above information submitted included in the application is correct.

Date and signature (of the person competent to act for the applicant referred to under point 1.1).

([1]) OJ L 153, 11.6.2011, p. 1.
([2]) OJ L 353, 31.12.2008, p. 1.