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 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 **[**F1 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;

[F1 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;**]**

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);

[F2 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.**]**

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 **[**F1 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 **[**F1 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.

[F3 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.**]**

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2020/103 of 17 January 2020 amending Implementing Regulation (EU) No 844/2012 as regards the harmonised classification of active substances (Text with EEA relevance).

F2 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).

F3 Inserted by Commission Implementing Regulation (EU) 2020/103 of 17 January 2020 amending Implementing Regulation (EU) No 844/2012 as regards the harmonised classification of active substances (Text with EEA relevance).

[*F4* *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.**]**

Textual Amendments

F4 Inserted by Commission Implementing Regulation (EU) 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605 (Text with EEA relevance).

[*F3* *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).**]**

Textual Amendments

F3 Inserted by Commission Implementing Regulation (EU) 2020/103 of 17 January 2020 amending Implementing Regulation (EU) No 844/2012 as regards the harmonised classification of active substances (Text with EEA relevance).

Article 12

Comments on the draft renewal assessment report

[[F1]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.**]**

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.

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2020/103 of 17 January 2020 amending Implementing Regulation (EU) No 844/2012 as regards the harmonised classification of active substances (Text with EEA relevance).

Article 13

Conclusion by the Authority

1 **[**[F1]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.

[[F4]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.

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.**]**

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[(2)], 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.

[[F5]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.**]**

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2020/103 of 17 January 2020 amending Implementing Regulation (EU) No 844/2012 as regards the harmonised classification of active substances (Text with EEA relevance).

F4 Inserted by Commission Implementing Regulation (EU) 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605 (Text with EEA relevance).

F5 Substituted by Commission Implementing Regulation (EU) 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605 (Text with EEA relevance).

[*[F6]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.**]**

Textual Amendments

F6 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 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.

[[F1]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.**]**

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

[[F4]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 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.**]**

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.

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2020/103 of 17 January 2020 amending Implementing Regulation (EU) No 844/2012 as regards the harmonised classification of active substances (Text with EEA relevance).

F4 Inserted by Commission Implementing Regulation (EU) 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605 (Text with EEA relevance).

(**1**) **[**[F4]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).**]**

(**2**) OJ L 165, 30.4.2004, p. 1.

Textual Amendments

F4 Inserted by Commission Implementing Regulation (EU) 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605 (Text with EEA relevance).

Status:
Point in time view as at 13/02/2020.

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 844/2012, CHAPTER 2.