

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 12 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;
- e where relevant, a suggestion for the classification or reclassification of the active substance in accordance with Regulation (EC) No 1272/2008;
- 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);
- h the points on which the co-rapporteur Member State did not agree with the assessment by the rapporteur Member State, where relevant.

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 12 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 12 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.

Article 12

Comments on the draft renewal assessment report

1 The Authority shall circulate the draft renewal assessment report received from the rapporteur Member State to the applicant and to the other Member States at the latest 30 days 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.

Article 13

Conclusion by the Authority

1 Within five months from the expiry of the period referred to in Article 12(3), 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

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.

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.

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, shall not be taken into account, unless it is submitted in accordance with Article 56 of Regulation (EC) No 1107/2009.

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.

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.

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

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.

(1) [OJ L 165, 30.4.2004, p. 1.](#)