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)

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)

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) Commission Implementing Regulation (EU) No 844/2012[(2)] provides for the implementation of the renewal procedure for active substances as provided for in Regulation (EC) No 1107/2009.

(2) Commission Regulation (EU) 2018/605[(3)] introduced new scientific criteria for the determination of endocrine disrupting properties, which reflect the current state of scientific and technical knowledge. Those criteria are to apply as of 10 November 2018 to applications for the renewal of the approval of active substances in accordance with Regulation (EC) No 1107/2009, including pending applications.

(3) Applications for the renewal of the approval of an active substance which are submitted before 10 November 2018 and for which, by that date, the Committee referred to in Article 79(1) of Regulation (EC) No 1107/2009 has not voted on a draft Regulation concerning the renewal or non-renewal of the approval of that active substance, should be considered pending applications.

(4) For such pending applications, it is possible that the information submitted by the applicant does not allow to conclude the assessment as regards whether the scientific criteria for the determination of endocrine disrupting properties set out in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 are met or not and to conclude whether the approval criteria set out in those points are met or not. Therefore, the European Food Safety Authority ('the Authority') should be able to request additional information from the applicant in order to conclude whether the approval criteria set out

in those points are met or not. Such additional information should be submitted within a time period set by the Authority, which should be as short as possible in order to avoid unjustified delays of the renewal procedure, and which should be based on the type of information to be submitted.

(5) Within the period given to provide the additional information, applicants should also be able to apply for the derogation under Article 4(7) of Regulation (EC) No 1107/2009.

(6) Where, based on the information already available, the Authority has been able to conclude that the substance meets the scientific criteria for the determination of endocrine disrupting properties, applicants should be able to submit additional information as regards the approval criteria set out in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 and/or be able to submit documentary evidence showing that the conditions for the application of the derogation under Article 4(7) of that Regulation are met.

(7) Where the Authority requires such additional information from the applicant, the period foreseen for the preparation of the conclusion by the Authority should be extended in order for that information to be taken into account.

(8) When requesting additional information from the applicant, the Authority should consider that animal testing is to be minimised and tests on vertebrates are to be undertaken only as a last resort, in accordance with Article 62 of Regulation (EC) No 1107/2009.

(9) Taking into account that the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605 apply as of 10 November 2018, this Regulation should enter into force as soon as possible and apply from 10 November 2018.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Implementing Regulation (EU) No 844/2012 is amended as follows:

(1) The following Article is inserted after Article 11:

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[(4)], 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.;.

(2) The following paragraph is inserted after Article 13(3):

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.;

(3) Paragraph 5 of Article 13 is replaced by the following:

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.;

(4) The following paragraph is inserted after Article 14(1):

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.

Article 2

The provisions of Implementing Regulation (EU) No 844/2012 inserted by Article 1 of this Regulation shall apply in addition to the other provisions of Implementing Regulation (EU) No 844/2012.

Article 3

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

It shall apply from 10 November 2018.

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

Done at Brussels, 7 November 2018.

For the Commission

The President

Jean-Claude JUNCKER

(**1**) OJ L 309, 24.11.2009, p. 1.

(**2**) 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 (OJ L 252, 19.9.2012, p. 26).

(**3**) 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).

(**4**) 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)’.