EUROPEAN
COMMISSION

Brussels, XXX
SANTE/11120/2017
[…](2017) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

amending Implementing Regulation (EU) No 844/2012 in view of the implementation of Commission Regulation setting out scientific criteria for the determination of endocrine disrupting properties

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

amending Commission Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties set out by Commission Regulation (EU) …/…

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, and in particular Article 19 thereof,

Whereas:

(1) Commission Implementing Regulation (EC) No 844/2012[1] is setting out the provisions for the implementation of the renewal procedure for active substances as provided for in Regulation (EC) No 1107/2009.

(2) Commission Regulation (EU) XXX[2] 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 to applications for the renewal of the approval of active substances in accordance with Regulation (EC) No 1107/2009 pending at the time of application of the new criteria.

(3) For pending applications, Member States or the Authority should be able to request additional information from the applicant in order to assess 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 satisfied. The period allowed to submit such information should be as short as possible and be justified in relation with the type of information to be submitted.

(4) Applications for the renewal of an active substance for which the supplementary dossier is submitted in accordance with Article 6 of Commission Implementing Regulation (EC) No 844/2012 before [*Date of application of the Commission Regulation on ED + 6 months*] and where the relevant Committee has not voted on a draft Regulation concerning the renewal or non-renewal of that active substance should be considered pending applications.

(5) Such additional information should be assessed by the rapporteur Member State and the Authority, which should be able to set a time period for providing that additional information.

Commented [s1]: Please explain what is meant by 'such', for instance by referring to recital 3

[1] 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).

[2] XXX

(6) Applicants should also be able to submit information to address the approval conditions in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 and/or be able to apply for derogations under Article 4(7) of Regulation (EC) No 1107/2009 within the time frame given to provide additional information.

(7) Where the rapporteur Member State or the Authority requires additional information from the applicant, the period foreseen for the preparation of the draft renewal report by the Rapporteur Member States or for the preparation of the conclusion by the Authority should be extended. As a consequence the assessment of the application for the renewal of the approval of the active substance may be delayed for reasons beyond the control of the applicant. In such cases, the approval period of the active substances concerned may ultimately need to be extended in accordance with Article 17 of Regulation (EC) No 1107/2009.

(8) 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 (EC) No 844/2012 is amended as follows:

(1) The following Article is inserted after Article 8:

"Article 8a

Concerning applications for which the supplementary dossier is submitted in accordance with Article 6 before [*Insert date of application of the Commission Regulation on the ED criteria + 6 months*], where the rapporteur Member State decides that some information necessary in order to assess whether the scientific criteria for the determination of endocrine disrupting properties set in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 are satisfied, is missing, it shall request from the applicant the information to be submitted. The rapporteur Member State shall, after consulting the applicant, set a period for the submission of this information. Such period shall be as short as possible, shall not exceed 30 months and be justified in relation with the type of information which has to be submitted.

In addition, the applicant may within the period referred to in the last two sentences of the first subparagraph:

(a) submit information to address the conditions of approval provided for in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 and/or
(b) apply for a derogation under Article 4(7) of that Regulation.

Where the applicant submits the information referred to in the first or second subparagraphs, the applicant shall also submit an updated supplementary dossier and a summary supplementary dossier including the additional information to the rapporteur Member State and the co-rapporteur Member State, the Commission and the Authority.

When submitting the updated supplementary dossier and summary supplementary dossier, the applicant may, pursuant to Article 63 of Regulation (EC) No 1107/2009, request certain information to be kept confidential.

Commented [5.1.2.e Woo] I do not understand this period. To my understanding the criteria will take effect/enter into force as they are published + 20 d. Half a year later, the criteria enter into applicability.
Apparently a second transitional period for pending applications is installed, which is also 6 months long. That is not the case for biocidal products.
Please explain the + 6 months after e.i.a..

This effectively extends the recovery period for pending applications incomplete on ED information to one year after the publication of the ED criteria.

Commented [5.1.2.e Woo]: Additional guidance is necessary for ASes that are obviously an EDC, or the opposite. It would be an inefficient use of time and resources to deliver extra data for those cases in which the conclusion can already be drawn without the extra data.

Commented [5.1.2.e Woo]: 'Some' is not a specific description. Please specify.
(Used 2x more in this text.)

Commented [5.1.2.e Woo]: Please define a 'maximum' to the window of applicability of art 8a.
Suggestion: once the draft renewal assessment report has been submitted, then article 8a no longer applies.

Commented [5.1.2.e Woo] The comma should be replaced.

Commented [5.1.2.e Woo] Not included how long this evaluation may last.

This is clearly included though in the EFSA and COM route, namely 60 d for the RMS in both cases, see (3) and (4).

Where the additional information to be submitted in accordance with the first or the second subparagraph has not been submitted within the period set for its submission, the rapporteur Member State shall, without delay, inform the applicant, the co-rapporteur Member State, the Commission, the other Member States and the Authority."

Commented 5.1.2.e Woo: New line suggested.

(2) The following paragraph is inserted after Article 11(5):

"5a. Where the rapporteur Member State requires additional information in accordance with Article 8a, the period referred to in paragraph 1 shall, where applicable, be extended by the period set in accordance with the last two sentences of the first subparagraph of Article 8a."

Commented 5.1.2.e Woo: Is this correct?
Now: 30 months
Shouldn't it be: 30 months and the evaluation period?

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

"3a. Concerning applications for which the supplementary dossier is submitted in accordance with Article 6 before [*Insert date of application of the Commission Regulation on the ED criteria + 6 months*] and the draft renewal assessment report is submitted in accordance with Article 11(1), the Authority may decide that some information, necessary in order to assess whether the scientific criteria for the determination of endocrine disrupting properties set in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 are satisfied, is missing. In such cases the Authority shall, in consultation with the rapporteur Member State, request from the applicant additional information to be submitted to the Rapporteur Member State and the Authority. The Authority shall, after consulting the Rapporteur Member State and the applicant, set a period for the submission of that information. Such period shall be as short as possible, shall not exceed 30 months and be justified in relation with the type of information which has to be submitted.

Commented 5.1.2.e Woo: Please define a 'maximum' to the window of applicability of art 3a.
Suggestion: once the conclusions of the Authority are adopted, then article 3a no longer applies.

In addition the applicant may, within the period referred to in the last two sentences of the first subparagraph:

a) submit information to address the conditions of approval in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 and/or,
b) apply for a derogation under Article 4(7) of that Regulation.

The applicant may, pursuant to Article 63 of Regulation (EC) No 1107/2009, request information to be kept confidential.

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.

Commented 5.1.2.e Woo: Half a year would be more realistic

Where the first subparagraph applies, the period referred to in paragraph 1 shall be extended by the period set in accordance with the last two sentences of the first subparagraph of this paragraph.

Commented 5.1.2.e Woo: Is this correct?
Now: 30 months.
Shouldn't it be: 30 months and the evaluation period of max. 60d?

Where the additional information requested in accordance with the first or the second subparagraph has not been submitted ~~at the expiry of~~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, the other Member States and the Authority.

Commented 5.1.2.e Woo: Inconsistency with the wording in paragraph (1).

Preference for 'within': at 'expiry' it seems like the Authority always has to wait until the deadline has passed, even if the applicant is clearly not complying.

This paragraph shall not apply to applications for which information was submitted pursuant to Article 8a.

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

"1a. Concerning applications for which the supplementary dossier is submitted in accordance with Article 6 before [*Date of application of the Commission Regulation on ED Criteria + 6 months*] and conclusions of the Authority are adopted but where the relevant Committee has not voted on a draft Regulation concerning the renewal or non-renewal of that active substance, the Commission may consider that some information necessary in order to assess whether the scientific criteria for the determination of the endocrine disrupting properties set in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 are satisfied, is missing. In such cases the Authority may, upon the request by the Commission and 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 and the Authority. The Authority shall, after consulting the rapporteur Member State and the applicant, set a period for the applicant to supply such information to the Member State, the Commission and the Authority. Such period shall be as short as possible, shall not exceed 30 months and be justified in relation with the type of information which has to be submitted.

In addition, the applicant may, within the period referred to in the last two sentences of the first subparagraph:

a) submit information to address the conditions of approval in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 and/or

b) apply for a derogation under Article 4(7) of that Regulation.

The applicant may, pursuant to Article 63 of Regulation (EC) No 1107/2009, request such information to be kept confidential.

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. The Authority shall, within 90 days from the date of receipt of the additional information, adopt an addendum to the conclusion referred to in paragraph 1.

Where the additional information requested in accordance with the first or the second subparagraph has not been submitted ~~at the expiry of~~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, the other Member States and the Authority.

Where the Authority considers that no additional information is to be requested from the applicant, it shall within 30 days adopt an addendum to the conclusion referred to in paragraph 1.

This paragraph shall not apply to applications for which information was submitted pursuant to Article 8a or Article 13(3)a.

Commented 3.1.2.e Woo: editorial

Commented 3.1.2.e Woo: Half a year would be more realistic

Commented 3.1.2.e Woo Inconsistency with the wording in paragraph (1).

Preference for 'within': at 'expiry' it seems like the Authority always has to wait until the deadline has passed, even if the applicant is clearly not complying.

Article 2

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

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

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER