

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 [^{F1}assessing competent authority]

1 Where the application is admissible in accordance with Article 8(1), the [^{F2}assessing competent authority must], at the latest [^{F3}13 months] after the date referred to in Article 6(3), prepare and submit to the [^{F4}other competent authorities] 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;
- ^{F3}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;

^{F5}g

^{F5}h

3 The [^{F6}assessing competent authority] 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 [^{F7}assessing competent authority] 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.

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5 Where the [F⁸assessing competent authority] requires additional information, it shall set a period for the applicant to supply that information. F⁹... The applicant may, pursuant to Article 63 of Regulation (EC) No 1107/2009, request such information to be kept confidential.

[F¹⁰5A. The 13 month period provided for in paragraph 1 is extended by any additional period set in accordance with paragraph 5.

5B. The additional period described in paragraph 5 must be for no more than 6 months and ceases at the earlier of—

- a the date on which the assessing competent authority receives the additional information;
- b the expiry of the additional period.]

[F¹¹6 The assessing competent authority may, as it considers appropriate—

- a obtain independent scientific advice;
- b consult with the other competent authorities.]

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 [F¹²When submitting the draft renewal assessment report to the other competent authorities, the assessing competent authority must require the applicant to notify the other competent authorities of the existence of any updated supplementary summary dossiers. Article 15(4) of Regulation (EC) No 1107/2009 applies to a notification under this paragraph as it applies to a notification under Article 15(3) of that Regulation.]

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 [F¹³assessing competent authority].

[F¹⁴9 The [F¹⁵assessing competent authority] shall at the latest at the time of submission of the draft renewal assessment report submit a proposal to the [F¹⁶Agency] pursuant to Article [F¹⁷37A(2)(2)] of Regulation (EC) No 1272/2008 and in accordance with the Agency's requirements to obtain an opinion on a [F¹⁸mandatory classification and labelling] 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 [F¹⁹assessing competent authority] 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 [F¹⁹assessing competent authority]

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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, [^{F20}or by an Agency opinion,] whether or not this opinion has formed the basis of a decision concerning an entry for [^{F21}mandatory classification] and labelling of a substance in [^{F22}the GB mandatory classification and labelling list], 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 [^{F23}the GB mandatory classification and labelling list], the existing classification remains valid as regards the hazard classes listed in the first subparagraph. The Agency may provide its views regarding the [^{F24}assessing competent authority's] submission.]

Textual Amendments

- F1** Words in Art. 11 heading substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(11)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F2** Words in Art. 11(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(11)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F3** 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** Words in Art. 11(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(11)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F5** Art. 11(2)(g)(h) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(11)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F6** Words in Art. 11(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(11)(d)**; 2020 c. 1, Sch. 5 para. 1(1)
- F7** Words in Art. 11(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(11)(d)**; 2020 c. 1, Sch. 5 para. 1(1)
- F8** Words in Art. 11(5) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(11)(e)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F9** Words in Art. 11(5) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(11)(e)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F10** Art. 11(5A)(5B) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(11)(f)** (as amended by S.I. 2020/1376, regs. 1(4), **3(16)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F11** Art. 11(6) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(11)(g)**; 2020 c. 1, Sch. 5 para. 1(1)

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

- F12** Words in Art. 11(8) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(11)(h)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F13** Words in Art. 11(8) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(11)(h)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F14** 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).
- F15** Words in Art. 11(9) substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(3)(a)(i)(aa)**
- F16** Word in Art. 11(9) substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(3)(a)(i)(bb)**
- F17** Word in Art. 11(9) substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(3)(a)(i)(cc)**
- F18** Words in Art. 11(9) substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(3)(a)(i)(dd)**
- F19** Words in Art. 11(9) substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(3)(a)(ii)**
- F20** Words in Art. 11(9) inserted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(3)(a)(iii)(aa)**
- F21** Words in Art. 11(9) substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(3)(a)(iii)(bb)**
- F22** Words in Art. 11(9) substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(3)(a)(iii)(cc)**
- F23** Words in Art. 11(9) substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(3)(a)(iii)(dd)**
- F24** Words in Art. 11(9) substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(3)(a)(iii)(ee)**

F²⁵ 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 [F²⁶ assessing competent authority] to conclude the assessment on whether these approval criteria are met and, where applicable, whether application of Article 4(7) is justified, the [F²⁶ assessing competent authority] 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

- F25** 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).
- F26** Words in Art. 11a substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(2)**; 2020 c. 1, Sch. 5 para. 1(1)

^{F14}Article 11b

The [^{F27}Agency] shall endeavour to adopt the opinion [^{F28}on a proposal from the assessing competent authority] within 13 months from the submission referred to in Article 11(9).]

Textual Amendments

- F14** 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).
- F27** Word in Art. 11b substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(4)(a)**
- F28** Words in Art. 11b substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(4)(b)**

Article 12

Comments on the draft renewal assessment report

^{F31} The [^{F29}assessing competent authority] shall examine whether the draft renewal assessment report ^{F30}... contains all the relevant information in the agreed format and circulate it to the applicant and to the other [^{F31}competent authorities] at the latest three months after its receipt.]

2 The [^{F32}assessing competent 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 [^{F33}assessing competent 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 [^{F33}assessing competent authority], which shall collate and forward those comments, including its own comments, to the [^{F34}other competent authorities].

4 The [^{F35}assessing competent 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

- F3** 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).
- F29** Words in Art. 12(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(12)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F30** Words in Art. 12(1) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(12)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

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- F31** Words in Art. 12(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(12)(a)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F32** Words in Art. 12(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(12)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F33** Words in Art. 12(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(12)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F34** Words in Art. 12(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(12)(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F35** Words in Art. 12(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(12)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 13

Conclusion by the ^{F36}assessing competent authority]

1 ^{F3}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 ^{F37}Agency] referred to in Article ^{F38}37A(4)] of Regulation (EC) No 1272/2008, if any adopted, whichever occurs later, the ^{F39}assessing competent 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 ^{F37}Agency] on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.]^{F40}The assessing competent authority may obtain independent scientific advice where it considers it appropriate to do so.] The Authority shall communicate its conclusion to the applicant ^{F41}and the other competent authorities].

^{F42} ...

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 ^{F43}assessing competent authority] shall make its conclusion available to the public, excluding any information in respect of which confidentiality has been granted by the ^{F43}assessing competent authority], unless there is an overriding public interest in its disclosure.

3 Where the ^{F44}assessing competent authority] considers that additional information from the applicant is necessary, it shall ^{F45}... set a period not exceeding ^{F46}90 days] for the applicant to supply such information to the ^{F47}other competent authorities] and the ^{F44}assessing competent authority]. The ^{F48}assessing competent authority] shall, within 60 days from the date of receipt of the additional information evaluate the information received ^{F49}....

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.

^{F25}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 ^{F50}assessing competent authority] is not yet adopted by that date, where the

information available in the dossier is not sufficient for the [F⁵⁰ assessing competent authority] to conclude the assessment on whether these approval criteria are met, the [F⁵⁰ assessing competent authority] shall, in consultation with the [F⁵¹ other competent authorities], request from the applicant the additional information to be submitted to the [F⁵² assessing competent authority and the other competent authorities] in the form of an updated supplementary dossier including the additional information. The [F⁵³ assessing competent authority] shall, in consultation with F⁵⁴ ... 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 [F⁵⁵ assessing competent 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 [F⁵⁶ assessing competent authority] 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 [F⁵⁷ assessing competent authority], the applicant may submit to the [F⁵⁸ assessing competent authority and the other competent authorities], 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 [F⁵⁹ assessing competent authority] shall, without delay, inform the applicant [F⁶⁰ and the other competent authorities] 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 [F⁶¹ assessing competent authority] shall, within 90 days from the date of receipt of the additional information evaluate the information received and [F⁶² circulate to the other competent authorities and the applicant] a revised draft renewal assessment report. The [F⁶³ assessing competent authority] shall conduct a consultation on the revised draft renewal assessment report with [F⁶⁴ the other competent authorities] and the applicant in accordance with Article 12. The [F⁶⁵ assessing competent authority] shall adopt the conclusion referred to in paragraph 1, within 120 days from the date of [F⁶⁶ circulation] 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 [F⁶⁷ assessing competent authority] may F⁶⁸ ... consult a F⁶⁹ ... reference laboratory designated, pursuant to [F⁷⁰ Regulation (EU) 2017/625 of the European Parliament and of the Council], 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 F⁷¹ ... reference laboratory, provide samples and analytical standards.

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

[^{F725} 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

- F3** 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 \(Text with EEA relevance\)](#).
- F25** 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 \(Text with EEA relevance\)](#).
- F36** Words in Art. 13 heading substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **20(13)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F37** Words in Art. 13(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), reg. 20(13)(b)(i)(aa) (as substituted by S.I. 2020/1376, regs. 1(4), **3(16)(c)**)
- F38** Word in Art. 13(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), reg. 20(13)(b)(i)(bb) (as substituted by S.I. 2020/1376, regs. 1(4), **3(16)(c)**)
- F39** Words in Art. 13(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), reg. 20(13)(b)(i)(cc) (as substituted by S.I. 2020/1376, regs. 1(4), **3(16)(c)**)
- F40** Words in Art. 13(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), reg. 20(13)(b)(i)(dd) (as substituted by S.I. 2020/1376, regs. 1(4), **3(16)(c)**)
- F41** Words in Art. 13(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), reg. 20(13)(b)(i)(ee) (as substituted by S.I. 2020/1376, regs. 1(4), **3(16)(c)**)
- F42** Words in Art. 13(1) omitted (31.12.2020) by virtue of [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), reg. 20(13)(b)(ii) (as substituted by S.I. 2020/1376, regs. 1(4), **3(16)(c)**)
- F43** Words in Art. 13(2) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **20(13)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F44** Words in Art. 13(3) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **20(13)(d)(i)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)
- F45** Words in Art. 13(3) omitted (31.12.2020) by virtue of [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **20(13)(d)(i)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)
- F46** Words in Art. 13(3) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **20(13)(d)(i)(cc)**; 2020 c. 1, Sch. 5 para. 1(1)
- F47** Words in Art. 13(3) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **20(13)(d)(i)(dd)**; 2020 c. 1, Sch. 5 para. 1(1)
- F48** Words in Art. 13(3) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **20(13)(d)(ii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

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

- F49** Words in Art. 13(3) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(13)(d)(ii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)
- F50** Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(a)(i)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)
- F51** Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(a)(i)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)
- F52** Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(a)(i)(cc)**; 2020 c. 1, Sch. 5 para. 1(1)
- F53** Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(a)(ii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)
- F54** Words in Art. 13(3a) omitted (31.12.2020) by virtue of The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(a)(ii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)
- F55** Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F56** Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F57** Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(c)(ii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)
- F58** Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(c)(ii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)
- F59** Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(d)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F60** Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(d)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F61** Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(e)(i)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)
- F62** Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(e)(i)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)
- F63** Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(e)(ii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)
- F64** Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(e)(ii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)
- F65** Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(e)(iii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

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

- F66** Word in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(e)(iii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)
- F67** Words in Art. 13(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(13)(e)(i)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)
- F68** Words in Art. 13(4) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(13)(e)(i)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)
- F69** Words in Art. 13(4) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(13)(e)(i)(cc)**; 2020 c. 1, Sch. 5 para. 1(1)
- F70** Words in Art. 13(4) substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1410), regs. 1(3), **3(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F71** Words in Art. 13(4) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(13)(e)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F72** 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).

^{F73}Article 13a

Fees and charges

Textual Amendments

- F73** Art. 13a omitted (31.12.2020) by virtue of The Pesticides (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1410), regs. 1(3), **3(3)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 14

Renewal [^{F74}decision]

[^{F75}1 Article 20 of Regulation (EC) No 1107/2009 applies.

- 1za. Paragraph 1a applies in relation to an application where—}
- a paragraph 7 of Schedule 1 to the Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 applies in relation to that application, and
 - b the European Food Safety Authority adopted a conclusion in relation to that application before 10th November 2018 in accordance with Article 13.]

[^{F25}1a ^{F76}...

[^{F77}For the purposes of assessment of the approval criteria set out in points 3.6.5 and 3.8.2 of Annex 2 to Regulation (EC) No 1107/2009, the assessing competent authority may] decide whether additional information is required and request the applicant to submit such information to the [^{F78}assessing competent authority and the other competent authorities] in the form of an updated supplementary dossier including the

additional information. The [F⁷⁹assessing competent authority] shall, in consultation with F⁸⁰... 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 [F⁸¹assessing competent 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 [F⁸²assessing competent authority] 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 [F⁸³assessing competent authority], the applicant may submit to the [F⁸⁴assessing competent authority and the other competent authorities] 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 [F⁸⁵assessing competent authority] shall, within 90 days from the date of receipt of the additional information evaluate the information received and [F⁸⁶circulate to the other competent authorities and the applicant] a revised draft renewal assessment report. The [F⁸⁷assessing competent authority] shall conduct a consultation of the revised renewal assessment report with [F⁸⁸the other competent authorities] and the applicant in accordance with Article 12.

The [F⁸⁹assessing competent authority] shall adopt an addendum to the conclusion referred to in paragraph 1, within 120 days from the date of [F⁹⁰circulation] 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 [F⁹¹assessing competent authority] shall, without delay, inform the applicant [F⁹²and the other competent authorities] 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.]

F⁹³2

Textual Amendments

- F25** 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 \(Text with EEA relevance\).](#)

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

- F74** Word in Art. 14 heading substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F75** Art. 14(1)(1za) substituted for Art. 14(1) (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F76** Words in Art. 14(1a) omitted (31.12.2020) by virtue of The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F77** Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(ii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)
- F78** Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(ii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)
- F79** Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(ii)(cc)**; 2020 c. 1, Sch. 5 para. 1(1)
- F80** Words in Art. 14(1a) omitted (31.12.2020) by virtue of The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(ii)(dd)**; 2020 c. 1, Sch. 5 para. 1(1)
- F81** Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F82** Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(iv)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)
- F83** Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(iv)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)
- F84** Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(iv)(cc)**; 2020 c. 1, Sch. 5 para. 1(1)
- F85** Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(v)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)
- F86** Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(v)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)
- F87** Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(v)(cc)**; 2020 c. 1, Sch. 5 para. 1(1)
- F88** Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(v)(dd)**; 2020 c. 1, Sch. 5 para. 1(1)
- F89** Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(vi)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)
- F90** Word in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(vi)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

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

- F91** Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(vii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)
- F92** Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(vii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)
- F93** Art. 14(2) omitted (31.12.2020) by virtue of The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

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

- (1) [^{F25}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).]

.....

Textual Amendments

- F25** 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).

Changes to legislation:

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