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 [F1assessing competent authority]

1 Where the application is admissible in accordance with Article 8(1), the **[**F2assessing competent authority must**]**, at the latest **[**F313 months**]** after the date referred to in Article 6(3), prepare and submit to the **[**F4other 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;

[F3e 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;

F5g . . . . . .

F5h . . . . . .

3 The **[**F6assessing 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 **[**F7assessing 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.

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.

[F10 5A. 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.**]**

[F11 6 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**]**.

[F14 9 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 **[**F17 37A(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**]**

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, **[**F20or by an Agency opinion,**]** whether or not this opinion has formed the basis of a decision concerning an entry for **[**F21mandatory classification**]** and labelling of a substance in **[**F22the 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 **[**F23the 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 **[**F24assessing 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)

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)**

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 844/2012, Article 11.