

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 14*

#### **Renewal [F1 decision]**

[F21 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.]

[F3 1a F4 ...

[F5 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 [F6 assessing competent authority and the other competent authorities] in the form of an updated supplementary dossier including the additional information. The [F7 assessing competent authority] shall, in consultation with F8 ... 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 [F9 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 [F10 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 [F11 assessing competent authority], the applicant may submit to the [F12 assessing 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.

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*Changes to legislation:* There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 844/2012, Article 14. (See end of Document for details)

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The [F<sup>13</sup>assessing competent authority] shall, within 90 days from the date of receipt of the additional information evaluate the information received and [F<sup>14</sup>circulate to the other competent authorities and the applicant] a revised draft renewal assessment report. The [F<sup>15</sup>assessing competent authority] shall conduct a consultation of the revised renewal assessment report with [F<sup>16</sup>the other competent authorities] and the applicant in accordance with Article 12.

The [F<sup>17</sup>assessing competent authority] shall adopt an addendum to the conclusion referred to in paragraph 1, within 120 days from the date of [F<sup>18</sup>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 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 [F<sup>19</sup>assessing competent authority] shall, without delay, inform the applicant [F<sup>20</sup>and 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.]

F<sup>21</sup><sub>2</sub> .....

#### Textual Amendments

- F1** 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)
- F2** 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)
- F3** 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).
- F4** 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)
- F5** 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)
- F6** 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)
- F7** 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)
- F8** 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)

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**Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 844/2012, Article 14. (See end of Document for details)

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- F9** 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)
- F10** 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)
- F11** 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)
- F12** 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)
- F13** 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)
- F14** 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)
- F15** 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)
- F16** 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)
- F17** 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)
- F18** 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)
- F19** 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)
- F20** 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)
- F21** 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, Article 14.