

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

CHAPTER II

ACTIVE SUBSTANCES, SAFENERS, SYNERGISTS AND CO-FORMULANTS

SECTION 1

Active substances

Subsection 2

Approval procedure

Article 12

Conclusion by the [F¹assessing competent authority]

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[F²a) The assessing competent authority must circulate the draft assessment report to the applicant and the other competent authorities at the latest 30 days after its completion. The assessing competent authority may ask the applicant to circulate any updated dossier to the assessing competent authority and the other competent authorities.]

[F³b) The [F⁴assessing competent authority] shall make the draft assessment report available to the public, after giving the applicant two weeks to request, pursuant to Article 63, that certain parts of the draft assessment report be kept confidential.

[F³c) The [F⁵assessing competent authority] shall allow a period of 60 days for the submission of written comments.

2 F⁶ ...

Within 120 days of the end of the period provided for the submission of written comments, the [F⁷assessing competent authority] shall adopt a conclusion in the light of current scientific and technical knowledge using guidance documents available at the time of application on whether the active substance can be expected to meet the approval criteria provided for in Article 4 and shall communicate it to the applicant [F⁸and the other competent authorities,] and shall make it available to the public. [F⁹In the event that independent scientific advice is obtained by the assessing competent authority in accordance with Article 7(5), the 120-day period must be extended by 90 days.]

Where appropriate, the [F¹⁰assessing competent authority] shall address in its conclusion the risk mitigation options identified in the draft assessment report.

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Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1107/2009 of the European Parliament and of the Council, Article 12. (See end of Document for details)

- [^{F11}a)] Where the [^{F12}assessing competent authority] needs additional information, it shall set a period of a maximum of 90 days for the applicant to supply it to the [^{F13}assessing competent authority and the other competent authorities].
- [^{F14}b)] The assessing competent authority must assess the additional information, and for that purpose the period provided for in paragraph 2 may be extended by a maximum of 60 days.]
- [^{F15}c)] The [^{F16}assessing competent authority] may ^{F17}... consult a ^{F18}... reference laboratory, designated pursuant to [^{F19}Regulation (EU) 2017/625] for the purposes of verifying whether the analytical method for the determination of the residues proposed by the applicant is satisfactory and meets the requirements in Article 29(1)(g) of this Regulation. The applicant shall, if requested by the ^{F18}... reference laboratory, provide samples and analytical standards.

4 The conclusion of the [^{F20}assessing competent authority] shall include details concerning the evaluation procedure and the properties of the active substance concerned.

^{F21}5

6 The time [^{F22}limit] for decisions on applications concerning maximum residue levels set out in Article 14 of Regulation (EC) No 396/2005 shall be without prejudice to the time limits laid down in this Regulation.

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Textual Amendments

- F1** Words in Art. 12 heading substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **4(11)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F2** Art. 12(1)(a) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **4(12)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F3** Words in Art. 12(1) renumbered as Art. 12(1)(b)(c) (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **4(12)(b)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**
- F4** Words in Art. 12(1)(b) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **4(12)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F5** Words in Art. 12(1)(c) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **4(12)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F6** Words in Art. 12(2) omitted (31.12.2020) by virtue of [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **4(13)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F7** 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), **4(13)(b)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F8** 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), **4(13)(b)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

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- F9** 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), **4(13)(b)(ii)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**
- F10** 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), **4(13)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F11** Words in Art. 12(3) renumbered as Art. 12(3)(a) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(14)(a)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**
- F12** Words in Art. 12(3)(a) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(14)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F13** Words in Art. 12(3)(a) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(14)(b)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F14** Art. 12(3)(b) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(14)(c)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**
- F15** Words in Art. 12(3) renumbered as Art. 12(3)(c) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(14)(d)**; 2020 c. 1, **Sch. 5 para. 1(1)**
- F16** Words in Art. 12(3)(c) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(14)(e)(i)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**
- F17** Words in Art. 12(3)(c) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(14)(e)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F18** Words in Art. 12(3)(c) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(14)(e)(iii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F19** Words in Art. 12(3)(c) substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1410), regs. 1(3), **2(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F20** 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), **4(15)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F21** Art. 12(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), **4(16)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F22** Word in Art. 12(6) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(17)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F23** Art. 12(7)(8) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(18)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation:

There are currently no known outstanding effects for the Regulation (EC) No 1107/2009 of the European Parliament and of the Council, Article 12.