

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 11*

**Draft assessment report**

1 Within 12 months of the date of the notification provided for in the first subparagraph of Article 9(3), the [F<sup>1</sup>assessing competent authority] shall prepare and submit to the [F<sup>2</sup>other competent authorities] a report, referred to as the ‘draft assessment report’, assessing whether the active substance can be expected to meet the approval criteria provided for in Article 4.

2 The draft assessment report shall also include where relevant, a proposal to set maximum residue levels.

The [F<sup>3</sup>assessing competent authority] shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge.

Where, pursuant to Article 4(1), the assessment establishes that the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are not satisfied, the draft assessment report shall be limited to those parts of the assessment.

3 Where the [F<sup>4</sup>assessing competent authority] needs additional studies or information, it shall set a period in which the applicant must supply those studies or that information. In that case, the 12-month period shall be extended by the additional period granted by the [F<sup>4</sup>assessing competent authority]. The additional period shall be of a maximum of 6 months and shall cease at the moment when the additional information is received by the [F<sup>4</sup>assessing competent authority]. It shall inform the [F<sup>5</sup>other competent authorities] accordingly.

Where at the end of the additional period, the applicant has not submitted the additional studies or information, the [F<sup>6</sup>assessing competent authority] shall inform the applicant [F<sup>7</sup>and the other competent authorities,] and shall state the missing elements in the assessment included 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 11. (See end of Document for details)

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### Textual Amendments

- F1** 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), **4(9)(a)(i)** (with Sch. 1); 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), **4(9)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F3** Words in Art. 11(2) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **4(9)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F4** 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), **4(9)(c)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F5** 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), **4(9)(c)(i)(bb)** (with Sch. 1); 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), **4(9)(c)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F7** 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), **4(9)(c)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F8** Art. 11(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), **4(9)(d)** (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 11.