

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 III

PLANT PROTECTION PRODUCTS

^{F1F1}*SECTION 1*

Authorisation

Subsection 2

Procedure

Article 33

Application for authorisation or amendment of an authorisation

^{F11} An applicant or a representative of the applicant may apply to the competent authority for authorisation to place a plant protection product on the market in a constituent territory.

1A An applicant or a representative of the applicant may apply to the competent authority which granted an authorisation to amend that authorisation.]

2 The application shall include the following:

- a a list of intended uses [^{F2}and the competent authorities to whom] the applicant has made or intends to make an application;
- ^{F3}b
- c where relevant, a copy of any authorisations already granted for that plant protection product [^{F4}by a competent authority];
- d where relevant, a copy of any conclusion of the [^{F5}competent authority] assessing equivalence as referred to in Article 38(2).

3 The application shall be accompanied by the following:

- a for the plant protection product concerned, a complete and a summary dossier for each point of the data requirements of the plant protection product;
- b for each active substance, safener and synergist contained in the plant protection product, a complete and a summary dossier for each point of the data requirements of the active substance, safener and synergist;
- c for each test or study involving vertebrate animals, a justification of the steps taken to avoid animal testing and duplication of tests and studies on vertebrate animals;
- d the reasons why the test and study reports submitted are necessary for first authorisation or for amendments to the conditions of the authorisation;

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- e where relevant a copy of the application for a maximum residue level as referred to in Article 7 of Regulation (EC) No 396/2005 or a justification for not supplying such information;
- f where relevant for an amendment of an authorisation an assessment of all information submitted in accordance with point (h) of Article 8(1);
- g a draft label.

4 When submitting the application, the applicant may pursuant to Article 63, request certain information, including certain parts of the dossier, to be kept confidential and shall physically separate that information.

The applicant shall at the same time submit the complete list of studies submitted pursuant to Article 8(2) and a list of test and study reports for which any claims for data protection pursuant to Article 59 are requested.

Upon a request for access to information the [^{F6}competent authority] examining the application [^{F7}(see Article 35)] shall decide what information is to be kept confidential.

[^{F85} Where permitted by the competent authority, the applicant may submit an application in a language other than English.]

6 On request, the applicant shall provide the [^{F9}competent authority] with samples of the plant protection product and analytical standards of its ingredients.

Textual Amendments

- F1** Art. 33(1)(1A) substituted for Art. 33(1) (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(9)(a)** (with Sch. 1 (as amended by: S.I. 2019/1410, regs. 1(2), **6(9)**; and S.I. 2020/1376, regs. 1(4), **3(21)**)); 2020 c. 1, **Sch. 5 para. 1(1)**
- F2** Words in Art. 33(2)(a) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(9)(b)(i)** (with Sch. 1 (as amended by: S.I. 2019/1410, regs. 1(2), **6(9)**; and S.I. 2020/1376, regs. 1(4), **3(21)**)); 2020 c. 1, **Sch. 5 para. 1(1)**
- F3** Art. 33(2)(b) omitted (31.12.2020) by virtue of [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(9)(b)(ii)** (with Sch. 1 (as amended by: S.I. 2019/1410, regs. 1(2), **6(9)**; and S.I. 2020/1376, regs. 1(4), **3(21)**)); 2020 c. 1, **Sch. 5 para. 1(1)**
- F4** Words in Art. 33(2)(c) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(9)(b)(iii)** (with Sch. 1 (as amended by: S.I. 2019/1410, regs. 1(2), **6(9)**; and S.I. 2020/1376, regs. 1(4), **3(21)**)); 2020 c. 1, **Sch. 5 para. 1(1)**
- F5** Words in Art. 33(2)(d) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(9)(b)(iv)** (with Sch. 1 (as amended by: S.I. 2019/1410, regs. 1(2), **6(9)**; and S.I. 2020/1376, regs. 1(4), **3(21)**)); 2020 c. 1, **Sch. 5 para. 1(1)**
- F6** Words in Art. 33(4) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(9)(c)(i)** (with Sch. 1 (as amended by: S.I. 2019/1410, regs. 1(2), **6(9)**; and S.I. 2020/1376, regs. 1(4), **3(21)**)); 2020 c. 1, **Sch. 5 para. 1(1)**
- F7** Words in Art. 33(4) inserted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(9)(c)(ii)** (with Sch. 1 (as amended by: S.I. 2019/1410, regs. 1(2), **6(9)**; and S.I. 2020/1376, regs. 1(4), **3(21)**)); 2020 c. 1, **Sch. 5 para. 1(1)**

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- F8** Art. 33(5) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(9)(d)** (with Sch. 1 (as amended by: [S.I. 2019/1410](#), regs. 1(2), **6(9)**; and [S.I. 2020/1376](#), regs. 1(4), **3(21)**)); 2020 c. 1, **Sch. 5 para. 1(1)**
- F9** Words in Art. 33(6) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(9)(e)** (with Sch. 1 (as amended by: [S.I. 2019/1410](#), regs. 1(2), **6(9)**; and [S.I. 2020/1376](#), regs. 1(4), **3(21)**)); 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 33.