

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 [F⁶competent 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 [F⁹competent 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)**

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, Subsection 2. (See end of Document for details)

- 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)**

Article 34

Exemption from the submission of studies

1 Applicants shall be exempted from supplying the test and study reports referred to in Article 33(3) where the ^{F10}[competent authority examining the application] has the test and study reports concerned and the applicants demonstrate that they have been granted access in accordance with Article 59, 61 or 62 or that any data protection period has expired ^{F11}[, or where paragraph 3 applies].

2 However, applicants to whom paragraph 1 applies shall provide the following information:

- a all necessary data for the identification of the plant protection product including its complete composition as well as a declaration that ^{F12}[, in respect of each constituent territory to which the application relates,] no unacceptable co-formulants are used;
- b the information needed to identify the active substance, safener or synergist, where they have been approved ^{F13}[in respect of each constituent territory to which the application relates], and to establish whether the conditions for approval are met and comply with point (b) of Article 29(1), where appropriate;
- c on the request of the ^{F14}[competent authority examining the application], the data needed to demonstrate that the plant protection product has comparable effects to the plant protection product for which they show access to the protected data.

^{F153} This paragraph applies where another competent authority has the test and study reports concerned.

4 Where paragraph 3 applies—

- a the competent authority examining the application must request those reports from the competent authority which has those reports, and
- b the competent authority which has those reports must send them to the competent authority examining the application as soon as reasonably practicable.]

Textual Amendments

- F10** Words in Art. 34(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(10)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F11** Words in Art. 34(1) inserted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(10)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F12** Words in Art. 34(2)(a) inserted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(10)(b)(i)** (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, Subsection 2. (See end of Document for details)

- F13** Words in Art. 34(2)(b) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(10)(b)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F14** Words in Art. 34(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(10)(b)(iii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F15** Art. 34(3)(4) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(10)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

[^{F16} Article 35

Competent authority examining the application

1 For the purposes of this Subsection “the competent authority examining the application” is the competent authority which receives the application under Article 33.

2 But a competent authority may examine an application on behalf of one or more of the other competent authorities (and consequently for the purposes of this Subsection is “the competent authority examining the application”) where—

- a each competent authority receives the same application;
- b each competent authority agrees which competent authority is to examine the application;
- c each active substance, safener or synergist in the plant protection product to which the application relates—
 - i) is approved in relation to the constituent territory of each competent authority, and the conditions of each approval are compatible with the proposed authorisation, and
 - ii) has an equivalent technical specification in relation to each constituent territory, where necessary as determined in accordance with Article 38;
- d any co-formulant in the plant protection product to which the application relates is not included on the unacceptable co-formulants register in relation to the constituent territory of each competent authority; and
- e any data requirements specified in regulations made under Article 8(4)(a) and (b), any uniform principles for evaluation and authorisation of plant protection products prescribed in regulations made under Article 29(6)(a) and any guidance relating to those requirements or principles are the same in relation to the constituent territory of each competent authority.

3 Where paragraph 2 applies in relation to an application—

- a the competent authority examining the application must inform the applicant that it is to examine the application;
- b the other competent authorities must —
 - i) not proceed to determine the application pending assessment by the competent authority examining the application;
 - ii) at the request of the competent authority examining the application, cooperate to ensure a fair division of the workload.]

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, Subsection 2. (See end of Document for details)

Textual Amendments

F16 Art. 35 substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(11)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 36

Examination for authorisation

1 The [^{F17}competent authority] examining the application shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge using guidance documents available at the time of application. [^{F18}Where Article 35(2) applies in relation to an application, the competent authority examining the application must give the other competent authorities] the opportunity to submit comments to be considered in the assessment.

It shall apply the uniform principles for evaluation and authorisation of plant protection products, referred to in [^{F19}Article 29(6)(a)], to establish, as far as possible, whether the plant protection product meets the requirements provided for in Article 29^{F20}... , where used in accordance with Article 55, and under realistic conditions of use.

[^{F21}Where Article 35(2) applies in relation to an application, the competent authority examining the application must make available its assessment to the other competent authorities.]

2 [^{F22}Where Article 35(2) applies in relation to an application, the competent authorities which received that application] shall grant or refuse authorisations accordingly on the basis of the conclusions of the assessment of the [^{F23}competent authority] examining the application as provided for in Articles 31 and 32.

3 By way of derogation from paragraph 2 and subject to [^{F24}retained EU] law, appropriate conditions may be imposed with respect to the requirements referred to in Article 31(3) and (4) and other risk mitigation measures deriving from specific conditions of use.

Where the concerns of a [^{F25}competent authority] relating to human or animal health or the environment cannot be controlled by the establishment of the^{F26}... risk mitigation measures referred to in the first subparagraph, [^{F27}that competent authority] may refuse authorisation of the plant protection product in its [^{F28}constituent] territory if, due to its specific environmental or agricultural circumstances, it has substantiated reasons to consider that the product in question still poses an unacceptable risk to human or animal health or the environment.

That [^{F29}competent authority] shall immediately inform the applicant and the [^{F30}other competent authorities] of its decision and provide a technical or scientific justification therefor.

^{F31}
...

Textual Amendments

F17 Words in Art. 36(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(12)(a)(i)(aa)** (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, Subsection 2. (See end of Document for details)

- F18** Words in Art. 36(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(a)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F19** Words in Art. 36(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(a)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F20** Words in Art. 36(1) 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(12)(a)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F21** Words in Art. 36(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(a)(iii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F22** Words in Art. 36(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F23** Words in Art. 36(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(b)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F24** Words in Art. 36(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(c)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F25** Words in Art. 36(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(c)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F26** Word in Art. 36(3) 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(12)(c)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F27** Words in Art. 36(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(c)(ii)(cc)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F28** Word in Art. 36(3) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(c)(ii)(dd)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F29** Words in Art. 36(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(c)(iii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F30** Words in Art. 36(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(12)(c)(iii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F31** Words in Art. 36(3) 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(12)(c)(iv)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 37

Period for examination

1 The [F32 competent authority] examining the application shall decide within 12 months of receiving it whether the requirements for authorisation are met.

Where the [F32 competent authority] needs additional information, it shall set a period for the applicant to supply it. In that case, the 12-month period shall be extended by the

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additional period granted by the [F32competent authority]. That additional period shall be a maximum of 6 months and shall cease at the moment when the additional information is received by the [F32competent authority]. Where at the end of that period the applicant has not submitted the missing elements, the [F32competent authority] shall inform the applicant that the application is inadmissible.

2 The time limits provided for in paragraph 1 shall be suspended during the application of the procedure set out in Article 38.

3 For an application for authorisation of a plant protection product containing an active substance not yet approved, the [F33competent authority] examining the application shall start the evaluation as soon as [F34the draft assessment report for that active substance is circulated in accordance with Article 12(1)(a)]. In case the application concerns the same plant protection product and the same uses as contained in the dossier referred to in Article 8, the [F33competent authority] shall decide on the application at the latest within six months of the active substance being approved.

[F353A Where Article 35(2) applies in relation to an application, the requirement in paragraph 3 to decide on the application within 6 months of the active substance being approved is to be read as a requirement to decide on the application within 6 months of the earliest date on which the active substance is approved by one of the competent authorities which received the application for authorisation.]

4 [F36Where Article 35(2) applies in relation to an application, the competent authorities which received the application for authorisation] shall at the latest within 120 days of the receipt of the assessment report and the copy of the authorisation of the [F37competent authority] examining the application decide on the application as referred to in Article 36(2) and (3).

Textual Amendments

- F32** Words in Art. 37(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(13)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F33** Words in Art. 37(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(13)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F34** Words in Art. 37(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(13)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F35** Art. 37(3A) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(13)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F36** Words in Art. 37(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(13)(d)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F37** Words in Art. 37(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(13)(d)(ii)** (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, Subsection 2. (See end of Document for details)

^{F38}Article 38

Assessment of equivalence under Article 29(1)(b)

1 This Article applies where it is necessary in relation to an application to establish for an active substance, safener or synergist whether a different source or, for the same source a change of the manufacturing process or location complies with Article 29(1)(b).

1A Where this Article applies, equivalence—

- a may be assessed by a competent authority examining the application, where—
 - i) each of the other competent authorities examining the application consents to that competent authority assessing equivalence, and
 - ii) in relation to the active substance, safener or synergist for which equivalence is to be assessed, any data requirements specified in regulations made under Article 8(4)(a) and (b), any uniform principles for evaluation and authorisation of plant protection products prescribed in regulations made under Article 29(6) (a) and any guidance issued under Article 77 relating to those requirements or principles are the same in relation to the constituent territory of each competent authority examining the application;
- b otherwise, must be assessed by each competent authority examining the application.

1B The applicant must submit all necessary data to each competent authority assessing equivalence.

2 A competent authority assessing equivalence must—

- a give the applicant the opportunity to submit comments,
- b prepare a report on the competent authority's conclusion on equivalence within 60 days from receiving the application, and
- c provide a copy of that report to—
 - i) the applicant, and
 - ii) where the assessment is undertaken in accordance with paragraph 1A(a), the other competent authorities examining the application.

3 Where an assessment is undertaken in accordance with paragraph 1A(a), a competent authority examining the application which does not agree with the conclusion in the report provided in accordance with paragraph 2(c)(ii) must notify the competent authority which assessed equivalence, the other competent authorities examining the application and the applicant, stating its reasons for not agreeing.

3A Following a notification under paragraph 3, the competent authorities concerned must—

- a give the applicant the opportunity to submit comments, and
- b try to reach agreement on whether Article 29(1)(b) is complied with.

4 Article 29(1)(b) is deemed not to be complied with where the competent authorities concerned under paragraph 3A do not reach agreement within 45 days of the latest date on which a notification from a competent authority is communicated in accordance with paragraph 3.]

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, Subsection 2. (See end of Document for details)

Textual Amendments

F38 Art. 38 substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(14)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 39

Reporting and exchange of information on applications for authorisation

1 ^{F39}A competent authority] shall compile a file on each application ^{F40}it receives]. Each file shall contain the following:

- a a copy of the application;
- b a report containing information on the evaluation of and decision on the plant protection product; ^{F41}...
- c a record of the administrative decisions taken by the ^{F42}competent authority] concerning the application and of the documentation provided for in Article 33(3) and Article 34 together with a summary of the latter;
- d the approved label, where applicable.

2 On request, ^{F43}a competent authority] shall, without delay, make available to the other ^{F44}competent authorities] a file containing the documentation provided for in points (a) to (d) of paragraph 1.

3 On request, applicants shall provide a copy of the documentation to be submitted with an application pursuant to Article 33(3) and Article 34 to ^{F45}the competent authorities].

^{F46}4

Textual Amendments

F39 Words in Art. 39(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(15)(a)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F40 Words in Art. 39(1) inserted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(15)(a)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F41 Words in Art. 39(1)(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(15)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F42 Words in Art. 39(1)(c) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(15)(a)(iii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F43 Words in Art. 39(2) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(15)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F44 Words in Art. 39(2) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(15)(b)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F45 Words in Art. 39(3) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(15)(c)** (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, Subsection 2. (See end of Document for details)

F46 Art. 39(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), **5(15)(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, Subsection 2.