

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

^{F1F2}SECTION 1

Authorisation

Subsection 1

Requirements and contents

Article 28

Authorisation for placing on the market and use

1 A plant protection product shall not be placed on the market or used [^{F3}in a constituent territory] unless it has been authorised [^{F4}by the relevant competent authority] in accordance with this Regulation.

2 By way of derogation from paragraph 1, no authorisation shall be required in the following cases:

- a use of products containing exclusively one or more basic substances;
- b placing on the market and use of plant protection products for research or development purposes in accordance with Article 54;
- c production, storage or movement of a plant protection product intended for use in [^{F5}the constituent territory of another competent authority], provided that the product is authorised [^{F6}by that other competent authority for that constituent territory];
- d production, storage or movement of a plant protection product intended for use [^{F7}outside Great Britain] provided that [^{F8}there are inspection requirements in place] to ensure that the plant protection product is exported from [^{F9}the United Kingdom or, where the product is intended for use in Northern Ireland, is transported to Northern Ireland];
- e placing on the market and use of plant protection products for which a parallel trade permit [^{F10}is in force] in accordance with [^{F11}Article 52A and, for these purposes, a plant protection product subject to a grace period granted in accordance with Article 46 (as applied by Article 52A) is to be treated as though it were a product for which a parallel trade permit is in force].

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, CHAPTER III. (See end of Document for details)

Textual Amendments

- F3** Words in Art. 28(1) inserted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(2)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F4** Words in Art. 28(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(2)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F5** Words in Art. 28(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(2)(b)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F6** Words in Art. 28(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(2)(b)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F7** Words in Art. 28(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(2)(b)(ii)(aa)** (with Sch. 1) (as amended by [S.I. 2020/1376](#), regs. 1(4), 3(5)(a)(i)); 2020 c. 1, Sch. 5 para. 1(1)
- F8** Words in Art. 28(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(2)(b)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F9** Words in Art. 28(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(2)(b)(ii)(cc)** (with Sch. 1) (as amended by [S.I. 2020/1376](#), regs. 1(4), 3(5)(a)(ii)); 2020 c. 1, Sch. 5 para. 1(1)
- F10** Words in Art. 28(2)(e) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(2)(b)(iii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F11** Words in Art. 28(2)(e) substituted (31.12.2023) by [The Plant Protection Products \(Miscellaneous Amendments\) Regulations 2023 \(S.I. 2023/1321\)](#), regs. 1(2), **4(2)** (with reg. 5)

Article 29

Requirements for the authorisation for placing on the market

1 Without prejudice to Article 50 a plant protection product shall only be authorised where following the uniform principles referred to in paragraph 6 [^{F12}for the constituent territory of authorisation] it complies with the following requirements:

- a its active substances, safeners and synergists [^{F13}are approved in the constituent territory of authorisation, and approval is not suspended in accordance with Article 69];
- b where its active substance, safener or synergist is produced by a different source, or by the same source with a change in the manufacturing process and/or manufacturing location:
 - (i) the specification, pursuant to Article 38, does not deviate significantly from the specification [^{F14}of that substance, safener or synergist as approved in the constituent territory of authorisation]; and
 - (ii) the active substance, safener or synergist has no more harmful effects within the meaning of Article 4(2) and (3) due to its impurities than if it had been produced in accordance with the manufacturing process specified in the dossier that supported the approval;

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, CHAPTER III. (See end of Document for details)

- c its co-formulants are not included [^{F15}on the unacceptable co-formulants register in relation to the constituent territory of authorisation];
- d its technical formulation is such that user exposure or other risks are limited as much as possible without compromising the functioning of the product;
- e in the light of current scientific and technical knowledge, it complies with the requirements provided for in Article 4(3);
- f the nature and quantity of its active substances, safeners and synergists and, where appropriate, any toxicologically, ecotoxicologically or environmentally relevant impurities and co-formulants can be determined by appropriate methods;
- g its residues, resulting from authorised uses, and which are of toxicological, ecotoxicological or environmental relevance, can be determined by appropriate methods in general use in [^{F16}Great Britain], with appropriate limits of determination on relevant samples;
- h its physical and chemical properties have been determined and deemed acceptable for the purposes of the appropriate use and storage of the product;
- i for plants or plant products to be used as feed or food, where appropriate, the maximum residue levels for the agricultural products affected by the use referred to in the authorisation have been set or modified [^{F17}in relation to the constituent territory of authorisation] in accordance with Regulation (EC) No 396/2005.

2 The applicant shall demonstrate that the requirements provided for in points (a) to (h) of paragraph 1 are met.

3 Compliance with the requirements set out in point (b) and points (e) to (h) of paragraph 1 shall be established by official or officially recognised tests and analyses carried out under agricultural, plant health and environmental conditions relevant to the use of the plant protection product in question and representative of the conditions prevailing in the [^{F18}areas of Great Britain] where the product is intended to be used.

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[^{F20}a) The appropriate authority may, by regulations, prescribe uniform principles for the evaluation and authorisation of plant protection products.]

[^{F21}b)] Following these principles, interaction between the active substance, safeners, synergists and co-formulants shall be taken into account in the evaluation of plant protection products.

Textual Amendments

- F12** Words in Art. 29(1) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(3)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F13** Words in Art. 29(1)(a) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(3)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F14** Words in Art. 29(1)(b)(i) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(3)(a)(iii)** (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, CHAPTER III. (See end of Document for details)

- F15** Words in Art. 29(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(3)(a)(iv)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F16** Words in Art. 29(1)(g) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(3)(a)(v)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(5)(b)); 2020 c. 1, Sch. 5 para. 1(1)
- F17** Words in Art. 29(1)(i) inserted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(3)(a)(vi)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F18** Words in Art. 29(3) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(3)(b)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(5)(b)); 2020 c. 1, Sch. 5 para. 1(1)
- F19** Art. 29(4)(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), **5(3)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F20** Art. 29(6)(a) substituted for words in Art. 29(6) (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(3)(d)(i)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**
- F21** Words in Art. 29(6) renumbered as Art. 29(6)(b) (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(3)(d)(ii)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

Article 30

Provisional authorisations

1 By way of derogation from Article 29(1)(a), Member States may authorise for a provisional period not exceeding 3 years, the placing on the market of plant protection products containing an active substance not yet approved, provided that:

- a the decision on approval could not be finalised within a period of 30 months from the date of admissibility of the application, extended by any additional period set in accordance with Article 9(2), Article 11(3) or Article 12(2) or (3); and
- b pursuant to Article 9 the dossier on the active substance is admissible in relation to the proposed uses; and
- c the Member State concludes that the active substance can satisfy the requirements of Article 4(2) and (3) and that the plant protection product may be expected to satisfy the requirements of Article 29(1)(b) to (h); and
- d maximum residue levels have been established in accordance with Regulation (EC) No 396/2005.

2 In such cases the Member State shall immediately inform the other Member States and the Commission of its assessment of the dossier and of the terms of the authorisation, giving at least the information provided for in Article 57(1).

3 The provisions laid down in paragraphs 1 and 2 shall apply until 14 June 2016. If necessary, that time limit may be extended in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

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, CHAPTER III. (See end of Document for details)

Article 31

Contents of authorisations

1 The authorisation shall define plants or plant products and non-agricultural areas (for example railways, public areas, storage rooms) on which and the purposes for which the plant protection product may be used.

2 The authorisation shall set out the requirements relating to the placing on the market and use of the plant protection product. Those requirements shall as a minimum include the conditions of use necessary to comply with the conditions and requirements provided for in the [F22approval of] the active substances, safeners and synergists [F23in the constituent territory of authorisation].

The authorisation shall include a classification of the plant protection product for the purpose of [F24Regulation (EC) No 1272/2008 of the European Parliament and of the Council]. [F25A competent authority] may provide that authorisation holders shall classify or update the label without undue delay following any change to the classification and labelling of the plant protection product in accordance with [F26Regulation (EC) No 1272/2008 of the European Parliament and of the Council]. In such cases, they shall immediately inform the competent authority thereof.

3 The requirements referred to in paragraph 2 shall also include where applicable:

- a the maximum dose per hectare in each application;
- b the period between the last application and harvest;
- c the maximum number of applications per year.

4 The requirements referred to in paragraph 2 may include the following:

- a a restriction with respect to the distribution and use of the plant protection product in order to protect the health of the distributors, users, bystanders, residents, consumers or workers concerned or the environment, taking into consideration requirements imposed by other [F27retained EU law]; such restriction shall be indicated on the label;
- b the obligation before the product is used to inform any neighbours who could be exposed to the spray drift and who have requested to be informed;
- c indications for proper use according to the principles of Integrated Pest Management referred to in Article 14 of and Annex III to Directive 2009/128/EC;
- d designation of categories of users, such as professional and non-professional;
- e the approved label;
- f the interval between applications;
- g the period between the last application and consumption of the plant product where applicable;
- h the re-entry interval;
- i the packaging size and material.

[F285 For the purposes of paragraph 4(c), Directive 2009/128/EC is to be read as if—

- a Article 3(10)(b) were omitted;
- b in Article 14—
 - i) obligations on Member States were obligations on the competent authorities;
 - ii) paragraph 3 were omitted.]

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, CHAPTER III. (See end of Document for details)

Textual Amendments

- F22** Words in Art. 31(2) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(5)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F23** Words in Art. 31(2) inserted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(5)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F24** Words in Art. 31(2) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(5)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F25** Words in Art. 31(2) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(5)(b)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F26** Words in Art. 31(2) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(5)(b)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F27** Words in Art. 31(4)(a) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(6)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F28** Art. 31(5) inserted by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(7)** (with Sch 1) (as substituted by S.I. 2019/1410, regs. 1(2), **6(2)(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Article 32

Duration

1 The period of authorisation shall be laid down in the authorisation.

Without prejudice to Article 44, the duration of an authorisation shall be set for a period not exceeding 1 year from the date of expiry of the approval [^{F29}in the constituent territory of authorisation] of the active substances, safeners and synergists contained in the plant protection product and thereafter for as long as the active substances, safeners and synergists contained in the plant protection product are approved [^{F30}in the constituent territory of authorisation].

This period shall allow the examination as provided for in Article 43 to be carried out.

2 Authorisations may be granted for shorter periods to synchronise the re-evaluation of similar products for the purposes of a comparative assessment of products containing candidates for substitution as provided for in Article 50.

Textual Amendments

- F29** Words in Art. 32(1) inserted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(8)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F30** Words in Art. 32(1) inserted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(8)(b)** (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, CHAPTER III. (See end of Document for details)

Subsection 2

Procedure

Article 33

Application for authorisation or amendment of an authorisation

^{F31}1 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 ^{F32}and the competent authorities to whom] the applicant has made or intends to make an application;

^{F33}b

c where relevant, a copy of any authorisations already granted for that plant protection product ^{F34}by a competent authority];

d where relevant, a copy of any conclusion of the ^{F35}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;

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 ^{F36}competent authority] examining the application ^{F37}(see Article 35)] shall decide what information is to be kept confidential.

^{F385} Where permitted by the competent authority, the applicant may submit an application in a language other than English.]

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, CHAPTER III. (See end of Document for details)

6 On request, the applicant shall provide the [^{F39}competent authority] with samples of the plant protection product and analytical standards of its ingredients.

Textual Amendments

- F31** 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)**
- F32** 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)**
- F33** 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)**
- F34** 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)**
- F35** 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)**
- F36** 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)**
- F37** 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)**
- F38** 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)**
- F39** 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 [^{F40}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 [^{F41}, or where paragraph 3 applies].

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, CHAPTER III. (See end of Document for details)

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 [^{F42}, 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 [^{F43} 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 [^{F44} 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.

[^{F45} 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

- F40** 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)
- F41** 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)
- F42** 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)
- F43** 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)
- F44** 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)
- F45** 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)

[^{F46} 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.

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, CHAPTER III. (See end of Document for details)

- 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.]

Textual Amendments

F46 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 [^{F47}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. [^{F48}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 [^{F49}Article 29(6)(a)], to establish, as far as possible, whether the plant protection product meets the requirements provided for in Article 29^{F50} ... , where used in accordance with Article 55, and under realistic conditions of use.

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, CHAPTER III. (See end of Document for details)

[^{F51}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 [^{F52}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 [^{F53}competent authority] examining the application as provided for in Articles 31 and 32.

3 By way of derogation from paragraph 2 and subject to [^{F54}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 [^{F55}competent authority] relating to human or animal health or the environment cannot be controlled by the establishment of the [^{F56}... risk mitigation measures referred to in the first subparagraph, [^{F57}that competent authority] may refuse authorisation of the plant protection product in its [^{F58}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 [^{F59}competent authority] shall immediately inform the applicant and the [^{F60}other competent authorities] of its decision and provide a technical or scientific justification therefor.

F61
...

Textual Amendments

- F47** 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)
- F48** 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)
- F49** 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)
- F50** 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)
- F51** 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)
- F52** 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)
- F53** 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)
- F54** 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)

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, CHAPTER III. (See end of Document for details)

- F55** 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)
- F56** 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)
- F57** 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)
- F58** 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)
- F59** 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)
- F60** 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)
- F61** 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 [F62]competent authority] examining the application shall decide within 12 months of receiving it whether the requirements for authorisation are met.

Where the [F62]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 additional period granted by the [F62]competent 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 [F62]competent authority]. Where at the end of that period the applicant has not submitted the missing elements, the [F62]competent 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 [F63]competent authority] examining the application shall start the evaluation as soon as [F64]the 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 [F63]competent authority] shall decide on the application at the latest within six months of the active substance being approved.

[F65]3A 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.]

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, CHAPTER III. (See end of Document for details)

4 [F66 Where 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 [F67 competent authority] examining the application decide on the application as referred to in Article 36(2) and (3).

Textual Amendments

- F62** 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)
- F63** 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)
- F64** 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)
- F65** 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)
- F66** 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)
- F67** 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)

[F68 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,

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, CHAPTER III. (See end of Document for details)

- 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.]

Textual Amendments

F68 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 [^{F69}A competent authority] shall compile a file on each application [^{F70}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; ^{F71}...
- c a record of the administrative decisions taken by the [^{F72}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, [^{F73}a competent authority] shall, without delay, make available to the other [^{F74}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 [^{F75}the competent authorities].

^{F76}4

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, CHAPTER III. (See end of Document for details)

Textual Amendments

- F69** 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)
- F70** 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)
- F71** 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)
- F72** 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)
- F73** 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)
- F74** 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)
- F75** 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)
- F76** 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)

Subsection 3

[^{F1}Ongoing applications for] mutual recognition of authorisations

^{F77}Article 40

Mutual recognition

Textual Amendments

- F77** Art. 40 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(16)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

^{F78}Article 40A

Application and interpretation

- 1 This Subsection applies where—

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, CHAPTER III. (See end of Document for details)

- a before IP completion day the holder of an authorisation of a plant protection product granted by a member State or EEA state in accordance with Article 29 as it had effect immediately before IP completion day had applied for—
 - i) authorisation of the same product in the United Kingdom in accordance with Article 40 as it had effect immediately before IP completion day, or
 - ii) authorisation of the same product for minor uses in accordance with Articles 40 and 51(7) as those Articles had effect immediately before IP completion day, and
 - b immediately before IP completion day that application had not been determined.
- 2 In this Subsection—
- a a reference to an Article as it had effect immediately before IP completion day in relation to an EEA state is a reference to that Article as adapted by the EEA Agreement as it had effect immediately before IP completion day;
 - b “reference state” means the member State or EEA state referred to in paragraph 1(a).]

Textual Amendments

- F78** Art. 40A inserted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(16)(c)** (with Sch. 1) (as amended by [S.I. 2020/1376](#), regs. 1(4), 3(5)(c)); 2020 c. 1, Sch. 5 para. 1(1)

Article 41

Authorisation

1 The [^{F79}competent authority] to which an application under Article 40 [^{F80}as it had effect immediately before IP completion day] is submitted shall, having examined the application and the accompanying documents referred to in Article 42(1), as appropriate with regard to the circumstances in its territory, authorise the plant protection product concerned under the same conditions as the [^{F81}reference state], except where Article 36(3) applies.

[^{F82}1A But where the application was for authorisation of minor uses in accordance with Article 51(7) as it had effect immediately before IP completion day, the competent authority must authorise such uses, except where—

- a Article 36(3) applies, or
- b the competent authority considers that those uses are not minor.]

2 By way of derogation from [^{F83}paragraphs 1 and 1A, the competent authority] may authorise the plant protection product where:

- a an authorisation under point (b) of Article 40(1) [^{F84}as it had effect immediately before IP completion day] was applied for;
- b it contains a candidate of substitution; [^{F85}or]
- c Article 30 has been applied; or

^{F86}d

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, CHAPTER III. (See end of Document for details)

Textual Amendments

- F79** Words in Art. 41(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(16)(d)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F80** Words in Art. 41(1) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(16)(d)(i)(bb)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(5)(d)); 2020 c. 1, Sch. 5 para. 1(1)
- F81** Words in Art. 41(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(16)(d)(i)(cc)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F82** Art. 41(1A) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(16)(d)(ii)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(5)(d)); 2020 c. 1, Sch. 5 para. 1(1)
- F83** Words in Art. 41(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(16)(d)(iii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F84** Words in Art. 41(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(16)(d)(iii)(bb)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(5)(d)); 2020 c. 1, Sch. 5 para. 1(1)
- F85** Word in Art. 41(2) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(16)(d)(iii)(cc)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F86** Art. 41(2)(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), **5(16)(d)(iii)(dd)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 42

Procedure

- 1 The application shall be accompanied by the following:
 - a a copy of the authorisation granted by the reference [F87state] as well as a translation of the authorisation into [F88English or another language permitted by the competent authority];
 - b a formal statement that the plant protection product is identical to that authorised by the reference [F89state];
 - c a complete or summary dossier as required in Article 33(3) [F90as it had effect immediately before IP completion day, when requested by the competent authority];
 - d an assessment report of the reference [F91state] containing information on the evaluation and decision on the plant protection product.
 - 2 The [F92competent authority] to which [F93the application] is submitted shall decide on the application within 120 days.
- [F943 Where permitted by the competent authority, the applicant may submit an application in a language other than English.]

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, CHAPTER III. (See end of Document for details)

Textual Amendments

- F87** Word in Art. 42(1)(a) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(18)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F88** Words in Art. 42(1)(a) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(18)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F89** Word in Art. 42(1)(b) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(18)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F90** Words in Art. 42(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(18)(c)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(5)(e)); 2020 c. 1, Sch. 5 para. 1(1)
- F91** Word in Art. 42(1)(d) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(18)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F92** Words in Art. 42(2) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(19)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F93** Words in Art. 42(2) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(19)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F94** Art. 42(3) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(20)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

[^{F2}Subsection 3A

Mutual recognition of authorisations within Great Britain

Article 42A

Mutual recognition

1 This Subsection applies where a plant protection product has been authorised by a competent authority in accordance with Article 29 (the “reference competent authority”).

2 The following persons may apply for an authorisation for the same plant protection product, the same use and under comparable agricultural practices within the constituent territory of another competent authority—

- a the holder of the authorisation granted by the reference competent authority;
- b an official or scientific body involved in agricultural activities or a professional agricultural organisation—
 - i) with the consent of the authorisation holder, or
 - ii) where consent is refused, with the consent of the competent authority to which the application is made on the grounds of public interest.

3 An applicant under paragraph 2(b) must demonstrate that the use of such a plant protection product is of general interest within the constituent territory of the competent authority.

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, CHAPTER III. (See end of Document for details)

- 4 An application may not be made under paragraph 2 where—
- a the plant protection product contains an active substance, safener, synergist, low-risk active substance, basic substance or candidate for substitution which is not approved in relation to the constituent territory of the other competent authority;
 - b the plant protection product contains an active substance, safener, synergist, low-risk active substance, basic substance or candidate for substitution which is approved in relation to the constituent territory of the other competent authority, but—
 - i) the conditions of that approval are incompatible with the product to which the application relates, or
 - ii) the technical specification relating to that approval is not equivalent to the technical specification of the approval of the same substance, safener, synergist or candidate in relation to the constituent territory of the reference competent authority, where necessary as determined in accordance with Article 38;
 - b the plant protection product contains a co-formulant which is entered on the unacceptable co-formulants register in relation to the constituent territory of the other competent authority; or
 - c the relevant data requirements specified in regulations made under Article 8(4)(a) and (b), the relevant uniform principles for evaluation and authorisation of plant protection products prescribed in regulations made under Article 29(6)(a) or any guidance issued under Article 77 relating to those requirements or principles are not the same in relation to the constituent territory of each competent authority.

Article 42B

Authorisation

- 1 The competent authority to which an application under Article 42A(2) is submitted, having examined the application and the accompanying documents referred to in Article 42C(1), and as appropriate with regards to the circumstances in its constituent territory, must authorise the plant protection product concerned under the same conditions as the reference competent authority, except in accordance with paragraph 2 or 3.
- 2 The competent authority may authorise the plant protection product where it contains a candidate for substitution or a substance approved in accordance with Article 4(7).
- 3 Paragraphs 1 and 2 do not apply where Article 36(3) applies.

Article 42C

Procedure

- 1 An application under Article 42A must be accompanied by the following—
- a a copy of the authorisation granted by the reference competent authority;
 - b a formal statement that the plant protection product is identical to that authorised by the reference competent authority;
 - c a complete or summary dossier as required in Article 33(3) when requested by the competent authority;
 - d an assessment report of the reference competent authority containing information on the evaluation and decision on the plant protection product.

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2 The competent authority to which an application under Article 42A is submitted must decide on the application within 120 days.]

Subsection 4

Renewal, withdrawal and amendment

Article 43

Renewal of authorisation

1 An authorisation shall be renewed upon application by the authorisation holder, provided that the requirements referred to in Article 29 are still met.

2 Within 3 months from the renewal of the approval [^{F95}in relation to a constituent territory] of an active substance, safener or synergist contained in the plant protection product [^{F96}authorised in that constituent territory], the applicant shall submit the following information [^{F97}to the competent authority for that constituent territory]:

- a a copy of the authorisation of the plant protection product;
- b any new information required as a result of amendments in data requirements or criteria;
- c evidence that the new data submitted are the result of data requirements or criteria which were not in force when the authorisation of the plant protection product was granted or necessary to amend the conditions of approval;
- d any information required to demonstrate that the plant protection product meets the requirements set [^{F98}by the competent authority] on the renewal of the approval of the active substance, safener or synergist contained therein;
- e a report on the monitoring information, where the authorisation was subject to monitoring.

3

[^{F99}a] [^{F100}The competent authority examining the application] shall check compliance of all plant protection products containing the active substance, safener or synergist concerned with any conditions and restrictions provided for [^{F101}on renewal of the approval of the active substance, safener or synergist].

[^{F102}b] The competent authority which examined the plant protection product application in accordance with Article 35(2) may coordinate the compliance check and assessment of the information submitted for all competent authorities which receive an application for renewal of authorisation for the same product, provided that the conditions in Article 35(2) apply in relation to the renewal application.]

^{F103}4

.....

5 [^{F104}The competent authority examining the application] shall decide on the renewal of the authorisation of a plant protection product at the latest 12 months after the renewal of the approval of the active substance, safener or synergist contained therein.

6 Where, for reasons beyond the control of the holder of the authorisation, no decision is taken on the renewal of the authorisation before its expiry, the [^{F105}competent authority examining the application] shall extend the authorisation for the period necessary to complete the examination and adopt a decision on the renewal.

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, CHAPTER III. (See end of Document for details)

Textual Amendments

- F95** Words in Art. 43(2) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(22)(a)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F96** Words in Art. 43(2) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(22)(a)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F97** Words in Art. 43(2) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(22)(a)(i)(cc)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F98** Words in Art. 43(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(22)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F99** Words in Art. 43(3) renumbered as Art. 43(3)(a) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(22)(b)(i)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**
- F100** Words in Art. 43(3)(a) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(22)(b)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F101** Words in Art. 43(3)(a) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(22)(b)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F102** Art. 43(3)(b) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(22)(b)(iii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F103** Art. 43(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(22)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F104** Words in Art. 43(5) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(22)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F105** Words in Art. 43(6) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(22)(e)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 44

Withdrawal or amendment of an authorisation

1 [F106A competent authority] may review an authorisation at any time where there are indications that a requirement referred to in Article 29 is no longer satisfied.

A [F107competent authority] shall review an authorisation where it concludes that the [F108environmental objectives of a river basin district] may not be achieved.

2 Where a [F109competent authority] intends to withdraw or amend an authorisation, it shall inform the authorisation holder and give him the possibility to submit comments or further information.

3 The [F110competent authority] shall withdraw or amend the authorisation, as appropriate, where:

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- a the requirements referred to in Article 29 are not or are no longer satisfied;
- b false or misleading information was supplied concerning the facts on the basis of which the authorisation was granted;
- c a condition included in the authorisation has not been met;
- d on the basis of developments in scientific and technical knowledge, the manner of use and amounts used can be modified; or
- e the authorisation holder fails to comply with the obligations resulting from this Regulation.

4 Where a ^[F111]competent authority] withdraws or amends an authorisation in accordance with paragraph 3, it shall immediately inform the holder of the authorisation ^[F112]and the other competent authorities]. The other ^[F113]competent authorities may] withdraw or amend the authorisation accordingly taking into account ^[F114]conditions in its constituent territory] and risk mitigation measures except for cases where the second ^[F115]or third] subparagraphs of Article 36(3) have been applied. Article 46 shall apply where appropriate.

^[F1165] In paragraph 1, “environmental objectives”—

- a in relation to the Northumbria River Basin District, means the objectives referred to in the WFD Regulations as applied by regulation 5 of the Water Environment (Water Framework Directive) (Northumbria River Basin District) Regulations 2003;
- b in relation to the Solway Tweed River Basin District, means the objectives as defined in regulation 2 of the Water Environment (Water Framework Directive) (Solway Tweed River Basin District) Regulations 2004;
- c in relation to any other river basin district, within the meaning of the WFD Regulations, has the same meaning as in those regulations;
- d in relation to a river basin district in Scotland, means the objectives set under section 9(1)(a)(i) of the Water Environment and Water Services (Scotland) Act 2003.

6 In paragraph 4, the “conditions” in the constituent territory of a competent authority include—

- a any data requirements specified in regulations made under Article 8(4)(a) or (b) in relation to that constituent territory;
- b any uniform principles prescribed by regulations made under Article 29(6)(a) in relation to that constituent territory;
- c any guidance issued under Article 77 in relation to that constituent territory.

7 In this Article—

- a “river basin district” means any of the following—
 - i) the Northumbria River Basin District;
 - ii) the Solway Tweed River Basin District;
 - iii) a river basin district within the meaning of the WFD Regulations;
 - iv) in relation to Scotland, an area designated as a river basin district by order under section 4(1) of the Water Environment and Water Services (Scotland) Act 2003;
- b “the WFD Regulations” means the Water Environment (Water Framework Directive) (England and Wales) Regulations 2017.]

Textual Amendments

F106 Words in [Art. 44\(1\)](#) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(23)(a)(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, CHAPTER III. (See end of Document for details)

- F107** Words in Art. 44(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(23)(a)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F108** Words in Art. 44(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(23)(a)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F109** Words in Art. 44(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(23)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F110** Words in Art. 44(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(23)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F111** Words in Art. 44(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(23)(c)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F112** Words in Art. 44(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(23)(c)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F113** Words in Art. 44(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(23)(c)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F114** Words in Art. 44(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(23)(c)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F115** Words in Art. 44(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(23)(c)(ii)(cc)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F116** Art. 44(5)-(7) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(23)(d)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), **3(5)(g)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Article 45

Withdrawal or amendment of an authorisation at the request of the authorisation holder

- 1 An authorisation may be withdrawn or amended at the request of the holder of the authorisation, who shall state the reasons for his request.
- 2 Amendments may only be granted where it is established that the requirements referred to in Article 29 continue to be met.
- 3 Article 46 shall apply where appropriate.

Article 46

Grace period

Where a [^{F117}competent authority] withdraws or amends an authorisation or does not renew it, it may grant a grace period for the disposal, storage, placing on the market and use of existing stocks.

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, CHAPTER III. (See end of Document for details)

Where the reasons for withdrawal, amendment or non-renewal of the authorisation are not related to the protection of human and animal health or the environment, the grace period shall be limited and shall not exceed 6 months for the sale and the distribution and an additional maximum of 1 year for the disposal, storage, and use of existing stocks of the plant protection products concerned.

Textual Amendments

F117 Words in Art. 46 substituted (31.12.2020) by [The Environment \(Miscellaneous Amendments and Revocations\) \(EU Exit\) Regulations 2019 \(S.I. 2019/559\)](#), regs. 1(3), 9; 2020 c. 1, Sch. 5 para. 1(1)

Subsection 5

Special cases

Article 47

Placing on the market of low-risk plant protection products

1 Where all the active substances contained in a plant protection product are low-risk active substances as referred to in Article 22, that product shall be authorised as a low-risk plant protection product provided no specific risk mitigation measures are needed following a risk assessment. This plant protection product shall also meet the following requirements:

- a the low-risk active substances, safeners and synergists contained in it have been approved under Chapter II [F118; in relation to the constituent territory of application];
- b it does not contain a substance of concern;
- c it is sufficiently effective;
- d it does not cause unnecessary pain and suffering to vertebrates to be controlled;
- e it complies with points (b), (c) and (f) to (i) of Article 29(1).

These products are referred to as ‘low-risk plant protection products’.

2 An applicant for authorisation of a low-risk plant protection product shall demonstrate that the requirements set out in paragraph 1 are met and shall submit with the application a complete and a summary dossier for each point of the data requirements of the active substance and the plant protection product.

3 [F119; A competent authority] shall decide within 120 days whether to approve an application for authorisation of a low-risk plant protection product.

Where the [F120; competent authority] needs additional information, it shall set a time limit for the applicant to supply it. In that case, the period specified shall be extended by the additional time limit granted by the [F120; 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 [F120; competent authority]. Where at the end of that period the applicant has not submitted the missing elements, the [F120; competent authority] shall inform the applicant that the application is inadmissible.

4 Unless otherwise specified, all provisions relating to authorisations under this Regulation shall apply.

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, CHAPTER III. (See end of Document for details)

Textual Amendments

- F118** Words in Art. 47(1)(a) inserted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(25)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F119** Words in Art. 47(3) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(25)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F120** Words in Art. 47(3) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(25)(b)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 48

Placing on the market and use of plant protection products containing a genetically modified organism

1 A plant protection product which contains [^{F121}a genetically modified organism] shall be examined in respect of the genetic modification in accordance with [^{F122}the examination legislation], in addition to the assessment under this Chapter.

An authorisation under this Regulation shall not be granted for such a plant protection product unless written consent [^{F123}to market the genetically modified organism under section 111(1) of the Environmental Protection Act 1990] has been granted for it.

2 Unless otherwise specified, all provisions relating to authorisations under this Regulation shall apply.

[^{F124}3 In paragraph 1, “the examination legislation” means—

- a in relation to England, regulation 23(1)(c) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002;
- b in relation to Wales, regulation 24(1)(c) of the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002;
- c in relation to Scotland, regulation 23(1)(c) of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002.]

Textual Amendments

- F121** Words in Art. 48(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(26)(a)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F122** Words in Art. 48(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(26)(a)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F123** Words in Art. 48(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(26)(a)(ii)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(5)(h)(i)); 2020 c. 1, Sch. 5 para. 1(1)
- F124** Art. 48(3) inserted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(26)(b)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(5)(h)(ii)); 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, CHAPTER III. (See end of Document for details)

Article 49

Placing on the market of treated seeds

1 ^{F125}A competent authority] shall not prohibit placing on the market and use of seeds treated with plant protection products authorised for that use ^{F126}by at least one competent authority].

^{F127}2 The appropriate authority may, by regulations, implement measures to restrict or prohibit the use or sale of treated seeds as referred to in paragraph 1 where the appropriate authority has substantial concerns that—

- a the treated seeds are likely to constitute a serious risk to human or animal health or to the environment, and
- b such risk cannot be contained satisfactorily by measures taken by the competent authorities concerned.

2A Before making regulations in accordance with paragraph 2, the appropriate authority may obtain independent scientific advice where the appropriate authority considers it appropriate to do so.]

^{F128}3

4 Without prejudice to other ^{F129}retained EU law] concerning the labelling of seeds, the label and documents accompanying the treated seeds shall include the name of the plant protection product with which the seeds were treated, the name(s) of the active substance(s) in that product, standard phrases for safety precautions as provided for in ^{F130}Regulation (EC) No 1272/2008 of the European Parliament and of the Council] and risk mitigation measures set out in the authorisation for that product where appropriate.

Textual Amendments

- F125** Words in Art. 49(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(27)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F126** Words in Art. 49(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(27)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F127** Art. 49(2)(2A) substituted for Art. 49(2) (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(27)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F128** Art. 49(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(27)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F129** Words in Art. 49(4) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(27)(d)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F130** Words in Art. 49(4) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(27)(d)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 50

Comparative assessment of plant protection products containing candidates for substitution

1 A comparative assessment shall be performed by [^{F131}a competent authority] when evaluating an application for authorisation for a plant protection product containing an active substance approved as a candidate for substitution [^{F132}in relation to its constituent territory]. [^{F133}A competent authority] shall not authorise or shall restrict the use of a plant protection product containing a candidate for substitution for use on a particular crop where the comparative assessment weighing up the risks and benefits, as set out in Annex IV, demonstrates that:

- a for the uses specified in the application an authorised plant protection product, or a non-chemical control or prevention method, already exists which is significantly safer for human or animal health or the environment;
- b the substitution by plant protection products or non-chemical control or prevention methods referred to in point (a) does not present significant economic or practical disadvantages;
- c the chemical diversity of the active substances, where relevant, or methods and practices of crop management and pest prevention are adequate to minimise the occurrence of resistance in the target organism; and
- d the consequences on minor use authorisations are taken into account.

2 By way of derogation from Article 36(2) [^{F134}a competent authority] may in exceptional cases also apply the provisions of paragraph 1 of this Article when evaluating an application for authorisation of a plant protection product not containing a candidate for substitution or a low-risk active substance, if a non-chemical control or prevention method exists for the same use and it is in general use in [^{F135}Great Britain].

3 By way of derogation from paragraph 1, a plant protection product containing a candidate for substitution shall be authorised without comparative assessment in cases where it is necessary to acquire experience first through using that product in practice.

Such authorisations shall be granted once for a period not exceeding five years.

4 For plant protection products containing a candidate for substitution [^{F136}a competent authority] shall perform the comparative assessment provided for in paragraph 1 regularly and at the latest at renewal or amendment of the authorisation.

Based on the results of that comparative assessment, [^{F137}the competent authority] shall maintain, withdraw or amend the authorisation.

5 Where a [^{F138}competent authority] decides to withdraw or amend an authorisation pursuant to paragraph 4, that withdrawal or amendment shall take effect 3 years after the decision of the [^{F138}competent authority] or at the end of the approval period of the candidate for substitution [^{F139}in relation to its constituent territory] where that period ends earlier.

6 Unless otherwise specified, all provisions relating to authorisations under this Regulation shall apply.

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, CHAPTER III. (See end of Document for details)

Textual Amendments

- F131** Words in Art. 50(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(28)(a)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F132** Words in Art. 50(1) inserted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(28)(a)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F133** Words in Art. 50(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(28)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F134** Words in Art. 50(2) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(28)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F135** Words in Art. 50(2) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(28)(b)(ii)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(5)(i)); 2020 c. 1, Sch. 5 para. 1(1)
- F136** Words in Art. 50(4) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(28)(c)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F137** Words in Art. 50(4) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(28)(c)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F138** Words in Art. 50(5) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(28)(d)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F139** Words in Art. 50(5) inserted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(28)(d)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 51

Extension of authorisations for minor uses

1 The authorisation holder, official or scientific bodies involved in agricultural activities, professional agricultural organisations or professional users may ask for the authorisation of a plant protection product already authorised [^{F140}by a competent authority] to be extended to minor uses not yet covered by that authorisation.

- 2 [^{F141}The competent authority] shall extend the authorisation provided that:
- a the intended use is minor in nature;
 - b the conditions referred to in points (b), (d) and (e) of Article 4(3) and Article 29(1)(i) are satisfied;
 - c the extension is in the public interest; and
 - d the documentation and information to support the extension of use has been submitted by the persons or bodies referred to in paragraph 1, especially data on the magnitude of residues and where necessary on the risk assessment to the operator, worker and bystander.

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3 [F142A competent authority] may take measures to facilitate or encourage the submission of applications to extend the authorisation of already authorised plant protection products to minor uses.

4 The extension may take the form of an amendment to the existing authorisation or may be a separate authorisation F143 ...

5 When [F144the competent authority grants] an extension of authorisation for a minor use, [F145the competent authority] shall inform if necessary the authorisation holder and request him to change the labelling accordingly.

Where the authorisation holder declines, the [F146competent authority] shall ensure that users are fully and specifically informed as to instructions for use, by means of an official publication or an official website.

The official publication or where applicable the label shall include a reference to the liability of the person using the plant protection product with respect to failures concerning the efficacy or to phytotoxicity of the product for which the minor use was granted. The minor use extension shall be separately identified in the label.

6 Extensions on the basis of this Article shall be separately identified and separate reference shall be made to liability restrictions.

7 The applicants referred to in paragraph 1 may also apply for authorisation of a plant protection product for minor uses in accordance with [F147Article 42A, except where one or more of the conditions in Article 42A(4) are met]. [F148The competent authority which receives such an application] shall authorise such uses in accordance with the provisions of [F149Article 42B] provided that those uses are also considered minor [F150by that competent authority].

8 [F151Each competent authority] shall establish and regularly update a list of minor uses.

9 By 14 December 2011, the Commission shall present a report to the European Parliament and the Council on the establishment of a European fund for minor uses, accompanied, if appropriate, by a legislative proposal.

10 Unless otherwise specified, all provisions relating to authorisations under this Regulation shall apply.

Textual Amendments

F140 Words in Art. 51(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(29)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F141 Words in Art. 51(2) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(29)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F142 Words in Art. 51(3) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(29)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F143 Words in Art. 51(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(29)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F144 Words in Art. 51(5) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(29)(e)(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, CHAPTER III. (See end of Document for details)

- F145** Words in Art. 51(5) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(29)(e)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F146** Words in Art. 51(5) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(29)(e)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F147** Words in Art. 51(7) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(29)(f)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F148** Words in Art. 51(7) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(29)(f)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F149** Words in Art. 51(7) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(29)(f)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F150** Words in Art. 51(7) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(29)(f)(ii)(cc)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F151** Words in Art. 51(8) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(29)(g)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

^{F152}Article 52

Parallel trade

Textual Amendments

- F152** Art. 52 omitted (31.12.2023) by virtue of The Plant Protection Products (Miscellaneous Amendments) Regulations 2023 (S.I. 2023/1321), regs. 1(2), **4(3)** (with reg. 5)

^{F153}Article 52A

Parallel trade

1. This Article applies in respect of a parallel trade permit which—
 - a immediately before IP completion day was a permit of a description referred to in Article 52(4A), and
 - b by virtue of Article 52(6)(b), ceased to be valid on 1st January 2023 (an “original parallel trade permit”).
2. The person to which an original parallel trade permit was issued may submit an application to the competent authority for the reinstatement of that permit as it had effect in relation to a constituent territory immediately before it ceased to be valid.
3. An application for the reinstatement of the original parallel trade permit must be made no later than 1st April 2024.
4. The application must be accompanied by—

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- a a duplicate of the information that was submitted in connection with—
 - i the initial application for the original parallel trade permit, and
 - ii any subsequent application to amend that permit before it ceased to be valid;
 - b where applicable, notification of any changes to the contact details supplied in connection with applications concerning the original parallel trade permit;
 - c as regards the plant protection product authorised in the Member State of origin at the time of application for the original parallel trade permit—
 - i confirmation that the product remains authorised and available for sale in the Member State of origin at the time of application for the reinstatement of the permit,
 - ii confirmation that the label for the product as submitted with the application for the original parallel trade product remains unchanged as regards the identification of the product in the Member State of origin at the time of application for the reinstatement of the permit, and
 - iii photographs of the plant protection product container (including all sides of the container) with visible and readable label, showing the product as it is being marketed in the Member State of origin at the time of application for the reinstatement of the permit;
 - d as regards the label for the plant protection product as it is to be marketed in the constituent territory concerned—
 - i confirmation that the label for the product as submitted with the initial application for the original parallel trade product remains unchanged, or
 - ii notification of any change to the label for the plant protection product, together with the draft label which is to be attached to the product as it is to be marketed in the constituent territory concerned;
 - e a declaration by the applicant that, to the best of that person's knowledge—
 - i all information supplied in accordance with this paragraph is accurate, as it applies to the manufacture and placing on the market of the plant protection product in respect of which the application for reinstatement of the original parallel trade permit is made, and
 - ii for the purposes of paragraph (i), that the duplicate information supplied in accordance with subparagraph (a) continues to apply in respect of that product, subject to any changes required to be notified in accordance with this paragraph.
5. At any time after receiving an application and before determining it the competent authority may require the applicant to provide it with such further information as it reasonably considers necessary to determine the application.
6. The competent authority must grant the application for the reinstatement of the original parallel trade permit where—
- a at the time of application for that permit, the authorisation of the reference product granted prior to the application for the original parallel trade permit has not been withdrawn by that authority in relation to the constituent territory concerned;
 - b the authority is satisfied that—
 - i the application complies with the requirements of paragraphs 2 and 3;
 - ii all information and documentation required to accompany the application in accordance with paragraphs 4 and 5 is complete;
 - iii where the applicant has notified a change to the label for the plant protection product in accordance with paragraph 4(d), that change—

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- aa is consistent with the proposition that the product must be placed on the market and used only in accordance with the provisions of the authorisation of the reference product, or
 - bb is a minor change (such as a change of address) that is not material to the identity of that label with the label for the reference product;
 - iv the declaration made by the applicant in accordance with paragraph 4(e) is valid on the basis of all relevant information available to the authority concerning the plant protection product.
7. Where the reinstatement of a parallel trade permit is granted in accordance with this Article—
- a the competent authority must issue the parallel trade permit and must specify the date on which the permit has effect, and
 - b the parallel trade permit is valid in relation to a constituent territory until the earlier of—
 - i the date on which the authorisation of the reference product expires in relation to that constituent territory;
 - ii the date two years after the day on which the permit was specified to have effect under this Article.
8. A plant protection product for which a parallel trade permit has been issued in accordance with this Article must be placed on the market and used only in accordance with the provisions of the authorisation of the reference product.
9. The plant protection product for which the parallel trade permit has been issued may be the subject of a grace period granted in accordance with Article 46 as though the permit for the product concerned were an authorisation and, for these purposes, Article 46 applies—
- a where a parallel trade permit ceases to be valid in accordance with paragraph 7(b), or
 - b where a parallel trade permit is withdrawn under paragraph 10(a).
10. A parallel trade permit that has been issued in accordance with this Article is to be treated as an authorisation for the purposes of Articles 44 and 45 and—
- a may be withdrawn—
 - i in accordance with either Article, or
 - ii without prejudice to Article 44, where the authorisation of the plant protection product in respect of which the original parallel trade permit was issued is withdrawn in the Member State of origin for safety or efficacy reasons;
 - b may be amended in accordance with either Article, but only to the extent necessary to enable the product to be placed on the market and used in accordance with the provisions of the authorisation of the reference product.
11. The holder of a parallel trade permit must report any available information to the competent authority in accordance with Article 56(4) as though the authority had authorised the plant protection product concerned.
12. Chapters 6 to 10 apply in respect of any plant protection product for which a parallel trade permit has been granted in accordance with this Article, as if references in those Chapters to an authorisation were references to the parallel trade permit.
13. Subject to Chapter 6, each competent authority must take steps to make publicly available information which it holds about parallel trade permits.
14. In this Article—

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“Member State of origin” means the Member State or EEA state which was the Member State of origin in accordance with paragraph 1 of Article 52 as it had effect immediately before IP completion day, as adapted by the EEA agreement as it had effect immediately before IP completion day;

“reference product” means the plant protection product which was already authorised in the United Kingdom prior to the application for the original parallel trade permit, and to which the product to which that permit relates (including that permit in its reinstated form), is identical in composition.]

Textual Amendments

F153 Art. 52A inserted (31.12.2023) by [The Plant Protection Products \(Miscellaneous Amendments\) Regulations 2023 \(S.I. 2023/1321\)](#), regs. 1(2), **4(4)** (with reg. 5)

Subsection 6

Derogations

Article 53

Emergency situations in plant protection

1 By way of derogation from Article 28, in special circumstances a [^{F154}competent authority] may authorise, for a period not exceeding 120 days, the placing on the market of plant protection products, for limited and controlled use [^{F155}in its constituent territory], where such a measure appears necessary because of a danger which cannot be contained by any other reasonable means.

The [^{F156}competent authority] concerned shall immediately inform the other [^{F157}competent authorities] of the measure taken, providing detailed information about the situation and any measures taken to ensure consumer safety.

^{F158}2

^{F158}3

4 [^{F159}Paragraph 1] shall not apply to plant protection products containing or composed of genetically modified organisms unless such release has been accepted in accordance with [^{F160}section 111(1) of the Environmental Protection Act 1990].

Textual Amendments

F154 Words in Art. 53(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(31)(a)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F155 Words in Art. 53(1) inserted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(31)(a)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F156 Words in Art. 53(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(31)(a)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

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- F157** Words in Art. 53(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(31)(a)(ii)(bb)** (with Sch. 1) (as amended by S.I. 2019/1410, regs. 1(2), 6(2)(c)); 2020 c. 1, Sch. 5 para. 1(1)
- F158** Art. 53(2)(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(31)(b)** (with Sch. 1) ; 2020 c. 1, Sch. 5 para. 1(1)
- F159** Words in Art. 53(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(31)(c)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F160** Words in Art. 53(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(31)(c)(ii)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(5)(k)); 2020 c. 1, Sch. 5 para. 1(1)

Article 54

Research and development

1 By way of derogation from Article 28, experiments or tests for research or development purposes involving the release into the environment of an unauthorised plant protection product or involving unauthorised use of a plant protection product may be carried out if the [^{F161}competent authority] in whose [^{F162}constituent] territory the experiment or test is to be carried out has assessed the available data and granted a permit for trial purposes. The permit may limit the quantities to be used and the areas to be treated and may impose further conditions to prevent any harmful effects on human or animal health or any unacceptable adverse effect on the environment, such as the need to prevent entry into the food chain of feed and food containing residues unless a relevant provision has already been established under Regulation (EC) No 396/2005 [^{F163}in relation to that constituent territory].

The [^{F161}competent authority] may authorise a programme of experiments or tests in advance or require a permit for each experiment or test.

2 An application shall be submitted to the [^{F164}competent authority] in whose [^{F165}constituent] territory the experiment or test is to be conducted, together with a dossier containing all the available data to permit an assessment of possible effects on human or animal health or the possible impact on the environment.

3 A permit for trial purposes shall not be granted for experiments or tests involving the release into the environment of a genetically modified organism unless such release has been accepted under [^{F166}section 111(1) of the Environmental Protection Act 1990].

4 Paragraph 2 shall not apply if the [^{F167}competent authority] has granted the person concerned the right to undertake certain experiments and tests and has determined the conditions under which the experiments and tests have to be undertaken.

^{F168}5

Textual Amendments

- F161** Words in Art. 54(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(32)(a)(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, CHAPTER III. (See end of Document for details)

- F162** Words in Art. 54(1) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(32)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F163** Words in Art. 54(1) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(32)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F164** Words in Art. 54(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(32)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F165** Words in Art. 54(2) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(32)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F166** Words in Art. 54(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(32)(c)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), **3(5)(k)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F167** Words in Art. 54(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(32)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F168** Art. 54(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), **5(32)(e)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Textual Amendments

- F1** Words in Ch. 3 Section 1 Subsection 3 heading inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(16)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F2** Ch. 3 Section 1 Subsection 3A inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **5(21)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), **3(5)(f)**); 2020 c. 1, **Sch. 5 para. 1(1)**

SECTION 2

Use and information

Article 55

Use of plant protection products

[^{F169}1] Plant protection products shall be used properly.

[^{F169}2] Proper use shall include the application of the principles of good plant protection practice and compliance with the conditions established in accordance with Article 31 and specified on the labelling. It shall also comply with the provisions of Directive 2009/128/EC and, in particular, with general principles of integrated pest management, as referred to in Article 14 of and Annex III to that Directive ^{F170}...

[^{F171}3] For the purposes of this Article, Article 14 of Directive 2009/128/EC is to be read as if—

- a obligations on Member States were obligations on the competent authorities;

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b paragraph 3 were omitted.]

Textual Amendments

- F169** Words in Art. 55 renumbered as Art. 55(1)(2) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(33)(a)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**
- F170** Words in Art. 55(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), **5(33)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F171** Art. 55(3) inserted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(33)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 56

Information on potentially harmful or unacceptable effects

1 The holder of an authorisation for a plant protection product shall immediately notify [^{F172}each competent authority] that granted an authorisation of any new information concerning that plant protection product, the active substance, its metabolites, a safener, synergist or co-formulant contained in the plant protection product, which suggests that the plant protection product no longer complies with the criteria set out in Articles 29 and 4 respectively.

In particular, potentially harmful effects of that plant protection product, or of residues of an active substance, its metabolites, a safener, synergist or co-formulant contained in it, on human or animal health or on groundwater, or their potentially unacceptable effects on plants or plant products or the environment shall be notified.

To this end the authorisation holder shall record and report all suspected adverse reactions in humans, in animals and the environment related to the use of the plant protection product.

The obligation to notify shall include relevant information on decisions or assessments by international organisations or by public bodies which authorise plant protection products or active substances in [^{F173}other] countries.

2 The notification shall include an assessment of whether and how the new information would result in the plant protection product or the active substance, its metabolites, a safener, or synergist or co-formulant no longer complying with the requirements set out in Article 29 and Article 4 or Article 27, respectively.

3 Without prejudice to the right of [^{F174}competent authorities] to adopt interim protective measures, [^{F175}where paragraph 3A applies, the competent authority] which first granted an authorisation [^{F176}... shall evaluate the information received and inform the other [^{F177}competent authorities which granted authorisation for the plant protection product], where it decides to withdraw or amend the authorisation under Article 44.

That [^{F178}competent authority] shall inform the other [^{F179}competent authorities] where it considers that the conditions of the approval of the active substance, safener or synergist contained in the plant protection product are no longer fulfilled or whether in the case of a co-formulant it has been considered unacceptable and propose that the approval be withdrawn or the conditions amended.

[^{F180}3A This paragraph applies where—

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- a each competent authority which granted authorisation agrees which competent authority is to evaluate the information;
 - b each active substance, safener or synergist in the plant protection product to which the information relates has the same conditions of approval in relation to the constituent territory of each competent authority concerned;
 - c 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 by 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 concerned.]
- 4 The holder of an authorisation for a plant protection product shall report annually to the competent authorities ^{F181}... which authorised his plant protection product if he has any information available relating to the lack of expected efficacy, the development of resistance and to any unexpected effect on plants, plant products or the environment.

Textual Amendments

- F172** Words in Art. 56(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(34)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F173** Word in Art. 56(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(34)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F174** Words in Art. 56(3) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(34)(b)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F175** Words in Art. 56(3) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(34)(b)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F176** Words in Art. 56(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(34)(b)(i)(cc)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F177** Words in Art. 56(3) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(34)(b)(i)(dd)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F178** Words in Art. 56(3) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(34)(b)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F179** Words in Art. 56(3) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(34)(b)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F180** Art. 56(3A) inserted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(34)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F181** Words in Art. 56(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(34)(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, CHAPTER III. (See end of Document for details)

Article 57

Obligation to keep information available

1 ^{F182}A competent authority] shall keep information electronically available to the public on plant protection products authorised or withdrawn in accordance with this Regulation, containing at least:

- a the name or business name of the holder of the authorisation and the authorisation number;
- b the trade name of the product;
- c the type of preparation;
- d the name and amount of each active substance, safener or synergist which it contains;
- e the classification, risk and safety phrases in accordance [^{F183}with Regulation (EC) No 1272/2008 of the European Parliament and of the Council and any regulations made under Article 65(1A)];
- f the use or uses for which it is authorised;
- g the reasons for withdrawal of an authorisation if they are related to safety concerns;
- h the list of minor uses referred to in Article 51(8).

2 The information referred to in paragraph 1 shall be readily accessible and updated at least once every 3 months.

^{F184}3

Textual Amendments

F182 Words in Art. 57(1) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(35)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F183 Words in Art. 57(1)(e) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **5(35)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F184 Art. 57(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(35)(b)** (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, CHAPTER III.