

Regulation (EC) No 1107/2009 of the European Parliament and of the Council
of 21 October 2009 concerning the placing of plant protection products on
the market and repealing Council Directives 79/117/EEC and 91/414/EEC

CHAPTER III

PLANT PROTECTION PRODUCTS

^{F1F1}SECTION 1

Authorisation

Subsection 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 [^{F1}in a constituent territory] unless it has been authorised [^{F2}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 [^{F3}the constituent territory of another competent authority], provided that the product is authorised [^{F4}by that other competent authority for that constituent territory];
- d production, storage or movement of a plant protection product intended for use [^{F5}outside Great Britain] provided that [^{F6}there are inspection requirements in place] to ensure that the plant protection product is exported from [^{F7}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 [^{F8}is in force] in accordance with [^{F9}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, Subsection 1. (See end of Document for details)

Textual Amendments

- F1** 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)
- F2** 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)
- F3** 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)
- F4** 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)
- F5** 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)
- F6** 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)
- 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)(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)
- F8** 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)
- F9** 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 [^{F10}for the constituent territory of authorisation] it complies with the following requirements:

- a its active substances, safeners and synergists [^{F11}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 [^{F12}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;

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- c its co-formulants are not included [^{F13}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 [^{F14}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 [^{F15}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 [^{F16}areas of Great Britain] where the product is intended to be used.

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[^{F18}a) The appropriate authority may, by regulations, prescribe uniform principles for the evaluation and authorisation of plant protection products.]

[^{F19}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

- F10** 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)
- F11** 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)
- F12** 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, Subsection 1. (See end of Document for details)

- F13** 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)
- F14** 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)
- F15** 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)
- F16** 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)
- F17** 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)
- F18** 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)**
- F19** 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, Subsection 1. (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 [F20approval of] the active substances, safeners and synergists [F21in the constituent territory of authorisation].

The authorisation shall include a classification of the plant protection product for the purpose of [F22Regulation (EC) No 1272/2008 of the European Parliament and of the Council]. [F23A 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 [F24Regulation (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 [F25retained 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.

[F265 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, Subsection 1. (See end of Document for details)

Textual Amendments

- F20** 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)
- F21** 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)
- 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)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F23** 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)
- 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)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F25** 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)
- F26** 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 [^{F27}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 [^{F28}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

- F27** 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)
- F28** 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, Subsection 1.