

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**

<sup>F1F1</sup>SECTION 1

*Authorisation*

*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 [<sup>F1</sup>in relation to a constituent territory] of an active substance, safener or synergist contained in the plant protection product [<sup>F2</sup>authorised in that constituent territory], the applicant shall submit the following information [<sup>F3</sup>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 [<sup>F4</sup>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.

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[<sup>F5</sup>a] [<sup>F6</sup>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 [<sup>F7</sup>on renewal of the approval of the active substance, safener or synergist].

[<sup>F8</sup>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

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1107/2009 of the European Parliament and of the Council, Subsection 4. (See end of Document for details)*

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renewal of authorisation for the same product, provided that the conditions in Article 35(2) apply in relation to the renewal application.]

<sup>F9</sup>4 .....

5 [F<sup>10</sup>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 [F<sup>11</sup>competent authority examining the application] shall extend the authorisation for the period necessary to complete the examination and adopt a decision on the renewal.

#### Textual Amendments

- F1** 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)
- F2** 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)
- F3** 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)
- F4** 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)
- F5** 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)**
- F6** 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)
- F7** 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)
- F8** 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)
- F9** 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)
- F10** 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)
- F11** 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)

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## Article 44

### Withdrawal or amendment of an authorisation

1 [F<sup>12</sup>A 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 [F<sup>13</sup>competent authority] shall review an authorisation where it concludes that the [F<sup>14</sup>environmental objectives of a river basin district] may not be achieved.

2 Where a [F<sup>15</sup>competent 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 [F<sup>16</sup>competent authority] shall withdraw or amend the authorisation, as appropriate, where:

- 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 [F<sup>17</sup>competent authority] withdraws or amends an authorisation in accordance with paragraph 3, it shall immediately inform the holder of the authorisation [F<sup>18</sup>and the other competent authorities]. The other [F<sup>19</sup>competent authorities may] withdraw or amend the authorisation accordingly taking into account [F<sup>20</sup>conditions in its constituent territory] and risk mitigation measures except for cases where the second [F<sup>21</sup>or third] subparagraphs of Article 36(3) have been applied. Article 46 shall apply where appropriate.

[F<sup>22</sup>5 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.

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- 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

- F12** 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)
- F13** 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)
- F14** 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)
- F15** 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)
- F16** 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)
- F17** 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)
- F18** 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)
- F19** 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)
- F20** 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)
- F21** 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)
- F22** 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)**

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#### 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 [<sup>F23</sup>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.

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.

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#### Textual Amendments

- F23** 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)

**Changes to legislation:**

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