

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 II

**ACTIVE SUBSTANCES, SAFENERS, SYNERGISTS AND CO-FORMULANTS**

*SECTION 1*

*Active substances*

*Subsection 4*

*Derogations*

*[<sup>F1</sup>Article 22*

**Low-risk active substances**

- 1 An active substance complying with the criteria provided for in Article 4 must be approved as a low-risk active substance where—
  - a that substance complies with the criteria in point 5 of Annex 2, and
  - b it may be expected that plant protection products containing that substance will pose only a low risk to human and animal health and the environment as provided for in Article 47(1).
- 2 Articles 4 to 21 apply.
- 3 The appropriate authority may, by regulations, amend point 5 of Annex 2 to specify new criteria for approving an active substance as a low-risk active substance.]

**Textual Amendments**

- F1** Art. 22 substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **4(28)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

*Article 23*

**Approval criteria for basic substances**

- 1 Basic substances shall be approved in accordance with [<sup>F2</sup>this Article]. <sup>F3</sup>...
- For the purpose of [<sup>F2</sup>this Article], a basic substance is an active substance which:
- a is not a substance of concern; and
  - b does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects; and

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- c is not predominantly used for plant protection purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent; and
- d is not placed on the market as a plant protection product.

For the purpose of this Regulation, an active substance which fulfils the criteria of a ‘foodstuff’ as defined in Article 2 of Regulation (EC) No 178/2002 shall be considered as a basic substance.

2 By way of derogation from Article 4, a basic substance shall be approved where any relevant evaluations, carried out in accordance with other <sup>F4</sup>... legislation regulating the use of that substance for purposes other than for a plant protection product, show that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment.

3 By way of derogation from Article 7 an application for the approval of a basic substance shall be submitted <sup>F5</sup>... by any interested party to the [<sup>F6</sup>the competent authority for the constituent territory in relation to which approval is sought].

The application shall be accompanied by the following information:

- a any evaluations of its possible effects on human or animal health or the environment carried out in accordance with other <sup>F7</sup>... legislation regulating the use of the substance; and
- b other relevant information on its possible effects on human or animal health or the environment.

<sup>F8</sup>4 .....

[<sup>F9</sup>5 Article 6 applies to the approval of a basic substance.

5A Within the decision period following receipt of the application and accompanying information, the competent authority must decide to either—

- a approve the basic substance, subject to conditions or restrictions, as referred to in Article 6(1), where appropriate, or
- b refuse to approve the basic substance.

5B In paragraph 5A, the “decision period” is—

- a where the competent authority obtains independent scientific advice in respect of the application, nine months;
- b otherwise, six months.

5C In making a decision under paragraph 5A, the competent authority must have regard to—

- a the application and accompanying information,
- b where the competent authority considers it appropriate to obtain it, any independent scientific advice obtained,
- c where the conditions laid down in Article 7(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council are relevant, the precautionary principle, and
- d any other matters which the competent authority considers relevant to the competent authority's determination of the application.

5D As soon as reasonably practicable after making a decision under paragraph 5A, the competent authority must—

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- a notify the applicant and the other competent authorities in writing of that decision and the reasons for it, and
- b update the approvals register accordingly.

5E Article 20A applies to an approval of a basic substance which is subject to a condition in accordance with Article 6(1)(f) as it applies to an approval of an active substance.

5F The Secretary of State may make a decision under paragraph 5A instead of a competent authority—

- a in relation to Wales, with the consent of the Welsh Ministers;
- b in relation to Scotland, with the consent of the Scottish Ministers.

5G Where the Secretary of State makes a decision in accordance with paragraph 5F, a reference in paragraphs 5A to 5D to the competent authority is to be read as a reference to the Secretary of State.]

F<sup>10</sup>6 .....

#### Textual Amendments

- F2** Words in Art. 23(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(29)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F3** Words in Art. 23(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), **4(29)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F4** Word in Art. 23(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), **4(29)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F5** Words in Art. 23(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), **4(29)(c)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F6** Words in Art. 23(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(29)(c)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F7** Word in Art. 23(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), **4(29)(c)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F8** Art. 23(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), **4(29)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)
- F9** Art. 23(5)-(5G) substituted for Art. 23(5) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(29)(e)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(4)(e)); 2020 c. 1, Sch. 5 para. 1(1)
- F10** Art. 23(6) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(29)(f)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

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## *F11* Article 23A

### Review of basic substance approval

- 1 A competent authority may review the approval of a basic substance at any time.
- 2 A competent authority must review the approval of a basic substance where—
  - a the competent authority has received and assessed confirmatory information in accordance with Article 20A (as applied by Article 23(5E));
  - b further information required in accordance with a condition under Article 6(1)(f) has not been provided within the period specified in that condition.
- 3 Where the competent authority considers that there are indications that the substance no longer satisfies the criteria provided for in Article 23(1) to (3), the competent authority must inform the other competent authorities and the interested party referred to in Article 23(3) accordingly, setting a period for the submission of comments.
- 4 The competent authority may obtain independent scientific advice, where the competent authority considers it appropriate to do so.
- 5 Where the competent authority concludes that, having considered comments received during the period set in accordance with paragraph 3 and any other information or matters that the competent authority considers important and relevant to the review, the substance no longer satisfies the criteria provided for in Article 23(1), the competent authority must decide to either—
  - a amend the conditions of the approval, or
  - b withdraw the approval.
- 6 As soon as reasonably practicable after making a decision under paragraph 5, the competent authority must—
  - a notify the other competent authorities and the interested party referred to in Article 23(3) in writing of the decision and the reasons for it, and
  - b update the approvals register accordingly.
- 7 The Secretary of State may review an active substance under paragraph 1 or 2 instead of a competent authority—
  - a in relation to Wales, with the consent of the Welsh Ministers;
  - b in relation to Scotland, with the consent of the Scottish Ministers.
- 8 Where the Secretary of State reviews an active substance in accordance with paragraph 7, a reference in paragraphs 3 to 6 to the competent authority is to be read as a reference to the Secretary of State.]

#### Textual Amendments

- F11** Art. 23A inserted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **4(30)** (with Sch. 1) (as amended by [S.I. 2020/1376](#), regs. 1(4), **3(4)(f)**); 2020 c. 1, **Sch. 5 para. 1(1)**

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## Article 24

### Candidates for substitution

1 An active substance complying with the criteria provided for in Article 4 shall be approved <sup>F12</sup>... as a candidate for substitution if it meets one or more of the additional criteria laid down in point 4 of Annex II. <sup>F13</sup>...

2 Without prejudice to paragraph 1, Articles 4 to 21 shall apply. <sup>F14</sup>...

#### Textual Amendments

**F12** Words in Art. 24(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), **4(31)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

**F13** Words in Art. 24(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), **4(31)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

**F14** Words in Art. 24(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), **4(31)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

**Changes to legislation:**

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