

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***

*Article 23*

**Approval criteria for basic substances**

1 Basic substances shall be approved in accordance with [<sup>F1</sup>this Article]. <sup>F2</sup>...

For the purpose of [<sup>F1</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
- 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>F3</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>F4</sup>... by any interested party to the [<sup>F5</sup>the competent authority for the constituent territory in relation to which approval is sought].

The application shall be accompanied by the following information:

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- a any evaluations of its possible effects on human or animal health or the environment carried out in accordance with other <sup>F6</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>F7</sup>4 .....

[<sup>F8</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—

- 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.]

<sup>F9</sup>6 .....

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### Textual Amendments

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

**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, Article 23.