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 1

Requirements and conditions for approval

Article 4

Approval criteria for active substances

1 An active substance shall be approved in accordance with Annex II if it may be expected, in the light of current scientific and technical knowledge, that, taking into account the approval criteria set out in points 2 and 3 of that Annex, plant protection products containing that active substance meet the requirements provided for in paragraphs 2 and 3.

The assessment of the active substance shall first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied. If these criteria are satisfied the assessment shall continue to establish whether the other approval criteria set out in points 2 and 3 of Annex II are satisfied.

2 The residues of the plant protection products, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements:

a they shall not have any harmful effects on human health, including that of vulnerable groups, or animal health, taking into account known cumulative and synergistic effects where the scientific methods accepted **[**[F1]in accordance with paragraph 8**]** to assess such effects are available, or on groundwater;

b they shall not have any unacceptable effect on the environment.

For residues which are of toxicological, ecotoxicological, environmental or drinking water relevance, there shall be methods in general use for measuring them. Analytical standards shall be commonly available.

3 A plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements:

a it shall be sufficiently effective;

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 4. (See end of Document for details)*

b it shall have no immediate or delayed harmful effect on human health, including that of vulnerable groups, or animal health, directly or through drinking water (taking into account substances resulting from water treatment), food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects where the scientific methods accepted **[**[F2]in accordance with paragraph 8**]** to assess such effects are available; or on groundwater;

c it shall not have any unacceptable effects on plants or plant products;

d it shall not cause unnecessary suffering and pain to vertebrates to be controlled;

e it shall have no unacceptable effects on the environment, having particular regard to the following considerations where the scientific methods accepted **[**[F3]in accordance with paragraph 8**]** to assess such effects are available:

(i) its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, groundwater, air and soil taking into account locations distant from its use following long-range environmental transportation;

(ii) its impact on non-target species, including on the ongoing behaviour of those species;

(iii) its impact on biodiversity and the ecosystem.

4 The requirements of paragraphs 2 and 3 shall be evaluated in the light of uniform principles as referred to in **[**[F4]Article 29(6)(a) which apply to each constituent territory to which approval of the active substance relates**]**.

5 For approval of an active substance, paragraphs 1, 2 and 3 shall be deemed to be satisfied where this has been established with respect to one or more representative uses of at least one plant protection product containing that active substance.

6 In relation to human health, no data collected on humans shall be used to lower the safety margins resulting from tests or studies on animals.

7 By way of derogation from paragraph 1, where on the basis of documented evidence included in the application an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, such active substance may be approved for a limited period necessary to control that serious danger but not exceeding five years even if it does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II, provided that the use of the active substance is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised. For such substances maximum residue levels shall be set in accordance with Regulation (EC) No 396/2005.

This derogation shall not apply to active substances which are or have to be classified in accordance with Regulation (EC) No 1272/2008, as carcinogenic category 1A, carcinogenic category 1B without a threshold, or toxic for reproduction category 1A.

[[F5]A competent authority**]** may authorise plant protection products containing active substances approved in accordance with this paragraph only when it is necessary to control that serious danger to plant health in **[**[F6]its constituent**]** territory.

At the same time, **[**[F7]the competent authority**]** shall draw up a phasing out plan concerning the control of the serious danger by other means, including non-chemical methods, and shall without delay **[**[F8]publish that plan in a manner which the competent authority considers appropriate**]**.

[[F9]8 For the purposes of paragraphs 2(a) and 3(b) and (e), scientific methods are accepted if they are accepted—

a in relation to England, by the Secretary of State;

b in relation to Wales—

i) by the Secretary of State with the consent of the Welsh Ministers, or

ii) by the Welsh Ministers;

c in relation to Scotland—

i) by the Secretary of State with the consent of the Scottish Ministers, or

ii) by the Scottish Ministers;**]**

Textual Amendments

F1 Words in Art. 4(2)(a) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(2)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F2 Words in Art. 4(3)(b) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(2)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F3 Words in Art. 4(3)(e) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(2)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F4 Words in Art. 4(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(2)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F5 Words in Art. 4(7) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(2)(c)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F6 Words in Art. 4(7) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(2)(c)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F7 Words in Art. 4(7) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(2)(c)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F8 Words in Art. 4(7) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(2)(c)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F9 Art. 4(8) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(2)(d)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(4)(a)); 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 4.