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 U.K.

ACTIVE SUBSTANCES, SAFENERS, SYNERGISTS AND CO-FORMULANTS

SECTION 1 U.K.

Active substances

Subsection 1 U.K.

Requirements and conditions for approval

Article 4 *U.K.*

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 **[**F1in 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;

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 **[**F2in 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 **[**F3in 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 **[**F4Article 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.

[F5A 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 **[**F6its constituent**]** territory.

At the same time, **[**F7the 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 **[**F8publish 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)

*I*F10 *Article 5* U.K.

First approval

1 First approval must be for a period not exceeding—

a 10 years for an active substance, safener or synergist;

b 15 years for a low-risk active substance (see Article 22);

c 7 years for a candidate for substitution (see Article 24).

2 Paragraph 1 is subject to Article 17.

3 Approval for a basic substance (see Article 23) is for an unlimited period.**]**

Textual Amendments

F10 Art. 5 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(3)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 6 U.K.

Conditions and restrictions

[F11 1.**]** Approval may be subject to conditions and restrictions including:

(a) the minimum degree of purity of the active substance;

(b) the nature and maximum content of certain impurities;

(c) restrictions arising from the evaluation of the information referred to in Article 8 taking account of the agricultural, plant health and environmental, including climatic, conditions in question;

(d) type of preparation;

(e) manner and conditions of application;

(f) submission of further confirmatory information to **[**F12 each specified competent authority within a specified period**]**, where new requirements are established during the evaluation process or as a result of new scientific and technical knowledge;

(g) designation of categories of users, such as professional and non-professional;

(h) designation of areas where the use of plant protection products, including soil treatment products, containing the active substance may not be authorised or where the use may be authorised under specific conditions;

(i) the need to impose risk mitigation measures and monitoring after use;

(j) any other particular conditions that result from the evaluation of information made available in the context of this Regulation.

[F13 2 A competent authority may request from a specified competent authority a copy of any confirmatory information received in accordance with paragraph 1(f), which the specified competent authority must provide as soon as reasonably practicable.

3 In this Article, "specified" means specified in the condition referred to in paragraph 1(f).**]**

Textual Amendments

F11 Art. 6 renumbered as Art. 6(1) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(4)(a)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

F12 Words in Art. 6(1)(f) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(4)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F13 Art. 6(2)(3) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(4)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Subsection 2 U.K.

Approval procedure

Article 7 *U.K.*

Application

[F14 1 An application for the approval of an active substance may be submitted by the producer of the active substance to a competent authority.

1A An application for an amendment to the conditions of an approval may be submitted by the producer of the active substance to a competent authority for a constituent territory to which the approval applies.

1B A joint application may be submitted under paragraph 1 or 1A by an association of producers designated by the producers for the purpose of compliance with this Regulation.

1C For the purposes of this Subsection, "the assessing competent authority" in relation to an application is the competent authority referred to in paragraph 1 or 1A respectively, except where a transfer has been agreed under Article 12A(1).

1D An application under paragraph 1 or 1A must be submitted together with a summary and a complete dossier as provided for in Article 8(1) and (2) or a scientifically reasoned justification for not providing certain parts of those dossiers, demonstrating that the active substance fulfils the approval criteria provided for in Article 4.**]**

F15 2 . . . . . .

3 When submitting the application, the applicant may pursuant to Article 63 request certain information, including certain parts of the dossier, to be kept confidential and shall physically separate that information.

[F16 The assessing competent authority**]** shall assess the confidentiality requests. Upon a request for access to information, the **[**F17 assessing competent authority**]** shall decide what information is to be kept confidential.

4 When submitting the application the applicant shall at the same time join a complete list of tests and studies submitted pursuant to Article 8(2) and a list of any claims for data protection pursuant to Article 59.

[F18 5 When assessing the application the assessing competent authority may obtain independent scientific advice, where the assessing competent authority considers it appropriate to do so.**]**

Textual Amendments

F14 Art. 7(1)-(1D) substituted for Art. 7(1) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(5)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F15 Art. 7(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(5)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F16 Words in Art. 7(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(5)(c)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F17 Words in Art. 7(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(5)(c)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F18 Art. 7(5) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(5)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 8 U.K.

Dossiers

1 The summary dossier shall include the following:

a information with respect to one or more representative uses on a **[**F19crop grown in the United Kingdom**]** of at least one plant protection product containing the active substance, demonstrating that the approval criteria provided for in Article 4 are met; where the information submitted does not F20... concern a crop F21... , justification for this approach;

b for each point of the data requirements for the active substance **[**F22which apply in each of the constituent territories to which the application relates**]**, the summaries and results of tests and studies, the name of their owner and of the person or institute that has carried out the tests and studies;

c for each point of the data requirements for the plant protection product **[**F23which apply in each of the constituent territories to which the application relates**]**, the summaries and results of tests and studies, the name of their owner and of the person or institute that carried out the tests and studies, relevant to the assessment of the criteria provided for in Article 4(2) and (3) for one or more plant protection products which are representative of the uses referred to in point (a), taking into account the fact that data gaps in the dossier, as provided for in paragraph 2 of this Article, resulting from the proposed limited range of representative uses of the active substance, may lead to restrictions in the approval;

d for each test or study involving vertebrate animals, a justification of the steps taken to avoid animal testing and duplication of tests and studies on vertebrate animals;

e a checklist demonstrating that the dossier provided for in paragraph 2 of this Article is complete in view of the uses applied for;

f the reasons why the test and study reports submitted are necessary for first approval of the active substance or for amendments to the conditions of the approval;

g where relevant, a copy of an application for a maximum residue level as referred to in Article 7 of Regulation (EC) No 396/2005 or a justification for not supplying such information;

h an assessment of all information submitted.

2 The complete dossier shall contain the full text of the individual test and study reports concerning all the information referred to in points (b) and (c) of paragraph 1. It shall not contain any reports of tests or studies involving the deliberate administration of the active substance or the plant protection product to humans.

F243 . . . . . .

[F25 4 The appropriate authority may by regulations prescribe the data requirements for—

a one or more active substances, safeners and synergists for the purposes of paragraph 1(b);

b plant protection products for the purposes of paragraph 1(c).**]**

5 Scientific peer-reviewed open literature, as **[**F26 described in guidance issued under Article 77**]**, on the active substance and its relevant metabolites dealing with side-effects on health, the environment and non-target species and published within the last 10 years before the date of submission of the dossier shall be added by the applicant to the dossier.

Textual Amendments

F19 Words in Art. 8(1)(a) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(6)(a)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F20 Words in Art. 8(1)(a) 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(6)(a)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F21 Words in Art. 8(1)(a) 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(6)(a)(i)(cc)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F22 Words in Art. 8(1)(b) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(6)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F23 Words in Art. 8(1)(c) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(6)(a)(iii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F24 Art. 8(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(6)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F25 Art. 8(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(6)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F26 Words in Art. 8(5) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(6)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 9 *U.K.*

Admissibility of the application

1 Within 45 days of receiving the application, the **[**F27 assessing competent authority**]** shall send the applicant a written acknowledgement, stating the date of receipt, and check whether the dossiers submitted with the application contain all the elements provided for in Article 8, using the checklist referred to in point (e) of Article 8(1). It shall also check the requests for confidentiality referred to in Article 7(3) and the complete lists of tests and studies submitted pursuant to Article 8(2).

2 Where one or more of the elements provided for in Article 8 are missing, the **[**F28 assessing competent authority**]** shall inform the applicant, setting a period for their submission. Such period shall be a maximum of 3 months.

Where at the end of that period, the applicant has not submitted the missing elements, the **[**F28assessing competent authority**]** shall inform the applicant **[**F29and the other competent authorities**]** that the application is inadmissible.

A new application for the same substance may be submitted at any time.

3 Where the dossiers submitted with the application contain all the elements provided for in Article 8, the **[**F30assessing competent authority**]** shall notify the applicant **[**F31and the other competent authorities**]** of the admissibility of the application and start assessing the active substance.

After receiving that notification, the applicant **[**F32must on request**]** forward the dossiers as provided for in Article 8 to the other **[**F33competent authorities**]**, including the information about those parts of the dossiers in respect of which confidentiality has been requested as referred to in Article 7(3).

Textual Amendments

F27 Words in Art. 9(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(7)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F28 Words in Art. 9(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(7)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F29 Words in Art. 9(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(7)(b)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F30 Words in Art. 9(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(7)(c)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F31 Words in Art. 9(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(7)(c)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F32 Words in Art. 9(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(7)(c)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F33 Words in Art. 9(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(7)(c)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 10 U.K.

Access to the summary dossier

The **[**F34assessing competent authority**]** shall without delay make the summary dossier referred to in Article 8(1) available to the public, excluding any information in respect of which confidential treatment has been requested and justified pursuant to Article 63, unless there is an overriding public interest in its disclosure.

Textual Amendments

F34 Words in Art. 10 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(8)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 11 U.K.

Draft assessment report

1 Within 12 months of the date of the notification provided for in the first subparagraph of Article 9(3), the **[**F35assessing competent authority**]** shall prepare and submit to the **[**F36other competent authorities**]** a report, referred to as the 'draft assessment report', assessing whether the active substance can be expected to meet the approval criteria provided for in Article 4.

2 The draft assessment report shall also include where relevant, a proposal to set maximum residue levels.

The **[**F37assessing competent authority**]** shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge.

Where, pursuant to Article 4(1), the assessment establishes that the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are not satisfied, the draft assessment report shall be limited to those parts of the assessment.

3 Where the **[**F38assessing competent authority**]** needs additional studies or information, it shall set a period in which the applicant must supply those studies or that information. In that case, the 12-month period shall be extended by the additional period granted by the **[**F38assessing competent authority**]**. The additional period shall be of a maximum of 6 months and shall cease at the moment when the additional information is received by the **[**F38assessing competent authority**]**. It shall inform the **[**F39other competent authorities**]** accordingly.

Where at the end of the additional period, the applicant has not submitted the additional studies or information, the **[**F40assessing competent authority**]** shall inform the applicant **[**F41and the other competent authorities,**]** and shall state the missing elements in the assessment included in the draft assessment report.

F42 4 . . . . . .

Textual Amendments

F35 Words in Art. 11(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(9)(a)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F36 Words in Art. 11(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(9)(a)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F37 Words in Art. 11(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(9)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F38 Words in Art. 11(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(9)(c)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F39 Words in Art. 11(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(9)(c)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F40 Words in Art. 11(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(9)(c)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F41 Words in Art. 11(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(9)(c)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F42 Art. 11(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(9)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 12 U.K.

Conclusion by the [F43assessing competent authority]

1

[F44a) The assessing competent authority must circulate the draft assessment report to the applicant and the other competent authorities at the latest 30 days after its completion. The assessing competent authority may ask the applicant to circulate any updated dossier to the assessing competent authority and the other competent authorities.]

[F45b)] The [F46assessing competent authority] shall make the draft assessment report available to the public, after giving the applicant two weeks to request, pursuant to Article 63, that certain parts of the draft assessment report be kept confidential.

[F45c)] The [F47assessing competent authority] shall allow a period of 60 days for the submission of written comments.

2 F48...

Within 120 days of the end of the period provided for the submission of written comments, the [F49assessing competent authority] shall adopt a conclusion in the light of current scientific and technical knowledge using guidance documents available at the time of application on whether the active substance can be expected to meet the approval criteria provided for in Article 4 and shall communicate it to the applicant [F50and the other competent authorities,] and shall make it available to the public. [F51In the event that independent scientific advice is obtained by the assessing competent authority in accordance with Article 7(5), the 120-day period must be extended by 90 days.]

Where appropriate, the [F52assessing competent authority] shall address in its conclusion the risk mitigation options identified in the draft assessment report.

3

[F53a)] Where the [F54assessing competent authority] needs additional information, it shall set a period of a maximum of 90 days for the applicant to supply it to the [F55assessing competent authority and the other competent authorities].

[F56b) The assessing competent authority must assess the additional information, and for that purpose the period provided for in paragraph 2 may be extended by a maximum of 60 days.]

[F57c)] The [F58assessing competent authority] may F59... consult a F60... reference laboratory, designated pursuant to [F61Regulation (EU) 2017/625] for the purposes of verifying whether the analytical method for the determination of the residues proposed by

the applicant is satisfactory and meets the requirements in Article 29(1)(g) of this Regulation. The applicant shall, if requested by the [F60]... reference laboratory, provide samples and analytical standards.

4 The conclusion of the **[**[F62]assessing competent authority**]** shall include details concerning the evaluation procedure and the properties of the active substance concerned.

[F63]5 . . . . . .

6 The time **[**[F64]limit**]** for decisions on applications concerning maximum residue levels set out in Article 14 of Regulation (EC) No 396/2005 shall be without prejudice to the time limits laid down in this Regulation.

[F65]7 . . . . . .

[F65]8 . . . . . .

Textual Amendments

F43 Words in Art. 12 heading substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(11)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F44 Art. 12(1)(a) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(12)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F45 Words in Art. 12(1) renumbered as Art. 12(1)(b)(c) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(12)(b)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

F46 Words in Art. 12(1)(b) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(12)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F47 Words in Art. 12(1)(c) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(12)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F48 Words in Art. 12(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(13)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F49 Words in Art. 12(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(13)(b)(i)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F50 Words in Art. 12(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(13)(b)(i)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F51 Words in Art. 12(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(13)(b)(ii)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

F52 Words in Art. 12(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(13)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F53 Words in Art. 12(3) renumbered as Art. 12(3)(a) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(14)(a)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

F54 Words in Art. 12(3)(a) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(14)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F55 Words in Art. 12(3)(a) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(14)(b)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F56 Art. 12(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(14)(c)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

F57 Words in Art. 12(3) renumbered as Art. 12(3)(c) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(14)(d)**; 2020 c. 1, **Sch. 5 para. 1(1)**

F58 Words in Art. 12(3)(c) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(14)(e)(i)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

F59 Words in Art. 12(3)(c) 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(14)(e)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F60 Words in Art. 12(3)(c) 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(14)(e)(iii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F61 Words in Art. 12(3)(c) substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1410), regs. 1(3), **2(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F62 Words in Art. 12(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(15)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F63 Art. 12(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), **4(16)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F64 Word in Art. 12(6) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(17)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F65 Art. 12(7)(8) 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(18)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

I[F66] *Article 12A* U.K.

Application for approval: transfer of assessment functions

1 The assessing competent authority may by agreement transfer the functions listed in paragraph 2 in relation to an application for approval to another competent authority for a constituent territory in relation to which the same application has been made, and upon transfer that competent authority is the assessing competent authority for the purposes of this Subsection.

2 For the purposes of paragraph 1 the functions are the functions of the assessing competent authority under Articles 7(3) and (5), 9, 10, 11 and 12.

3 Following a transfer under paragraph 1, the assessing competent authority must notify the applicant of the transfer.

4 A transfer in accordance with paragraph 1 does not—

a affect anything done by the assessing competent authority prior to transfer;

b affect the timing of any requirements placed on the assessing competent authority under this Subsection.**]**

Textual Amendments

F66 Art. 12A inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(19)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

[F67Article 13 U.K.

Approval Decision

1 Within six months of the relevant conclusion date, a competent authority for a constituent territory to which the application relates must decide to do one of the following—

a approve the active substance, subject to conditions or restrictions, as referred to in Article 6(1), where appropriate;

b amend the conditions of the approval; or

c refuse to approve the active substance.

2 In making a decision under paragraph 1, the competent authority must have regard to—

a the conclusion of the assessing competent authority;

b any comments received by the assessing competent authority in relation to the application, including any environmental monitoring information submitted by an appropriate agency;

c where the competent authority considers it appropriate to obtain it, any independent scientific advice obtained;

d where the conditions laid down in Article 7(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety are relevant, the precautionary principle;

e any other matters which the competent authority considers relevant to the competent authority's decision.

3 As soon as reasonably practicable after making a decision under paragraph 1, the competent authority must—

a notify the applicant and the other competent authorities in writing of the decision and the reasons for it, and

b update the approvals register accordingly.

4 The Secretary of State may make a decision under paragraph 1 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;

5 Where the Secretary of State makes a decision in accordance with paragraph 4—

a a reference in paragraphs 2 and 3 to the competent authority is to be read as a reference to the Secretary of State;

b paragraph 3(a) is to be read as if "other" were omitted.

6 In paragraph 1, the "relevant conclusion date" means—

a where the competent authority is the assessing competent authority, the date on which the competent authority adopts a conclusion under Article 12(2);

b otherwise, the date on which the competent authority receives the conclusion of the assessing competent authority in accordance with Article 12(2).

7 In paragraph 2(b), "appropriate agency" means one of the following—

a the Environment Agency;

b the Natural Resources Body for Wales;

c the Scottish Environment Protection Agency.**]**

Textual Amendments

F67 Art. 13 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(20)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(4)(b)); 2020 c. 1, Sch. 5 para. 1(1)

Subsection 3 U.K.

Renewal and review

Article 14 *U.K.*

Renewal of approval

1 On application the approval of an active substance shall be renewed where it is established that the approval criteria provided for in Article 4 are satisfied.

Article 4 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.

Such renewal of the approval may include conditions and restrictions, as referred to in **[**[F68]Article 6(1)**]**.

[[F69]2 The renewal of the approval must be for a period not exceeding—

a where the active substance is covered by Article 4(7), 5 years;

b for a candidate for substitution (see Article 24), 7 years;

c otherwise, 15 years.

3 Paragraph 2 is subject to Article 17.**]**

Textual Amendments

F68 Words in Art. 14(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(21)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F69 Art. 14(2)(3) substituted for Art. 14(2) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(21)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 15 U.K.

Application for renewal

1 The application provided for in Article 14 shall be submitted by a producer of the active substance to a **[**F70competent authority for a constituent territory in relation to which the active substance is approved**]**, no later than three years before the expiry of the approval.

[F71 1A For the purposes of this Subsection, "the assessing competent authority" in relation to an application is the competent authority referred to in paragraph 1, except where a transfer has been agreed under Article 15A(1).**]**

2 When applying for renewal, the applicant shall identify new data he intends to submit and demonstrate that they are necessary, because of data requirements or criteria which were not applicable at the time of the last approval of the active substance or because his request is for an amended approval. The applicant shall at the same time submit a timetable of any new and ongoing studies.

The applicant shall identify, giving reasons, the parts of the information submitted that he requests to be kept confidential in accordance with Article 63 and at the same time any data protection claims pursuant to Article 59.

[F72 3 The assessing competent authority must notify the other competent authorities as soon as reasonably practicable after receipt of an application under paragraph 1.

4 A competent authority which receives a notification under paragraph 3 may request in writing from the applicant a copy of the application and any accompanying information, which the applicant must provide as soon as reasonably practicable.**]**

Textual Amendments

F70 Words in Art. 15(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(22)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F71 Art. 15(1A) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(22)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F72 Art. 15(3)(4) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(22)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

[F73 *Article 15A* U.K.

Applications for renewal: transfer of assessment

1 The assessing competent authority may by agreement transfer the function of assessing an application for renewal to another competent authority for a constituent territory in relation to which the active substance to be renewed is approved, and upon transfer that competent authority is the assessing competent authority for that application for the purposes of the renewal provisions.

2 The application for renewal and any supporting dossiers or information must be transferred at the same time as the transfer under paragraph 1.

3 Following a transfer under paragraph 1, the assessing competent authority must notify the applicant of the transfer.

4 A transfer in accordance with paragraph 1 does not—

a affect anything done by the assessing competent authority prior to transfer;

b affect the timing of any requirements placed on the assessing competent authority under the renewal provisions.

5 In this Article, the "renewal provisions" means the provisions of—

a this Subsection, and

b Commission Implementing Regulation (EU) No 844/2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances.**]**

Textual Amendments

F73 Art. 15A inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(23)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 16 U.K.

Access to the information for renewal

The **[**F74assessing competent authority**]** shall, without delay, make available to the public the information provided by the applicant under Article 15, excluding any information in respect of which confidential treatment has been requested and justified pursuant to Article 63, unless there is an overriding public interest in its disclosure.

Textual Amendments

F74 Words in Art. 16 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(24)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 17 U.K.

Extension of approval period for the duration of the procedure

[F751 Where for reasons beyond the control of the applicant it appears to a competent authority that the approval is likely to expire before a decision has been taken on renewal, the competent authority must extend the approval period by a further period sufficient to examine the application.**]**

F76 . . . . . .

[F773**]** The length of that period shall be established on the basis of the following:

(a) the time needed to provide the information requested;

(b) the time needed to complete the procedure;

(c) where appropriate, the need to ensure the establishment of a coherent work programme, as provided for in Article 18.

[F78 4 As soon as reasonably practicable after extending the approval period in accordance with the first paragraph, the competent authority must—

a notify the applicant and the other competent authorities of the extension, and

b update the approvals register accordingly.

5 The Secretary of State may extend approval under paragraph 1 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.

6 Where the Secretary of State extends approval in accordance with paragraph 5, paragraph 4 is to be read as if—

a in the words before point (a), the reference to the competent authority were a reference to the Secretary of State;

b in point (a), "other" were omitted.**]**

Textual Amendments

F75 Art. 17(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(25)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F76 Words in Art. 17 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(25)(b)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F77 Words in Art. 17 renumbered as Art. 17(3) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(25)(c)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

F78 Art. 17(4)-(6) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(25)(d)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), 3(4)(c)); 2020 c. 1, Sch. 5 para. 1(1)

Article 18 *U.K.*

Work programme

[F79 1**]** **[**F80 A competent authority**]** may establish a work programme grouping together similar active substances setting priorities on the basis of safety concerns for human and animal health or the environment and taking into account, as far as possible, the need for an effective control and resistance management of target pest. The programme may require interested parties to submit all the necessary data to the **[**F81 competent authority**]** within a period provided for in the programme.

[F82 2**]** The programme shall include the following:

(a) the procedures concerning the submission and assessment of applications for renewal of approvals;

(b) the necessary data to be submitted, including measures to minimise animal testing, in particular the use of non-animal test methods and intelligent testing strategies;

(c) the periods for submission of such data;

(d) rules on the submission of new information;

(e) period for assessment and decision making;

(f) [F83] . . . . . .

[[F84]3 The competent authority may vary or withdraw a work programme established by it.

4 The competent authority must publish the work programme and notice of any variation or withdrawal of a work programme in such manner as the competent authority thinks appropriate.

5 The Secretary of State may establish, vary or withdraw a work programme under paragraph 1 or 3 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.

6 Where the Secretary of State establishes, varies or withdraws a work programme in accordance with paragraph 5, a reference in paragraph 4 to the competent authority is to be read as a reference to the Secretary of State.

7 Where the Secretary of State establishes, varies or withdraws a work programme in accordance with paragraph 5 in respect of one or more competent authorities, the programme must also include an allocation of evaluation of active substances to the Secretary of State and those competent authorities, taking into account a balance in the responsibilities and work to be done among the Secretary of State and those competent authorities.

8 A competent authority may request in writing from the competent authority which receives data relating to an active substance in accordance with a work programme under this Article a copy of that data, which the competent authority must provide as soon as reasonably practicable.**]**

Textual Amendments

F79 Words in Art. 18 renumbered as Art. 18(1) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(26)(a)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

F80 Words in Art. 18(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(26)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F81 Words in Art. 18(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(26)(b)(ii)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F82 Words in Art. 18 renumbered as Art. 18(2) (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(26)(c)** (with Sch. 1); 2020 c. 1, **Sch. 5 para. 1(1)**

F83 Art. 18(2)(f) 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(26)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F84 Art. 18(3)-(8) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(26)(e)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), **3(4)(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F85 Article 19 U.K.

Implementing measures

The appropriate authority may, by regulations, make provision necessary for the implementation of the renewal procedure. **]**

Textual Amendments

F85 Arts. 19, 20, 20A, 21 substituted for Arts. 19-21 (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(27)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), **3(4)(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F85 Article 20 U.K.

Renewal decision

1 Within six months of the relevant conclusion date, a competent authority for a constituent territory to which the application relates must decide to either—

a renew the approval of the active substance, subject to conditions or restrictions, as referred to in Article 6(1), where appropriate; or

b refuse to renew approval of the active substance.

2 In making a decision under paragraph 1, the competent authority must have regard to—

a the conclusion of the assessing competent authority and the opinion of the Agency, if any, referred to in Article 37(4) of Regulation (EC) No 1272/2008;

b any comments received by the assessing competent authority in relation to the application, including any environmental monitoring information submitted by an appropriate agency;

c where the competent authority considers it appropriate to obtain it, any independent scientific advice obtained;

d 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;

e any other matters which the competent authority considers relevant to the competent authority's decision.

3 Where the reasons for not renewing the approval of an active substance—

a relate to immediate concerns for the protection of human or animal health or the environment, plant protection products containing that active substance must be withdrawn from the market immediately;

b do not fall within point (a), the competent authority must set a grace period in respect of existing stocks of the plant protection products containing that active substance.

4 The grace period—

a for the sale and distribution of the plant protection products must take into account the normal period of use of those plant protection products but must not exceed six months;

b for the disposal, storage, and use of the plant protection products must be consecutive to the period described in point (a) and must not exceed one year.

5 As soon as reasonably practicable after making a decision under paragraph 1, the competent authority must—

a notify the applicant and the other competent authorities in writing of the decision under paragraph 1, the reasons for that decision and the details of any grace period set in accordance with paragraphs 3 and 4, and

b update the approvals register accordingly.

6 The Secretary of State may make a decision under paragraph 1 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.

7 Where the Secretary of State makes a decision in accordance with paragraph 6, a reference in paragraphs 2, 3 and 5 to the competent authority is to be read as a reference to the Secretary of State.

8 In paragraph 1, the "relevant conclusion date" means—

a where the competent authority is the assessing competent authority, the date on which the competent authority adopts a conclusion under Article 13(1) of Commission Implementing Regulation (EU) No 844/2012;

b otherwise, the date on which the competent authority receives the conclusion of the assessing competent authority in accordance with Article 13(1) of Commission Implementing Regulation (EU) No 844/2012.

9 In paragraph 2(b), "appropriate agency" has the meaning given by Article 13(7).**]**

Textual Amendments

F85 Arts. 19, 20, 20A, 21 substituted for Arts. 19-21 (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(27)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), **3(4)(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

I[F85] *Article 20A* U.K.

Review of further information submitted

1 Where an approval is subject to a condition in accordance with Article 6(1)(f), any confirmatory information received within the period specified in the condition must be assessed by the reviewing authority.

2 Within 6 months of receipt of the confirmatory information, the reviewing authority must—

a assess that information, and

b submit its assessment to the other competent authorities.

3 For the purposes of this Article, the "reviewing authority" is—

a the competent authority specified in the condition to which the approval is subject, or

b a competent authority to which the function of reviewing the confirmatory information is transferred in accordance with paragraph 4.

4 The reviewing authority may by agreement transfer the function of reviewing confirmatory information received to another competent authority.

5 Any confirmatory information received must be transferred at the same time as the transfer under paragraph 4.

6 Following a transfer under paragraph 4, the competent authority to which the function is transferred must notify the applicant of the transfer.

7 A transfer in accordance with paragraph 4 does not—

a affect anything done by the reviewing authority prior to transfer;

b affect the timing of the requirement in paragraph 2.**]**

Textual Amendments

F85 Arts. 19, 20, 20A, 21 substituted for Arts. 19-21 (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(27)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), **3(4)(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F85Article 21 U.K.

Review of approval

1 A competent authority may review the approval of an active substance in relation to its constituent territory at any time.

2 The competent authority must review the approval of an active substance in relation to its constituent territory where—

a the competent authority has assessed confirmatory information as reviewing authority in accordance with Article 20A(1),

b the competent authority receives the assessment of the reviewing competent authority in accordance with Article 20A(2)(b), or

c further information required in accordance with a condition under Article 6(1)(f) has not been provided within the period specified in the condition.

3 Where the competent authority considers that—

a in light of new scientific and technical knowledge or the assessment of the reviewing authority in accordance with Article 20A, there are indications that the active substance no longer satisfies the approval criteria provided for in Article 4, or

b further information required in accordance with a condition under Article 6(1)(f) has not been provided

the competent authority must inform each of the other competent authorities and the producer of the active substance 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, having considered comments received during the period set in accordance with paragraph 3 and any other information or matters that the competent authority considers relevant to the review, that paragraph 3(a) or (b) apply, the competent authority must decide to either—

a amend the conditions or restrictions of the approval, or

b withdraw the approval.

6 Where the reasons for withdrawing the approval of an active substance—

a relate to immediate concerns for the protection of human or animal health or the environment, plant protection products containing that active substance must be withdrawn from the market immediately;

b do not fall within point (a), the competent authority must set a grace period in respect of existing stocks of the plant protection products containing that active substance.

7 The grace period—

a for the sale and distribution of the plant protection products must take into account the normal period of use of those plant protection products but must not exceed six months;

b for the disposal, storage, and use of the plant protection products must be consecutive to the period described in point (a) and must not exceed one year.

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

a notify the producer of the active substance and the other competent authorities in writing of the decision, the reasons for that decision, and the details of any grace period set in accordance with paragraphs 6 and 7, and

b update the approvals register accordingly.

9 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.

10 Where the Secretary of State reviews an active substance in accordance with paragraph 9, a reference in paragraphs 3 to 6 and 8 to the competent authority is to be read as a reference to the Secretary of State.**]**

Textual Amendments

F85 Arts. 19, 20, 20A, 21 substituted for Arts. 19-21 (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(27)** (with Sch. 1) (as amended by S.I. 2020/1376, regs. 1(4), **3(4)(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Subsection 4 U.K.

Derogations

***I**F86 Article 22* U.K.

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

F86 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 *U.K.*

Approval criteria for basic substances

1 Basic substances shall be approved in accordance with **[**[F87]this Article**]**. [F88]...

For the purpose of **[**[F87]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 [F89]... 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 [F90]... by any interested party to the **[**[F91]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 [F92]... legislation regulating the use of the substance; and

b other relevant information on its possible effects on human or animal health or the environment.

[F93]4 . . . . . .

[[F94]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.**]**

F95 6 . . . . . .

Textual Amendments

F87 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)

F88 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)

F89 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)

F90 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)

F91 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)

F92 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)

F93 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)

F94 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)

F95 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)

I[F96] *Article 23A* U.K.

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

F96 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)**

Article 24 U.K.

Candidates for substitution

1 An active substance complying with the criteria provided for in Article 4 shall be approved [F97]... as a candidate for substitution if it meets one or more of the additional criteria laid down in point 4 of Annex II. [F98]...

2 Without prejudice to paragraph 1, Articles 4 to 21 shall apply. [F99]...

Textual Amendments

F97 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)

F98 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)

F99 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)

SECTION 2 U.K.

Safeners and synergists

Article 25 U.K.

Approval of safeners and synergists

1 A safener or synergist shall be approved, where it complies with Article 4.

2 Articles 5 to 21 shall apply.

[F100]3 . . . . . .

Textual Amendments

F100 Art. 25(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(32)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

I[F101]*Article 25A* U.K.

Safeners and synergists on the market on or before 14th June 2011

1 A safener or synergist is deemed to be approved for the purposes of this Regulation in each constituent territory if on or before 14th June 2011 it was—

a held for the purpose of sale within the European Union, an EEA state or the United Kingdom, including being offered for sale or other form of transfer, whether free of charge or not;

b sold, distributed or otherwise transferred within the European Union, an EEA state or the United Kingdom, but not including return to the previous seller; or

c released for free circulation into the territory of the European Union, an EEA state or the United Kingdom.

2 For the purposes of paragraph 1, "the European Union" does not include the Republic of Croatia.

3 A safener or synergist is deemed to be approved in accordance with paragraph 1 in a constituent territory until—

a where an application for approval of that safener or synergist is received in accordance with Article 7 (as applied by Article 25(2)), the date on which a decision is made by the competent authority for that constituent territory or the Secretary of State in accordance with Article 13 (as applied by Article 25(2));

b otherwise, the earliest of the following dates—

i) the date on which the competent authority or the Secretary of State decides to withdraw approval of the safener or synergist for that constituent territory in accordance with Article 21 as applied by paragraph 4;

ii) the date on which the first regulations made under Article 8(4)(a) in respect of safeners or synergists (as the case may be) which apply to that constituent territory come into force.

4 Article 21 applies to a safener or synergist deemed to be approved in accordance with paragraph 1 as if—

a a reference to an active substance were a reference to that safener or synergist;

b paragraph 2 were omitted;

c in paragraph 3—

i) in point (a), the words from "or the assessment" to "Article 20A," were omitted;

ii) point (b) (and the "or" immediately preceding it) were omitted;

d in paragraph 5, for "or (b) apply" there were substituted "applies";

e paragraph 8(b) (and the "and" immediately preceding it) were omitted;

f in paragraph 9, in the words before point (a) "or 2" were omitted.**]**

Textual Amendments

F101 Art. 25A inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(33)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

Article 26 U.K.

Safeners and synergists already on the market

By 14 December 2014, a Regulation shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4) establishing a work programme for the gradual review of synergists and safeners on the market when that Regulation enters into force. The Regulation shall include the establishment of data requirements, including measures to minimise animal testing, notification, evaluation, assessment and decision-making procedures. It shall require interested parties to submit all the necessary data to the Member States, the Commission and the Authority within a specified period.

SECTION 3 U.K.

Unacceptable co-formulants

Article 27 U.K.

Co-formulants

1 A co-formulant shall not be accepted for inclusion in a plant protection product where it has been established that:

a its residues, consequent on application consistent with good plant protection practice, and having regard to realistic conditions of use, have a harmful effect on human or animal health or on groundwater or an unacceptable effect on the environment; or

b its use, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, has a harmful effect on human or animal health or an unacceptable effect on plants, plant products or the environment.

2 Co-formulants which are not accepted for inclusion in a plant protection product pursuant to paragraph 1 shall be included **[**F102on the unacceptable co-formulants register**]**.

3 **[**F103A competent authority may review co-formulants which are not accepted in the competent authority's constituent territory for inclusion in a plant protection product at any time.**][**F104The competent authority**]** may take into account relevant information provided by **[**F105the other competent authorities**]**.

F1064 . . . . . .

[F1075 The appropriate authority may, by regulations, make provision necessary for the implementation of this Article.**]**

Textual Amendments

F102 Words in Art. 27(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(34)(a)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F103 Words in Art. 27(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(34)(b)(i)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F104 Words in Art. 27(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(34)(b)(ii)(aa)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F105 Words in Art. 27(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(34)(b)(ii)(bb)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F106 Art. 27(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(34)(c)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

F107 Art. 27(5) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(34)(d)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

[F108 SECTION 4 U.K.

Registers

Article 27A U.K.

Approvals register

1 The competent authorities must jointly establish and maintain a register of active substances, safeners, synergists, low-risk active substances, basic substances and candidates for substitution approved in accordance with this Regulation.

2 The entry on the register for each substance must contain the following information—

a the common name and identification numbers of the substance;

b the IUPAC name of the substance, where available;

c the minimum purity of the substance;

d in respect of each constituent territory to which the entry relates—

i) whether the substance has been approved as an active substance, safener, synergist, low-risk active substance, basic substance or candidate for substitution;

ii) the date of the approval decision;

iii) except in relation to approved basic substances, the expiration date of approval;

iv) information on any specific provisions, conditions or requirements in respect of the approved substance.

3 The register must contain a search facility.

4 The competent authorities must jointly make the register available for inspection by the public on a website maintained by one or more of the competent authorities.

Article 27B U.K.

Unacceptable co-formulants register

1 The competent authorities must jointly establish and maintain a register of co-formulants which are not acceptable for inclusion in a plant protection product in accordance with Article 27.

2 The entry on the register for each co-formulant must contain the following information—

a the common name of the co-formulant;

b the IUPAC name of the co-formulant (where available);

c the CAS number of the co-formulant (where available);

d the EC number of the co-formulant (where available);

e in respect of each constituent territory to which the entry relates—

i) the date of the decision that the co-formulant was not acceptable for inclusion in a plant protection product;

ii) the sunset date for the co-formulant;

iii) any conditions of restriction relating to the co-formulant;

iv) any other information regarding the co-formulant that the competent authority considers relevant.

3 The register must contain a search facility.

4 The competent authorities must jointly make the register available for inspection by the public on a website maintained by one or more of the competent authorities.**]**

Textual Amendments

F108 Ch. 2 Section 4 inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **4(35)** (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, CHAPTER II.