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 2

Approval procedure

Article 7

Application

[F1 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.**]**

F2 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.

[F3 The assessing competent authority**]** shall assess the confidentiality requests. Upon a request for access to information, the **[**F4 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.

[F5 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

F1 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)

F2 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)

F3 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)

F4 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)

F5 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

Dossiers

1 The summary dossier shall include the following:

a information with respect to one or more representative uses on a **[**F6 crop 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 F7 ... concern a crop F8 ... , justification for this approach;

b for each point of the data requirements for the active substance **[**F9 which 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 **[**F10 which 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.

F11 3 . . . . . .

[F12 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 **[**F13 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

F6 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)

F7 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)

F8 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)

F9 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)

F10 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)

F11 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)

F12 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)

F13 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

Admissibility of the application

1 Within 45 days of receiving the application, the **[**[F14]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 **[**[F15]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 **[**[F15]assessing competent authority**]** shall inform the applicant **[**[F16]and 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 **[**[F17]assessing competent authority**]** shall notify the applicant **[**[F18]and the other competent authorities**]** of the admissibility of the application and start assessing the active substance.

After receiving that notification, the applicant **[**[F19]must on request**]** forward the dossiers as provided for in Article 8 to the other **[**[F20]competent 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

F14 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)

F15 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)

F16 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)

F17 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)

F18 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)

F19 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)

F20 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

Access to the summary dossier

The **[**F21assessing 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

F21 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

Draft assessment report

1 Within 12 months of the date of the notification provided for in the first subparagraph of Article 9(3), the **[**F22assessing competent authority**]** shall prepare and submit to the **[**F23other 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 **[**F24assessing 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 **[**F25assessing 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 **[**F25assessing 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 **[**F25assessing competent authority**]**. It shall inform the **[**F26other competent authorities**]** accordingly.

Where at the end of the additional period, the applicant has not submitted the additional studies or information, the **[**F27assessing competent authority**]** shall inform the applicant **[**F28and the other competent authorities,**]** and shall state the missing elements in the assessment included in the draft assessment report.

F29 4 . . . . . .

Textual Amendments

F22 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)

F23 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)

F24 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)

F25 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)

F26 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)

F27 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)

F28 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)

F29 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

Conclusion by the [F30assessing competent authority]

1

[F31a) 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.]

[F32b)] The [F33assessing 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.

[F32c)] The [F34assessing competent authority] shall allow a period of 60 days for the submission of written comments.

2 F35...

Within 120 days of the end of the period provided for the submission of written comments, the [F36assessing 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 [F37and the other competent authorities,] and shall make it available to the public. [F38In 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 **[**F39assessing competent authority**]** shall address in its conclusion the risk mitigation options identified in the draft assessment report.

3

[F40a)**]** Where the **[**F41assessing competent authority**]** needs additional information, it shall set a period of a maximum of 90 days for the applicant to supply it to the **[**F42assessing competent authority and the other competent authorities**]**.

[F43b) 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.**]**

[F44c)**]** The **[**F45assessing competent authority**]** may F46... consult a F47... reference laboratory, designated pursuant to **[**F48Regulation (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 F47... reference laboratory, provide samples and analytical standards.

4 The conclusion of the **[**F49assessing competent authority**]** shall include details concerning the evaluation procedure and the properties of the active substance concerned.

F505 . . . . . .

6 The time **[**F51limit**]** 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.

F527 . . . . . .

F528 . . . . . .

Textual Amendments

F30 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)

F31 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)

F32 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)**

F33 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)

F34 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)

F35 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)

F36 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)

F37 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)

F38 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)**

F39 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)

F40 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)**

F41 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)

F42 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)

F43 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)**

F44 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)**

F45 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)**

F46 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)

F47 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)

F48 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)

F49 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)

F50 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)

F51 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)

F52 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)

[F53 Article 12A

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

F53 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)

[F54 Article 13

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

F54 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)

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 1107/2009 of the European Parliament and of the Council, Subsection 2.