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 3

Renewal and review

Article 14

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 **[**[F1]Article 6(1)**]**.

[[F2]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

F1 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)

F2 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

Application for renewal

1 The application provided for in Article 14 shall be submitted by a producer of the active substance to a **[**F3competent 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.

[F4 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.

[F5 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

F3 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)

F4 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)

F5 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)

[**F6 Article 15A

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

F6 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

Access to the information for renewal

The **[**F7assessing 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

F7 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

Extension of approval period for the duration of the procedure

[F8 1 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.**]**

F9 . . . . . .

[F10 3**]** 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.

[F11 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

F8 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)

F9 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)

F10 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)**

F11 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

Work programme

[F12 1**]** **[**F13 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 **[**F14 competent authority**]** within a period provided for in the programme.

[F15 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) [F16] . . . . . .

[F17 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

F12 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)**

F13 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)

F14 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)

F15 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)**

F16 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)

F17 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)**

[F18 Article 19

Implementing measures

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

Textual Amendments

F18 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)**

[F18 Article 20

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

F18 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)**

[F18 Article 20A

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

F18 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[F18 Article 21

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

F18 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)**

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 3.