Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 844/2012

of 18 September 2012

setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[(1)], and in particular Article 19 thereof,

Whereas:

(1) Regulation (EC) No 1107/2009 provides that the approval of an active substance may be renewed upon expiry.

(2) It is appropriate to set out the provisions necessary for the implementation of the renewal procedure.

(3) In particular, periods should be set for the different steps of the renewal procedure to ensure that it functions properly.

(4) Rules should be set out as regards confidentiality and the publication of the application for renewal, the supplementary dossiers and their updates.

(5) Rules should also be set out as regards the submission of the application for renewal and its contents and format. The applicant should be obliged to justify the submission of new information and to list separately studies concerning vertebrate animals that they intend to submit.

(6) Rules should be set out as regards the checking of the application by the rapporteur Member State.

(7) In order to ensure the proper functioning of the renewal procedure, the rapporteur Member State should, at the applicant's request, organise prior to the submission of the supplementary dossier, a meeting to discuss the application.

(8) The supplementary dossiers submitted for renewal should, in particular, include necessary new data and new risk assessments and demonstrate why such data and risk assessments are necessary.

(9) Rules should be set out as regards the establishment of the admissibility of the application by the rapporteur Member State.

(10) Where all applications submitted are inadmissible, the Commission should adopt a Regulation on the non-renewal of the active substance concerned.

(11) Rules should be set out to ensure an independent, objective and transparent assessment of the active substance.

(12) The applicant, the Member States, with the exception of the rapporteur Member State, and the public should be given the opportunity to submit comments on the draft renewal assessment report.

(13) The European Food Safety Authority should provide conclusions and organise consultations of experts, except where the Commission informs it that a conclusion is not necessary.

(14) Rules should be set out as regards the renewal report and the adoption of a regulation on the renewal of the approval of the active substance.

(15) Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances[(2)] should continue to apply with respect to the renewal of the approval of the active substances listed in Annex I thereto.

(16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

CHAPTER 1

ADMISSIBILITY

SECTION 1

Application for renewal

Article 1

Submission of the application

1 **[**[F1]An application for the renewal of an approval of an active substance must be submitted by a producer of the active substance to a competent authority for a constituent

territory in relation to which the active substance is approved (in this Regulation, the "assessing competent authority") no later than three years before the expiry of the approval.**]**

When submitting an application, the applicant may, pursuant to Article 63 of Regulation (EC) No 1107/2009, request certain information to be kept confidential. In that event, the applicant shall present such parts of the application physically separated, setting out the reasons for requesting confidentiality.

At the same time, the applicant shall submit any data protection claims pursuant to Article 59 of Regulation (EC) No 1107/2009.

F2...

F32 . . . . . .

3 A joint application may be submitted by an association of producers designated by the producers for the purpose of compliance with this Regulation.

Textual Amendments

F1 Words in Art. 1(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), **reg. 20(2)(a)(i)** (as substituted by S.I. 2019/1410, regs. 1(2), **6(6)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F2 Words in Art. 1(1) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), **reg. 20(2)(a)(ii)** (as substituted by S.I. 2019/1410, regs. 1(2), **6(6)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F3 Art. 1(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), **20(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 2

Format and contents of the application

1 The application shall be submitted in the format set out in the Annex.

2 The application shall list the new information the applicant intends to submit. It shall demonstrate that such information is necessary in accordance with the first subparagraph of Article 15(2) of Regulation (EC) No 1107/2009.

The application shall list separately any new studies involving vertebrate animals that the applicant intends to submit.

Article 3

Checking of the application

1 Where the application has been submitted by the date provided for in the first subparagraph of Article 1(1) and contains all the elements provided for in Article 2, the **[**[F4]assessing competent authority**]** shall, within one month of the date of receipt of the application, inform the applicant **[**[F5]and the other competent authorities**]** of the date of receipt of the application and the fact that it has been submitted by the date provided for in the first subparagraph of Article 1(1) and contains all the elements provided for in Article 2.

The **[**F6assessing competent authority**]** shall assess any request for confidentiality. Upon a request for access to information, the **[**F6assessing competent authority**]** shall decide what information is to be kept confidential.

2 Where the application has been submitted by the date provided for in the first subparagraph of Article 1(1) but one or more elements provided for in Article 2 are missing, the **[**F7assessing competent authority**]** shall, within one month of the date of receipt of the application, inform the applicant which elements are missing and set a period of 14 days for the submission of those elements to the **[**F8assessing competent authority**]**.

Where the application contains all the elements provided for in Article 2 at the expiry of that period, the **[**F9assessing competent authority**]** shall, without delay, proceed in accordance with paragraph 1.

3 Where the application has not been submitted by the date provided for in the first subparagraph of Article 1(1), or where the application still does not contain all the elements provided for in Article 2 at the expiry of the period set for the submission of the missing elements in accordance with paragraph 2, the **[**F10assessing competent authority**]** shall, without delay, inform the applicant **[**F11and the other competent authorities**]** that the application is inadmissible and of the reasons why it is inadmissible.

4 Within 14 days from the date of receipt of the information that the application has been submitted by the date provided for in the first subparagraph of Article 1(1) and that it contains all the elements provided for in Article 2, the applicant shall submit to the **[**F12assessing competent authority**]** a copy of the application, including the information about those parts of the application in respect of which confidentiality has been requested and justified by the applicant pursuant to Article 63 of Regulation (EC) No 1107/2009.

At the same time, the applicant shall forward a copy of the application to the **[**F12assessing competent authority**]**, excluding any information in respect of which confidentiality has been requested and justified by the applicant pursuant to Article 63 of Regulation (EC) No 1107/2009.

5 Where, by the date provided for in the first subparagraph of Article 1(1), two or more applications for the same active substance have been submitted separately **[**F13to the same assessing competent authority**]** and each of them contains all the elements provided for in Article 2, the **[**F14assessing competent authority**]** shall communicate the contact details of each applicant to the other applicant(s).

6 The **[**F15assessing competent authority**]** shall publish, for each active substance, the names and the addresses of the applicants whose applications have been submitted by the date provided for in the first subparagraph of Article 1(1) and contain all the elements provided for in Article 2.

Textual Amendments

F4 Words in Art. 3(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(3)(a)(i)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F5 Words in Art. 3(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(3)(a)(i)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F6 Words in Art. 3(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(3)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F7 Words in Art. 3(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(3)(b)(i)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F8 Words in Art. 3(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(3)(b)(i)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F9 Words in Art. 3(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(3)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F10 Words in Art. 3(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(3)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F11 Words in Art. 3(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(3)(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F12 Words in Art. 3(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(3)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

F13 Words in Art. 3(5) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(3)(e)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F14 Words in Art. 3(5) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(3)(e)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F15 Words in Art. 3(6) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(3)(f)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 4

Contacts prior to submission of supplementary dossiers

The applicant may request a meeting with the **[**F16assessing competent authority**]** to discuss the application.

If requested, such pre-submission contacts shall take place prior to the submission of supplementary dossiers, as provided for in Article 6.

Textual Amendments

F16 Words in Art. 4 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(4)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 5

Access to the application

Upon receipt of the application, as provided for in Article 3(4), the **[**F17assessing competent authority**]** shall make it available to the public without delay, excluding any information in respect of which confidentiality has been requested and justified by the

applicant pursuant to Article 63 of Regulation (EC) No 1107/2009, unless there is an overriding public interest in its disclosure.

Textual Amendments

F17 Words in Art. 5 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(5)**; 2020 c. 1, Sch. 5 para. 1(1)

SECTION 2

Supplementary dossiers

Article 6

Submission of supplementary dossiers

1 Where the **[**F18assessing competent authority**]** has informed the applicant in accordance with Article 3(1) that its application has been submitted by the date provided for in the first subparagraph of Article 1(1) and that it contains all the elements provided for in Article 2, the applicant shall submit the supplementary dossiers to the **[**F19assessing competent authority**]**.

[F20 1A. The assessing competent authority must notify the other competent authorities as soon as reasonably practicable after receipt of the supplementary dossiers under paragraph 1.

1B. A competent authority which receives a notification under paragraph 1A may request in writing from the applicant a copy of supplementary dossiers, which the applicant must provide as soon as reasonably practicable.**]**

2 The contents of the supplementary summary dossier and the supplementary complete dossier shall comply with Article 7.

[F21 3 The supplementary dossiers shall be submitted no later than 33 months before the expiry of the approval.**][**F22 The requirement applies to substances approved for use within Great Britain where that approval expires on or after 13 May 2026.**]**

4 Where there is more than one applicant requesting renewal of the approval of the same active substance, those applicants shall take all reasonable steps to submit their dossiers jointly.

Where such dossiers are not submitted jointly by all the applicants concerned, the reasons shall be set out in the dossiers.

5 When submitting the supplementary dossiers, the applicant may pursuant to Article 63 of Regulation (EC) No 1107/2009 request certain information, including certain parts of the dossier, to be kept confidential and shall physically separate that information.

Textual Amendments

F18 Words in Art. 6(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(6)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F19 Words in Art. 6(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(6)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F20 Art. 6(1A)(1B) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(6)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F21 Substituted by Commission Implementing Regulation (EU) 2020/103 of 17 January 2020 amending Implementing Regulation (EU) No 844/2012 as regards the harmonised classification of active substances (Text with EEA relevance).

F22 Words in Art. 6(3) inserted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(2)**

Article 7

Contents of supplementary dossiers

1 The supplementary summary dossier shall include the following:

a a copy of the application;

b where the applicant is joined or replaced by one or more other applicants, the name and address of that applicant or those other applicants and, if applicable, the name of the association of producers provided for in Article 1(3);

c information with respect to one or more representative uses on a **[**F23crop grown in Great Britain**]** of at least one plant protection product containing the active substance, demonstrating that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are fulfilled; where the information submitted does not **[**F24concern a**]** crop, a justification shall be submitted;

d data and risk assessments which were not part of the approval dossier or subsequent renewal dossiers and which are necessary:

(i) to reflect changes in legal requirements which have occurred since the approval or last renewal of the approval of the active substance concerned;

(ii) to reflect changes in scientific and technical knowledge since the approval or last renewal of the approval of the active substance concerned;

(iii) to reflect changes to representative uses; or

(iv) because the application is for an amended renewal;

e for each point of the data requirements for the active substance, as set out in **[**F25legislation**]** setting out data requirements for active substances under Regulation (EC) No 1107/2009 **[**F26in relation to each constituent territory to which the application for renewal relates**]**, for which new data are necessary in accordance with point (d), the summaries and results of tests and studies, the name of their owner and of the person or institute that has carried them out and the reason why each test or study is necessary;

f for each point of the data requirements for the plant protection product, as set out in **[**F27legislation**]** setting out data requirements for plant protection products under Regulation (EC) No 1107/2009 **[**F28in relation to each constituent territory to which the application for renewal relates**]**, for which new data are necessary in accordance with point (d), 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, for one or more plant protection products which are representative of the supported uses, and the reason why each test or study is necessary;

g where relevant, documented evidence as referred to in Article 4(7) of Regulation (EC) No 1107/2009;

h for each test or study involving vertebrate animals, a description of the steps taken to avoid animal testing on vertebrate animals;

i where relevant, a copy of an application for maximum residue levels as referred to in Article 7 of Regulation (EC) No 396/2005 of the European Parliament and of the Council[3];

[[F21]j a proposal for classification where it is considered that the substance has to be classified or reclassified in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[4];**]**

k an assessment of all information submitted;

l a checklist demonstrating that the supplementary dossier provided for in paragraph 3 is complete in view of the uses applied for and indicating which data are new;

m the summaries and results of scientific peer-reviewed open literature, as referred in Article 8(5) of Regulation (EC) No 1107/2009.

2 The uses referred to in paragraph 1(c) shall, where appropriate, include the uses evaluated for the approval or subsequent renewals. At least one plant protection product referred to in paragraph 1(c) shall contain no other active substance, where such a product exists for a representative use.

3 The supplementary complete dossier shall contain the full text of each test and study report referred to in paragraph 1(e), (f) and (m).

It shall not contain any reports of tests or studies involving the deliberate administration of the active substance or the plant protection product containing it to humans.

Textual Amendments

F21 Substituted by Commission Implementing Regulation (EU) 2020/103 of 17 January 2020 amending Implementing Regulation (EU) No 844/2012 as regards the harmonised classification of active substances (Text with EEA relevance).

F23 Words in Art. 7(1)(c) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(7)(a)(i)** (as amended by S.I. 2020/1376, regs. 1(4), **3(16)(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F24 Words in Art. 7(1)(c) substituted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(7)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F25 Word in Art. 7(1)(e) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(7)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F26 Words in Art. 7(1)(e) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(7)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F27 Word in Art. 7(1)(f) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(7)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F28 Words in Art. 7(1)(f) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(7)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 8

Admissibility of the application

1 Where the supplementary dossiers have been submitted by the date provided for in Article 6(3) and contain all the elements provided for in Article 7, the **[**F29assessing competent authority**]** shall, within a period of one month, inform the applicant **[**F30and the other competent authorities**]** of the date of receipt of the supplementary dossiers and of the admissibility of the application.

The **[**F31assessing competent authority**]** shall assess any requests for confidentiality. In the event of a request for access to information, the **[**F31assessing competent authority**]** shall decide what information is to be kept confidential.

2 Where the supplementary dossiers have been submitted by the date provided for in Article 6(3), but one or more elements provided for in Article 7 are missing, the **[**F32assessing competent authority**]** shall, within a period of one month from the date of receipt of the supplementary dossiers, inform the applicant which elements are missing and set a period of 14 days for the submission of those elements to the **[**F33assessing competent authority**]**.

Where at the expiry of that period the supplementary dossiers contain all the elements provided for in Article 7, the **[**F34assessing competent authority**]** shall, without delay, proceed in accordance with paragraph 1.

3 F35...

[F36Before the end of the period stated in paragraph 1**]**, the applicant shall forward the supplementary summary dossiers to the **[**F37assessing competent authority**]**, excluding any information in respect of which confidentiality has been requested and justified by the applicant pursuant to Article 63 of Regulation (EC) No 1107/2009.

4 The **[**F38assessing competent authority**]** shall make the supplementary summary dossier available to the public, without delay, excluding any information in respect of which confidentiality has been requested and justified by the applicant pursuant to Article 63 of Regulation (EC) No 1107/2009, unless there is an overriding public interest in its disclosure.

5 At the request of **[**F39a competent authority**]**, the applicant shall make available the dossiers submitted for the approval and subsequent renewals of the approval, where it has access to them.

6 Where the supplementary dossiers have not been submitted by the date referred to in Article 6(3), or where at the end of the period set for the submission of the missing elements in accordance with paragraph 2 of this Article the supplementary dossiers still do not contain all the elements provided for in Article 7, the **[**F40assessing competent authority**]** shall, without delay, inform the applicant **[**F41and the other competent authorities**]** that the application is inadmissible and of the reasons why it is inadmissible.

Textual Amendments

F29 Words in Art. 8(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(8)(a)(i)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F30 Words in Art. 8(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(8)(a)(i)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F31 Words in Art. 8(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(8)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F32 Words in Art. 8(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(8)(b)(i)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F33 Words in Art. 8(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(8)(b)(i)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F34 Words in Art. 8(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(8)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F35 Words in 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), **20(8)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F36 Words in Art. 8(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(8)(c)(ii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F37 Words in Art. 8(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(8)(c)(ii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F38 Words in 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), **20(8)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

F39 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), **20(8)(e)**; 2020 c. 1, Sch. 5 para. 1(1)

F40 Words in Art. 8(6) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(8)(f)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F41 Words in Art. 8(6) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(8)(f)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 9

Replacement of the applicant

An applicant may be replaced by another producer in respect of all of its rights and obligations under this Regulation by informing the **[**[F42]assessing competent authority**]**, through a joint declaration by the applicant and the other producer. In that case, the applicant and the other producer shall, at the same time, inform the **[**[F43]other competent authorities**]** and any other applicants that have submitted an application for the same active substance of the replacement.

Textual Amendments

F42 Words in Art. 9 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(9)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F43 Words in Art. 9 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(9)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

[F44 Article 10

Refusal of renewal where applications are inadmissible

Where all of the applications submitted for renewal of the approval of an active substance in relation to a constituent territory are inadmissible in accordance with Article 3(3) or 8(6), the competent authority for that constituent territory must refuse to renew approval of the active substance in accordance with Article 20(1)(b) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council.**]**

Textual Amendments

F44 Art. 10 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(10)**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER 2

ASSESSMENT

Article 11

Assessment by the [F45assessing competent authority]

1 Where the application is admissible in accordance with Article 8(1), the **[**F46assessing competent authority must**]**, at the latest **[**F2113 months**]** after the date referred to in Article 6(3), prepare and submit to the **[**F47other competent authorities**]** a report assessing whether the active substance can be expected to meet the approval criteria, as provided for in Article 4 of Regulation (EC) No 1107/2009 (‘the draft renewal assessment report’).

2 The draft renewal assessment report shall also include the following:

a a recommendation with regard to the renewal of the approval;

b a recommendation on whether the substance should be considered a ‘low-risk’ substance;

c a recommendation on whether the substance should be considered a candidate for substitution;

d where relevant, a proposal to set maximum residue levels;

[F21e a suggestion for the classification, or its confirmation, where applicable, or reclassification of the active substance in accordance with the criteria of Regulation

(EC) No 1272/2008, as specified in and consistent with the dossier to be submitted pursuant to paragraph 9;**]**

f a conclusion on which of the new studies included in the supplementary dossiers are relevant for the assessment;

[F48]g . . . . . .

[F48]h . . . . . .

3 The **[**[F49]assessing competent authority**]** shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge. It shall take into account the supplementary dossiers, and, where appropriate, the dossiers submitted for the approval and subsequent renewals of approval.

4 The **[**[F50]assessing competent authority**]** shall first establish whether the approval criteria set out in points 3.6.2, 3.6.3, 3.6.4 and 3.7 of Annex II to Regulation (EC) No 1107/2009 are satisfied.

Where those criteria are not satisfied, the draft renewal assessment report shall be limited to those parts of the assessment, unless Article 4(7) of Regulation (EC) No 1107/2009 applies.

5 Where the **[**[F51]assessing competent authority**]** requires additional information, it shall set a period for the applicant to supply that information. [F52]... The applicant may, pursuant to Article 63 of Regulation (EC) No 1107/2009, request such information to be kept confidential.

[[F53]5A. The 13 month period provided for in paragraph 1 is extended by any additional period set in accordance with paragraph 5.

5B. The additional period described in paragraph 5 must be for no more than 6 months and ceases at the earlier of—

a the date on which the assessing competent authority receives the additional information;

b the expiry of the additional period.**]**

[[F54]6 The assessing competent authority may, as it considers appropriate—

a obtain independent scientific advice;

b consult with the other competent authorities.**]**

7 Information submitted by the applicant without having been requested, or provided after the expiry of the period set for its submission in accordance with the first sentence of paragraph 5, shall not be taken into account, unless it is submitted in accordance with Article 56 of Regulation (EC) No 1107/2009.

8 **[**[F55]When submitting the draft renewal assessment report to the other competent authorities, the assessing competent authority must require the applicant to notify the other competent authorities of the existence of any updated supplementary summary dossiers. Article 15(4) of Regulation (EC) No 1107/2009 applies to a notification under this paragraph as it applies to a notification under Article 15(3) of that Regulation.**]**

The applicant may pursuant to Article 63 of Regulation (EC) No 1107/2009 request such information to be kept confidential. Any such requests shall be addressed to the **[**[F56]assessing competent authority**]**.

[[F57]9 The **[**[F58]assessing competent authority**]** shall at the latest at the time of submission of the draft renewal assessment report submit a proposal to the **[**[F59]Agency**]** pursuant to Article **[**[F60]37A(2)(2)**]** of Regulation (EC) No 1272/2008 and in accordance with the Agency's

requirements to obtain an opinion on a **[**[F61]mandatory classification and labelling**]** of the active substance at least for the following hazard classes:

— explosives,
— acute toxicity,
— skin corrosion/irritation,
— serious eye damage/eye irritation,
— respiratory or skin sensitisation,
— germ cell mutagenicity,
— carcinogenicity,
— reproductive toxicity,
— specific target organ toxicity – single exposure,
— specific target organ toxicity – repeated exposure;
— hazardous to the aquatic environment.

The **[**[F62]assessing competent authority**]** shall duly justify its view that the criteria for classification for one or more of these hazard classes are not fulfilled.

Where a proposal for classification of an active substance has already been submitted to the Agency and its assessment is ongoing, the **[**[F62]assessing competent authority**]** shall submit an additional proposal for classification, limited to any hazard classes listed above that are not covered by the pending proposal unless new information has become available that was not part of the pending dossier as regards the hazard classes listed above.

For the hazard classes, which are already covered by an existing opinion of the Committee for Risk Assessment of the Agency set up pursuant to Article 76(1)(c) of Regulation (EC) No 1907/2006, **[**[F63]or by an Agency opinion,**]** whether or not this opinion has formed the basis of a decision concerning an entry for **[**[F64]mandatory classification**]** and labelling of a substance in **[**[F65]the GB mandatory classification and labelling list**]**, it is sufficient that the rapporteur Member State duly justifies in its submission to the Agency that the existing opinion, or where it has already formed the basis of a decision concerning the inclusion in **[**[F66]the GB mandatory classification and labelling list**]**, the existing classification remains valid as regards the hazard classes listed in the first subparagraph. The Agency may provide its views regarding the **[**[F67]assessing competent authority's**]** submission.**]**

Textual Amendments

F21 Substituted by Commission Implementing Regulation (EU) 2020/103 of 17 January 2020 amending Implementing Regulation (EU) No 844/2012 as regards the harmonised classification of active substances (Text with EEA relevance).

F45 Words in Art. 11 heading substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(11)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F46 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), **20(11)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F47 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), **20(11)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F48 Art. 11(2)(g)(h) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(11)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F49 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), **20(11)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

F50 Words in Art. 11(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(11)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

F51 Words in Art. 11(5) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(11)(e)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F52 Words in Art. 11(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), **20(11)(e)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F53 Art. 11(5A)(5B) inserted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(11)(f)** (as amended by S.I. 2020/1376, regs. 1(4), **3(16)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F54 Art. 11(6) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(11)(g)**; 2020 c. 1, Sch. 5 para. 1(1)

F55 Words in Art. 11(8) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(11)(h)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F56 Words in Art. 11(8) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(11)(h)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F57 Inserted by Commission Implementing Regulation (EU) 2020/103 of 17 January 2020 amending Implementing Regulation (EU) No 844/2012 as regards the harmonised classification of active substances (Text with EEA relevance).

F58 Words in Art. 11(9) substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(3)(a)(i)(aa)**

F59 Word in Art. 11(9) substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(3)(a)(i)(bb)**

F60 Word in Art. 11(9) substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(3)(a)(i)(cc)**

F61 Words in Art. 11(9) substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(3)(a)(i)(dd)**

F62 Words in Art. 11(9) substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(3)(a)(ii)**

F63 Words in Art. 11(9) inserted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(3)(a)(iii)(aa)**

F64 Words in Art. 11(9) substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(3)(a)(iii)(bb)**

F65 Words in Art. 11(9) substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(3)(a)(iii)(cc)**

F66 Words in Art. 11(9) substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(3)(a)(iii)(dd)**

F67 Words in Art. 11(9) substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(3)(a)(iii)(ee)**

[F68 Article 11a

For the purposes of assessment of the approval criteria set out in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 as amended by Commission Regulation (EU) 2018/605(5), in relation to applications submitted in accordance with Article 1 before 10 November 2018 for which the draft renewal assessment report has not been submitted by that date, where the information available in the supplementary dossiers is not sufficient for the **[**F69assessing competent authority**]** to conclude the assessment on whether these approval criteria are met and, where applicable, whether application of Article 4(7) is justified, the **[**F69assessing competent authority**]** shall specify in the draft renewal assessment report, in a detailed way, the additional information which is necessary in order to make the assessment concerned.**]**

Textual Amendments

F68 Inserted by Commission Implementing Regulation (EU) 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605 (Text with EEA relevance).

F69 Words in Art. 11a substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(2)**; 2020 c. 1, Sch. 5 para. 1(1)

[F57 Article 11b

The **[**F70Agency**]** shall endeavour to adopt the opinion **[**F71on a proposal from the assessing competent authority**]** within 13 months from the submission referred to in Article 11(9).**]**

Textual Amendments

F57 Inserted by Commission Implementing Regulation (EU) 2020/103 of 17 January 2020 amending Implementing Regulation (EU) No 844/2012 as regards the harmonised classification of active substances (Text with EEA relevance).

F70 Word in Art. 11b substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(4)(a)**

F71 Words in Art. 11b substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1376), regs. 1(2), **2(4)(b)**

Article 12

Comments on the draft renewal assessment report

[F21 1 The **[**F72assessing competent authority**]** shall examine whether the draft renewal assessment report F73... contains all the relevant information in the agreed format and circulate it to the applicant and to the other **[**F74competent authorities**]** at the latest three months after its receipt.**]**

2 The **[**F75assessing competent authority**]** shall make the draft renewal assessment report available to the public, after giving the applicant two weeks to request, pursuant to Article 63 of Regulation (EC) No 1107/2009, that certain parts of the draft renewal assessment report are kept confidential.

3 The [F76assessing competent authority] shall allow a period of 60 days from the date the report is made available to the public for the submission of written comments. Such comments shall be communicated to the [F76assessing competent authority], which shall collate and forward those comments, including its own comments, to the [F77other competent authorities].

4 The [F78assessing competent authority] shall make the updated supplementary summary dossiers available to the public, excluding any information in respect of which confidentiality has been requested and justified by the applicant pursuant to Article 63 of Regulation (EC) No 1107/2009, unless there is an overriding public interest in its disclosure.

Textual Amendments

F21 Substituted by Commission Implementing Regulation (EU) 2020/103 of 17 January 2020 amending Implementing Regulation (EU) No 844/2012 as regards the harmonised classification of active substances (Text with EEA relevance).

F72 Words in Art. 12(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(12)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F73 Words in Art. 12(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), **20(12)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F74 Words in Art. 12(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(12)(a)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

F75 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), **20(12)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F76 Words in Art. 12(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(12)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F77 Words in Art. 12(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(12)(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F78 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), **20(12)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 13

Conclusion by the [F79assessing competent authority]

1 [F21Within five months from the expiry of the period referred to in Article 12(3), or within two weeks from the adoption of the opinion of the [F80Agency] referred to in Article [F81]37A(4)] of Regulation (EC) No 1272/2008, if any adopted, whichever occurs later, the [F82assessing competent authority] shall adopt a conclusion in the light of current scientific and technical knowledge using guidance documents applicable at the date of the submission of the supplementary dossiers and in the light of the opinion of the [F80Agency] on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.][F83The assessing competent authority may obtain independent scientific advice where it considers it appropriate to do so.] The Authority shall communicate its conclusion to the applicant [F84and the other competent authorities].

F85 …

2 After giving the applicant two weeks to request, pursuant to Article 63 of Regulation (EC) No 1107/2009, that certain parts of the conclusion be kept confidential, the **[**F86assessing competent authority**]** shall make its conclusion available to the public, excluding any information in respect of which confidentiality has been granted by the **[**F86assessing competent authority**]**, unless there is an overriding public interest in its disclosure.

3 Where the **[**F87assessing competent authority**]** considers that additional information from the applicant is necessary, it shall F88... set a period not exceeding **[**F8990 days**]** for the applicant to supply such information to the **[**F90other competent authorities**]** and the **[**F87assessing competent authority**]**. The **[**F91assessing competent authority**]** shall, within 60 days from the date of receipt of the additional information evaluate the information received F92....

Where the first subparagraph applies, the period referred to in paragraph 1 shall be extended by the periods referred to in the first subparagraph of this paragraph.

[F683a For the purposes of assessment of the approval criteria set out in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 as amended by Commission Regulation (EU) 2018/605, in relation to applications submitted in accordance with Article 1 before 10 November 2018, for which the draft renewal assessment report has been submitted but the conclusion by the **[**F93assessing competent authority**]** is not yet adopted by that date, where the information available in the dossier is not sufficient for the **[**F93assessing competent authority**]** to conclude the assessment on whether these approval criteria are met, the **[**F93assessing competent authority**]** shall, in consultation with the **[**F94other competent authorities**]**, request from the applicant the additional information to be submitted to the **[**F95assessing competent authority and the other competent authorities**]** in the form of an updated supplementary dossier including the additional information. The **[**F96assessing competent authority**]** shall, in consultation with F97... the applicant, set a period for the submission of that information. Such period shall be at least of 3 months, shall not exceed 30 months, and shall be justified in relation to the type of information which has to be submitted.

Within this period set by the **[**F98assessing competent authority**]**, the applicant may also submit where applicable, documentary evidence showing that the conditions for the application of the derogation under Article 4(7) of Regulation (EC) No 1107/2009 are met.

Where the **[**F99assessing competent authority**]** is able to conclude without requesting additional information that the scientific criteria for the determination of endocrine disrupting properties set out in point 3.6.5 and/or point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 are met, it shall inform the applicant. Within 3 months after being informed by the **[**F100assessing competent authority**]**, the applicant may submit to the **[**F101assessing competent authority and the other competent authorities**]**, additional information to address the approval criteria set in point 3.6.5 and/or point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, and/or documentary evidence showing that the conditions for the application of the derogation under Article 4(7) of that Regulation are met.

Where the first or third subparagraphs apply, the period referred to in paragraph 1 shall be extended by the period set for submission of the additional information.

Where no additional information is submitted in accordance with the first, second or third subparagraph within the period set for its submission, the **[**F102assessing competent authority**]** shall, without delay, inform the applicant **[**F103and the other competent authorities**]** and conclude the assessment based on the available information.

Where additional information is submitted in accordance with the first, second or third subparagraph within the period set for its submission, the **[**F104assessing competent authority**]** shall, within 90 days from the date of receipt of the additional information evaluate the information received and **[**F105circulate to the other competent authorities and the applicant**]** a revised draft renewal assessment report. The **[**F106assessing competent authority**]** shall conduct a consultation on the revised draft renewal assessment report with **[**F107the other competent authorities**]** and the applicant in accordance with Article 12. The **[**F108assessing competent authority**]** shall adopt the conclusion referred to in paragraph 1, within 120 days from the date of **[**F109circulation**]** of the revised draft renewal assessment report, using the guidance for identification of endocrine disruptors applicable at the date of the submission of the updated supplementary dossier referred to in the first subparagraph.**]**

4 The **[**F110assessing competent authority**]** may F111... consult a F112... reference laboratory designated, pursuant to **[**F113Regulation (EU) 2017/625 of the European Parliament and of the Council **]**, for the purposes of verifying whether the analytical method for the determination of the residues proposed by the applicant is satisfactory and complies with the requirements in Article 29(1)(g) of Regulation (EC) No 1107/2009. The applicant shall, if requested by the F114... reference laboratory, provide samples and analytical standards.

[F1155 Information submitted by the applicant without having been requested, or provided after the expiry of the period set for its submission in accordance with the first subparagraph of paragraph 3 or in accordance with the first or third subparagraphs of paragraph 3a of this Article, shall not be taken into account, unless it is submitted in accordance with Article 56 of Regulation (EC) No 1107/2009.**]**

Textual Amendments

F21 Substituted by Commission Implementing Regulation (EU) 2020/103 of 17 January 2020 amending Implementing Regulation (EU) No 844/2012 as regards the harmonised classification of active substances (Text with EEA relevance).

F68 Inserted by Commission Implementing Regulation (EU) 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605 (Text with EEA relevance).

F79 Words in Art. 13 heading substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(13)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F80 Words in Art. 13(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), reg. 20(13)(b)(i)(aa) (as substituted by S.I. 2020/1376, regs. 1(4), **3(16)(c)**)

F81 Word in Art. 13(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), reg. 20(13)(b)(i)(bb) (as substituted by S.I. 2020/1376, regs. 1(4), **3(16)(c)**)

F82 Words in Art. 13(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), reg. 20(13)(b)(i)(cc) (as substituted by S.I. 2020/1376, regs. 1(4), **3(16)(c)**)

F83 Words in Art. 13(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), reg. 20(13)(b)(i)(dd) (as substituted by S.I. 2020/1376, regs. 1(4), **3(16)(c)**)

F84 Words in Art. 13(1) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), reg. 20(13)(b)(i)(ee) (as substituted by S.I. 2020/1376, regs. 1(4), **3(16)(c)**)

F85 Words in Art. 13(1) omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), reg. 20(13(b)(ii) (as substituted by S.I. 2020/1376, regs. 1(4), **3(16)(c)**)

F86 Words in Art. 13(2) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(13)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F87 Words in Art. 13(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(13)(d)(i)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F88 Words in Art. 13(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), **20(13)(d)(i)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F89 Words in Art. 13(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(13)(d)(i)(cc)**; 2020 c. 1, Sch. 5 para. 1(1)

F90 Words in Art. 13(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(13)(d)(i)(dd)**; 2020 c. 1, Sch. 5 para. 1(1)

F91 Words in Art. 13(3) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(13)(d)(ii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F92 Words in Art. 13(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), **20(13)(d)(ii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F93 Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(a)(i)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F94 Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(a)(i)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F95 Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(a)(i)(cc)**; 2020 c. 1, Sch. 5 para. 1(1)

F96 Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(a)(ii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F97 Words in Art. 13(3a) omitted (31.12.2020) by virtue of The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(a)(ii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F98 Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F99 Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F100 Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(c)(ii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F101 Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(c)(ii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F102 Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(d)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F103 Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(d)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F104 Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(e)(i)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F105 Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(e)(i)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F106 Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(e)(ii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F107 Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(e)(ii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F108 Words in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(e)(iii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F109 Word in Art. 13(3a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(3)(e)(iii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F110 Words in Art. 13(4) substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(13)(e)(i)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F111 Words in Art. 13(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), **20(13)(e)(i)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F112 Words in Art. 13(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), **20(13)(e)(i)(cc)**; 2020 c. 1, Sch. 5 para. 1(1)

F113 Words in Art. 13(4) substituted (31.12.2020) by The Pesticides (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1410), regs. 1(3), **3(2)**; 2020 c. 1, Sch. 5 para. 1(1)

F114 Words in Art. 13(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), **20(13)(e)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F115 Substituted by Commission Implementing Regulation (EU) 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605 (Text with EEA relevance).

F116 Article 13a

Fees and charges

. . . . . .

Textual Amendments

F116 Art. 13a omitted (31.12.2020) by virtue of The Pesticides (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1410), regs. 1(3), **3(3)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 14

Renewal [F117decision]

[F118**1** Article 20 of Regulation (EC) No 1107/2009 applies.

1za. Paragraph 1a applies in relation to an application where—}

a paragraph 7 of Schedule 1 to the Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 applies in relation to that application, and

b the European Food Safety Authority adopted a conclusion in relation to that application before 10th November 2018 in accordance with Article 13.**]**

[F68**1a** F119...

[F120For the purposes of assessment of the approval criteria set out in points 3.6.5 and 3.8.2 of Annex 2 to Regulation (EC) No 1107/2009, the assessing competent authority may**]** decide whether additional information is required and request the applicant to submit such information to the **[**F121assessing competent authority and the other competent authorities**]** in the form of an updated supplementary dossier including the additional information. The **[**F122assessing competent authority**]** shall, in consultation with F123... the applicant, set a period for the submission of that information. Such period shall be at least of 3 months, shall not exceed 30 months, and shall be justified in relation to the type of information which has to be submitted.

Within this period set by the **[**F124assessing competent authority**]**, the applicant may also submit where applicable, documentary evidence showing that the conditions for the application of the derogation under Article 4(7) of Regulation (EC) No 1107/2009 are met.

Where the **[**F125assessing competent authority**]** is able to conclude without requesting additional information that the scientific criteria for the determination of endocrine disrupting properties set out in point 3.6.5 and/or point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 are met, it shall inform the applicant. Within 3 months after being informed by the **[**F126assessing competent authority**]**, the applicant may submit to the **[**F127assessing competent authority and the other competent authorities**]** additional information to address the approval criteria set out in point 3.6.5 and/or point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, and/or documentary evidence showing that the conditions for the application of the derogation under Article 4(7) of that Regulation are met.

The **[**F128assessing competent authority**]** shall, within 90 days from the date of receipt of the additional information evaluate the information received and **[**F129circulate to the other competent authorities and the applicant**]** a revised draft renewal assessment report. The **[**F130assessing competent authority**]** shall conduct a consultation of the revised renewal assessment report with **[**F131the other competent authorities**]** and the applicant in accordance with Article 12.

The **[**F132assessing competent authority**]** shall adopt an addendum to the conclusion referred to in paragraph 1, within 120 days from the date of **[**F133circulation**]** of the revised draft renewal assessment report, using the guidance for identification of endocrine disruptors applicable at the date of the submission of the updated supplementary dossier referred to in the second subparagraph.

Where no additional information is submitted in accordance with the second, the third or the fourth subparagraph within the period set for its submission, the **[**F134assessing competent authority**]** shall, without delay, inform the applicant **[**F135and the other competent authorities**]** and conclude the assessment based on the available information within 30 days from the expiry of the period referred to in the second or fourth subparagraph.

Information submitted by the applicant without having been requested, or provided after the expiry of the period set for its submission in accordance with the second or fourth subparagraph of this Article, shall not be taken into account, unless it is submitted in accordance with Article 56 of Regulation (EC) No 1107/2009.**]**

F1362 . . . . . .

Textual Amendments

F68 Inserted by Commission Implementing Regulation (EU) 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605 (Text with EEA relevance).

F117 Word in Art. 14 heading substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F118 Art. 14(1)(1za) substituted for Art. 14(1) (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F119 Words in Art. 14(1a) omitted (31.12.2020) by virtue of The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F120 Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(ii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F121 Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(ii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F122 Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(ii)(cc)**; 2020 c. 1, Sch. 5 para. 1(1)

F123 Words in Art. 14(1a) omitted (31.12.2020) by virtue of The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(ii)(dd)**; 2020 c. 1, Sch. 5 para. 1(1)

F124 Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

F125 Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(iv)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F126 Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(iv)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F127 Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(iv)(cc)**; 2020 c. 1, Sch. 5 para. 1(1)

F128 Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(v)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F129 Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(v)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F130 Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(v)(cc)**; 2020 c. 1, Sch. 5 para. 1(1)

F131 Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(v)(dd)**; 2020 c. 1, Sch. 5 para. 1(1)

F132 Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(vi)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F133 Word in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(vi)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F134 Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(vii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F135 Words in Art. 14(1a) substituted (31.12.2020) by The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(c)(vii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F136 Art. 14(2) omitted (31.12.2020) by virtue of The Environment (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2019 (S.I. 2019/559), regs. 1(3), **11(4)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER 3

TRANSITIONAL AND FINAL PROVISIONS

Article 15

Transitional provisions

Regulation (EU) No 1141/2010 shall continue to apply with respect to the **[**[F137]existing renewal applications within the meaning of Article 1(2) of that Regulation**]**.

Textual Amendments

F137 Words in Art. 15 substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(15)**; 2020 c. 1, Sch. 5 para. 1(1)

F138 Article 16

Entry into force and application

. . . . . .

Textual Amendments

F138 Art. 16 omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(16)**; 2020 c. 1, Sch. 5 para. 1(1)

F139…

Textual Amendments

F139 Words in Signature omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(17)**; 2020 c. 1, Sch. 5 para. 1(1)

ANNEX

Format for applications, as provided for in Article 2(1)

The application shall be in writing, signed by the applicant, and sent to the **[**[F140]assessing competent authority**]**.

Textual Amendments

F140 Words in Annex substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(18)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F141...

Textual Amendments

F141 Words in Annex omitted (31.12.2020) by virtue of The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(18)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

MODEL

1. Information concerning the applicant

1.1. Name and address of the applicant including the name of the natural person responsible for the application and other obligations resulting from this Regulation:

1.1.1. (a) Telephone No:

(b) E-mail address:

1.1.2. (a) Contact:

(b) Alternative contact:

2. Information to facilitate identification

2.1. Common name (proposed or ISO-accepted) specifying, where relevant, any variants thereof such as salts, esters or amines manufactured by the producer.

2.2. Chemical name (IUPAC and CAS nomenclature).

2.3. CAS, CIPAC and EC numbers (if available).

2.4. Empirical and structural formula, molecular mass.

2.5. Specification of purity of the active substance in g/kg which must be, whenever possible, identical or already accepted as equivalent to the one listed in the **[**[F142]approvals register in relation to each constituent territory to which the application relates**]**.

Textual Amendments

F142 Words in Annex substituted (31.12.2020) by The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 (S.I. 2019/556), regs. 1(1), **20(18)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

2.6. Classification and labelling of the active substance in accordance with the provisions of Regulation (EC) No 1272/2008 of the European Parliament and of the Council[6] (health and environment effects).

3. New information

3.1. List of new information intended to be submitted together with a justification showing that they are considered necessary, in accordance with Article 15(2) of Regulation (EC) No 1107/2009.

3.2. List of new studies intended to be submitted on vertebrate animals.

3.3. Timetable of any new and ongoing studies.

The applicant confirms that the above information submitted included in the application is correct.

Date and signature (of the person competent to act for the applicant referred to under point 1.1).

(**1**) OJ L 309, 24.11.2009, p. 1.

(**2**) OJ L 322, 8.12.2010, p. 10.

(**3**) OJ L 70, 16.3.2005, p. 1.

(**4**) **[**[F21]Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1.).**]**

(**5**) **[**[F68]Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).**]**

(**6**) OJ L 353, 31.12.2008, p. 1.

Textual Amendments

F21 Substituted by Commission Implementing Regulation (EU) 2020/103 of 17 January 2020 amending Implementing Regulation (EU) No 844/2012 as regards the harmonised classification of active substances (Text with EEA relevance).

F68 Inserted by Commission Implementing Regulation (EU) 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605 (Text with EEA relevance).

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 844/2012.