The Secretary of State makes these Regulations in exercise of the powers conferred by section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018.

In accordance with paragraph 1(1) of Schedule 7 to the European Union (Withdrawal) Act 2018, a draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament.

PART 1

Introductory

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019, and come into force on exit day.

(2) In these Regulations—


“competent authority” and “constituent territory” have the meanings given in Article 3A of Regulation (EC) No 1107/2009 (as inserted by regulation 3(5)).
PART 2

Amendment of retained direct EU legislation

CHAPTER 1


2. Regulation (EC) No 1107/2009 is amended in accordance with regulations 3 to 14.

Chapter 1

3.—(1) Chapter 1 is amended as follows.

(2) In Article 1—

(a) in paragraph 1, for “Community” substitute “United Kingdom”;
(b) in paragraph 3, omit “internal”;
(c) in paragraph 4, in the second sentence—
   (i) for “Member States” substitute “a competent authority”;
   (ii) after “authorised in their” insert “constituent”.

(3) In Article 2(1)(c), for “special Community” substitute “retained EU law”.

(4) In Article 3—

(a) for the heading substitute “Definitions: general”;
(b) in paragraph 4, in the definition of “substance of concern”, in the second subparagraph—
   (i) for “dangerous” substitute “hazardous”;
   (ii) for “Article 3 of Directive 1999/45/EC(2)” substitute “that Regulation”;
(c) in paragraph 9, in the definition of “placing on the market”—
   (i) in the first sentence, for “Community” substitute “United Kingdom”;
   (ii) in the second sentence, for “into the territory of the Community” substitute “in the United Kingdom”;
(d) in paragraph 10, in the definition of “authorisation of a plant protection product”—
   (i) for “the competent authority of a Member State” substitute “a competent authority”;
   (ii) after “product in its” insert “constituent”;
(e) in paragraph 16, at the end insert “, as last amended by Directive (EU) 2015/412 of the European Parliament and of the Council(3)”;
(f) omit paragraphs 17 and 22;
(g) in paragraph 25, in the definition of “professional user”, after “Directive 2009/128/EC(4)” insert “, and for these purposes, Directive 2009/128/EC is to be read as if Article 3(10) (b) were omitted”;

(3) OJ No L 68, 13.3.2015, p 1, as corrected by a Corrigendum (OJ No L 82, 26.3.2018, p 17).
(h) in paragraph 26, in the definition of “minor use”—
   (i) in the words before point (a), omit “in a particular Member State”;  
   (ii) in point (a), for “that Member State” substitute “the United Kingdom”;  
(i) omit paragraph 30;  
(j) after paragraph 31 insert—
   “31A. ‘the Department’ means the Department of Agriculture, Environment and Rural Affairs in Northern Ireland;  
   31B. ‘approvals register’ means the register maintained in accordance with Article 27A;  
   31C. ‘unacceptable co-formulants register’ means the register maintained in accordance with Article 27B;  
   31D. ‘EU-derived domestic legislation’ has the meaning given by section 2(2) of the European Union (Withdrawal) Act 2018;”.  
(5) After Article 3 insert—

“Article 3A  
Definitions: competent authority, constituent territory and appropriate authority  
1. In this Regulation, a reference to a competent authority or a constituent territory is to be interpreted in accordance with the provisions of this Article.  
2. The Secretary of State is the competent authority for the constituent territory of England.  
3. The Welsh Ministers are the competent authority for the constituent territory of Wales.  
4. The Scottish Ministers are the competent authority for the constituent territory of Scotland.  
5. The Department is the competent authority for the constituent territory of Northern Ireland.  
6. In this Regulation, “the appropriate authority” means—  
   (a) for regulations applying in relation to England, the Secretary of State;  
   (b) for regulations applying in relation to Wales, the Welsh Ministers;  
   (c) for regulations applying in relation to Scotland, the Scottish Ministers;  
   (d) for regulations applying in relation to Northern Ireland, the Department.  
7. But the appropriate authority is the Secretary of State if consent is given by—  
   (a) for regulations applying in relation to Wales, the Welsh Ministers;  
   (b) for regulations applying in relation to Scotland, the Scottish Ministers;  
   (c) for regulations applying in relation to Northern Ireland, the Department.”.  

Chapter 2  
4.—(1) Chapter 2 is amended as follows.  
(2) In Article 4—
   (a) in paragraphs 2(a) and 3(b) and (e), for “by the Authority” substitute “in accordance with paragraph 8”;
(b) in paragraph 4, for “Article 29(6)” substitute “Article 29(6)(a) which apply to each constituent territory to which approval of the active substance relates”;

(c) in paragraph 7—

(i) in the third subparagraph—

(aa) for “Member States” substitute “A competent authority”;

(bb) for “their” substitute “its constituent”;

(ii) in the fourth subparagraph—

(aa) for “they” substitute “the competent authority”;

(bb) for “transmit that plan to the Commission” substitute “publish that plan in a manner which the competent authority considers appropriate”;

(d) after paragraph 7 insert—

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

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

(b) in relation to Wales—

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

(ii) by the Welsh Ministers;

(c) in relation to Scotland—

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

(ii) by the Scottish Ministers;

(d) in relation to Northern Ireland—

(i) by the Secretary of State with the consent of the Department, or

(ii) by the Department.”.

(3) For Article 5 substitute—

“Article 5

First approval

1. First approval must be for a period not exceeding—

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

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

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

2. Paragraph 1 is subject to Article 17.

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

(4) In Article 6—

(a) the existing text becomes paragraph 1;

(b) in that paragraph, in point (f), for the words from “Member States” to “(the Authority)” substitute “each specified competent authority within a specified period”;

(c) after that paragraph insert—

“2. A competent authority may request from a specified competent authority a copy of any confirmatory information received in accordance with paragraph 1(f), which the specified competent authority must provide as soon as reasonably practicable.”
3. In this Article, “specified” means specified in the condition referred to in paragraph 1(f).”.

(5) In Article 7—
(a) for paragraph 1 substitute—

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

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

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

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

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

(b) omit paragraph 2;
(c) in paragraph 3, in the second subparagraph—

(i) in the first sentence for “Member States” substitute “The assessing competent authority”;

(ii) in the second sentence, for “rapporteur Member State” substitute “assessing competent authority”;

(d) for paragraph 5, substitute—

“5. When assessing the application the assessing competent authority may obtain independent scientific advice, where the assessing competent authority considers it appropriate to do so.”.

(6) In Article 8—
(a) in paragraph 1—

(i) in point (a)—

(aa) for “widely grown crop in each zone” substitute “crop grown in the United Kingdom”;

(bb) omit “cover all zones or”;

(cc) omit “which is not widely grown”;

(ii) in point (b), after “substance” insert “which apply in each of the constituent territories to which the application relates”;

(iii) in point (c), after “product” insert “which apply in each of the constituent territories to which the application relates”;

(b) omit paragraph 3;
(c) for paragraph 4 substitute—

“4. The appropriate authority may by regulations prescribe the data requirements for—
(a) one or more active substances, safeners and synergists for the purposes of paragraph 1(b);

(b) plant protection products for the purposes of paragraph 1(c).”;

(d) in paragraph 5, for “determined by the Authority” substitute “described in guidance issued under Article 77”.

(7) In Article 9—

(a) in paragraph 1, for “rapporteur Member State” substitute “assessing competent authority”;

(b) in paragraph 2—

(i) for “rapporteur Member State” in both places it occurs substitute “assessing competent authority”;

(ii) in the second subparagraph, for “the other Member States and the Commission” substitute “and the other competent authorities”;

(c) in paragraph 3—

(i) in the first subparagraph—

(aa) for “rapporteur Member State” substitute “assessing competent authority”;

(bb) for “the other Member States, the Commission and the Authority” substitute “and the other competent authorities”;

(ii) in the second subparagraph—

(aa) for “shall immediately” substitute “must on request”;  

(bb) for “Member States, the Commission and the Authority” substitute “competent authorities”.

(8) In Article 10, for “Authority” substitute “assessing competent authority”.

(9) In Article 11—

(a) in paragraph 1—

(i) for “rapporteur Member State” substitute “assessing competent authority”;

(ii) for “Commission, with a copy to the Authority,” substitute “other competent authorities”;

(b) in paragraph 2, in the second subparagraph, for “rapporteur Member State” substitute “assessing competent authority”;

(c) in paragraph 3—

(i) in the first subparagraph—

(aa) for “rapporteur Member State” in each place it occurs substitute “assessing competent authority”;

(bb) in the fourth sentence, for “Commission and the Authority” substitute “other competent authorities”;

(ii) in the second subparagraph—

(aa) for “rapporteur Member State” substitute “assessing competent authority”;

(bb) for “the Commission and the Authority” substitute “and the other competent authorities,”;

(d) omit paragraph 4.

(10) Article 12 is amended in accordance with paragraphs (11) to (18).
(11) In the heading, for “Authority” substitute “assessing competent authority”.

(12) In paragraph 1—

(a) for the first subparagraph substitute—

“(a) The assessing competent authority must circulate the draft assessment report to the applicant and the other competent authorities at the latest 30 days after its completion. The assessing competent authority may ask the applicant to circulate any updated dossier to the assessing competent authority and the other competent authorities.”;

(b) the existing second and third subparagraphs become points (b) and (c);

(c) in those points (b) and (c), for “Authority” substitute “assessing competent authority”.

(13) In paragraph 2—

(a) omit the first subparagraph;

(b) in the second subparagraph—

(i) in the first sentence—

(aa) for “Authority” substitute “assessing competent authority”;

(bb) for “, the Member States and the Commission” substitute “and the other competent authorities,”;

(ii) for the second sentence substitute—

“In the event that independent scientific advice is obtained by the assessing competent authority in accordance with Article 7(5), the 120-day period must be extended by 90 days.”;

(c) in the third subparagraph, for “Authority” substitute “assessing competent authority”.

(14) In paragraph 3—

(a) the existing first subparagraph becomes point (a);

(b) in that point (a)—

(i) for “Authority” in the first place it occurs substitute “assessing competent authority”;

(ii) for “Member States, the Commission and the Authority” substitute “assessing competent authority and the other competent authorities”;

(c) for the second subparagraph, substitute—

“(b) The assessing competent authority must assess the additional information, and for that purpose the period provided for in paragraph 2 may be extended by a maximum of 60 days.”;

(d) the existing third subparagraph becomes point (c);

(e) in that point (c)—

(i) for “Authority” substitute “assessing competent authority”;

(ii) omit “ask the Commission to”;

(iii) omit “Community” in both places it occurs.

(15) In paragraph 4, for “Authority” substitute “assessing competent authority”.

(16) Omit paragraph 5.

(17) In paragraph 6, for the words from “limits for the Authority’s” to “Article 11 and” substitute “limit”.

(18) Omit paragraphs 7 and 8.
(19) After Article 12 insert—

“Article 12A

Application for approval: transfer of assessment functions

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

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

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

4. A transfer in accordance with paragraph 1 does not—
   (a) affect anything done by the assessing competent authority prior to transfer;
   (b) affect the timing of any requirements placed on the assessing competent authority under this Subsection.”.

(20) For Article 13, substitute—

“Article 13

Approval Decision

1. Within six months of the relevant conclusion date, a competent authority for a constituent territory to which the application relates must decide to do one of the following—
   (a) approve the active substance, subject to conditions or restrictions, as referred to in Article 6(1), where appropriate;
   (b) amend the conditions of the approval; or
   (c) refuse to approve the active substance.

2. In making a decision under paragraph 1, the competent authority must have regard to—
   (a) the conclusion of the assessing competent authority;
   (b) any comments received by the assessing competent authority in relation to the application, including any environmental monitoring information submitted by an appropriate agency;
   (c) where the competent authority considers it appropriate to obtain it, any independent scientific advice obtained;
   (d) where the conditions laid down in Article 7(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety are relevant, the precautionary principle;
   (e) any other matters which the competent authority considers relevant to the competent authority’s decision.

3. As soon as reasonably practicable after making a decision under paragraph 1, the competent authority must—
(a) notify the applicant and the other competent authorities in writing of the decision and the reasons for it, and
(b) update the approvals register accordingly.

4. The Secretary of State may make a decision under paragraph 1 instead of a competent authority—
   (a) in relation to Wales, with the consent of the Welsh Ministers;
   (b) in relation to Scotland, with the consent of the Scottish Ministers;
   (c) in relation to Northern Ireland, with the consent of the Department.

5. Where the Secretary of State makes a decision in accordance with paragraph 4—
   (a) a reference in paragraphs 2 and 3 to the competent authority is to be read as a reference to the Secretary of State;
   (b) paragraph 3(a) is to be read as if “other” were omitted.

6. In paragraph 1, the “relevant conclusion date” means—
   (a) where the competent authority is the assessing competent authority, the date on which the competent authority adopts a conclusion under Article 12(2);
   (b) otherwise, the date on which the competent authority receives the conclusion of the assessing competent authority in accordance with Article 12(2).

7. In paragraph 2(b), “appropriate agency” means one of the following—
   (a) the Environment Agency;
   (b) the Natural Resources Body for Wales;
   (c) the Scottish Environment Protection Agency;
   (d) the Department.

(21) In Article 14—
   (a) in paragraph 1, in the third subparagraph, for “Article 6” substitute “Article 6(1)”;
   (b) for paragraph 2 substitute—
      “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.”.

(22) In Article 15—
   (a) in paragraph 1, for the words from “Member State” to “and the Authority” substitute “competent authority for a constituent territory in relation to which the active substance is approved”;
   (b) after paragraph 1 insert—
      “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).”;
   (c) after paragraph 2 insert—
      “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.”.

(23) After Article 15 insert—

“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.”.

(24) In Article 16, for “Authority” substitute “assessing competent authority”.

(25) In Article 17—
   (a) for the first paragraph, substitute—
       “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.”;
   (b) omit the second paragraph;
   (c) the existing third paragraph becomes paragraph 3;
   (d) after that paragraph 3, insert—
       “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.”.

(26) In Article 18—

(a) the existing first paragraph becomes paragraph 1;

(b) in that paragraph 1—

(i) in the first sentence, for “The Commission” substitute “A competent authority”;

(ii) in the second sentence, for “Member States, the Commission and the Authority” substitute “competent authority”;

(c) the existing second paragraph becomes paragraph 2;

(d) in that paragraph 2, omit point (f);

(e) after that paragraph 2, insert—

“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;

(c) in relation to Northern Ireland, with the consent of the Department.

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.”.

(27) For Articles 19 to 21 substitute—
Article 19

Implementing measures

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

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;
   (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; or
   (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;
(c) in relation to Northern Ireland, with the consent of the Department.

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).

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.

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;
(c) in relation to Northern Ireland, with the consent of the Department.

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.”.

(28) For Article 22 substitute—

“Article 22
Low-risk active substances

1. An active substance complying with the criteria provided for in Article 4 must be
approved as a low-risk active substance where—
(a) that substance complies with the criteria in point 5 of Annex 2, and
(b) it may be expected that plant protection products containing that substance will pose
only a low risk to human and animal health and the environment as provided for in
Article 47(1).

2. Articles 4 to 21 apply.

3. The appropriate authority may, by regulations, amend point 5 of Annex 2 to specify new
criteria for approving an active substance as a low-risk active substance.”.

(29) In Article 23—
(a) in paragraph 1—
(i) for “paragraphs 2 to 6” in both places it occurs substitute “this Article”;
(ii) in the first subparagraph, omit the second sentence;
(b) in paragraph 2, omit “Community”;
(c) in paragraph 3—
(i) in the first subparagraph—
(aa) omit “by a Member State or”;
(bb) for “Commission” substitute “the competent authority for the constituent
territory in relation to which approval is sought”;
(ii) in the second subparagraph, in point (a) omit “Community”;
(d) omit paragraph 4;
(e) for paragraph 5 substitute—

5. Article 6 applies to the approval of a basic substance.

5A. Within the decision period following receipt of the application and accompanying
information, the competent authority must decide to either—
(a) approve the basic substance, subject to conditions or restrictions, as referred to
in Article 6(1), where appropriate, or
(b) refuse to approve the basic substance.

5B. In paragraph 5A, the “decision period” is—
(a) where the competent authority obtains independent scientific advice in respect
of the application, nine months;
(b) otherwise, six months.

5C. In making a decision under paragraph 5A, the competent authority must have regard to—

(a) the application and accompanying information,
(b) where the competent authority considers it appropriate to obtain it, any independent scientific advice obtained,
(c) where the conditions laid down in Article 7(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council are relevant, the precautionary principle, and
(d) any other matters which the competent authority considers relevant to the competent authority’s determination of the application.

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

(a) notify the applicant and the other competent authorities in writing of that decision and the reasons for it, and
(b) update the approvals register accordingly.

5E. Article 20A applies to an approval of a basic substance which is subject to a condition in accordance with Article 6(1)(f) as it applies to an approval of an active substance.

5F. The Secretary of State may make a decision under paragraph 5A instead of a competent authority—

(a) in relation to Wales, with the consent of the Welsh Ministers;
(b) in relation to Scotland, with the consent of the Scottish Ministers;
(c) in relation to Northern Ireland, with the consent of the Department.

5G. Where the Secretary of State makes a decision in accordance with paragraph 5F, a reference in paragraphs 5A to 5D to the competent authority is to be read as a reference to the Secretary of State.”;

(f) omit paragraph 6.

(30) After Article 23 insert—

"Article 23A

Review of basic substance approval

1. A competent authority may review the approval of a basic substance at any time.

2. A competent authority must review the approval of a basic substance where—

(a) the competent authority has received and assessed confirmatory information in accordance with Article 20A (as applied by Article 23(5E));

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

3. Where the competent authority considers that there are indications that the substance no longer satisfies the criteria provided for in Article 23(1) to (3), the competent authority must inform the other competent authorities and the interested party referred to in Article 23(3) accordingly, setting a period for the submission of comments."
4. The competent authority may obtain independent scientific advice, where the competent authority considers it appropriate to do so.

5. Where the competent authority concludes that, having considered comments received during the period set in accordance with paragraph 3 and any other information or matters that the competent authority considers important and relevant to the review, the substance no longer satisfies the criteria provided for in Article 23(1), the competent authority must decide to either—
   (a) amend the conditions of the approval, or
   (b) withdraw the approval.

6. As soon as reasonably practicable after making a decision under paragraph 5, the competent authority must—
   (a) notify the other competent authorities and the interested party referred to in Article 23(3) in writing of the decision and the reasons for it, and
   (b) update the approvals register accordingly.

7. The Secretary of State may review an active substance under paragraph 1 or 2 instead of a competent authority—
   (a) in relation to Wales, with the consent of the Welsh Ministers;
   (b) in relation to Scotland, with the consent of the Scottish Ministers;
   (c) in relation to Northern Ireland, with the consent of the Department.

8. Where the Secretary of State reviews an active substance in accordance with paragraph 7, a reference in paragraphs 3 to 6 to the competent authority is to be read as a reference to the Secretary of State.”.

(31) In Article 24—
   (a) in paragraph 1—
      (i) in the first sentence, omit “, for a period not exceeding seven years,”;
      (ii) omit the second sentence;
   (b) in paragraph 2, omit the second sentence.

(32) Omit Article 25(3).

(33) After Article 25 insert—

“Article 25A

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

1. A safener or synergist is deemed to be approved for the purposes of this Regulation in each constituent territory if on or before 14th June 2011 it was—
   (a) held for the purpose of sale within the European Union, an EEA state or the United Kingdom, including being offered for sale or other form of transfer, whether free of charge or not;
   (b) sold, distributed or otherwise transferred within the European Union, an EEA state or the United Kingdom, but not including return to the previous seller; or
   (c) released for free circulation into the territory of the European Union, an EEA state or the United Kingdom.

2. For the purposes of paragraph 1, “the European Union” does not include the Republic of Croatia.
3. A safener or synergist is deemed to be approved in accordance with paragraph 1 in a constituent territory until—
   (a) where an application for approval of that safener or synergist is received in accordance with Article 7 (as applied by Article 25(2)), the date on which a decision is made by the competent authority for that constituent territory or the Secretary of State in accordance with Article 13 (as applied by Article 25(2));
   (b) otherwise, the earliest of the following dates—
      (i) the date on which the competent authority or the Secretary of State decides to withdraw approval of the safener or synergist for that constituent territory in accordance with Article 21 as applied by paragraph 4;
      (ii) the date on which the first regulations made under Article 8(4)(a) in respect of safeners or synergists (as the case may be) which apply to that constituent territory come into force.

4. Article 21 applies to a safener or synergist deemed to be approved in accordance with paragraph 1 as if—
   (a) a reference to an active substance were a reference to that safener or synergist;
   (b) paragraph 2 were omitted;
   (c) in paragraph 3—
      (i) in point (a), the words from “or the assessment” to “Article 20A,” were omitted;
      (ii) point (b) (and the “or” immediately preceding it) were omitted;
   (d) in paragraph 5, for “or (b) apply” there were substituted “applies”;
   (e) paragraph 8(b) (and the “and” immediately preceding it) were omitted;
   (f) in paragraph 9, in the words before point (a) “or 2” were omitted.”.

(34) In Article 27—
   (a) in paragraph 2, for the words from “in Annex III” to the end substitute “on the unacceptable co-formulants register”;
   (b) in paragraph 3—
      (i) for the first sentence substitute—
         “A competent authority may review co-formulants which are not accepted in the competent authority’s constituent territory for inclusion in a plant protection product at any time.”;
      (ii) in the second sentence—
         (aa) for “It” substitute “The competent authority”;
         (bb) for “Member States” substitute “the other competent authorities”;
   (c) omit paragraph 4;
   (d) for paragraph 5 substitute—
         “5. The appropriate authority may, by regulations, make provision necessary for the implementation of this Article.”.

(35) After Section 3, insert—
“SECTION 4

Registers

Article 27A

Approvals register

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

2. The entry on the register for each substance must contain the following information—
   (a) the common name and identification numbers of the substance;
   (b) the IUPAC name of the substance, where available;
   (c) the minimum purity of the substance;
   (d) in respect of each constituent territory to which the entry relates—
      (i) whether the substance has been approved as an active substance, safener, synergist, low-risk active substance, basic substance or candidate for substitution;
      (ii) the date of the approval decision;
      (iii) except in relation to approved basic substances, the expiration date of approval;
      (iv) information on any specific provisions, conditions or requirements in respect of the approved substance.

3. The register must contain a search facility.

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

Article 27B

Unacceptable co-formulants register

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

2. The entry on the register for each co-formulant must contain the following information—
   (a) the common name of the co-formulant;
   (b) the IUPAC name of the co-formulant (where available);
   (c) the CAS number of the co-formulant (where available);
   (d) the EC number of the co-formulant (where available);
   (e) in respect of each constituent territory to which the entry relates—
      (i) the date of the decision that the co-formulant was not acceptable for inclusion in a plant protection product;
      (ii) the sunset date for the co-formulant;
      (iii) any conditions of restriction relating to the co-formulant;
      (iv) any other information regarding the co-formulant that the competent authority considers relevant.
3. The register must contain a search facility.

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

Chapter 3

5.—(1) Chapter 3 is amended as follows.

(2) In Article 28—

(a) in paragraph 1—

(i) after “used” insert “in a constituent territory”;

(ii) for “in the Member State concerned” substitute “by the relevant competent authority”;

(b) in paragraph 2—

(i) in point (c)—

(aa) for “another Member State” substitute “the constituent territory of another competent authority”;

(bb) for the words from “in that Member State” to the end substitute “by that other competent authority for that constituent territory”;

(ii) in point (d)—

(aa) for “in a third country” substitute “outside the United Kingdom”;

(bb) for the words from “the Member State” to “inspection requirements” substitute “there are inspection requirements in place”;

(cc) for “its territory” substitute “the United Kingdom”;

(iii) in point (e), for “has been granted” substitute “is in force”.

(3) In Article 29—

(a) in paragraph 1—

(i) in the words before point (a), after “paragraph 6” insert “for the constituent territory of authorisation”;

(ii) in point (a), for “have been approved” substitute “are approved in the constituent territory of authorisation, and approval is not suspended in accordance with Article 69”;

(iii) in point (b)(i), for the words from “included in” to “synergist” substitute “of that substance, safener or synergist as approved in the constituent territory of authorisation”;

(iv) in point (c), for “in Annex III” substitute “on the unacceptable co-formulants register in relation to the constituent territory of authorisation”;

(v) in point (g), for “all Member States” substitute “the United Kingdom”;

(vi) in point (i), after “modified” insert “in relation to the constituent territory of authorisation”;

(b) in paragraph 3, for “zone” substitute “areas of the United Kingdom”;

(c) omit paragraphs 4 and 5;

(d) in paragraph 6—

(i) for the first subparagraph substitute—
“(a) The appropriate authority may, by regulations, prescribe uniform principles for the evaluation and authorisation of plant protection products.”;

(ii) the existing second subparagraph becomes point (b).

(4) Article 31 is amended in accordance with paragraphs (5) to (7).

(5) In paragraph 2—
(a) in the first subparagraph, in the second sentence—
(i) for “Regulation approving” substitute “approval of”;
(ii) at the end, insert “in the constituent territory of authorisation”;
(b) in the second subparagraph—
(ii) in the second sentence—
(aa) for “Member States” substitute “A competent authority”;

(6) In paragraph 4(a), for “Community provisions” substitute “retained EU law”.

(7) After paragraph 4 insert—

“5. For the purposes of paragraph 4(c), Article 14 of Directive 2009/128/EC is to be read as if—
(a) obligations on Member States were obligations on the competent authorities;
(b) paragraph 3 were omitted.”.

(8) In Article 32(1), in the second subparagraph—
(a) after “approval” insert “in the constituent territory of authorisation”; 
(b) at the end, insert “in the constituent territory of authorisation”.

(9) In Article 33—
(a) for paragraph 1, substitute—

“1. An applicant or a representative of the applicant may apply to the competent authority for authorisation to place a plant protection product on the market in a constituent territory.

1A. An applicant or a representative of the applicant may apply to the competent authority which granted an authorisation to amend that authorisation.”;

(b) in paragraph 2—
(i) in point (a), for the words from “in each zone” to “Member States where” substitute “and the competent authorities to whom”;
(ii) omit point (b);
(iii) in point (c), for “in a Member State” substitute “by a competent authority”;
(iv) in point (d), for “Member State” substitute “competent authority”; 
(c) in paragraph 4, in the third subparagraph—
(i) for “Member State” substitute “competent authority”;
(ii) after “application” insert “(see Article 35)”;

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(d) for paragraph 5 substitute—

“5. Where permitted by the competent authority, the applicant may submit an application in a language other than English.”;

(e) in paragraph 6, for “Member State” substitute “competent authority”.

(10) In Article 34—

(a) in paragraph 1—

(i) for the words from “Member State” to “application is made” substitute “competent authority examining the application”;

(ii) at the end insert “, or where paragraph 3 applies”;

(b) in paragraph 2—

(i) in point (a), after “declaration that” insert “, in respect of each constituent territory to which the application relates,”;

(ii) in point (b), after “approved” insert “in respect of each constituent territory to which the application relates”;

(iii) in point (c), for “concerned Member State” substitute “competent authority examining the application”;

(c) after paragraph 2 insert—

“3. This paragraph applies where another competent authority has the test and study reports concerned.

4. Where paragraph 3 applies—

(a) the competent authority examining the application must request those reports from the competent authority which has those reports, and

(b) the competent authority which has those reports must send them to the competent authority examining the application as soon as reasonably practicable.”.

(11) For Article 35 substitute—

“Article 35

Competent authority examining the application

1. For the purposes of this Subsection “the competent authority examining the application” is the competent authority which receives the application under Article 33.

2. But a competent authority may examine an application on behalf of one or more of the other competent authorities (and consequently for the purposes of this Subsection is “the competent authority examining the application”) where—

(a) each competent authority receives the same application;

(b) each competent authority agrees which competent authority is to examine the application;

(c) each active substance, safener or synergist in the plant protection product to which the application relates—

(i) is approved in relation to the constituent territory of each competent authority, and the conditions of each approval are compatible with the proposed authorisation, and
(ii) has an equivalent technical specification in relation to each constituent
territory, where necessary as determined in accordance with Article 38;

(d) any co-formulant in the plant protection product to which the application relates is
not included on the unacceptable co-formulants register in relation to the constituent
territory of each competent authority; and

(e) any data requirements specified in regulations made under Article 8(4)(a) and (b),
any uniform principles for evaluation and authorisation of plant protection products
prescribed in regulations made under Article 29(6)(a) and any guidance relating to
those requirements or principles are the same in relation to the constituent territory
of each competent authority.

3. Where paragraph 2 applies in relation to an application—

(a) the competent authority examining the application must inform the applicant that it
is to examine the application;

(b) the other competent authorities must —
   (i) not proceed to determine the application pending assessment by the competent
   authority examining the application;
   (ii) at the request of the competent authority examining the application, cooperate
to ensure a fair division of the workload.”.

(12) In Article 36—

(a) in paragraph 1—
   (i) in the first subparagraph—
      (aa) in the first sentence, for “Member State” substitute “competent authority”;
      (bb) in the second sentence, for “It shall give all Member States in the same
zone” substitute “Where Article 35(2) applies in relation to an application,
the competent authority examining the application must give the other
competent authorities”;
   (ii) in the second subparagraph—
      (aa) for “Article 29(6)” substitute “Article 29(6)(a)”;
      (bb) omit “in the same zone”;
   (iii) for the third subparagraph substitute—
      “Where Article 35(2) applies in relation to an application, the competent authority
examining the application must make available its assessment to the other competent
authorities.”;

(b) in paragraph 2—
   (i) for “The Member States concerned” substitute “Where Article 35(2) applies in
   relation to an application, the competent authorities which received that application”;
   (ii) for “Member State” substitute “competent authority”;

(c) in paragraph 3—
   (i) in the first subparagraph, for “Community” substitute “retained EU”;
   (ii) in the second subparagraph—
      (aa) for “Member State” in the first place it occurs substitute “competent
authority”;
      (bb) omit “national”;
(cc) for “a Member State” in the second place it occurs substitute “that competent authority”;
(dd) after “its” insert “constituent”;
(iii) in the third subparagraph—
(aa) for “Member State” substitute “competent authority”;
(bb) for “Commission” substitute “other competent authorities”;
(iv) omit the fourth subparagraph.

(13) In Article 37—
(a) in paragraphs 1 and 3, for “Member State” in each place it occurs substitute “competent authority”;
(b) in paragraph 3, in the first sentence, for the words from “it has received” to the end substitute “the draft assessment report for that active substance is circulated in accordance with Article 12(1)(a)”;
(c) after paragraph 3 insert—

“3A. Where Article 35(2) applies in relation to an application, the requirement in paragraph 3 to decide on the application within 6 months of the active substance being approved is to be read as a requirement to decide on the application within 6 months of the earliest date on which the active substance is approved by one of the competent authorities which received the application for authorisation.”;
(d) in paragraph 4—
(i) for “The other Member States concerned” substitute “Where Article 35(2) applies in relation to an application, the competent authorities which received the application for authorisation”;
(ii) for “Member State” substitute “competent authority”.

(14) For Article 38 substitute—

“Article 38
Assessment of equivalence under Article 29(1)(b)

1. This Article applies where it is necessary in relation to an application to establish for an active substance, safener or synergist whether a different source or, for the same source a change of the manufacturing process or location complies with Article 29(1)(b).

1A. Where this Article applies, equivalence—
(a) may be assessed by a competent authority examining the application, where—
(i) each of the other competent authorities examining the application consents to that competent authority assessing equivalence, and
(ii) in relation to the active substance, safener or synergist for which equivalence is to be assessed, any data requirements specified in regulations made under Article 8(4)(a) and (b), any uniform principles for evaluation and authorisation of plant protection products prescribed in regulations made under Article 29(6)(a) and any guidance issued under Article 77 relating to those requirements or principles are the same in relation to the constituent territory of each competent authority examining the application;
(b) otherwise, must be assessed by each competent authority examining the application.
1B. The applicant must submit all necessary data to each competent authority assessing equivalence.

2. A competent authority assessing equivalence must—
   (a) give the applicant the opportunity to submit comments,
   (b) prepare a report on the competent authority’s conclusion on equivalence within 60 days from receiving the application, and
   (c) provide a copy of that report to—
      (i) the applicant, and
      (ii) where the assessment is undertaken in accordance with paragraph 1A(a), the other competent authorities examining the application.

3. Where an assessment is undertaken in accordance with paragraph 1A(a), a competent authority examining the application which does not agree with the conclusion in the report provided in accordance with paragraph 2(c)(ii) must notify the competent authority which assessed equivalence, the other competent authorities examining the application and the applicant, stating its reasons for not agreeing.

3A. Following a notification under paragraph 3, the competent authorities concerned must—
   (a) give the applicant the opportunity to submit comments, and
   (b) try to reach agreement on whether Article 29(1)(b) is complied with.

4. Article 29(1)(b) is deemed not to be complied with where the competent authorities concerned under paragraph 3A do not reach agreement within 45 days of the latest date on which a notification from a competent authority is communicated in accordance with paragraph 3.”.

(15) In Article 39—
   (a) in paragraph 1—
      (i) in the words before point (a)—
         (aa) for “Member States” substitute “A competent authority”;
         (bb) after “application” insert “it receives”;
      (ii) in point (b), omit the words from “the format” to “Article 79(2);”;
      (iii) in point (c), for “Member State” substitute “competent authority”;
   (b) in paragraph 2—
      (i) for “Member States” in the first place it occurs substitute “a competent authority”; 
      (ii) for “Member States, the Commission and the Authority” substitute “competent authorities”;
   (c) in paragraph 3, for “Member States, the Commission and the Authority” substitute “the competent authorities”;
   (d) omit paragraph 4.

(16) In Subsection 3—
   (a) in the heading, at the beginning insert “Ongoing applications for”;
   (b) omit Article 40;
   (c) before Article 41 insert—
“Article 40A

Application and interpretation

1. This Subsection applies where—
   (a) before exit day the holder of an authorisation of a plant protection product granted by a member State or EEA state in accordance with Article 29 as it had effect immediately before exit day had applied for—
      (i) authorisation of the same product in the United Kingdom in accordance with Article 40 as it had effect immediately before exit day, or
      (ii) authorisation of the same product for minor uses in accordance with Articles 40 and 51(7) as those Articles had effect immediately before exit day, and
   (b) immediately before exit day that application had not been determined.

2. In this Subsection—
   (a) a reference to an Article as it had effect immediately before exit day in relation to an EEA state is a reference to that Article as adapted by the EEA Agreement as it had effect immediately before exit day;
   (b) “reference state” means the member State or EEA state referred to in paragraph 1(a).”;

(d) in Article 41—
   (i) in paragraph 1—
      (aa) for “Member State” in the first place it occurs substitute “competent authority”;  
      (bb) after “Article 40” insert “as it had effect immediately before exit day”;
      (cc) for “Member State examining the application” substitute “reference state”;
   (ii) after paragraph 1 insert—
      “1A. But where the application was for authorisation of minor uses in accordance with Article 51(7) as it had effect immediately before exit day, the competent authority must authorise such uses, except where—
      (a) Article 36(3) applies, or
      (b) the competent authority considers that those uses are not minor.”;

(iii) in paragraph 2—
   (aa) in the words before point (a), for “paragraph 1, the Member State” substitute “paragraphs 1 and 1A, the competent authority”;
   (bb) in point (a), after “Article 40(1)” insert “as it had effect immediately before exit day”;
   (cc) in point (b), at the end insert “or”;
   (dd) omit point (c).

(17) Article 42 is amended in accordance with paragraphs (18) to (20).

(18) In paragraph 1—
   (a) in point (a)—
      (i) for “Member State” in the first place it occurs substitute “state”;

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(ii) for the words from “an official language” to the end substitute “English or another language permitted by the competent authority”;

(b) in point (b), for “Member State” substitute “state”;

(c) in point (c), for “when requested by the Member State” substitute “as it had effect immediately before exit day, when requested by the competent authority”;

(d) in point (d), for “Member State” substitute “state”.

(19) In paragraph 2—

(a) for “Member State” substitute “competent authority”;

(b) for “an application under Article 40” substitute “the application”.

(20) For paragraph 3 substitute—

“3. Where permitted by the competent authority, the applicant may submit an application in a language other than English.”.

(21) After Subsection 3 insert—

“Subsection 3A

Mutual recognition of authorisations within the UK

Article 42A

Mutual recognition

1. This Subsection applies where a plant protection product has been authorised by a competent authority in accordance with Article 29 (the “reference competent authority”).

2. The following persons may apply for an authorisation for the same plant protection product, the same use and under comparable agricultural practices within the constituent territory of another competent authority—

(a) the holder of the authorisation granted by the reference competent authority;

(b) an official or scientific body involved in agricultural activities or a professional agricultural organisation—

(i) with the consent of the authorisation holder, or

(ii) where consent is refused, with the consent of the competent authority to which the application is made on the grounds of public interest.

3. An applicant under paragraph 2(b) must demonstrate that the use of such a plant protection product is of general interest within the constituent territory of the competent authority.

4. An application may not be made under paragraph 2 where—

(a) the plant protection product contains an active substance, safener, synergist, low-risk active substance, basic substance or candidate for substitution which is not approved in relation to the constituent territory of the other competent authority;

(b) the plant protection product contains an active substance, safener, synergist, low-risk active substance, basic substance or candidate for substitution which is approved in relation to the constituent territory of the other competent authority, but—

(i) the conditions of that approval are incompatible with the product to which the application relates, or

(ii) the technical specification relating to that approval is not equivalent to the technical specification of the approval of the same substance, safener, synergist
or candidate in relation to the constituent territory of the reference competent authority, where necessary as determined in accordance with Article 38;

(b) the plant protection product contains a co-formulant which is entered on the unacceptable co-formulants register in relation to the constituent territory of the other competent authority; or

(c) the relevant data requirements specified in regulations made under Article 8(4)(a) and (b), the relevant uniform principles for evaluation and authorisation of plant protection products prescribed in regulations made under Article 29(6)(a) or any guidance issued under Article 77 relating to those requirements or principles are not the same in relation to the constituent territory of each competent authority.

Article 42B
Authorisation

1. The competent authority to which an application under Article 42A(2) is submitted, having examined the application and the accompanying documents referred to in Article 42C(1), and as appropriate with regards to the circumstances in its constituent territory, must authorise the plant protection product concerned under the same conditions as the reference competent authority, except in accordance with paragraph 2 or 3.

2. The competent authority may authorise the plant protection product where it contains a candidate for substitution or a substance approved in accordance with Article 4(7).

3. Paragraphs 1 and 2 do not apply where Article 36(3) applies.

Article 42C
Procedure

1. An application under Article 42A must be accompanied by the following—

(a) a copy of the authorisation granted by the reference competent authority;

(b) a formal statement that the plant protection product is identical to that authorised by the reference competent authority;

(c) a complete or summary dossier as required in Article 33(3) when requested by the competent authority;

(d) an assessment report of the reference competent authority containing information on the evaluation and decision on the plant protection product.

2. The competent authority to which an application under Article 42A is submitted must decide on the application within 120 days.”.

(22) In Article 43—
(a) in paragraph 2—

(i) in the words before point (a)—

(aa) after “approval” insert “in relation to a constituent territory”;

(bb) after “product” insert “authorised in that constituent territory”;

(cc) after “information” insert “to the competent authority for that constituent territory”;

(ii) in point (d), for “out in the Regulation” substitute “by the competent authority”;

(b) in paragraph 3—
(i) the existing first subparagraph becomes point (a);
(ii) in that point (a)—

(aa) for “Member States” substitute “The competent authority examining the application”;
(bb) for the words from “in the Regulation” to the end substitute “on renewal of the approval of the active substance, safener or synergist”;
(iii) for the second subparagraph substitute—

“(b) The competent authority which examined the plant protection product application in accordance with Article 35(2) may coordinate the compliance check and assessment of the information submitted for all competent authorities which receive an application for renewal of authorisation for the same product, provided that the conditions in Article 35(2) apply in relation to the renewal application.”;

(c) omit paragraph 4;
(d) in paragraph 5, for “Member States” substitute “The competent authority examining the application”;
(e) in paragraph 6, for “Member State in question” substitute “competent authority examining the application”.

(23) In Article 44—

(a) in paragraph 1—

(i) in the first subparagraph, for “Member States” substitute “A competent authority”;
(ii) in the second subparagraph—

(aa) for “Member State” substitute “competent authority”;
(bb) for “objectives of Article 4(1)(a)(iv) and (b)(i) and Article 7(2) and (3) of Directive 2000/60/EC” substitute “environmental objectives of a river basin district”;

(b) in paragraphs 2 and 3, for “Member State” substitute “competent authority”;
(c) in paragraph 4—

(i) in the first sentence—

(aa) for “Member State” substitute “competent authority”;
(bb) for “, the other Member States, the Commission and the Authority” substitute “and the other competent authorities”;
(ii) in the second sentence—

(aa) for “Member States belonging to the same zone shall” substitute “competent authorities may”;
(bb) for “national conditions” substitute “conditions in its constituent territory”;
(cc) for “, third or fourth” substitute “or third”;
(d) after paragraph 4 insert—

“5. In paragraph 1, “environmental objectives”—

(a) in relation to the Northumbria River Basin District, means the objectives referred to in the WFD Regulations as applied by regulation 5 of the Water Environment
(Water Framework Directive) (Northumbria River Basin District) Regulations 2003(5);

(b) in relation to the Solway Tweed River Basin District, means the objectives as defined in regulation 2 of the Water Environment (Water Framework Directive) (Solway Tweed River Basin District) Regulations 2004(6);

(c) in relation to any other river basin district, within the meaning of the WFD Regulations, has the same meaning as in those regulations;

(d) in relation to a river basin district in Scotland, means the objectives set under section 9(1)(a)(i) of the Water Environment and Water Services (Scotland) Act 2003(7);

(e) in relation to a river basin district in Northern Ireland, means the objectives set under regulation 12, in accordance with regulation 13, of the Water Environment (Water Framework Directive) Regulations (Northern Ireland) 2017(8).

6. In paragraph 4, the “conditions” in the constituent territory of a competent authority include—

(a) any data requirements specified in regulations made under Article 8(4)(a) or (b) in relation to that constituent territory;

(b) any uniform principles prescribed by regulations made under Article 29(6)(a) in relation to that constituent territory;

(c) any guidance issued under Article 77 in relation to that constituent territory.

7. In this Article—

(a) “river basin district” means any of the following—

(i) the Northumbria River Basin District;

(ii) the Solway Tweed River Basin District;

(iii) a river basin district within the meaning of the WFD Regulations;

(iv) in relation to Scotland, an area designated as a river basin district by order under section 4(1) of the Water Environment and Water Services (Scotland) Act 2003;

(v) in relation to Northern Ireland, a river basin district within the meaning of the Water Environment (Water Framework Directive) Regulations (Northern Ireland) 2017;

(b) “the WFD Regulations” means the Water Environment (Water Framework Directive) (England and Wales) Regulations 2017(9),

(24) For Article 46 substitute—

“Article 46

Grace period

1. A competent authority may grant a grace period for the disposal, storage, placing on the market and use of existing stocks of a plant protection product in its constituent territory where—

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(6) S.I. 2004/99, amended by S.I. 2016/139; there are other amending instruments but none is relevant.
(7) 2003 asp 3. Section 9(1) was amended by section 54(1) and (4)(a)(i) of the Aquaculture and Fisheries (Scotland) Act 2013 (asp 7).
(8) S.R. 2017 No.81.
(9) S.I. 2017/407.
(a) the authority withdraws, amends or does not renew authorisation for the plant protection product, and
(b) the reasons for withdrawal, amendment or non-renewal are not related to the protection of human and animal health or the environment.

2. The grace period—
   (a) for the sale and distribution of the existing stocks must not exceed six months;
   (b) for the disposal, storage, and use of the existing stocks must be consecutive to the period described in point (a) and must not exceed one year.”.

(25) In Article 47
   (a) in paragraph 1(a), at the end insert “in relation to the constituent territory of application”;
   (b) in paragraph (3)—
      (i) in the first subparagraph, for “The Member State” substitute “A competent authority”;
      (ii) in the second and third subparagraphs, for “Member State” in both places it occurs substitute “competent authority”.

(26) In Article 48—
   (a) in paragraph 1—
      (i) in the first subparagraph—
         (aa) for “an organism falling within the scope of Directive 2001/18/EC(10)” substitute “a genetically modified organism”;
         (bb) for “that Directive” substitute “the examination legislation”;
      (ii) in the second subparagraph, for “, as referred to in Article 19 of Directive 2001/18/EC,” substitute “to market the genetically modified organism under section 111(1) of the Environmental Protection Act 1990(11) or Article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991(12)”;
   (b) after paragraph 2 insert—

“3. In paragraph 1, “the examination legislation” means—
   (a) in relation to England, regulation 23(1)(c) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002(13);
   (b) in relation to Wales, regulation 24(1)(c) of the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002(14);
   (c) in relation to Scotland, regulation 23(1)(c) of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002(15);
   (d) in relation to Northern Ireland, regulation 23(1)(c) of the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003(16).”.

(27) In Article 49—
   (a) in paragraph 1—
      (i) for “Member States” substitute “A competent authority”;

(11) 1990 c.43.
(12) S.I. 1991/1714 (N.I. 19), to which there are amendments not relevant to these Regulations.
(13) S.I. 2002/2443, to which there are amendments not relevant to these Regulations.
(14) S.I. 2002/3188 (W 304), to which there are amendments not relevant to these Regulations.
(15) SSI 2002/541, to which there are amendments not relevant to these Regulations.
(16) S.R. 2003 No. 167, to which there are amendments not relevant to these Regulations.
(ii) for “in at least one Member State” substitute “by at least one competent authority”;  
(b) for paragraph 2 substitute—

“2. The appropriate authority may, by regulations, implement measures to restrict or prohibit the use or sale of treated seeds as referred to in paragraph 1 where the appropriate authority has substantial concerns that—

(a) the treated seeds are likely to constitute a serious risk to human or animal health or to the environment, and

(b) such risk cannot be contained satisfactorily by measures taken by the competent authorities concerned.

2A. Before making regulations in accordance with paragraph 2, the appropriate authority may obtain independent scientific advice where the appropriate authority considers it appropriate to do so.”;

(c) omit paragraph 3;

(d) in paragraph 4—

(i) for “Community legislation” substitute “retained EU law”;


(28) In Article 50—

(a) in paragraph 1, in the words before point (a)—

(i) in the first sentence—

(aa) for “Member States” substitute “a competent authority”;

(bb) at the end insert “in relation to its constituent territory”;

(ii) in the second sentence, for “Member States” substitute “A competent authority”;

(b) in paragraph 2—

(i) for “Member States” substitute “a competent authority”;

(ii) for “that Member State” substitute “the United Kingdom”;

(c) in paragraph 4—

(i) in the first subparagraph, for “Member States” substitute “a competent authority”;

(ii) in the second subparagraph, for “Member States” substitute “the competent authority”;

(d) in paragraph 5—

(i) for “Member State” in both places it occurs substitute “competent authority”;

(ii) after “substitution” insert “in relation to its constituent territory”.

(29) In Article 51—

(a) in paragraph 1, for “in the Member State concerned” substitute “by a competent authority”;

(b) in paragraph 2, for “Member States” substitute “The competent authority”;

(c) in paragraph 3, for “Member States” substitute “A competent authority”;

(d) in paragraph 4, omit the words from “, in accordance with” to the end;

(e) in paragraph 5—

(i) in the first subparagraph—

(aa) for “Member States grant” substitute “the competent authority grants”;
(bb) for “they” substitute “the competent authority”; 
(ii) in the second subparagraph, for “Member States” substitute “competent authority”; 
(f) in paragraph 7—
   (i) in the first sentence, for the words from “Article 40(1)” to the end substitute “Article 42A, except where one or more of the conditions in Article 42A(4) are met”; 
   (ii) in the second sentence—
      (aa) for “Member States” in the first place it occurs substitute “The competent authority which receives such an application”; 
      (bb) for “Article 41” substitute “Article 42B”; 
      (cc) for “in the Member States of application” substitute “by that competent authority”; 
(g) in paragraph 8, for “Member States” substitute “Each competent authority”. 

(30) In Article 52—
   (a) omit paragraphs 1 to 4; 
   (b) before paragraph 5 insert—
      “4A. This Article applies to a parallel trade permit issued before exit day by the United Kingdom as the Member State of introduction in accordance with this Article as it had effect immediately before exit day, where immediately before exit day the validity of that permit had not expired.”;
   (c) in paragraph 5, in the second sentence—
      (i) for “the Commission shall” substitute “the appropriate authority may”; 
      (ii) for “a Regulation” substitute “regulations”; 
      (iii) for “Article 68” substitute “Article 68(3)”; 
   (d) for paragraph 6 substitute—
      “6. The parallel trade permit is valid in relation to a constituent territory until the earlier of—
         (a) the date on which the authorisation of the reference product expires in relation to that constituent territory; 
         (b) 31st March 2021. 

6A. Paragraph 6B applies to a parallel trade permit where—
   (a) the authorisation holder of the reference product for that permit applies for a withdrawal of authorisation in accordance with Article 45(1), and 
   (b) the requirements of Article 29 are still fulfilled in respect of the product to which that permit relates. 

6B. Where this paragraph applies, the date of expiry of the reference product for the purposes of paragraph 6(a) is deemed to be the date on which the authorisation of the reference product would have expired if the application under Article 45(1) had not been made. 

6C. In paragraphs 4 to 6B, “reference product” means the plant protection product which was already authorised in the United Kingdom prior to the application for the parallel trade permit under paragraph 1 of this Article as it had effect immediately before exit day, and to which the product to which that permit relates is identical in composition.”;
   (e) after paragraph 8, insert—
“8A. In paragraph 8, “Member State of origin” means the member State or EEA state which was the Member State of origin in accordance with paragraph 1 of this Article as it had effect immediately before exit day, as adapted by the EEA agreement as it had effect immediately before exit day.”;

(f) omit paragraphs 9 and 10;

(g) in paragraph 11, for “Member State” substitute “competent”.

(31) In Article 53—

(a) in paragraph 1—

(i) in the first subparagraph—

(aa) for “Member State” substitute “competent authority”;

(bb) after “controlled use” insert “in its constituent territory”;

(ii) in the second subparagraph—

(aa) for “Member State” substitute “competent authority”;

(bb) for “Member States and the Commission” substitute “other competent authorities”;

(b) omit paragraphs 2 and 3;

(c) in paragraph 4—

(i) for “Paragraphs 1 to 3” substitute “Paragraph 1”;

(ii) for “Directive 2001/18/EC” substitute “section 111(1) of the Environmental Protection Act 1990 or article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991”.

(32) In Article 54—

(a) in paragraphs 1 and 2—

(i) for “Member State” in each place it occurs substitute “competent authority”;

(ii) after “in whose” insert “constituent”;

(b) in paragraph 1, in the first subparagraph, at the end insert “in relation to that constituent territory”;

(c) in paragraph 3, for “Directive 2001/18/EC” substitute “section 111(1) of the Environmental Protection Act 1990 or article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991”;

(d) in paragraph 4, for “Member State” substitute “competent authority”;

(e) omit paragraph 5.

(33) In Article 55—

(a) the existing first and second paragraphs become paragraphs 1 and 2;

(b) in that paragraph 2, omit the words from “, which shall apply” to the end;

(c) after that paragraph 2 insert—

“3. For the purposes of this Article, Article 14 of Directive 2009/128/EC is to be read as if—

(a) obligations on Member States were obligations on the competent authorities;

(b) paragraph 3 were omitted.”.

(34) In Article 56—

(a) in paragraph 1—
(i) in the first subparagraph, for “the Member States” substitute “each competent authority”;
(ii) in the fourth subparagraph, for “third” substitute “other”;
(b) in paragraph 3—
   (i) in the first subparagraph—
      (aa) for “Member States” in the first place it occurs substitute “competent authorities”;
      (bb) for “the Member State” substitute “where paragraph 3A applies, the competent authority”;
      (cc) omit “within each zone”;  
      (dd) for “Member States, belonging to the same zone” substitute “competent authorities which granted authorisation for the plant protection product”;
   (ii) in the second subparagraph—
      (aa) for “Member State” substitute “competent authority”;
      (bb) for “Member States and the Commission” substitute “competent authorities”;
(c) after paragraph 3 insert—
   “3A. This paragraph applies where—
   (a) each competent authority which granted authorisation agrees which competent authority is to evaluate the information;
   (b) each active substance, safener or synergist in the plant protection product to which the information relates has the same conditions of approval in relation to the constituent territory of each competent authority concerned;
   (c) any data requirements specified in regulations made under Article 8(4)(a) and (b), any uniform principles for evaluation and authorisation of plant protection products prescribed by regulations made under Article 29(6)(a) and any guidance issued under Article 77 relating to those requirements or principles are the same in relation to the constituent territory of each competent authority concerned.”;
(d) in paragraph 4, omit “of the Member States”.
(35) In Article 57—
   (a) in paragraph 1—
      (i) in the words before point (a), for “Member States” substitute “A competent authority”;
      (ii) in point (e), for the words from “to Directive 1999/45/EC” to the end substitute “with Regulation (EC) No 1272/2008 of the European Parliament and of the Council and any regulations made under Article 65(1A)”;
   (b) omit paragraph 3.

Chapter 4

6.—(1) Chapter 4 is amended as follows.
(2) For Article 58 substitute—
"Article 58

Placing on the market and use of adjuvants

1. An adjuvant must not be placed on the market or used in a constituent territory unless it has been authorised in that territory in accordance with Schedule 2 to the Plant Protection Products Regulations 2011(17) or Schedule 2 to the Plant Protection Products Regulations (Northern Ireland) 2011(18).

2. The appropriate authority may, by regulations, make provision regarding the authorisation of adjuvants including (but not limited to) data requirements, notification, evaluation, assessment and decision making procedures.”.

Chapter 5

7.—(1) Chapter 5 is amended as follows.

(2) In Article 59—

(a) in paragraph 1—

   (i) in the second subparagraph, in the words before point (a)—

      (aa) omit “, adjuvants”;

      (bb) for “Member State” substitute “competent authority”;

   (ii) in the third subparagraph—

      (aa) for “the Member State which received it” substitute “any competent authority”;

      (bb) omit “and adjuvants”;

   (iii) in the fourth subparagraph, for “first authorisation in that Member State” substitute “the first authorisation by a competent authority in the United Kingdom in relation to which the report is submitted”;

   (iv) in the fifth subparagraph, for “in that Member State” substitute “described in the fourth subparagraph”;

(b) in paragraph 3—

   (i) omit “, adjuvant”;

   (ii) for “Member State” substitute “competent authority”.

(3) In Article 60—

(a) in paragraph 1—

   (i) for “and adjuvant, rapporteur Member States” substitute “, the assessing competent authority”;

   (ii) for “Member States and the Commission” substitute “other competent authorities”;

(b) in paragraph 2—

   (i) in the words before point (a), for “Member States” substitute “a competent authority”;

   (ii) in point (a), omit “, adjuvant”;

(c) after paragraph 3 insert—

(17) S.I. 2011/2131, to which there are amendments not relevant to these Regulations.

“4. In paragraph 1, “assessing competent authority” has the same meaning as in Subsection 2 of Section 1 of Chapter 2.”.

(4) In Article 61—
   (a) in paragraph 1, in the first subparagraph—
      (i) in the first sentence, omit “or for an adjuvant”;
      (ii) in the second sentence, for “The competent authority” substitute “A competent authority”;
   (b) in paragraph 2, for “The competent authority of the Member State” substitute “A competent authority”.

(5) In Article 62—
   (a) in paragraph 2—
      (i) for “Member States” substitute “A competent authority”;
   (b) in paragraph 4—
      (i) in the first subparagraph—
         (aa) omit “, or of adjuvants”;
         (bb) omit “of the Member State”;
      (ii) in the second subparagraph, omit “of that Member State”;
   (c) in paragraph 6—
      (i) in the second sentence—
         (aa) omit “of the Member State”;
         (bb) omit “administered under national law”;
      (ii) in the third sentence, omit “of the Member States”;
      (iii) in the fourth sentence, for “in the courts of the Member States” substitute “as a civil debt”.

Chapter 6

8.—(1) Chapter 6 is amended as follows.

Chapter 7

9.—(1) Chapter 7 is amended as follows.
   (2) In Article 64(3)—

(20) S.I. 2004/3391, amended by paragraphs 305 to 309 of Schedule 19 to the Data Protection Act 2018 (c. 12) and by S.I. 2015/1897.
(b) for “Directive” in the second place it occurs substitute “Regulation”.

(3) In Article 65—

(a) for paragraph 1 substitute—

“1. The labelling of plant protection products must include—

(a) the classification, labelling and packaging requirements of Regulation (EC) No 1272/2008 of the European Parliament and of the Council, and

(b) any requirements contained in regulations made under paragraph 1A which apply in relation to the constituent territory in which the product is to be placed on the market or used.

1A. The appropriate authority may, by regulations, specify additional requirements for the labelling of plant protection products, including (but not limited to) standard phrases for special risks and safety precautions which supplement the phrases provided for in Regulation (EC) No 1272/2008 of the European Parliament and of the Council.”;

(b) in paragraph 2, for “Member States” substitute “A competent authority”;

(c) omit paragraph 3.

(4) In Article 66(3)—

(a) for “Member States” substitute “A competent authority”;

(b) for “Community” substitute “retained EU”.

Chapter 8

10.—(1) Chapter 8 is amended as follows.

(2) In Article 67—

(a) in paragraph 1—

(i) in the second subparagraph—

(aa) in the first sentence, for “the competent authority” substitute “a competent authority”;

(bb) in the second sentence, after “addressing the” insert “relevant”;

(ii) in the third subparagraph, omit “or Community”;

(b) in paragraph 2—

(i) in the first sentence, for “the competent authorities” substitute “a competent authority”;

(ii) in the second sentence, for “authorities” substitute “authority”;

(c) in paragraph 3—

(i) omit “of the Member States”;

(ii) for the words from “in accordance” to the end substitute “for the purposes of establishing and maintaining risk indicators in accordance with Annex 4 to Directive 2009/128/EC”;

(d) omit paragraph 4.

(3) In Article 68—

(a) the existing first paragraph becomes paragraph 1;

(b) in that paragraph 1—

(i) in the first sentence, for “Member States” substitute “A competent authority”;
(ii) in the second sentence—

(aa) for “They shall finalise and transmit to the Commission” substitute “A competent authority must publish”;

(bb) after “controls” insert “in relation to its constituent territory, in a manner which the competent authority considers appropriate,”;

(c) omit the second paragraph;

(d) for the third paragraph substitute—

“The appropriate authority may, by regulations, make provision in respect of the official controls to be carried out in accordance with this Article, in particular concerning—

(a) the production, packaging, labelling, storage, transport, marketing, formulation, parallel trade and use of plant protection products;

(b) the collection of information and reporting on suspected poisonings.”.

Chapter 9

11.—(1) Chapter 9 is amended as follows.

(2) For Article 69 substitute—

“Article 69

Emergency measures

1. Where a competent authority is satisfied that the conditions in paragraph 2 are met, the competent authority may—

(a) in the case of an active substance, safener or synergist approved in relation to its constituent territory—

(i) amend the conditions of approval, or

(ii) suspend approval;

(b) in the case of a co-formulant, add that co-formulant to the unacceptable co-formulants register in relation to its constituent territory;

(c) in the case of a plant protection product authorised in its constituent territory—

(i) amend the authorisation for that product;

(ii) suspend the authorisation for that product.

2. The conditions referred to in paragraph 1 are—

(a) the approved active substance, safener, synergist, co-formulant or plant protection product is likely to constitute a serious risk to human or animal health or the environment, and

(b) that risk cannot be contained satisfactorily by means of other measures taken by the competent authority.

3. In performing a function under paragraph 1, the competent authority may obtain independent scientific advice, where the competent authority considers it appropriate to do so.

4. As soon as reasonably practicable after acting in accordance with paragraph 1(a), (b) or (c), the competent authority must—

(a) update the approvals register or unacceptable co-formulants register accordingly;
(b) in relation to an amendment or suspension under paragraph 1(a), begin a review of the active substance, safener or synergist in accordance with Article 21 or that Article as applied by Article 25A(4);
(c) in relation to a register addition under paragraph 1(b), begin a review of the co-formulant under Article 27(3);
(d) in relation to an amendment or suspension under paragraph 1(c), begin a review of the plant protection product authorisation under Article 44.

5. An amendment or suspension under paragraph 1(a) expires upon the completion of the review described in paragraph 4(b).

6. A register addition under paragraph 1(b) expires upon the completion of the review described in paragraph 4(c).

7. An amendment or suspension under paragraph 1(c) expires upon the completion of the review described in paragraph 4(d).

8. Following the expiry of an amendment or suspension under paragraph 1(a), or a register addition under paragraph 1(b), the competent authority must update the approvals register or unacceptable co-formulants register accordingly.

9. The Secretary of State may perform a function 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;
   (c) in relation to Northern Ireland, with the consent of the Department.

10. Where the Secretary of State performs a function in accordance with paragraph 9, a reference to the competent authority in paragraphs 3 and 8 is to be read as a reference to the Secretary of State.”.

(3) Omit Articles 70 and 71.

Chapter 10

12.—(1) Chapter 10 is amended as follows.
(2) Omit Article 72.
(3) In Article 73, for “Member States” substitute “United Kingdom”.
(4) Omit Article 74.
(5) In Article 75—
   (a) omit paragraphs 1 and 2;
   (b) in paragraph 3, for “Member States shall ensure that competent authorities have” substitute “A competent authority must ensure that it has”;
   (c) omit paragraphs 4 and 5.
(6) For Articles 77 and 78 substitute—

“Article 77

Guidance documents

1. A competent authority may issue, amend or withdraw technical and other guidance documents relating to the implementation of this Regulation, including (but not limited to)—
(a) guidance relating to the format of the summary or complete dossiers to be used for the purposes of Article 8;
(b) guidance relating to the format of the draft assessment report for the purposes of Article 11;
(c) guidance relating to the format of the assessment for the purposes of Article 36;
(d) guidance regarding the rules and procedure for the assessment of equivalence under Article 38;
(e) guidelines on the coordination of compliance checks to be undertaken in accordance with Article 43(3);
(f) guidance on the application of Article 54, including—
   (i) the maximum quantities of plant protection products that may be released during experiments or tests;
   (ii) the minimum data to be submitted in accordance with Article 54(2);
(g) guidance concerning the content of the application concerning micro-organisms, pheromones and biological products.

2. A competent authority must publish any guidance document issued or amended, or a notice specifying any guidance document withdrawn, under paragraph 1 in a manner which that competent authority considers appropriate.

3. Before issuing, amending or withdrawing a guidance document under paragraph 1 a competent authority may obtain independent scientific advice, where the competent authority considers it appropriate to do so.

4. The Secretary of State may issue, amend or withdraw a guidance document 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;
   (c) in relation to Northern Ireland, with the consent of the Department.

5. Where the Secretary of State issues, amends or withdraws a guidance document in accordance with paragraph 4, a reference in paragraphs 2 and 3 to the competent authority is to be read as a reference to the Secretary of State.

6. In complying with any obligation under this Regulation, a person or competent authority must have regard to any guidance issued in accordance with paragraph 1.

Article 78
Amendments and implementing measures

The appropriate authority may by regulations—
(a) amend the Annexes to take account of current scientific and technical knowledge;
(b) make further provision as necessary for the implementation of this Regulation.

Article 78A
Regulations

1. Regulations made by the Secretary of State or Welsh Ministers under this Regulation are to be made by statutory instrument.
2. For regulations made under this Regulation by the Scottish Ministers, see section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010(22).

3. Any power to make regulations conferred on the Department under this Regulation is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979(23).

4. A statutory instrument containing regulations made by the Secretary of State under this Regulation is subject to annulment in pursuance of a resolution of either House of Parliament.

5. A statutory instrument containing regulations made by the Welsh Ministers under this Regulation is subject to annulment in pursuance of a resolution of the National Assembly for Wales.

6. Regulations made by the Scottish Ministers under this Regulation are subject to the negative procedure (see section 28 of the Interpretation and Legislative Reform (Scotland) Act 2010).

7. Regulations made by the Department under this Regulation are subject to negative resolution within the meaning of section 41(6) of the Interpretation Act (Northern Ireland) Act 1954(24).

8. Such regulations may—
   (a) contain consequential, incidental, supplementary, transitional or saving provision (including provision amending, repealing or revoking enactments);
   (b) make different provision for different purposes.”.

(7) Omit Article 79.

Chapter 11

13.—(1) Chapter 11 is amended as follows.

(2) For Article 80, substitute—

“Article 80

Existing transitional measures

1. The following application is taken to have been made under Article 7(1) on the date it was made—

<table>
<thead>
<tr>
<th>Common Name, CIPAC Identification Number</th>
<th>Applicant</th>
<th>Date of application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethametsulfuron</td>
<td>DuPont de Nemours GmbH</td>
<td>29th June 2010</td>
</tr>
<tr>
<td>CIPAC-No: 834</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1A. For the determination of the application described in paragraph 1, this Regulation is to be read subject to the modifications in paragraphs 1B to 1F.

1B. Article 4(1) is to be read as if—
   (a) in the first subparagraph—

(22)  2010 asp 10.
(23)  S.I. 1979/1573 (NI 12).
(24)  1954 c.33.
(i) “in accordance with Annex II” were omitted;
(ii) the words from “, taking into account” to “that Annex,” were omitted;
(b) the second subparagraph were omitted.

1C. Article 4(2)(a) is to be read as if the words from “, taking into account” to “available,” were omitted.

1D. Article 4(3) is to be read as if—
(a) point (a) were omitted;
(b) in point (b), the words from “or consequences” to “effects are available;” were omitted;
(c) points (c), (d) and (e)(iii) were omitted;

1E. Article 4(7) is to be ignored.

1F. Article 11(2) is to be read as if the third subparagraph were omitted.

1G. Anything done before exit day in relation to the application described in paragraph 1—
(a) by the United Kingdom—
(i) under Directive 91/414/EEC, as the member State described in Article 6 of that Directive;
(ii) as the rapporteur Member State under Regulation 188/2011;
(b) by the European Food Safety Authority under Directive 91/414/EEC or Regulation 188/2011,
is taken to have been done by the relevant competent authority as the assessing competent authority.

1H. If the application described in paragraph 1 is approved in accordance with Article 13—
(a) Article 13(1) to (4) of Directive 91/414/EEC applies in relation to that approval for a period of 10 years beginning with the date of approval;
(b) Regulation 544/2011 and Regulation 545/2011 apply in relation to that approval as if, for Article A1(1)(a) of each Regulation, for the words from “as it had effect” in the first place it occurs to the end there were substituted “as read with Article 80(1) of that Regulation”.

1I. In paragraph 1G—
(a) “rapporteur Member State” has the meaning given by Article 2(1) of Regulation 188/2011;
(b) the “relevant competent authority” is the Secretary of State.

2. Paragraphs 2A to 2E apply to an active substance—
(a) included in Annex 1 to Directive 91/414/EEC;
(b) approved in accordance with paragraph 1 of this Article as it had effect immediately before exit day.

2A. Article 13(1) to (4) of Directive 91/414/EEC applies—
(a) for active substances covered by Article 8(2) of Directive 91/414/EEC, for a period of five years beginning with the date of the inclusion or approval of the active substance;
(b) for active substances which were not on the market in the European Union, an EEA state or the United Kingdom on 26th July 1993, for a period of 10 years from the date of the inclusion or approval of the active substance.

2B. In paragraph 2A(b), “on the market” means any supply, whether in return for payment or free of charge, other than for storage followed by consignment from the territory of the European Union, an EEA state or the United Kingdom or disposal.

2C. In paragraphs 2A(b) and 2B, the “European Union” does not include the Republic of Croatia.

2D. Regulation 544/2011 applies to the active substance, and is to be read as if, in Article A1(1) of that Regulation—
   (a) point (a) were omitted;
   (b) for point (b)(i) there were substituted—
        “(i) described in Article 80(2) of Regulation (EC) No 1107/2009, and”.

2E. Regulation 545/2011 applies to the active substance, and is to be read as if, in Article A1(1) of that Regulation—
   (a) point (a) were omitted;
   (b) in point (b)(ii), for “to which point (a) applies” there were substituted “described in Article 80(2) of Regulation (EC) No 1107/2009”.

2F. In this Article—
   (a) “assessing competent authority” has the same meaning as in Subsection 2 of Section 1 of Chapter 2;
   (b) “Directive 91/414/EEC” means Council Directive 91/414/EEC concerning the placing of plant protection products on the market, as it had effect by virtue of paragraph 1 and 2 of this Article as those paragraphs had effect immediately before exit day, read in accordance with paragraph 2G;
   (c) “Regulation 188/2011” means Commission Regulation (EU) No 188/2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive as it had effect immediately before exit day;

2G. For the purposes of this Article, Article 13(1) to (4) of Directive 91/414/EEC is to be read as if—
   (a) a term used in those paragraphs which is defined in this Regulation has the meaning given in this Regulation;
   (b) in paragraph 1—
        (i) in the words before point (a), for “Without prejudice to Article 10, Member States” there were substituted “A competent authority”;
        (ii) in point (a), for “Annex III” there were substituted “Regulation 545/2011”;
        (iii) in point (b), for “Annex II” there were substituted “Regulation 544/2011”;

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(c) in paragraph 3—
(i) for “Member States” there were substituted “a competent authority”;  
(ii) for “Annex II” there were substituted “Regulation 544/2011”;  
(iii) in point (b), for the words from “two years” to the end there were substituted “by 26th July 1993”;  
(iv) point (c) (and the “or” immediately preceding it) were omitted;  
(v) in point (d), for “paragraphs 3(b) and (c)” there were substituted “paragraph 3(b)”;  

(d) in paragraph 4—
(i) for “Member States” there were substituted “a competent authority”;  
(ii) for “Annex III” there were substituted “Regulation 545/2011”;  
(iii) point (c) (and the “or” immediately preceding it) were omitted.”.  

(3) Omit Article 81.  
(4) In Article 83—
(a) in the first paragraph—
(i) omit “by the Acts listed in Annex V”;
(ii) omit the words from “, without prejudice” to the end;  
(b) in the second paragraph, omit “in other Community legislation, such as Regulation (EC) No 1782/2003,”.  

(5) Omit Article 84.  
(6) After Article 84, omit the words from “This Regulation” to “all Member States”.  

Annexes  
14.—(1) The Annexes are amended as follows.  
(2) Omit Annex 1.  
(3) In Annex 2—
(a) in point 1.1, for “rapporteur Member State and the Authority” substitute “assessing competent authority”;  
(b) in point 1.2, for “Authority and the rapporteur Member State” substitute “assessing competent authority”;  
(c) after point 1.2 insert—
“1.2A. In this Annex, “the assessing competent authority” has the meaning given by Article 7(1C) or 15(1A) as the case may be.”;  
(d) omit point 1.3;  
(e) in point 2.1, for “in at least one Member State” substitute “by at least one competent authority”;  
(f) in point 2.3—
(i) in the first paragraph, for “Article 6” substitute “Article 6(1)”;
(ii) in the second paragraph, for “rapporteur Member State” substitute “assessing competent authority”;  
(g) in point 3.1, in the first, second and fourth paragraphs, for “Article 7(1)” substitute “Article 7(1D)”;

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(h) in points 3.2 and 3.5.3, for “Article 29(6)” substitute “Article 29(6)(a) in relation to the relevant constituent territory”;

(i) in point 3.6.2, omit “, reviewed by the Authority”;

(j) in point 3.6.3—
   (i) after “synergist” in the second place it appears insert “in relation to the relevant constituent territory”;
   (ii) omit “, reviewed by the Authority”;

(k) in point 3.6.4—
   (i) after “synergists” insert “in relation to the relevant constituent territory”;
   (ii) omit “, reviewed by the Authority”;

(l) in point 3.6.5—
   (i) omit the first, third and fourth paragraphs;
   (ii) in the sixth paragraph, in point (1)—
      (aa) in point (a), for the words from “the Commission” to “products,” substitute “guidance issued”;
      (bb) in point (b), for the words from “which is” to “products” substitute “issued”;

(m) in point 3.8.1, for “Article 29(6)” substitute “Article 29(6)(a) in relation to the relevant constituent territory”;

(n) in point 3.8.2—
   (i) omit the first paragraph;
   (ii) in the third paragraph, in point (1)(a) and (b), for the words from “the Commission” to “products,” substitute “guidance issued”;

(o) in point 3.8.3, for “Community” substitute “nationally”; 

(p) in point 3.10, for “Article 29(6)” substitute “Article 29(6)(a) in relation to the relevant constituent territory”;

(q) in point 4, in the seventh indent—
   (i) for “Community” substitute “nationally”;
   (ii) omit “, reviewed by the Authority”;

(r) in point 5.1.1(b), for “under” substitute “and is listed in Annex 10 to”.

(4) Omit Annexes 3 and 5.

CHAPTER 2
Amendment of other EU Regulations


(2) For Article 1, substitute—
“Article 1

Scope

1. This Regulation lays down the procedure for the determination of the existing renewal application by the relevant competent authority as assessing competent authority.

2. The “existing renewal application” is the application for the renewal of the approval of the active substance famoxadone which—
   (a) was made to the United Kingdom as rapporteur Member State in accordance with Article 4 as it had effect immediately before exit day, and
   (b) is taken as being made under this Regulation and Article 15(1) of Regulation (EC) No 1107/2009 on the date on which it was made.

3. Anything done under this Regulation as it had effect immediately before exit day in relation to the existing renewal application—
   (a) by the United Kingdom as rapporteur Member State;
   (b) by the European Food Safety Authority;

is taken to have been done by the relevant competent authority as the assessing competent authority.

4. In this Article—
   (a) “rapporteur Member State” has the meaning given in Article 2(c) as it had effect immediately before exit day;
   (b) the “relevant competent authority” is the Secretary of State.”.

3) In Article 2—
   (a) for point (b) substitute—
       “(b) ‘applicant’ means the producer who made the existing renewal application;”;
   (b) omit points (c) to (f);
   (c) after point (f) insert—
       (h) ‘assessing competent authority’ has the meaning given by Article 15(1) of Regulation (EC) No 1107/2009;
       (i) ‘existing renewal application’ has the meaning given by Article 1(2).”.

4) After Article 2 insert—

“Article 2A

Determination of existing renewal application

1. Where the assessing competent authority considers that additional data from the applicant is necessary to finalise the relevant conclusion, the assessing competent authority may set a period of up to one month for the applicant to supply that data.

2. The assessing competent authority must notify the other competent authorities—
   (a) as to the data received in accordance with paragraph 1, or
   (b) where no data is received during the period described in paragraph 1.
3. On request from a competent authority, the assessing competent authority must provide a copy of data received in accordance with paragraph 1.

4. The assessing competent authority must send the other competent authorities a finalised conclusion as soon as reasonably practicable after the conclusion is finalised.

5. Article 20 of Regulation (EC) No 1107/2009 applies to the determination of an existing renewal application, and for the purpose of that Article an existing renewal application is taken to relate to each constituent territory.

6. In paragraph 1, “relevant conclusion” means the conclusion of the European Food Safety Authority in respect of the existing renewal application, delivered in accordance with the second subparagraph of Article 16(2) as it had effect immediately before exit day.

7. In this Article, “competent authority” and “constituent territory” have the meanings given in Article 3A of Regulation (EC) No 1107/2009.

(5) Omit Articles 3 to 21.

(6) After Article 21, omit the words from “This Regulation” to “Member States”.

(7) Omit Annexes 1 and 2.


(2) Before Article 1, insert—

"**Article A1**

Scope and interpretation

1. This Regulation applies in relation to—

(a) an application under Article 7 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market as it had effect immediately before exit day where—

   (i) paragraph 6 of Schedule 1 to the Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 applies to that application, and

   (ii) on or before 31st December 2013 dossiers were submitted in accordance with Article 8(1) and (2) of Regulation (EC) No 1107/2009 as it had effect immediately before exit day;

(b) an application under Article 15 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market as it had effect immediately before exit day where—

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

   (ii) on or before 31st December 2013 dossiers were submitted in accordance with Article 9 of Commission Regulation (EU) No 1141/2010 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 as it had effect immediately before exit day;
(c) an application for authorisation of a plant protection product, as referred to in Article 28 of Regulation (EC) No 1107/2009, which was submitted before 31st December 2015, to the submission of data concerning an active substance—

(i) to which point (a) or (b) applies, or

(ii) for which approval has not been renewed in accordance with Article 14 of Regulation (EC) No 1107/2009 or Commission Implementing Regulation (EU) No 844/2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, whether before or after exit day.

2. Paragraph 1(b) does not apply where the applicant for the authorisation notifies the competent authority in writing when submitting the application that the data requirements of Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances apply instead.

3. Paragraph 4 applies where Commission Regulation (EU) No 284/2013 setting out the data requirements for active substances applies in relation to an application by virtue of—

(a) Article 1 of that Regulation, or


4. Where this paragraph applies, a reference in this Regulation to Commission Regulation (EU) No 545/2011, or a specified part of Commission Regulation (EU) No 545/2011, is to be read in relation to the application as a reference to Commission Regulation (EU) No 284/2013, or the equivalent part of Commission Regulation (EU) No 284/2013 (as the case may be).”.

(3) Omit Article 2.

(4) After Article 2, omit the words from “This Regulation shall” to “Member States”.

(5) In the Annex—

(a) in the Introduction—

(i) in point 1.2, for the words from “the entry” to “Annex,” substitute “14th June 2011”;

(ii) in point 1.3, for “Member States” substitute “the competent authority”;

(iii) in point 1.6, for “Council Directive 86/609/EEC(25)” substitute “the Animals (Scientific Procedures) Act 1986(26)”;

(iv) in point 2.1, after “laid down in” insert “Annex 1 to”;

(v) in point 2.2, in the first paragraph—

(aa) for “Member States” substitute “the competent authority”;

(bb) after “their” insert “constituent”;

(vi) in point 2.3, in the first paragraph—

(aa) for “Member States” substitute “the competent authority”;

(bb) after “their” insert “constituent”;

(cc) for “2 years after notification of the Directive 91/414/EEC(27)” substitute “on or before 25th July 1993”;

(b) in Part A—


(i) in point 1.1, in the second paragraph, for the words from “Member State” in the first place it occurs to “Commission” substitute “United Kingdom”;
(ii) in point 1.2, in the third sentence, for “the Commission and the Member States” substitute “each competent authority which granted approval”;
(iii) in point 1.5, in the second sentence, omit “Member States or”;
(iv) in point 1.9, in the second paragraph for “the Commission and the Member States” substitute “each competent authority which granted approval”;
(v) in point 4.2.1, for “Member States” substitute “competent authorities”;
(vi) in point 5.9, in the first paragraph, in the first sentence, after “the provisions of” insert “the EU-derived domestic legislation which transposed(28)”;
(vii) in the Introduction to Section 6, in point (iii), for “the EU Guidelines for” substitute “guidance issued under Article 77 of Regulation (EC) No 1107/2009 regarding”;
(viii) in point 6.10, omit “of the Member States”;
(ix) in point 7.1, in the fourth paragraph, for “EU” substitute “UK”;
(x) in point 7.1.1.2.1, under “Aerobic degradation”, under “Test conditions”, in the second paragraph, omit “EU”;

(c) in Part B—
(i) in point 1.1, in the second paragraph, for the words from “Member State” in the first place it occurs to “Commission” substitute “United Kingdom”;
(ii) in point 1.2, for “the Commission and the Member States” substitute “each competent authority which granted approval”;
(iii) in point 1.4.1, in the second paragraph for “the Commission and the Member States” substitute “each competent authority which granted approval”;
(iv) in point 5.1.1, in the first paragraph, in the first sentence, after “the provisions of” insert “the EU-derived domestic legislation which transposed”;
(v) in point 7.1.1, for “EU” substitute “UK”;
(vi) in point 9, omit “of the Member States”.


(2) Before Article 1, insert—

**“Article A1**

*Scope and interpretation*

1. This Regulation applies—

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(a) in relation to an application under Article 7 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market as it had effect immediately before exit day where—
   (i) paragraph 6 of Schedule 1 to the Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 applies to that application, and
   (ii) on or before 31st December 2013 dossiers were submitted in accordance with Article 8(1) and (2) of Regulation (EC) No 1107/2009 as it had effect immediately before exit day;
(b) in relation to an application under Article 15 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market as it had effect immediately before exit day where—
   (i) paragraph 7 of Schedule 1 to the Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019 applies to that application, and
   (ii) on or before 31st December 2013 dossiers were submitted in accordance with Article 9 of Commission Regulation (EU) No 1141/2010 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 as it had effect immediately before exit day;
(c) in relation to an application for authorisation of a plant protection product, as referred to in Article 28 of Regulation (EC) No 1107/2009, where—
   (i) the application was submitted before 31st December 2015, and
   (ii) the plant protection product contains at least one active substance to which point (a) or (b) applies;
(d) in relation to the renewal of the authorisation of a plant protection product in accordance with Article 43(2) of Regulation (EC) No 1107/2009 following the renewal (whether before or after exit day) of an active substance in accordance with Commission Regulation (EU) No 1141/2010.

2. Paragraph 1(c) or (d) does not apply where the applicant for the authorisation notifies the competent authority in writing when submitting the application that the data requirements of Commission Regulation (EU) No 284/2013 setting out the data requirements for plant protection products apply instead.

3. Paragraph 4 applies where Commission Regulation (EU) No 283/2013 setting out the data requirements for plant protection products applies in relation to an application by virtue of—
   (a) Article 1 of that Regulation, or

4. Where this paragraph applies, a reference in this Regulation to Commission Regulation (EU) No 544/2011, or a specified part of Commission Regulation (EU) No 544/2011, is to be read in relation to that application as a reference to Commission Regulation (EU) No 283/2013, or the equivalent part of Commission Regulation (EU) No 283/2013 (as the case may be).”.

(3) Omit Article 2.
(4) After Article 2, omit the words from “This Regulation shall” to “Member States”.
(5) The Annex is amended in accordance with paragraphs (6) to (8).
(6) In the Introduction—
(a) in point 1.2, for the words from “the entry” to “Annex,” substitute “14th June 2011”;
(b) in point 1.3, for “Member States” substitute “competent authorities”;
(c) in point 1.6, for “Council Directive 86/609/EEC” substitute “the Animals (Scientific Procedures) Act 1986”;
(d) in point 2.1, after “laid down in” insert “Annex 1 to”;
(e) in point 2.2, in the seventh indent, for “Union” substitute “United Kingdom”;
(f) in point 2.3—
   (i) in the first indent, for “to the relevant national authority” substitute “in accordance with the official recognition scheme”;
   (ii) in the second indent—
      (aa) for “Member State” substitute “competent authority”;
      (bb) after “on its” insert “constituent”;
(g) in points 2.4 and 2.5—
   (i) for “Member States” substitute “the competent authority”;
   (ii) after “their” insert “constituent”;
(h) in point 3, omit the words from “Directive 1999/45/EC” to “or with”;
(i) in point 4, in the first indent, for “EU legislation” substitute “retained EU law”.

(7) In Part A—

(a) in point 1.1, in the second paragraph, for the words from “Member State” to “sought” substitute “United Kingdom”;
(c) in point 6.5, after the heading “Test guideline”, in the second paragraph—
   (i) for “Member State” in the first place it occurs substitute “competent authority”;
   (ii) for “territory of this Member State” substitute “constituent territory of that competent authority”;
(d) in points 7.1, 7.1.1 and 7.1.2, omit “Directive 1999/45/EC or”;
(e) in point 7.2, after “the requirements of” insert “the EU-derived domestic legislation which transposed(29)”;
(f) in point 7.2.1.1, omit “Directive 1999/45/EC or”;
(g) in points 7.2.1.2 and 7.2.3.2, after “in accordance with” insert “the EU-derived domestic legislation which transposed”;
(h) in point 7.3, in the second paragraph, in the second indent, after “in accordance with” insert “the EU-derived domestic legislation which transposed”;
(i) in point 8.9, in the first paragraph, omit “of the Member States”;
(j) in section 11, omit “of the Member States”;
(k) in point 12.3, in the heading, omit “and Directive 1999/45/EC”.

(8) In Part B—

(a) in point 1.1, in the second paragraph, for the words from “Member State” to “sought” substitute “United Kingdom”;

(c) in point 6.5, after the heading “Test guideline”, in the second paragraph—
   (i) for “Member State” in the first place it occurs substitute “competent authority”;
   (ii) for “territory of this Member State” substitute “constituent territory of that competent authority”;
(d) in points 7.1, 7.1.1 and 7.1.3, omit “Directive 1999/45/EC or”;
(e) in Section 11, omit “of the Member States”.


(2) Before Article 1, insert—

   “Article A1
   Interpretation

1. Paragraph 2 applies where Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances applies in relation to an application by virtue of—
   (a) Article 1 of that Regulation, or

2. Where this paragraph applies, a reference in this Regulation to Commission Regulation (EU) No 544/2011, or a specified part of Commission Regulation (EU) No 544/2011, is to be read in relation to that application as a reference to Commission Regulation (EU) No 283/2013, or the equivalent part of Commission Regulation (EU) No 283/2013 (as the case may be).

3. Paragraph 4 applies where Commission Regulation (EU) No 284/2013 setting out the data requirements for plant protection products applies in relation to an application by virtue of—
   (a) Article 1 of that Regulation, or

4. Where this paragraph applies, a reference in this Regulation to Commission Regulation (EU) No 545/2011, or a specified part of Commission Regulation (EU) No 545/2011, is to be read in relation to the application as a reference to Commission Regulation (EU) No 284/2013, or the equivalent part of Commission Regulation (EU) No 284/2013 (as the case may be).”.

(3) In Article 1, for “Article 29(6)” substitute “Article 29(6)(a)”.  
(4) Omit Article 2.  
(5) After Article 2, omit the words from “This Regulation shall” to “Member States”.  
(6) The Annex is amended in accordance with paragraphs (7) to (9).
(7) In the heading, for “Article 29(6)” substitute “Article 29(6)(a)”.
(8) In Part 1—
   (a) in Part A—
      (i) in points 1, 2 and 4, for “Member States” substitute “competent authorities”;
      (ii) in point 5—
         (aa) in the first paragraph, for “Member States” substitute “competent authorities”;
         (bb) in the second paragraph, for “Member States” substitute “Competent authorities”;
      (iii) in point 6, omit “of the Member States”;
   (b) in Part B—
      (i) in points 1.1, 1.2, 1.3 and 1.4, for “Member States” in each place it occurs substitute “competent authorities”;
      (ii) in Section 2, in the text before point 2.1, for “Member States” substitute “Competent authorities”;
      (iii) in points 2.1.1 and 2.1.2, for “Member States” substitute “competent authorities”;
      (iv) in point 2.1.3, for “Member States” substitute “Competent authorities”;
      (v) in point 2.1.4—
         (aa) in the first paragraph, for “Member States” substitute “Competent Authorities”;
         (bb) in the second paragraph, for “Member States” substitute “competent authorities”;
      (vi) in point 2.1.5, for “Member States” in each place it occurs substitute “competent authorities”;
      (vii) in point 2.2.1, in the words before point (a), for “Member States” substitute “Competent authorities”;
      (viii) in points 2.2.2 and 2.3, for “Member States” substitute “competent authorities”;
      (ix) in points 2.4.1.1, 2.4.1.2, 2.4.1.3, 2.4.1.4, and 2.4.2.1 for “Member States” substitute “Competent authorities”;
      (x) in points 2.4.2.2 and 2.4.2.3, for “Member States” substitute “competent authorities”;
      (xi) in points 2.4.2.4, 2.4.2.5 and 2.4.2.6, for “Member States” substitute “Competent authorities”;
      (xii) in point 2.5.1, for “Member States” substitute “competent authorities”;
      (xiii) in point 2.5.1.1, in the first paragraph, for “Member States” substitute “Competent authorities”;
      (xiv) points 2.5.1.2 and 2.5.1.3 are amended as follows;
      (xv) in the first paragraph—
         (aa) for “Member States” substitute “Competent authorities”;
         (bb) for “suitable calculation model validated at EU level” substitute “suitable validated calculation model”;
      (xvi) in the second paragraph—
         (aa) omit “EU” in the first place it occurs;
(bb) for “Member States” substitute “competent authorities”;

(xvii) in points 2.5.1.4 and 2.5.1.5, for “Member States” substitute “Competent authorities”;

(xviii) in point 2.5.2, for “Member States” substitute “competent authorities”;

(xix) in points 2.5.2.1, 2.5.2.2, 2.5.2.3, 2.5.2.4, 2.5.2.5, 2.5.2.6, 2.6, 2.7.1 and 2.7.2, for “Member States” substitute “Competent authorities”;

(c) in Part C—

(i) in point 1.1, for “Member States” substitute “competent authorities”;

(ii) in point 1.2—

(aa) for “Member States” substitute “Competent authorities”;

(bb) for “Member State” substitute “constituent territory of the competent authority”;

(iii) in points 1.3 and 1.4, for “Member States” substitute “Competent authorities”;

(iv) in point 1.5, for “Member States” substitute “competent authorities”;

(v) in point 1.6—

(aa) the first paragraph is amended as follows;

(bb) in the words before the first indent, for “Member States” substitute “competent authorities”;

(cc) in the second indent, for “EU legislation” substitute “retained EU law”;


(vi) in point 1.7—

(aa) in the words before point (a), for “Member States” substitute “competent authorities”;


(vii) in point 1.9—

(aa) in the first paragraph, for “Member States” substitute “competent authorities”;

(bb) in the second paragraph, for “Member States” substitute “Competent authorities”;

(viii) in point 2.1.4, for “Member State” substitute “constituent territory of the competent authority”;

(ix) in point 2.1.5, in the second paragraph, for “Member States” substitute “competent authorities”;

(x) in point 2.4.1.1, in the second paragraph, after “in accordance with” in both places it occurs insert “the EU-derived domestic legislation which transposed”;

(xi) in point 2.4.1.2, for “EU provisions” substitute “retained EU law”;

(xii) in point 2.4.1.4, omit “EU”;

(xiii) in points 2.4.2.2 and 2.4.2.3, for “Member States” substitute “competent authorities”;

(xiv) in point 2.4.2.4, for “Member State” substitute “constituent territory of the competent authority”;

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(xv) in point 2.5.1.2(i), after “laid down by” insert “the EU-derived domestic legislation which transposed(30)”;  
(xvi) in point 2.5.1.3, in the first indent, after “in accordance with” insert “the EU-derived domestic legislation which transposed(31)”;  
(xvii) in point 2.6.2(v), in the table heading, for “or EU” substitute “MRL”.  

(9) In Part 2—  
(a) in Part A—  
(i) in points 1, 2 and 4, for “Member States” substitute “competent authorities”;  
(ii) in point 5—  
(aa) in the first paragraph, for “Member State” substitute “competent authority”;  
(bb) in the second paragraph, for “Member States” substitute “Competent authorities”;  
(iii) in point 6, omit “of the Member States”;  
(iv) in point 8—  
(aa) for “Member States” substitute “Competent authorities”;  
(v) in point 9—  
(aa) in the first sentence, after “micro-organisms,” insert “the EU-derived domestic legislation which transposed(32)”;  
(bb) in the second sentence, for “Directive” substitute “legislation”;
(b) in Part B—  
(i) in point 1.1, in the words before point (a), for “Member States” substitute “competent authorities”;  
(ii) in point 1.3, for “Member States” substitute “competent authorities”;  
(iii) in point 1.4—

(aa) for “Member States” in both places it occurs substitute “Competent authorities”;
(bb) for “in that Member State” substitute “to that competent authority”;
(iv) in points 1.5 and 1.6, for “Member States” in each place it occurs substitute “competent authorities”;
(v) in Section 2, in the words before point 2.1, for “Member States” substitute “Competent authorities”;
(vi) in point 2.1.2, for “Member States” substitute “Competent authorities”;
(vii) in point 2.2.1.2, for “Member States” substitute “competent authorities”;  
(viii) in point 2.2.2.3, for “Member States” substitute “Competent authorities”;
(ix) in point 2.4.1, for “Member States” substitute “competent authorities”;
(x) in points 2.4.2 and 2.4.3, for “Member States” substitute “Competent authorities”;
(xi) in points 2.4.4—
   (aa) in the first paragraph, for “Member States” substitute “Competent authorities”;
   (bb) in the second paragraph, for “Member States” substitute “competent authorities”;  
(xii) in point 2.4.5, for “Member States” substitute “Competent authorities”;
(xiii) in points 2.4.6, 2.4.7 and 2.4.8, for “Member States” in each place it occurs substitute “competent authorities”;
(xiv) in points 2.5, 2.5.1.1, 2.5.1.2, 2.5.2.1, and 2.5.2.2, in the first paragraph, for “Member States” substitute “Competent authorities”;
(xv) in point 2.6, in the words before point (a), for “Member States” substitute “competent authorities”;
(xvi) in point 2.6.1.1, in the words before point (a)—
   (aa) in the first sentence, for “Member States” substitute “Competent authorities”;
   (bb) omit the third sentence;
(xvii) in points 2.6.1.2, 2.6.1.3 and 2.6.1.4, for “Member States” substitute “Competent authorities”;
(xviii) in points 2.6.2.1 and 2.6.2.2, in points (a) and (b), for “Member States” substitute “Competent authorities”;
(xix) in point 2.7, in the fourth paragraph, for “Member States” substitute “competent authorities”;
(xx) in point 2.7.1—
   (aa) in the first paragraph, for “Member States” substitute “Competent authorities”;
   (bb) in the second paragraph, for “Member States” substitute “competent authorities”;
(xxi) in point 2.7.2—
   (aa) in the first paragraph, for “Member States” substitute “Competent authorities”;

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(bb) in the second paragraph, in point (f), after “provided for in” insert “the EU-derived domestic legislation which transposed”;

(xxii) in points 2.7.3, 2.7.4, 2.8, 2.8.1, 2.8.2, 2.8.3, 2.8.4, 2.8.5, 2.8.6, 2.8.6.2, and 2.9, for “Member States” in each place it occurs substitute “Competent authorities”;

(c) in Part C—

(i) in point 1.1, for “Member States” substitute “competent authorities”;

(ii) in point 1.2—

(aa) in the first sentence, for “Member States” substitute “Competent authorities”;

(bb) in the second sentence, for “Member State in question” substitute “constituent territory of the competent authority”;

(iii) in point 1.3, for “Member States” substitute “Competent authorities”;

(iv) in point 1.4—

(aa) for “Member States” substitute “Competent authorities”;

(bb) for “control” substitute “management”;

(v) in point 1.5, for “Member States” substitute “competent authorities”;

(vi) in point 1.6—

(aa) in the words before point (a), for “Member States” substitute “competent authorities”;

(bb) in point (b), for “EU legislation” substitute “retained EU law”;

(cc) in point (d), for “Article 10(1.2), (2.4), (2.5) and (2.6) of Directive 1999/45/EC” substitute “Articles 19, 21 and 22 of, and part 4 of Annex 2 to Regulation (EC) No 1272/2008 of the European Parliament and of the Council”;

(vii) in point 1.7—

(aa) in the words before point (a), for “Member States” substitute “competent authorities”;


(viii) in point 1.9—

(aa) in the first paragraph, for “Member States” substitute “competent authorities”;

(bb) in the second paragraph, for “Member States” substitute “Competent authorities”;

(ix) in point 1.10, for “Member States” substitute “Competent authorities”;

(x) in point 1.11, after “in accordance with” in both places it occurs insert “the EU-derived domestic legislation which transposed”;

(xi) in point 1.12, after “in accordance with” in the second place it occurs insert “the EU-derived domestic legislation which transposed”;

(xii) in point 1.14, for “Member States” substitute “Competent authorities”;

(xiii) in point 2.1, for “Member States” substitute “competent authorities”;

(xiv) in point 2.2.1, in the third sentence, for “Member States” substitute “Competent authorities”;

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Paragraph 2 applies where Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances applies in relation to an application by virtue of—

(a) Article 1 of that Regulation, or


2. Where this paragraph applies, a reference in this Regulation to Commission Regulation (EU) No 544/2011, or a specified part of Commission Regulation (EU) No 544/2011, is to be read in relation to the application as a reference to Commission Regulation (EU) No 283/2013, or the equivalent part of Commission Regulation (EU) No 283/2013 (as the case may be).

3. Paragraph 4 applies where Commission Regulation (EU) No 284/2013 setting out the data requirements for plant protection products applies in relation to an application by virtue of—

(a) Article 1 of that Regulation, or


4. Where this paragraph applies, a reference in this Regulation to Commission Regulation (EU) No 545/2011, or a specified part of Commission Regulation (EU) No 545/2011, is to be read in relation to the application as a reference to Commission Regulation (EU) No 284/2013, or the equivalent part of Commission Regulation (EU) No 284/2013 (as the case may be).”.

(3) Omit Article 2.

(4) After Article 2, omit the words from “This Regulation shall” to “Member States”.

(5) In Annex 1—


(b) for point (4) substitute—

“(4) A competent authority may make the placing of plant protection products on the market in its constituent territory subject to the additional labelling of the product in a language other than English.”.

(6) In Annex 2—

(a) in the words before point 1, in the first paragraph—


(ii) in the second sentence, for “Directive” substitute “Regulation”;

(b) for point 1.1 substitute—

“1.1. Special risks related to humans (RSh)

RSh 1
— Toxic by eye contact.

RSh 2
— May cause photosensitisation.

RSh 3
— Contact with vapour causes burns to skin and eyes and contact with liquid causes freezing.”;

(c) in point 2.1, for “risk phrases R34 or R35, as set out in Directive 1999/45/EC” substitute “hazard statement H314 in Regulation (EC) No 1272/2008 of the European Parliament and of the Council”.

(7) In Annex 3—

(a) in the words before point 1, in the first paragraph—


(ii) in the second sentence, for “Directive” substitute “Regulation”;

(b) for point 1 substitute—

“1. General provisions

All plant-protection products shall be labelled with the following phrase, which shall be supplemented by the text in parentheses, as appropriate:
SP 1
— Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).”;

(c) for points 2.1 to 2.4 substitute—

“2.1 Safety precautions for operators (SPo)

General provisions

1. Competent authorities may identify suitable personal protective equipment for operators and prescribe specific elements of this equipment (e.g. coveralls, apron, gloves, sturdy shoes, rubber boots, face protection, face shield, tightly fitting glasses, hat, hood or respirator of a specified type). Such supplementary safety precautions are without prejudice to the standard phrases applicable according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council.

2. Competent authorities may further identify the specific tasks which require particular protective equipment, such as mixing, loading or handling the undiluted product, applying or spraying the diluted product, handling recently treated materials like plants or soil or entering recently treated areas.

3. Competent authorities may add specifications of engineering controls, such as:
— a closed transfer system must be used when transferring the pesticide from the product container to the spray tank,
— the operator must work within a closed cabin (with an air conditioning/air filtration system) during spraying,
— engineering controls may replace personal protective equipment if they provide an equal or higher standard of protection.

Specific provisions

SPo 1
— After contact with skin, first remove product with a dry cloth and then wash the skin with plenty of water.

SPo 2
— Wash all protective clothing after use.

SPo 3
— After igniting the product, do not inhale smoke and leave the treated area immediately.

SPo 4
— The container must be opened outdoors and in dry conditions.

SPo 5
— Ventilate treated areas/greenhouses thoroughly/time to be specified/until spray has dried before re-entry.

2.2 Safety precautions related to the environment (SPe)

SPe 1
To protect groundwater/soil organisms do not apply this or any other product containing (identify active substance or class of substances, as appropriate) more than (time period or frequency to be specified).

SPe 2
To protect groundwater/aquatic organisms do not apply to (soil type or situation to be specified) soils.

SPe 3
To protect aquatic organisms/non-target plants/non-target arthropods/insects respect an unsprayed buffer zone of (distance to be specified) to non-agricultural land/surface water bodies.

SPe 4
To protect aquatic organisms/non-target plants do not apply on impermeable surfaces such as asphalt, concrete, cobblestones, railway tracks and other situations with a high risk of run-off.

SPe 5
To protect birds/wild mammals the product must be entirely incorporated in the soil; ensure that the product is also fully incorporated at the end of rows.

SPe 6
To protect birds/wild mammals remove spillages.

SPe 7
Do not apply during the bird breeding period.

SPe 8
Dangerous to bees./To protect bees and other pollinating insects do not apply to crop plants when in flower./Do not use where bees are actively foraging./Remove or cover beehives during application and for (state time) after treatment./Do not apply when flowering weeds are present./Remove weeds before flowering./Do not apply before (state time).

2.3 Safety precautions related to good agricultural practice (SPa)

SPa 1
To avoid the build-up of resistance do not apply this or any other product containing (identify active substance or class of substances, as appropriate) more than (number of applications or time period to be specified).

2.4 Specific safety precautions for rodenticides (SPr)

SPr 1
The baits must be securely deposited in a way so as to minimise the risk of consumption by other animals. Secure bait blocks so that they cannot be dragged away by rodents.

SPr 2
Treatment area must be marked during the treatment period. The danger from being poisoned (primary or secondary) by the anticoagulant and the antidote against it should be mentioned.
Dead rodents must be removed from the treatment area each day during treatment. Do not place in refuse bags or on rubbish tips.

(d) in point 3.1, for the words from “Annex to Regulation (EU) No” to “products]” substitute “Annex to Commission Regulation (EU) No 546/2011”;

(e) in point 3.3, for “Member States” in both places it occurs substitute “competent authorities”.

Commission Implementing Regulation (EU) No 844/2012 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

20.—(1) Commission Implementing Regulation (EU) No 844/2012 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 is amended as follows.

(2) In Article 1—

(a) in paragraph 1, in the first subparagraph, for the words from “the rapporteur” to “of that Annex,” substitute “a competent authority for a constituent territory in relation to which the active substance is approved (in this Regulation, the “assessing competent authority”);”;

(b) omit paragraph 2.

(3) In Article 3—

(a) in paragraph 1—

(i) in the first subparagraph—

(aa) for “rapporteur Member State” substitute “assessing competent authority”;

(bb) for “, the co-rapporteur Member State, the Commission and the Authority” substitute “and the other competent authorities”;

(ii) in the second subparagraph, for “rapporteur Member State” in both places it occurs substitute “assessing competent authority”;

(b) in paragraph 2—

(i) in the first subparagraph—

(aa) for “rapporteur Member State” substitute “assessing competent authority”;

(bb) for “Rapporteur Member State and to the co-rapporteur Member State” substitute “assessing competent authority”;

(ii) in the second subparagraph, for “rapporteur Member State” substitute “assessing competent authority”;

(c) in paragraph 3—

(i) for “rapporteur Member State” substitute “assessing competent authority”;  
(ii) for the words from “, the co-rapporteur” to “Authority” substitute “and the other competent authorities”;

(d) in paragraph 4, for “Authority” in both places it occurs, substitute “assessing competent authority”;

(e) in paragraph 5—

(i) after “separately” insert “to the same assessing competent authority”;

(ii) for “rapporteur Member State” substitute “assessing competent authority”;

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(f) in paragraph 6, for “Commission” substitute “assessing competent authority”.

(4) In Article 4, for “rapporteur Member State and the co-rapporteur Member State” substitute “assessing competent authority”.

(5) In Article 5, for “Authority” substitute “assessing competent authority”.

(6) In Article 6—

(a) in paragraph 1—

(i) for “rapporteur Member State” in the first place it occurs substitute “assessing competent authority”;

(ii) for the words from “rapporteur Member State” in the second place it occurs to the end substitute “assessing competent authority”;

(b) after paragraph 1 insert—

“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.”.

(7) In Article 7(1)—

(a) in point (c)—

(i) for “widely grown crop in each zone” substitute “crop grown in the United Kingdom”;

(ii) for the words from “cover all zones” to “widely grown” substitute “concern a”;

(b) in points (e) and (f)—

(i) for “a Regulation” substitute “legislation”;

(ii) after “Regulation (EC) No 1107/2009” insert “in relation to each constituent territory to which the application for renewal relates”.

(8) In Article 8—

(a) in paragraph 1—

(i) in the first subparagraph—

(aa) for “rapporteur Member State” substitute “assessing competent authority”;

(bb) for the words from “, the co-rapporteur” to “Authority” substitute “and the other competent authorities”;

(ii) in the second subparagraph, for “rapporteur Member State” in both places it occurs substitute “assessing competent authority”;

(b) in paragraph 2—

(i) in the first subparagraph—

(aa) for “rapporteur Member State” in the first place it occurs substitute “assessing competent authority”;

(bb) for “rapporteur Member State and co-rapporteur Member State” substitute “assessing competent authority”;

(ii) in the second subparagraph, for “rapporteur Member State” substitute “assessing competent authority”;

(c) in paragraph 3—
(i) omit the first subparagraph;
(ii) in the second subparagraph—
   (aa) for “At the same time” substitute “Before the end of the period stated in paragraph 1”;
   (bb) for “Authority” substitute “assessing competent authority”;
(d) in paragraph 4, for “Authority” substitute “assessing competent authority”;
(e) in paragraph 5, for “the Authority or a Member State” substitute “a competent authority”;
(f) in paragraph 6—
   (i) for “rapporteur Member State” substitute “assessing competent authority”;
   (ii) for the words from “, the co-rapporteur” to “Authority” substitute “and the other competent authorities”.

(9) In Article 9—
   (a) in the first sentence, for “rapporteur Member State” substitute “assessing competent authority”;
   (b) in the second sentence, for the words from “co-rapporteur” to “Authority” substitute “other competent authorities”.

(10) For Article 10 substitute—

"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.”.

(11) In Article 11—
   (a) in the heading, for “rapporteur Member State and the co-rapporteur Member State” substitute “assessing competent authority”;
   (b) in paragraph 1—
      (i) for “rapporteur Member State shall, after consulting the co-rapporteur Member State” substitute “assessing competent authority must”;
      (ii) for “Commission, with a copy to the Authority,” substitute “other competent authorities”;
   (c) omit paragraph 2(g) and (h);
   (d) in paragraphs 3 and 4, for “rapporteur Member State” substitute “assessing competent authority”;
   (e) in paragraph 5—
      (i) in the first sentence, for “rapporteur Member State” substitute “assessing competent authority”;
      (ii) omit the second sentence,
   (f) after paragraph 5 insert—
      “5A. The 12 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.”;

(g) for paragraph 6 substitute—

“6. The assessing competent authority may, as it considers appropriate—

(a) obtain independent scientific advice;
(b) consult with the other competent authorities.”;

(h) in paragraph 8—

(i) for the first subparagraph substitute—

“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.”;

(ii) in the second subparagraph, in the second sentence, for “Authority” substitute “assessing competent authority”.

(12) In Article 12—

(a) in paragraph 1—

(i) for “Authority” substitute “assessing competent authority”;
(ii) omit “received from the rapporteur Member State”;
(iii) for “Member States” substitute “competent authorities”;
(b) in paragraph 2, for “Authority” substitute “assessing competent authority”;
(c) in paragraph 3—

(i) for “Authority” in both places it occurs substitute “assessing competent authority”;
(ii) for “Commission” substitute “other competent authorities”;
(d) in paragraph 4, for “Authority” substitute “assessing competent authority”.

(13) In Article 13—

(a) in the heading, for “Authority” substitute “assessing competent authority”;

(b) in paragraph 1—

(i) for “Authority” in each place it occurs substitute “assessing competent authority”;
(ii) in the first subparagraph—

(aa) for the second sentence substitute—

“The assessing competent authority may obtain independent scientific advice where it considers it appropriate to do so.”;

(bb) in the third sentence, for “, the Member States and the Commission” substitute “and the other competent authorities”;

(iii) omit the second subparagraph;

(c) in paragraph 2, for “Authority” in both places it occurs substitute “assessing competent authority”;

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(d) in paragraph 3, in the first subparagraph—
   (i) in the first sentence—
      (aa) for “Authority” in both places it occurs substitute “assessing competent authority”;
      (bb) omit “, in consultation with the rapporteur Member State,”;
      (cc) for “one month” substitute “90 days”;
      (dd) for “Member States, the Commission” substitute “other competent authorities”;
   (ii) in the second sentence—
      (aa) for “rapporteur Member State” substitute “assessing competent authority”;
      (bb) omit “and send its evaluation to the Authority”;
(e) in paragraph 4—
   (i) in the first sentence—
      (aa) for “Authority” substitute “assessing competent authority”;
      (bb) omit “ask the Commission to”;
      (cc) omit “European Union”;
   (ii) in the second sentence, omit “European Union”.

(14) For Article 14 substitute—

“Article 14
Renewal decision

Article 20 of Regulation (EC) No 1107/2009 applies.”.

(15) In Article 15, for the words from “renewal” to the end substitute “existing renewal applications within the meaning of Article 1(2) of that Regulation”.

(16) Omit Article 16.

(17) After Article 16, omit the words from “This Regulation” to “Member States.”.

(18) In the Annex—
   (a) in the “Format for applications, as provided for in Article 2(1)” section—
      (i) in the first paragraph, for “rapporteur Member State and to the co-rapporteur Member State” substitute “assessing competent authority”;
      (ii) omit the second paragraph;
   (b) in the “Model” section, in point 2.5, for “Annex to Commission Implementing Regulation (EU) No 540/2011” substitute “approvals register in relation to each constituent territory to which the application relates”.


(2) In Article 1—
(a) the existing text becomes paragraph 1;
(b) after that paragraph insert—

“2. Paragraph 1 does not apply where Regulation (EU) No 544/2011 applies (see Article A1 of that Regulation).”.

(3) Omit Articles 2 to 5.
(4) After Article 5, omit the words from “This Regulation” to “Member States”.
(5) In the Annex—
  (a) in the Introduction—
   (i) in points 1.6 and 1.7, omit “European”;
   (iii) in point 1.13, for “accepted by European Food Safety Authority, (the Authority)” substitute “set out in guidance issued in accordance with Article 77 of Regulation (EC) No 1107/2009”;
   (iv) in point 2, omit “at national level”;
   (v) in point 3.1, after “laid down in” insert “Annex 1 to”;
   (vi) in point 3.2.3, for “the application of this Regulation” substitute “1st January 2014”;
   (vii) omit point 6;
  (b) in Part A—
   (i) in point 1.2, for “Commission, the Authority and the Member States” substitute “competent authorities”;
   (ii) in point 1.5, omit “Member States or”;
   (iv) in point 4.2, in the first paragraph, in point (a) for “Member States” substitute “competent authorities”;
   (v) in point 5.8.3, in the second paragraph for “Union” substitute “national”;
   (vi) in point 5.9, in the first paragraph, in the first sentence, after “prejudice to” insert “the EU-derived domestic legislation which transposed”;
   (vii) in point 6.3, under “Test conditions”—
      (aa) for the fourth paragraph substitute—
      “For the evaluation of residue behaviour and the setting of maximum residue levels (MRLs) according to Regulation (EC) No 396/2005, residues trials data relevant to the agricultural practices in the UK must be provided. The trials must correspond to the critical GAP and the production conditions (such as cultural practices, climatic conditions) must be comparable to the UK. Differences in agricultural production methods (for example outdoor

versus indoor uses), seasons of production, and types of formulation shall be taken into account.”;

(bb) in the fifth paragraph, omit “for each residue zone”;

(cc) omit the sixth paragraph;

(dd) in the seventh paragraph, in the second sentence, omit “per zone” in both places it occurs;

(ee) in the ninth paragraph, for “different zones” substitute “growing areas representative of those in the UK”;

(ff) omit the tenth paragraph;

(viii) in point 6.5.3, in the third paragraph, for “European” substitute “relevant”;

(ix) in point 6.6.2, in the sixth paragraph—

(aa) in the fifth sentence, for “the Union” substitute “areas relevant to the United Kingdom”;

(bb) in the sixth sentence, for “across the Union” substitute “relevant to the United Kingdom”;

(cc) in the eighth sentence, for “national competent authorities in the Member States” substitute “competent authorities”;

(x) in point 6.10.1, in the second paragraph, omit “national”;

(xi) in point 7.1, in the third paragraph, for “Union” substitute “United Kingdom”;

(xii) in points 7.1.2.2.2 and 7.1.3.2—

(aa) omit the words from “being included” to “introduction”;

(bb) omit “national” in each place it occurs;

(xiii) in points 7.1.4.3, 7.2.2.4, 7.2.3 and 7.3.2, omit “national” in each place it occurs;

(xiv) in Section 8, in the Introduction, in paragraph 1, in the third sentence, omit “national”;

(xv) in point 8.1.5—

(aa) in the first sentence, for “Union” substitute “national”;

(bb) in the fourth sentence, omit “national”;

(xvi) in points 8.2 and 8.2.2.2, omit “national”;

(xvii) in point 8.2.3—

(aa) in the first sentence, for “Union” substitute “national”;

(bb) in the third sentence, omit “national”;

(xviii) in points 8.2.7, 8.2.8, 8.3.2 and 8.4.2, omit “national” in each place it occurs;

(c) in Part B—

(i) in point 1.1, in the second paragraph, for the words from “Member State” in the first place it occurs to “Commission” substitute “United Kingdom”;

(ii) in points 1.2 and 1.4.1, for “Commission and the Member States” substitute “competent authorities”;

(iii) in point 5.1.1, in the first paragraph, in the first sentence, after “provisions of” insert “the EU-derived domestic legislation which transposed”;

(iv) in point 7.1.1, in the first sentence omit “EU”;

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(v) in point 8.6, in the fifth sentence, for “crop management (ICM)” substitute “pest management (IPM)”;  
(vi) in Section 9, in the first sentence, omit “of the Member States”.

(2) In Article 1—  
(a) the existing text becomes paragraph 1;  
(b) after that paragraph insert—  
2. Paragraph 1 does not apply where Regulation (EU) No 545/2011 applies (see Article A1 of that Regulation).”.
(3) Omit Articles 2 to 5.  
(4) After Article 5, omit the words from “This Regulation” to “Member States”.  
(5) In the Annex—  
(a) in the Introduction—  
(i) in point 1.6, omit “European”;  
(ii) in point 1.8, for “Directive 2010/63/EU of the European Parliament and of the Council” substitute “the Animals (Scientific Procedures) Act 1986”;  
(iii) in point 1.11, for “Union legislation” substitute “retained EU law”;  
(iv) in point 1.14, for “accepted by the European Food Safety Authority (the Authority)” substitute “set out in guidance issued in accordance with Article 77 of Regulation (EC) No 1107/2009”;  
(v) in point 2, omit the second sentence;  
(vi) in point 3.1, after “laid down in” insert “Annex 1 to”;  
(vii) in point 3.2(g), for “in a Member State” substitute “by at least one competent authority”;  
(viii) in point 3.3—  
(aa) for “Member State” substitute “competent authority”;
(bb) after “its” insert “constituent”;  
(ix) omit point 6;  
(b) in Part A—  
(i) in points 1.4.3 and 4.4, for “Union legislation” substitute “retained EU law”;  
(iii) in points 7.1.7 and 7.1.8, omit “national”;
(iv) in points 7.2.1.2 and 7.2.3.2, after “in accordance with” in the second place it occurs
insert “the EU-derived domestic legislation which transposed”;
(v) in point 9.1.1.2.2, in the fourth paragraph—
   (aa) omit the words from “being included” to “introduction”;
   (bb) omit “national”;
(vi) in points 9.1.2.3 and 9.2.3, omit “national”;
(vii) in point 9.2.4.1, in the second paragraph, omit “EU”;
(viii) in point 9.2.4.2, omit “national”;
(ix) in point 9.2.5—
   (aa) in the second paragraph, omit “EU”;
   (bb) in the fourth paragraph, omit “national”;
(x) in points 9.4, 10.1.3, 10.2.2, 10.4.2.2, 10.6.3 and 10.6.4, omit “national” in each
place it occurs;
(c) in Part B—
   (i) in point 1.1, in the second paragraph, for “Member State in which the authorisation
is being sought” substitute “United Kingdom”;
Council” substitute “Regulation (EC) No 1272/2008”;
   (iii) in point 6.5, in the eighth paragraph—
      (aa) for “Member State” in the first place it occurs substitute “competent
authority”;
      (bb) for “territory of this Member State” substitute “constituent territory of that
competent authority”;
(vi) in points 7.1, 7.1.1 and 7.1.3, omit “Directive 1999/45/EC or”;
(v) in Section 11, in the first paragraph, omit “of the Member States”.

PART 3

Transferred functions from Directive 2009/128/EC of the European
Parliament and of the Council establishing a framework for
Community action to achieve the sustainable use of pesticides

Power to update references to Annexes to Directive 2009/128/EC in light of scientific and
technical progress

23.—(1) The appropriate authority may, by regulations, make provision for a reference to a
a framework for Community action to achieve the sustainable use of pesticides in any enactment to
be read as a reference to that Annex as modified by the regulations.

(2) But the appropriate authority may exercise the power in paragraph (1) only to the extent
that the appropriate authority considers that it is appropriate to do so as a result of scientific and
technical progress.

(3) The appropriate authority may, by regulations, amend any enactment which makes provision
concerning to that made by a relevant Annex to Directive 2009/128/EC for the purposes of
ensuring that the provision made by the enactment continues to correspond to that made by the
Annex as modified by regulations made under paragraph (1).

(4) The relevant Annexes to Directive 2009/128/EC are—
(a) Annex 1 (training subjects referred to in Article 5 of Directive 2009/128/EC);
(b) Annex 2 (health and safety and environmental requirements relating to the inspection of
pesticide application equipment);
(c) Annex 3 (general principles of integrated pest management);
(d) Annex 4 (harmonised risk indicators).

(5) In this regulation, “the appropriate authority” means—
(a) for regulations applying in relation to England, the Secretary of State;
(b) for regulations applying in relation to Wales, the Welsh Ministers;
(c) for regulations applying in relation to Scotland, the Scottish Ministers;
(d) for regulations applying in relation to Northern Ireland, the Department.

(6) But the appropriate authority is the Secretary of State if consent is given by—
(a) for regulations applying in relation to Wales, the Welsh Ministers;
(b) for regulations applying in relation to Scotland, the Scottish Ministers;
(c) for regulations applying in relation to Northern Ireland, the Department.

(7) In this regulation, “the Department” means the Department of Agriculture, Environment and
Rural Affairs in Northern Ireland.

Regulations

24.—(1) Regulations made by the Secretary of State or Welsh Ministers under regulation 23 are
to be made by statutory instrument.

(2) For regulations made under regulation 23 by the Scottish Ministers, see section 27 of the
Interpretation and Legislative Reform (Scotland) Act 2010.

(3) Any power to make regulations conferred on the Department under regulation 23 is

(4) A statutory instrument containing regulations made by the Secretary of State under
regulation 23 is subject to annulment in pursuance of a resolution of either House of Parliament.

(5) A statutory instrument containing regulations made by the Welsh Ministers under
regulation 23 is subject to annulment in pursuance of a resolution of the National Assembly for
Wales.

(6) Regulations made by the Scottish Ministers under regulation 23 are subject to the negative
procedure (see section 28 of the Interpretation and Legislative Reform (Scotland) Act 2010).

(7) Regulations made by the Department under regulation 23 are subject to negative resolution
within the meaning of section 41(6) of the Interpretation Act (Northern Ireland) 1954.

(8) Such regulations may—
(a) contain consequential, incidental, supplementary, transitional or saving provision
(including provision amending, repealing or revoking enactments);
(b) make different provision for different purposes.

(9) In this regulation, “the Department” has the meaning given in regulation 23(7).
PART 4

Consequential amendments, savings, transitional provisions and revocations


“1. The following are regarded as being registered, and the registration as completed, for manufacture or import for the use as a plant protection product and therefore as fulfilling the requirements of Chapters 1 and 5 of this Title—

(a) active substances manufactured or imported for use in plant protection products only and included in the approvals register in relation to at least one constituent territory;

(b) co-formulants manufactured or imported for use in plant protection products only and not included in the unacceptable co-formulants register in relation to the whole of the UK;

(c) any substance in relation to which the applicant has been notified in accordance with Article 9(3) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

1A. In paragraph 1—

(a) in point (a)—

(i) “approvals register” means the register maintained in accordance with Article 27A of Regulation (EC) No 1107/2009;

(ii) “constituent territory” has the meaning given by Article 3A of Regulation (EC) No 1107/2009;

(b) in point (b), “unacceptable co-formulants register” means the register maintained in accordance with Article 27B of Regulation (EC) No 1107/2009.”.

Amendment of the Plant Protection Products Regulations 2011

26.—(1) The Plant Protection Products Regulations 2011 are amended as follows.

(2) In regulation 10—

(a) for paragraph (1) substitute—

“(1) A person must not place on the market or use in a constituent territory (“the relevant constituent territory”) seeds treated with a plant protection product, other than an appropriate plant protection product, or cause or permit another person to do so.

(1A) Paragraph (1) does not apply in relation to seeds which a competent authority must not prohibit in accordance with Article 49 as read with paragraph 14 of Schedule 1 to the Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019.”;

(b) in paragraph (3), for the words from “plant” to the end, substitute “an appropriate plant protection product, or seeds which a competent authority must not prohibit in accordance with Article 49 as read with paragraph 14 of Schedule 1 to the Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019.”;
(c) after paragraph (3) insert—

“(4) In this regulation, “appropriate plant protection product” means—

(a) a plant protection product authorised in relation to the relevant constituent territory for use on such seeds, or

(b) a plant protection product authorised in relation to another constituent territory for use on such seeds, where—

(i) every active substance, low-risk active substance or candidate for substitution in that product is approved in relation to the relevant constituent territory, and

(ii) every co-formulant in that product does not appear on the unacceptable co-formulants register in relation to the relevant constituent territory.”.

Saving: the Plant Protection Products Regulations 2011

27.—(1) The amendments made to regulation 10 of the Plant Protection Products Regulations 2011 by regulation 26 do not affect—

(a) any obligation or liability acquired, accrued or incurred before exit day;

(b) any penalty, forfeiture or punishment incurred in respect of any offence committed before exit day; or

(c) any investigation, legal proceeding or remedy in respect of (a) or (b) above.

(2) Any penalty, forfeiture or punishment referred to in paragraph (1)(b) may be imposed as if regulation 26 had not come into force.

(3) Any investigation, legal proceeding or remedy referred to in paragraph (1)(c) may be instituted, continued or enforced as if regulation 26 had not come into force.

Transitional provisions

28. Schedule 1 has effect.

Revocation of retained EU legislation and saving

29.—(1) The retained EU legislation in Schedule 2 is revoked.

(2) Despite paragraph (1), a grace period contained within an EU instrument listed in Schedule 2 which expires after exit day continues to have effect, and is treated as if it had been set by each competent authority in relation to its constituent territory in accordance with Article 21(6)(b) of Regulation (EC) No 1107/2009.

Revocation: EEA agreement

30. In Annex 2 to the EEA agreement, in Chapter 15—

(a) omit points 12g and 12k;

(b) omit the adaptations in point 13;

(c) omit points 13a and 13aa;

(d) omit the adaptations in point 13e;

(e) omit points 13g to 13zzzzzzzn.
20th March 2019

Robert Goodwill
Minister of State
Department of Environment, Food and Rural Affairs
PART 1

Interpretation

1. In this Schedule—


“plant protection product” has the meaning given by Article 2(1) of Regulation (EC) No 1107/2009.

PART 2

Active substances, basic substances, low-risk
active substances and candidates for substitution

Existing approvals of active substances, etc.: general

2.—(1) An active substance, basic substance, low-risk active substance or candidate for substitution which is set out in an entry in a table in the Annex is deemed to have been approved by each competent authority in relation to its constituent territory under Article 13 of Regulation (EC) No 1107/2009 in accordance with sub-paragraphs 2(3) and 2(4).

(2) Sub-paragraph (1) does not apply to the following entries in the table in Part A of the Annex—

(a) entry 21 (Cyclanilide);
(b) entry 33 (Cinidon-ethyl);
(c) entry 43 (Ethoxysulfuron);
(d) entry 45 (Oxadiargyl);
(e) entry 49 (Cyfluthrin);
(f) entry 56 (Mecoprop);
(g) entry 72 (Molinate);
(h) entry 87 (Ioxynil);
(i) entry 94 (Imazosulfuron);
(j) entry 100 (Tepraloxydim);
(k) entry 113 (Maneb);
(l) entry 120 (Warfarin);
(m) entry 143 (Flusilazole);
(n) entry 144 (Carbendazim);
(o) entry 151 (Glufosinate);
(p) entry 157 (Fipronil);
(q) entry 159 (Spodoptera exigua nuclear polyhedrosis virus).

(3) An active substance, basic substance, low-risk active substance or candidate for substitution to which sub-paragraph (1) applies is deemed to have been approved—

(a) from the date of approval stated in the relevant entry in the Annex;
(b) until the existing expiration date, except—

(i) for a basic substance, or
(ii) as provided for in sub-paragraph (4);
(c) subject to the specific provisions stated in the relevant entry in the Annex as modified in accordance with paragraph 3.

(4) Where the existing expiration date for an approval is 31st March 2022 or earlier, approval is taken instead to expire at the end of a period of three years beginning with the existing expiration date.

(5) In this paragraph—

“the Annex” means the Annex to Commission Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances as it had effect immediately before exit day;
“existing expiration date” means the date for the expiration of approval stated in the relevant entry in the Annex.

Existing approvals: Annex modifications

3.—(1) For the purposes of paragraph 2(3)(c), the Annex is modified in accordance with this paragraph.

(2) In the Annex—

(a) a reference to Member States is to be read as a reference to competent authorities;
(b) a reference to Article 29(6) of Regulation (EC) No 1107/2009 is to be read as a reference to Article 29(6)(a) of that Regulation;
(c) a requirement on a notifier to submit, or on a member State to ensure that a notifier submits, further studies, data or information to the Commission, one or more member States or the Authority within a period of time which has expired before exit day is to be ignored;
(d) a requirement on member States to inform the Commission in accordance with Article 38 of Regulation (EC) No 1107/2009 is to be ignored;

(3) The entries in the table in Part A of the Annex are modified as follows—

(a) in entry 46 (Cyazofamid), in the seventh column, in the second paragraph, in the second sentence, the second indent is to be read as if “especially for Northern European regions” were omitted;
(b) in entry 173 (Difenoconazole), in the seventh column, Part B is to be read as if, for the fifth paragraph there were substituted—

“The notifier must submit to each competent authority the information set out in point (d) within 2 years from the issuing of specific guidance.”;
(c) in entry 175 (Imazaquin), in the seventh column, Part B is to be read as if, for the third paragraph there were substituted—
“The notifier must submit to each competent authority the information set out in point (b) within 2 years from the issuing of specific guidance.”;

(d) in entry 176 (Lenacil), in the seventh column, Part B is to be read as if, in the fourth paragraph, in the second sentence, for “the Commission” there were substituted “each competent authority”;

(e) in entry 210 (Abamectin), in the seventh column, in Part B, the fourth paragraph is to be read as if for “the Commission, the Member States and the Authority” there were substituted “each competent authority”;

(f) in entry 211 (Epoxiconazole), in the seventh column, Part B is to be read as if, for the third paragraph there were substituted—

“The notifier must submit to each competent authority further studies addressing the potential endocrine disrupting properties of epoxiconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, the issuing of test guidelines set by the competent authority.”;

(g) in entry 217 (Metazachlor), in the seventh column, Part B is to be read as if, in the fifth paragraph, for “the Commission” there were substituted “each competent authority”;

(h) in entry 268 (Tebuconazole), in the seventh column, Part B is to be read as if for the second paragraph there were substituted—

“The notifier must submit to each competent authority further information addressing the potential endocrine disrupting properties of tebuconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, the issuing of test guidelines set by the competent authority.”;

(i) in entry 269 (Triadimenol), in the seventh column, Part B is to be read as if, for the fifth paragraph there were substituted—

“The notifier must submit to each competent authority further information addressing the potential endocrine disrupting properties of triadimenol within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, the issuing of test guidelines set by the competent authority.”;

(j) in entry 282 (Chlorsulfuron), in the seventh column, Part B is to be read as if, in the fourth paragraph, for “the Commission” there were substituted “each competent authority”;

(k) in entry 284 (Dimethachlor), in the seventh column, Part B is to be read as if, in the fifth paragraph, for “the Commission” there were substituted “each competent authority”;

(l) in entry 289 (Triflusulfron), in the seventh column, Part B is to be read as if, in the third paragraph, for “the Commission” there were substituted “each competent authority”;

(m) in entry 307 (Sulfuryl fluoride), in the seventh column, Part B is to be read as if, in the fourth paragraph—

(i) for “the Commission, Member States and the Authority” there were substituted “each competent authority”;

(ii) for “2017” there were substituted “2022”;

(n) in entry 315 (Fenbuconazole), in the seventh column, Part B is to be read as if, for the sixth paragraph there were substituted—

“The notifier must submit to each competent authority further information addressing the potential endocrine disrupting properties of febuconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, the issuing of test guidelines set by the competent authority.”;
(o) in entry 318 (Bromuconazole), in the seventh column, Part B is to be read as if, for the fifth paragraph there were substituted—

“The notifier must submit to each competent authority further information addressing the potential endocrine disrupting properties of bromuconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, the issuing of test guidelines set by the competent authority.”;

(p) in entry 327 (Oryzalin), in the seventh column, Part B is to be read as if, for the fifth paragraph there were substituted—

“The applicant must submit to each competent authority the information set out in point (4) within six months of notification of a decision classifying oryzalin.”;

(q) in entry 328 (Tau-fluvalinate), in the seventh column, Part B is to be read as if, for the fifth paragraph there were substituted—

“The applicant must submit to each competent authority confirmatory information addressing the possible impact on the environment of the potential enantio-selective degradation in environmental matrices, within two years after the issuing of specific guidance.”;

(r) in entry 335 (Fluometuron), in the seventh column, Part B is to be read as if—

(i) in the third paragraph, in the words before point (a), for “the Commission” there were substituted “each competent authority”;

(ii) for the fourth paragraph there were substituted—

“The applicant must submit to each competent authority the information set out in point (d) within six months of notification of a decision classifying fluometuron.”;

(s) in entry 337 (Carboxin), in the seventh column, Part B is to be read as if, for the fifth paragraph there were substituted—

“The applicant must submit to each competent authority the information set out in point (h) within six months of notification of a decision classifying carboxin.”;

(t) in entry 338 (Cyproconazole), in the seventh column, Part B is to be read as if, for the fifth paragraph there were substituted—

“The applicant must submit to each competent authority the information set out in point (e) within two years of the issuing of specific guidance.”;

(u) in entry 344 (Diclofop), in the seventh column, Part B is to be read as if, for the fourth paragraph there were substituted—

“The applicant must submit to each competent authority the information set out in point (b) within two years of the issuing of a specific guidance document on evaluation of isomers mixtures.”;

(v) in entry 348 (Paclobutrazol), in the seventh column, Part B is to be read as if, for the fourth paragraph there were substituted—

“The applicant must submit to each competent authority—

(a) the information set out in point (4) within two years after the adoption of the OECD test guidelines on endocrine disruption, and

(b) the information set out in point (5) within two years after the issuing of specific guidance.”;

(w) in entry 352 (Hexythiazox), in the seventh column, Part B is to be read as if, for the fifth paragraph there were substituted—
“The applicant must submit to each competent authority the information set out in point (d) within two years after the issuing of specific guidance.”;

(x) in entry 354 (Flurochloridone), in the seventh column, Part B is to be read as if—

(i) in the fourth paragraph, in the words before point (1), for “the Commission” there were substituted “each competent authority”;

(ii) for the fourth paragraph there were substituted—

“The applicant must submit to each competent authority the information set out in point (4) within two years after the adoption of the OECD test guidelines on endocrine disruption.”.

(4) The entries in the table in Part B of the Annex are modified as follows—

(a) in entry 7 (Sprioxamine), in the seventh column, Part B is to be read as if, for the fifth paragraph there were substituted—

“The applicant must submit to each competent authority the information set out in point (a) within two years after the issuing of specific guidance.”;

(b) in entry 10 (Tefluthrin), in the seventh column, Part B is to be read as if, for the fourth paragraph there were substituted—

“The applicant must submit to each competent authority the information set out in point (3) within two years after the issuing of a specific guidance document on evaluation of isomers mixture.”;

(c) in entry 16 (Terbuthylazine), in the seventh column, Part B is to be read as if, for the fifth paragraph there were substituted—

“The applicant must submit to each competent authority the information set out in point (4) within six months of the notification of the classification decision for terbuthylazine.”;

(d) in entry 19 (Acrinathrin), in the seventh column, Part B is to be read as if, for the fourth paragraph there were substituted—

“The applicant must submit to each competent authority the information set out in point (4) within two years after the issuing of specific guidance.”;

(e) in entry 20 (Prochloraz), in the seventh column, Part B is to be read as if, for the fourth paragraph there were substituted—

“The applicant must submit to each competent authority the relevant information within two years after the adoption of the OECD test guidelines on endocrine disruption.”;

(f) in entry 48 (Sedaxane), in the seventh column, Part B is to be read as if for the sixth paragraph there were substituted—

“The notifier must submit to each competent authority the relevant information within six months of the notification of the classification decision for sedaxane.”;

(g) in entry 49 (Emamectin), the seventh column is to be read as if for the fifth paragraph there were substituted—

“The applicant must submit to each competent authority the relevant information within two years after the issuing of a specific guidance document on evaluation of isomers mixtures.”;

(h) in entry 51 (Fluopyram), the seventh column is to be read as if, for the fifth paragraph there were substituted—

“The applicant must submit to each competent authority the information set out in point (2) within two years after the adoption of the OECD test guidelines on endocrine disruption.”;
(i) in entry 55 (Penflufen), in the seventh column, Part B is to be read as if in the fourth paragraph for “the Commission, the Member States and the Authority” there were substituted “each competent authority”;

(j) in entry 57 (Penthiopyrad), the seventh column is to be read as if, for the fifth paragraph there were substituted—

“The notifier must submit to each competent authority the relevant information within six months of the notification of the classification decision for penthiopyrad.”;

(k) in entry 60 (Spirotetramat), the seventh column is to be read as if in the fourth paragraph—

(i) for “the Commission, the Member States and the Authority” there were substituted “each competent authority”;

(ii) for “Community agreed test guidelines” there were substituted “test guidelines set by the competent authority”;

(l) in entry 67 (Spinetoram), the seventh column is to be read as if in the fifth paragraph, for “the Commission, the Member States and the Authority” there were substituted “each competent authority”;

(m) in entry 69 (Amisulbrom), the seventh column is to be read as if, for the fifth paragraph there were substituted—

“The applicant must submit to each competent authority the information set out in point (5) within two years after the adoption of OECD test guidelines on endocrine disruption.”;

(n) in entry 73 (Ipconazole), the seventh column is to be read as if, for the fifth paragraph there were substituted—

“The applicant must submit to each competent authority—

(a) the information set out in point (c) of the fourth paragraph within two years after the issuing of a specific guidance document on evaluation of isomer mixtures, and

(b) the information set out in point (d) of the fourth paragraph within two years after the adoption of OECD or national test guidelines on endocrine disruption.”;

(o) in entry 80 (Meptyldinocap), the seventh column is to be read as if, for the fifth paragraph there were substituted—

“The applicant must submit to each competent authority the information set out in point (b) within two years after the issuing of specific guidance.”;

(p) in entry 91 (Flupyradifurone), the seventh column is to be read as if, for the fifth paragraph there were substituted—

“The applicant must submit to each competent authority the information set out in point (3) within two years after the issuing of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.”;

(q) in entry 97 (Pinoxaden), the seventh column is to be read as if, for the fifth paragraph there were substituted—

“The notifier must submit to each competent authority the relevant information within six months of the notification of the classification decision for pinoxaden.”;

(r) in entry 99 (Cyantraniliprole), the seventh column is to be read as if for the fourth paragraph there were substituted—

“The applicant must submit to each competent authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water
within two years after the issuing of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.”;

(s) in entry 100 (Isofetamid), the seventh column is to be read as if—

(i) in the fourth paragraph, in the words before point (1), for “the Commission, the Member States and the Authority” there were substituted “each competent authority”;

(ii) for the fifth paragraph there were substituted—

“The applicant must submit to each competent authority the information set out in point (1) within two years after the issuing of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.”;

(t) in entry 104 (Thifensulfuron-methyl), the seventh column is to be read as if—

(i) in the fourth paragraph, in the words before point (1), for “the Commission, the Member States and the Authority” there were substituted “each competent authority”;

(ii) for the fifth paragraph there were substituted—

“The applicant must submit to each competent authority the information set out in point (4) within six months of the notification of the classification decision for thifensulfuron-methyl.”;

(u) in entry 105 (Thiabendazole), the seventh column is to be read as if in the fourth paragraph for “the Commission, the Member States and the Authority” there were substituted “each competent authority”;

(v) in entry 107 (Iodosulfuron), the seventh column is to be read as if—

(i) in the fourth paragraph, in the words before point (1), for “the Commission, the Member States and the Authority” there were substituted “each competent authority”;

(ii) for the fifth paragraph there were substituted—

“The applicant must submit to each competent authority the information set out in point (2) within two years after the issuing of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.”;

(w) in entry 108 (Flazasulfuron) and entry 111 (Mesosulfuron), the seventh column is to be read as if for the fourth paragraph there were substituted—

“The applicant must submit to each competent authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface and groundwater within two years after the issuing of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.”;

(x) in entry 112 (Mesotrione), the seventh column is to be read as if, for the fifth paragraph there were substituted—

“The applicant must submit to each competent authority the information set out in point (3) within two years after the issuing of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.”;

(y) in entry 114 (Propoxycarbazone), the seventh column is to be read as if for the fourth paragraph there were substituted—
“The applicant must submit to each competent authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water within two years after the issuing of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.”;

(z) in entry 121 (Silthiofam), the seventh column is to be read as if—

(i) in the fourth paragraph, in the words before point 1, for “the Commission, the Member States and the Authority” there were substituted “each competent authority”;

(ii) in the fifth paragraph—

(aa) for “Commission” there were substituted “competent authority”;

(bb) for the words from “one year” to the end there were substituted “six months of the notification of the classification decision for Silithiofam”;

(aa) in entry 123 (Zoxamide), the seventh column is to be read as if, in the fourth paragraph—

(i) for “the Commission, the Member States and the Authority” there were substituted “each competent authority”;

(ii) for “Commission” in the second place it appears there were substituted “competent authority”;

(bb) in entry 124 (Trifloxystrobin), the seventh column is to be read as if—

(i) for the fifth paragraph, there were substituted—

“The applicant must submit to each competent authority the information set out in point (1) within six months of the notification of the classification decision for trifloxystrobin.”;

(ii) in the sixth paragraph, for “the Commission” there were substituted “each competent authority”;

(cc) in entry 125 (Carfentrazone-ethyl), the seventh column is to be read as if—

(i) for the fifth paragraph, there were substituted—

“The applicant must submit to each competent authority the information set out in point (1) within six months of the notification of the classification decision for carfentrazone-ethyl.”;

(ii) in the sixth paragraph, for “the Commission” there were substituted “each competent authority”;

(dd) in entry 126 (Fenpicoxamid), the seventh column is to be read as if—

(i) in the fourth paragraph, in point 3, “, as amended by Commission Regulation (EU) 2018/605,” were omitted;

(ii) in the fifth paragraph—

(aa) for “the Commission, the Member States and the Authority” there were substituted “each competent authority”;

(bb) for “Commission” in the second place it occurs there were substituted “competent authority”;

(ee) in entry 127 (Pethoxamid), in the seventh column, Part B is to be read as if—

(i) in the fourth paragraph, in the words before point 1, for “the Commission, the Member States and the Authority” there were substituted “each competent authority”;
(ii) in the fifth paragraph, for the words from “one year” to the end there were substituted “six months of the notification of the classification decision for pethoxamid”;

(iii) in the sixth paragraph, for “Commission” there were substituted “competent authority”;

(iv) in the seventh paragraph, the words from “in accordance with” to the end were omitted.

(5) The entries in the table in Part E of the Annex are modified as follows—

(a) in entry 4 (Benzovindiflupyr), the seventh column is to be read as if, for the fifth paragraph there were substituted—

“The applicant must submit to each competent authority the information set out in point (3) within two years after the issuing of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.”;

(b) in entry 7 (Pendimethalin), the seventh column is to be read as if—

(i) in the fifth paragraph, in the words before point (1), for “the Commission, the Member States and the Authority” there were substituted “each competent authority”;

(ii) for the sixth paragraph there were substituted—

“The applicant must submit to each competent authority the information set out in point (2) within two years after the issuing of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.”;

(c) in entry 9 (Propyzamide), the seventh column is to be read as if—

(i) in the fifth paragraph, in the words before point (1), for “the Commission, the Member States and the Authority” there were substituted “each competent authority”;

(ii) for the sixth paragraph there were substituted—

“The applicant must submit to each competent authority—

(a) the information set out in point (2) by 30th April 2019;

(b) the information set out in point (3) within two years after the issuing of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.”.

(6) In this paragraph, “the Annex” has the meaning given in paragraph 2(5).

Existing approvals: supplementary

4.—(1) When implementing the uniform principles as referred to in Article 29(6)(a) of Regulation (EC) No 1107/2009 for a plant protection product which contains an active substance, basic substance, low-risk active substance or candidate for substitution to which paragraph 2(1) applies, the competent authority must take into account the conclusions of the review report on that substance or candidate, and in particular Appendices 1 and 2 of that report.

(2) Each competent authority must make available on request a free copy of a review report for an active substance, basic substance, low-risk active substance or candidate for substitution to which paragraph 2(1) applies.

(3) Sub-paragraph (2) does not apply—

(a) to any confidential information within the meaning of Article 63 of Regulation (EC) No 1107/2009;
(b) otherwise, from the earliest of the following—
   (i) the date on which the approval of that substance or candidate is renewed;
   (ii) the date on which the approval of that substance or candidate is withdrawn or expires.

Existing candidates for substitution under Commission Implementing Regulation (EU) 2015/408

5.—(1) An active substance which immediately before exit day is set out in the Annex to Commission Implementing Regulation (EU) 2015/408 on implementing Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution is taken to have been approved by each competent authority in relation to its constituent territory under Article 13 of Regulation (EC) No 1107/2009 as a candidate for substitution.

(2) Sub-paragraph (1) does not apply for the purposes of applications for plant protection products—
   (a) which were submitted before 4th April 2018, where the plant protection product contains 8-hydroxyquinoline;
   (b) otherwise, which were submitted before 1st August 2015.

Ongoing active substance approval applications

6.—(1) This paragraph applies in relation to an application for approval of an active substance, or for amendment of the conditions of such an approval, where—
   (a) before exit day, that application was submitted to the United Kingdom as rapporteur Member State under Article 7 of Regulation (EC) No 1107/2009 as it had effect immediately before exit day, and
   (b) immediately before exit day, a Regulation adopted under Article 13(2) of Regulation (EC) No 1107/2009 as it had effect immediately before exit day in relation to that application has not entered into force.

(2) An application in relation to which this paragraph applies is taken as being made on the day on which it was made—
   (a) where the application is for approval of an active substance, under Article 7(1) of Regulation (EC) No 1107/2009;
   (b) where the application is for amendment of the conditions of approval of an active substance, under Article 7(1A) of Regulation (EC) No 1107/2009.

(3) The relevant competent authority is the assessing competent authority for an application to which this paragraph applies.

(4) Anything done before exit day in relation to an application to which this paragraph applies—
   (a) by the rapporteur Member State;
   (b) by the European Food Safety Authority under Article 10 or 12 of Regulation (EC) No 1107/2009 as it had effect immediately before exit day;

is taken to have been done by the relevant competent authority as the assessing competent authority.

(5) In sub-paragraphs (3) and (4), the “relevant competent authority” is the Secretary of State, subject to sub-paragraphs (6) to (8).

(6) The Secretary of State may appoint another competent authority as the relevant competent authority for an application to which this paragraph applies with the agreement of that competent authority.
(7) The relevant competent authority must notify the applicant following an appointment under sub-paragraph (6).

(8) An appointment in accordance with sub-paragraph (6) does not affect anything done by the Secretary of State as assessing competent authority prior to appointment.

(9) In this paragraph—

“assessing competent authority” has the same meaning as in Subsection 2 of Section 1 of Chapter 2 of Regulation (EC) No 1107/2009;

“rapporteur Member State” has the meaning given by Article 3(22) of Regulation (EC) No 1107/2009 as it had effect immediately before exit day.

Ongoing active substance renewal applications

7.—(1) This paragraph applies in relation to an application for renewal of the approval of an active substance where—

(a) before exit day, that application was submitted to the United Kingdom as rapporteur Member State or co-rapporteur Member State in accordance with Article 1 of Regulation (EU) No 844/2012 as it had effect immediately before exit day, and

(b) immediately before exit day a Regulation adopted under Article 20(1) of Regulation (EC) No 1107/2009 as it had effect immediately before exit day in relation to that application has not entered into force.

(2) An application in relation to which this paragraph applies is taken as being made under Article 1 of Regulation (EU) No 844/2012 on the date on which it was made, and the relevant competent authority is the assessing competent authority for that application.

(3) Anything done before exit day in relation to an application to which this paragraph applies—

(a) by the rapporteur Member State or the United Kingdom as co-rapporteur Member State;

(b) by the European Food Safety Authority under Regulation (EU) No 844/2012 as it had effect immediately before exit day;

is taken to have been done by the relevant competent authority as the assessing competent authority.

(4) In sub-paragraphs (2) and (3), the “relevant competent authority” is the Secretary of State subject to sub-paragraphs (5) to (7).

(5) The Secretary of State may appoint another competent authority as the relevant competent authority for an application to which this paragraph applies.

(6) The relevant competent authority must notify the applicant following an appointment under sub-paragraph (5).

(7) An appointment in accordance with sub-paragraph (5) does not affect anything done by the Secretary of State as assessing competent authority prior to appointment.

(8) In this paragraph—

“assessing competent authority” has the meaning given by Article 15(1) of Regulation (EC) No 1107/2009;

“co-rapporteur Member State” means the co-rapporteur Member State for the active substance which is the subject of the application as set out in the third column in the Annex to Commission Implementing Regulation (EU) No 686/2012 as it had effect immediately before exit day;

“rapporteur Member State” means the rapporteur Member State for the active substance which is the subject of the application as set out in the second column in the Annex to Commission Implementing Regulation (EU) No 686/2012 as it had effect immediately before exit day.
Requirement to provide existing maximum residue level applications in support of new active substance approval or renewal applications

8.—(1) Sub-paragraph (2) applies where—
(a) on or after exit day an application is made—
(i) for approval of an active substance or the amendment of the conditions of such an approval in accordance with Article 7(1) or (1A) of Regulation (EC) No 1107/2009, or
(ii) for renewal of approval of an active substance in accordance with Article 15 of Regulation (EC) No 1107/2009, and
(b) before exit day a relevant application for a maximum residue level was made in accordance with Article 7 of Regulation (EC) No 396/2005 as it had effect immediately before exit day.

(2) Where this sub-paragraph applies, the obligation in Article 8(1)(g) of Regulation (EC) No 1107/2009 or Article 7(1)(i) of Regulation (EU) No 844/2012 (as the case may be) to provide a copy of a relevant application for a maximum residue level as referred to in Article 7 of Regulation (EC) No 396/2005 is to be read as including an obligation to provide a copy of the application described in sub-paragraph (1)(b).

PART 3
Plant protection products

Ongoing plant protection product authorisation applications where a member State is examining the application under Article 35 of Regulation (EC) No 1107/2009

9.—(1) This paragraph applies in relation to an application for authorisation to place a plant protection product on the market in the United Kingdom or the amendment of such an authorisation where—
(a) before exit day—
(i) that application was made in accordance with Article 33 of Regulation (EC) No 1107/2009 as it had effect immediately before exit day,
(ii) a member State or EEA state had agreed to examine that application in accordance with the first paragraph of Article 35 of Regulation (EC) No 1107/2009 as it had effect immediately before exit day, and
(b) immediately before exit day a decision to grant or refuse the application had not been made by a competent authority in accordance with Article 36(2) of Regulation (EC) No 1107/2009 as it had effect immediately before exit day.

(2) An application in relation to which this paragraph applies is taken to have been made in accordance with Article 33 of Regulation (EC) No 1107/2009—
(a) where the member State or EEA state described in sub-paragraph (1)(a)(ii) had made its assessment available to the United Kingdom before exit day in accordance with the third subparagraph of Article 36(1) of Regulation (EC) No 1107/2009 as it had effect immediately before exit day, on the date on which the application was made,
(b) otherwise, on exit day.

(3) Where sub-paragraph (2)(a) applies to an application, anything done by the member State or EEA state in respect of the examination of the application before exit day is taken to have been done by a competent authority.
(4) In this paragraph, a reference to an Article of Regulation (EC) No 1107/2009 as it had effect immediately before exit day in respect of an EEA state means that Article as adapted by the EEA agreement as it had effect immediately before exit day.

Requirement to provide existing maximum residue level applications in support of new plant protection product authorisation applications

10.—(1) Sub-paragraph (2) applies where—

(a) on or after exit day an application is made for authorisation of a plant protection product or amendment of such an authorisation in accordance with Article 33 of Regulation (EC) No 1107/2009, and

(b) before exit day a relevant application for a maximum residue level was made in accordance with Article 7 of Regulation (EC) No 396/2005 as it had effect immediately before exit day.

(2) Where this sub-paragraph applies, the obligation in Article 33(3)(e) of Regulation (EC) No 1107/2009 to provide a copy of a relevant application for a maximum residue level in Article 7 of Regulation (EC) No 396/2005 is to be read as including a copy of the application described in sub-paragraph (1)(b).

Assessment of equivalence under Article 38(1) of Regulation (EC) No 1107/2009 where active substance last approved before exit day

11.—(1) Sub-paragraph (2) applies where—

(a) it is necessary to assess equivalence of an active substance in accordance with Article 38 of Regulation (EC) No 1107/2009, and

(b) the active substance was last approved before exit day in accordance with Regulation (EC) No 1107/2009 as it had effect immediately before exit day.

(2) Where this sub-paragraph applies, the assessing competent authority for the purposes of Article 38 of Regulation (EC) No 1107/2009 is the Secretary of State, subject to sub-paragraphs (3) to (5).

(3) The Secretary of State may appoint another competent authority as the assessing competent authority for the purposes of Article 38 of Regulation (EC) No 1107/2009.

(4) The assessing competent authority must notify the applicant for the authorisation of the plant protection product to which the assessment of equivalence relates following an appointment under sub-paragraph (3).

(5) An appointment in accordance with sub-paragraph (3) does not affect anything done by the Secretary of State as assessing competent authority prior to that appointment.

Compliance checks or assessment of information under Article 43(3) of Regulation (EC) No 1107/2009 where product examined before exit day

12.—(1) Sub-paragraph (2) applies where—

(a) it is necessary to complete compliance checks of a plant protection product or assess information relating to the renewal of that product in accordance with Article 43(3) of Regulation (EC) No 1107/2009, and

(b) before exit day a member State or EEA state examined the application for that plant protection product in accordance with the first paragraph of Article 35 of Regulation (EC) No 1107/2009 as it had effect immediately before exit day.
(2) Where this sub-paragraph applies, the competent authority which examined the application for the purposes of Article 43(3) of Regulation (EC) No 1107/2009 is taken to be the Secretary of State.

(3) In sub-paragraph (1)(b), the reference to Article 35 of Regulation (EC) No 1107/2009 as it had effect immediately before exit day in relation to an EEA state means that Article as adapted by the EEA agreement as it had effect immediately before exit day.

Ongoing evaluations under Article 56(3) of Regulation (EC) No 1107/2009

13.—(1) Sub-paragraph (2) applies where—

(a) before exit day the holder of an authorisation of a plant protection product had notified a competent authority in accordance with Article 56(1) of Regulation (EC) No 1107/2009 as it had effect immediately before exit day,

(b) in accordance with the first subparagraph of Article 56(3) of Regulation (EC) No 1107/2009 as it had effect immediately before exit day, a member State or EEA state was obliged to evaluate the information received, and

(c) immediately before exit day that member State or EEA state had not informed the competent authority in accordance with the first or second subparagraph of Article 56(3) of Regulation (EC) No 1107/2009 as it had effect immediately before exit day.

(2) Where this sub-paragraph applies, the first subparagraph of Article 56(3) of Regulation (EC) No 1107/2009 applies in respect of that notification as if the reference to the competent authority which first granted the authorisation were a reference to the competent authority referred to in sub-paragraph (1)(a) of this paragraph.

(3) In sub-paragraph (1)(b) and (c), the reference to Article 56(3) of Regulation (EC) No 1107/2009 as it had effect immediately before exit day in relation to an EEA state means that Article as adapted by the EEA agreement as it had effect immediately before exit day.

PART 4

Treated seeds

Treated seeds

14.—(1) Article 49(1) of Regulation (EC) No 1107/2009 applies to seeds to which sub-paragraph (2) applies as it applies to seeds to which Article 49(1) applies.

(2) This sub-paragraph applies to—

(a) seeds treated before exit day with a plant protection product which at the time of treatment was authorised for that use in at least one member State or EEA state but not the United Kingdom;

(b) seeds treated on or after exit day with a plant protection product which immediately before exit day was authorised for that use in at least one member State or EEA state but not the United Kingdom.

(3) But sub-paragraph (2) does not apply to the extent that immediately before exit day the sale or use of such seeds was restricted or prohibited by measures adopted in the United Kingdom or by the European Commission in accordance with Regulation (EC) No 1107/2009 as it had effect immediately before exit day (as adapted by the EEA agreement as it had effect immediately before exit day).
(4) Sub-paragraphs (1) and (3) cease to have effect in respect of seeds to which sub-paragraph (2)
applies in relation to a constituent territory on the earliest of the following dates—
(a) the date on which the plant protection product used to treat the seeds is no longer authorised
for that use in at least one member State or EEA state;
(b) 1st April 2022.
(5) In this paragraph, “EEA state” does not include the Principality of Liechtenstein.

PART 5
Existing guidance

Existing guidance

15.—(1) Sub-paragraph (2) applies to a guidance document which relates to Regulation (EC) No
1107/2009 as it had effect immediately before exit day, where—
(a) before exit day, the guidance document was noted by the Committee, and
(b) immediately before exit day, that guidance document had not been withdrawn or replaced.

(2) A guidance document to which this sub-paragraph applies is taken to have been issued by
each competent authority in relation to its constituent territory in accordance with Article 77(1) of

(3) Where the guidance document to which sub-paragraph (2) applies relates to scientific methods
referred to in Article 4(2)(a) or (3)(b) or (e) of Regulation (EC) No 1107/2009, those methods are
taken to have been accepted by each competent authority in accordance with Article 4(8).

(4) In sub-paragraph (1)(a), “the Committee” means the Standing Committee described in Article
79(1) of Regulation (EC) No 1107/2009 as it had effect immediately before exit day.

SCHEDULE 2

Revocations

PART 1
Regulations

1. Commission Regulation (EC) No 3600/92 laying down the detailed rules for the
implementation of the first stage of the programme of work referred to in Article 8(2) of Council

2. Commission Regulation (EC) No 933/94 laying down the active substances of plant protection
products and designating the rapporteur Member States for the implementation of Commission
Regulation (EEC) No 3600/92.

Regulation (EC) No 933/94, in particular with regard to the integration of the designated public
authorities and the producers in Austria, Finland and Sweden in the implementation of the first stage
of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning
the placing of plant protection products on the market.

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25. Commission Regulation (EC) No 33/2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I.


28. Commission Regulation (EU) No 78/2010 amending Regulation (EC) No 33/2008 as regards the scope and the period granted under the regular procedure to the Authority for the adoption of its conclusions concerning the inclusion of certain active substances in Annex I to Directive 91/414/EEC.

29. Commission Regulation (EU) No 114/2010 amending Regulation (EC) No 2229/2004 as regards the time period granted to EFSA for the delivery of its view on the draft review reports concerning the active substances for which there are clear indications that they do not have any harmful effects.

30. Commission Regulation (EU) No 741/2010 amending Regulations (EC) No 1490/2002 and (EC) No 2229/2004 as regards the date until which authorisations may continue to be in force in
cases where the notifier has submitted an application in accordance with the accelerated procedure under Regulation (EC) No 33/2008.


52. Commission Implementing Regulation (EU) No 943/2011 concerning the non-approval of the active substance propargite, in accordance with Regulation (EC) No 1107/2009 of the European...


69. Commission Implementing Regulation (EU) No 571/2012 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances aluminium silicate, hydrolysed proteins and 1,4-diaminobutane (putrescine).


74. Commission Implementing Regulation (EU) No 597/2012 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances aluminium ammonium sulphonate, fat distillation residues, repellents by smell of animal or plant origin/fish oil and urea.


76. Commission Implementing Regulation (EU) No 637/2012 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances iron sulphate, repellents by smell of animal or plant origin/tall oil crude and repellents by smell of animal or plant origin/tall oil pitch.
77. Commission Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of active substances whose approval expires by 31 December 2018 at the latest.


105. Commission Implementing Regulation (EU) No 485/2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances.


113. Commission Implementing Regulation (EU) No 781/2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substance fipronil, and prohibiting the use and sale of seeds treated with plant protection products containing this active substance.


and of the Council concerning the placing of plant protection products on the market, and amending

201. Commission Implementing Regulation (EU) 2015/1166 renewing the approval of the active
substance ferric phosphate in accordance with Regulation (EC) No 1107/2009 of the European
Parliament and of the Council concerning the placing of plant protection products on the market,

202. Commission Implementing Regulation (EU) 2015/1176 approving the active substance
Pepino mosaic virus strain CH2 isolate 1906, in accordance with Regulation (EC) No 1107/2009
of the European Parliament and of the Council concerning the placing of plant protection products

203. Commission Implementing Regulation (EU) 2015/1191 concerning the non-approval of
Artiumisia vulgaris L. as a basic substance in accordance with Regulation (EC) No 1107/2009
of the European Parliament and of the Council concerning the placing of plant protection products
on the market.

204. Commission Implementing Regulation (EU) 2015/1192 renewing the approval of the active
substance terpenoid blend QRD 460, in accordance with Regulation (EC) No 1107/2009 of the European
Parliament and of the Council concerning the placing of plant protection products on the market,

205. Commission Implementing Regulation (EU) 2015/1201 renewing the approval of the active
substance fenhexamid in accordance with Regulation (EC) No 1107/2009 of the European
Parliament and of the Council concerning the placing of plant protection products on the market,

206. Commission Implementing Regulation (EU) 2015/1295 approving the active substance
sulfoxaflor, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the
Council concerning the placing of plant protection products on the market, and amending the Annex

207. Commission Implementing Regulation (EU) 2015/1392 approving the basic substance
fructose in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the
Council concerning the placing of plant protection products on the market, and amending the Annex

208. Commission Implementing Regulation (EU) 2015/1396 correcting Implementing
Regulation (EU) No 540/2011 as regards the active substance Bacillus subtilis (Cohn 1872) strain
QST 713, identical with strain AQ 713.

209. Commission Implementing Regulation (EU) 2015/1397 renewing the approval of the active
substance florasulam in accordance with Regulation (EC) No 1107/2009 of the European Parliament
and of the Council concerning the placing of plant protection products on the market, and amending

Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active
substances 2,4-D, acibenzolar-s-methyl, amitrole, bentazon, cyhalofop butyl, diquat, esfenvalerate,
famoxadone, flumioxazine, DPX KE 459 (flupyrsulfuron-methyl), glyphosate, iprovalicarb,
isoproturon, lambda-cyhalothrin, metaxalyl-M, metsulfuron methyl, picolinafen, prosulfuron,
pymetrozine, pyraflufen-ethyl, thiabendazole, thifensulfuron-methyl and triasulfuron.

211. Commission Implementing Regulation (EU) 2015/2033 renewing the approval of the active
substance 2,4-D in accordance with Regulation (EC) No 1107/2009 of the European Parliament and
of the Council concerning the placing of plant protection products on the market, and amending the


228. Commission Implementing Regulation (EU) 2016/183 amending Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of the active substances whose approval expires by 31 December 2018 at the latest.


239. Commission Implementing Regulation (EU) 2016/950 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,4-DB, beta-cyfluthrin, carfentrazone ethyl, Coniothyrium minitans Strain CON/M/91-08 (DSM 9660), cyazofamid, deltamethrin, dimethenamid-P, ethofumesate, fenamidone, flufenacet, flurtamone, foramsulfuron, fosthiazate, imazamox, iodosulfuron, iprodione, isoxaflutole, linuron, maleic hydrazide, mesotrione, oxasulfuron, pendimethalin, picoxystrobin, silthiofam and trifloxystrobin.


and of the Council concerning the placing of plant protection products on the market, and amending

272. Commission Implementing Regulation (EU) 2017/419 approving the basic substance *Urtica*
spp. in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the
Council concerning the placing of plant protection products on the market, and amending the Annex

273. Commission Implementing Regulation (EU) 2017/428 approving the basic substance clayed
charcoal in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the
Council concerning the placing of plant protection products on the market, and amending the Annex

(EU) No 540/2011 as regards the conditions of approval of the active substance abamectin.

(EU) No 540/2011 as regards the extension of the approval periods of several active substances listed

276. Commission Implementing Regulation (EU) 2017/725 renewing the approval of the active
substance mesotrione in accordance with Regulation (EC) No 1107/2009 of the European
Parliament and of the Council concerning the placing of plant protection products on the market, and amending

277. Commission Implementing Regulation (EU) 2017/753 renewing the approval of the active
substance cyhalofop-butyl in accordance with Regulation (EC) No 1107/2009 of the European
Parliament and of the Council concerning the placing of plant protection products on the market, and amending

278. Commission Implementing Regulation (EU) 2017/755 renewing the approval of the active
substance mesosulfuron in accordance with Regulation (EC) No 1107/2009 of the European
Parliament and of the Council concerning the placing of plant protection products on the market, and amending

279. Commission Implementing Regulation (EU) 2017/781 withdrawing the approval of the active
substance methyl neryl ketone, in accordance with Regulation (EC) No 1107/2009 of the European
Parliament and of the Council concerning the placing of plant protection products on the market, and amending

280. Commission Implementing Regulation (EU) 2017/805 renewing the approval of the active
substance flazasulfuron in accordance with Regulation (EC) No 1107/2009 of the European
Parliament and of the Council concerning the placing of plant protection products on the market, and amending

281. Commission Implementing Regulation (EU) 2017/806 approving the low-risk active
substance *Bacillus amyloliquefaciens* strain FZB24, in accordance with Regulation (EC) No 1107/2009 of the European

282. Commission Implementing Regulation (EU) 2017/831 approving the active substance *Beauveria bassiana* strain 147, in accordance with Regulation (EC) No 1107/2009 of the European


305. Commission Implementing Regulation (EU) 2017/2065 confirming the conditions of approval of the active substance 8-hydroxyquinoline, as set out in Implementing Regulation (EU)
No 540/2011 and modifying Implementing Regulation (EU) 2015/408 as regards the inclusion of the active substance 8-hydroxyquinoline in the list of candidates for substitution.


317. Commission Implementing Regulation (EU) 2018/184 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances FEN 560 (also called fenugreek or fenugreek seed powder) and sulfuryl fluoride.


PART 2

Decisions

351. Commission Decision No 94/643/EC concerning the withdrawal of authorizations for plant protection products containing cyhalothrin as active substance.

352. Commission Decision No 95/276/EC concerning the withdrawal of authorizations for plant protection products containing ferbam or azinphos-ethyl as active substances.


361. Commission Decision No 96/586/EC concerning the withdrawal of authorizations for plant protection products containing propham as an active substance.


364. Commission Decision No 97/248/EC recognizing in principle the completeness of the dossier submitted for detailed examination in view of the possible inclusion of pseudomonas


370. Commission Decision No 98/269/EC concerning the withdrawal of authorisations for plant protection products containing dinotertb as an active substance.


381. Commission Decision No 2000/166/EC extending the possible time period for provisional authorisations of the new active substance quinoxyfen.

382. Commission Decision No 2000/180/EC extending the possible time period for provisional authorisations of the new active substance Pseudomonas chlororaphis.


388. Commission Decision No 2000/358/EC extending the possible time period for provisional authorisations of the new active substances flupyrsulfuron methyl, carfentrazone ethyl, prosulfuron, flurtamone, isoxaflutole.


401. Commission Decision No 2001/231/EC making it possible for Member States to extend provisional authorisations granted for the new active substances IKI 1145; TO 1145 (fosthiazate), CGA 329351 (metalaxyl-m), MON 37500 (sulfosulfuron) and Spodoptera exigua nuclear polyhedrosis virus.


404. Commission Decision No 2001/315/EC making it possible for Member States to extend provisional authorisations granted for the new active substances flupyrsulfuron-methyl, carfentrazone-ethyl, famoxadone, prosulfuron, isoxaflutole, flurtamone, ethoxysulfuron, paecilomyces fumosoroseus, and cyclanilide.


407. Commission Decision No 2001/529/EC making it possible for Member States to extend provisional authorisations granted for the new active substances benzoic acid and BAS 615H (cinidon-ethyl).


411. Commission Decision No 2001/810/EC concerning the decision on the possible inclusion of certain active substances into Annex I to Directive 91/414/EEC.


413. Commission Decision No 2002/133/EC making it possible for Member States to extend provisional authorisations granted for the new active substances carfentrazone-ethyl, cinidon-ethyl, cyhalofop-butyl, ethoxysulfuron, famoxadone, flazasulfuron, flufenacet, flumioxazine, flurtamone, fosthiazate, isoxaflutole, metalaxyl-M, prosulfuron, Pseudomonas chlororaphis, quinoxyfen, Spodoptera exigua nuclear polyhedrosis virus and sulfosulfuron.


431. Commission Decision No 2003/370/EC allowing Member States to extend provisional authorisations granted for the new active substances iodosulfuron-methyl-sodium, indoxacarb, S-metolachlor, Spodoptera exigua nuclear polyhedrosis virus, tepraloxydim and dimethenamid-P.


434. Commission Decision No 2003/896/EC allowing Member States to extend provisional authorisations granted for the new active substances thiacloprid, thiametoxam, quinoxyfen, flazasulfuron, Spodoptera exigua nuclear polyhedrosis virus, spinosad, Giocladium catenulatum, Pseudomonas chlororaphis and indoxacarb.


441. Commission Decision No 2004/390/EC allowing Member States to extend provisional authorisations granted for the new active substance acetamiprid.

442. Commission Decision No 2004/400/EC allowing Member States to extend provisional authorisations granted for the new active substance profoxydim.


444. Commission Decision No 2004/627/EC allowing Member States to extend provisional authorisations granted for the new active substances etoxazole and carvone.

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449. Commission Decision No 2005/743/EC allowing Member States to extend provisional authorisations granted for the new active substances boscalid, indoxacarb, spinosad and Spodoptera exigua nuclear polyhedrosis virus.


456. Commission Decision No 2006/409/EC allowing Member States to extend provisional authorisations granted for the new active substance profoxydim.


458. Commission Decision No 2006/584/EC allowing Member States to extend provisional authorisations granted for the new active substance beflubutamid.


469. Commission Decision No 2007/322/EC laying down protective measures concerning uses of plant protection products containing tolyfluanid leading to the contamination of drinking water.


495. Commission Decision No 2008/278/EC amending Decision 2006/589/EC as regards aviglycine HCI.

496. Commission Decision No 2008/296/EC allowing Member States to extend provisional authorisations granted for the new active substances cyflufenamid, FEN 560 and flonicamid.


500. Commission Decision No 2008/564/EC allowing Member States to extend provisional authorisations granted for the new active substance profoxydim.


504. Commission Decision No 2008/724/EC allowing Member States to extend provisional authorisations granted for the new active substances fluopicolide and pinoxaden.


527. Commission Decision No 2009/311/EC allowing Member States to extend provisional authorisations granted for the new active substances topramezone, sulfuryl fluoride and zucchini yellow mosaic virus — weak strain.


537. Commission Decision No 2009/865/EC allowing Member States to extend provisional authorisations granted for the new active substances metaflumizone and gamma-cyhalothrin.


540. Commission Decision No 2010/149/EU allowing Member States to extend provisional authorisations granted for the new active substances flonicamid, silver thiosulphate and tembotrione.


543. Commission Decision No 2010/206/EU allowing Member States to extend provisional authorisations granted for the new active substance FEN 560.


545. Commission Decision No 2010/353/EU allowing Member States to extend provisional authorisations granted for the new active substances amisulbrom, chlorantraniliprole, meptyldinocap and pinoxaden.


547. Commission Decision No 2010/356/EU allowing Member States to extend provisional authorisations granted for the new active substance profoxydim.

548. Commission Decision No 2010/455/EU amending Decisions 2008/934/EC and 2008/941/EC as regards the date until which authorisations may continue to be in force and the period of grace, in cases where the notifier has submitted an application in accordance with the accelerated procedure under Regulation (EC) No 33/2008.

549. Commission Decision No 2010/457/EU allowing Member States to extend provisional authorisations granted for the new active substances Candida oleophila strain O, potassium iodide and potassium thiocyanate.


559. Commission Implementing Decision No 2011/252/EU allowing Member States to extend provisional authorisations granted for the new active substances ascorbic acid, ipconazole, spiromesifen, topramezone, and Pseudomonas sp. strain DSMZ 13134.


565. Commission Implementing Decision No 2011/671/EU allowing Member States to extend provisional authorisations granted for the new active substances benalaxyl-M, gamma-cyhalothrin and valifenalate.


567. Commission Implementing Decision of 6 June 2018 on the establishment of a work programme for the assessment of applications for the renewal of approvals of active substances

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EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by section 8(1) of the European Union (Withdrawal) Act 2018 (c. 16) in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(a), (b), (c), (d), (f) and (g)) arising from the withdrawal of the UK from the European Union.


An impact assessment has not been produced for this instrument as no, or no significant, impact on the private or voluntary sector is foreseen.