DRAFT STATUTORY INSTRUMENTS

2019 No.

The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019

PART 2

Amendment of retained direct EU legislation

CHAPTER 1

Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

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 "Members 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(**1**)" 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"—

(**1**) OJ No L 200, 30.7.1999, p 1, repealed by Regulation (EC) No 1272/2008 of the European Parliament and of the Council (OJ No L 353, 31.12.2008, p 1).

(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(**2**)";

(f) omit paragraphs 17 and 22;

(g) in paragraph 25, in the definition of "professional user", after "Directive 2009/128/EC(**3**)" insert ", and for these purposes, Directive 2009/128/EC is to be read as if Article 3(10)(b) were omitted";

(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.

(**2**) OJ No L 68, 13.3.2015, p 1, as corrected by a Corrigendum (OJ No L 82, 26.3.2018, p 17).
(**3**) OJ No L 309, 24.11.2009, p 71, as last amended by Regulation (EU) No 652/2014 of the European Parliament and of the Council (OJ No L 189, 27.6.2014, p 1).

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, in the first sentence, 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;

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

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 is to be read as 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;

(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 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—

(i) in the first sentence, for "Directive 1999/45/EC" substitute "Regulation (EC) No 1272/2008 of the European Parliament and of the Council";

(ii) in the second sentence—

(aa) for "Member States" substitute "A competent authority";

(bb) for "Directive 1999/45/EC" substitute "Regulation (EC) No 1272/2008 of the European Parliament and of the Council".

(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)";

(d) in paragraph 5—

"**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 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 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";

(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(**4**);

(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(**5**);

(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(**6**);

(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(**7**).

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(**8**).".

(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—

(**4**) S.I. 2003/3245, amended by S.I. 2016/139 and 2017/407.
(**5**) S.I. 2004/99, amended by S.I. 2016/139; there are other amending instruments but none is relevant.
(**6**) 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).
(**7**) S.R. 2017 No.81.
(**8**) 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(**9**)" 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(**10**) or Article 8(1) of the Genetically Modified Organisms (Northern Ireland) Order 1991(**11**)";

(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(**12**);

(b) in relation to Wales, regulation 24(1)(c) of the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002(**13**);

(c) in relation to Scotland, regulation 23(1)(c) of the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002(**14**);

(d) in relation to Northern Ireland, regulation 23(1)(c) of the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003(**15**).".

(27) In Article 49—

(a) in paragraph 1—

(i) for "Member States" substitute "A competent authority";

(**9**) OJ No L 106, 17.4.2001, p 1, as last amended by Commission Directive (EU) 2018/350 (OJ No L 67, 9.3.2018, p 30).
(**10**) 1990 c.43.
(**11**) S.I. 1991/1714 (N.I. 19), to which there are amendments not relevant to these Regulations.
(**12**) S.I. 2002/2443, to which there are amendments not relevant to these Regulations.
(**13**) S.I. 2002/3188 (W 304), to which there are amendments not relevant to these Regulations.
(**14**) SSI 2002/541, to which there are amendments not relevant to these Regulations.
(**15**) 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";

(ii) for "Directive 1999/45/EC" substitute "Regulation (EC) No 1272/2008 of the European Parliament and of the Council".

(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(**16**) or Schedule 2 to the Plant Protection Products Regulations (Northern Ireland) 2011(**17**).

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—

(**16**) S.I. 2011/2131, to which there are amendments not relevant to these Regulations.
(**17**) S.R. 2011 No. 295, amended by S.R. 2012 No. 12.

"**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";

(ii) for "Annex II to Directive 1999/45/EC" substitute "Part 3 of Annex 1 to Regulation (EC) No 1272/2008 of the European Parliament and of the Council";

(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.

(2) In Article 63(3), for "Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information(**18**)" substitute "the Environmental Information Regulations 2004(**19**) or the Environmental Information (Scotland) Regulations 2004(**20**)".

Chapter 7

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

(2) In Article 64(3)—

(a) for "Article 9 of Directive 1999/45/EC" substitute "Article 35 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council";

(**18**) OJ No L 41, 14.2.2003, p 26.
(**19**) 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.
(**20**) S.S.I. 2004/520, amended by paragraphs 310 to 312 of Schedule 19 to the Data Protection Act 2018 and by S.S.I. 2013/127.

(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—

"**3.** 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 on—

(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(**21**).

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(**22**).

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(**23**).

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—

Common Name, CIPAC Identification Number	*Applicant*	*Date of application*
Ethametsulfuron CIPAC-No: 834	DuPont de Nemours GmbH	29th June 2010

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—

(**21**) 2010 asp 10.
(**22**) S.I. 1979/1573 (NI 12).
(**23**) 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 has 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 foe 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;

(d) "Regulation 544/2011" means Commission Regulation (EU) No 544/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances;

(e) "Regulation 545/2011" means Commission Regulation (EU) No 545/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products.

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";

(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)";

(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.