The Secretary of State makes these Regulations in exercise of the powers conferred by section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018. In accordance with paragraph 1(1) of Schedule 7 to the European Union (Withdrawal) Act 2018, a draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament.
PART 2

Amendment of retained direct EU legislation relating to maximum residue levels

CHAPTER 1

maximum residue levels of pesticides in or on food and feed of plant and animal origin

residue levels of pesticides in or on food and feed of plant and animal origin

2. Regulation (EC) No 396/2005 is amended in accordance with regulations 3 to 11.

Chapter 1

3.—(1) Chapter 1 is amended as follows.
(2) In Article 1, omit “and harmonised Community provisions”.
(3) In Article 2—
(a) in paragraphs 1, 2 and 3, for “covered by Annex I” substitute “listed in Part 1 of the MRLs
register in relation to a constituent territory”;
(b) in paragraph 3—
(i) omit “to third countries”;
(ii) omit “third” in the second place it occurs;
(c) omit paragraph 4.
(4) In Article 3—
(a) for the heading substitute “Definitions: general”;
(b) in paragraph 1, for “Article 2, points 1 and 4 of Directive 91/414/EEC(2)” substitute
“Article 2(1) and (2) of Regulation (EC) No 1107/2009”;
(c) in paragraph 2—
(i) before point (a) insert—
1107/2009 of the European Parliament and of the Council concerning the
placing of plant protection products on the market;
(zb) ‘MRLs register’ means the register maintained in accordance with
Article 46A;
(zc) ‘the Department’ means the Department of Agriculture, Environment
and Rural Affairs in Northern Ireland;”;
(ii) in point (a), in the second sentence—
(aa) for the words from “, in conformity with” to “in a given climate zone”
substitute “of the principles of integrated pest management referred to in
Parliament and of the Council establishing a framework for Community
action to achieve the sustainable use of pesticides(3)”;

(2) OJ No L 230, 19.8.1991, p 1, which was repealed by Regulation (EC) No 1107/2009 of the European Parliament and of the
Council (OJ No L 309, 24.11.2009, p 1).
Council (OJ No L 189, 27.6.2014, p 1).
(bb) at the end, insert—

“, and for these purposes Article 14 of Directive 2009/128/EC is to be read as if—

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

(ii) paragraph 3 were omitted.”;

(iii) in point (c)—

(aa) omit “as defined in Article 2, point 1 of Directive 91/414/EEC”;

(bb) for “covered by Annex I to this Regulation” substitute “listed in Part 1 of the MRLs register in relation to a constituent territory”;

(iv) in point (g)—

(aa) in the first indent, for “the Community” substitute “a constituent territory”;

(bb) in the second indent, omit “Community”.

(5) After Article 3 insert—

“Article 3A

Definitions: “competent authority” and “constituent territory”

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 Article 4—

(a) in the heading, omit “harmonised”;

(b) in paragraph 1—

(i) in the first sentence, for the words from “harmonised MRLs” to the end substitute “MRLs apply in relation to a constituent territory must be established and maintained by the competent authority in a list in Part 1 of the MRLs register”;

(ii) omit the second sentence;

(iii) in the third sentence—

(aa) for “Annex I” substitute “A list in Part 1 of the MRLs register in relation to a constituent territory”;

(bb) omit “harmonised”;

(c) for paragraph 2 substitute—

“2. A competent authority may add, amend or remove an entry from the list in Part 1 of the MRLs register accordingly as the competent authority considers appropriate.

3. The Secretary of State may exercise a function under this Article instead of the 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) For Article 5 substitute—

“Article 5

Active substances for which no MRLs are required

1. A competent authority must establish and maintain a list in Part 4 of the MRLs register of active substances evaluated under Regulation (EC) No 1107/2009 for which MRLs are not required in relation to its constituent territory, taking into account the uses of those active substances and the matters referred to in Article 14(2)(a), (c) and (d).

2. A competent authority must update the MRLs register accordingly as soon as reasonably practicable—

(a) after first establishing a list in accordance with paragraph 1, and
(b) after adding to or removing an entry from that list.

3. The Secretary of State may exercise a function under this Article instead of the 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.”.

Chapter 2

4.—(1) Chapter 2 is amended as follows.

(2) In Article 6—

(a) for paragraph 1 substitute—

“1. Where a competent authority envisages granting an authorisation for the use of a plant protection product in accordance with Regulation (EC) No 1107/2009, the competent authority must consider whether, in relation to its constituent territory—

(a) as a result of such use an MRL listed in Part 2 or 3 of the MRLs register needs to be modified;
(b) as a result of such use it is necessary to set a new MRL;
(c) the active substance contained in the plant protection product does not require the setting of an MRL and therefore should be listed in Part 4 of the MRLs register.

1A. The competent authority referred to in paragraph 1 may require the person requesting the grant of that authorisation for the plant protection product to submit an application in accordance with Article 7.”;

(b) in paragraph 2—

(i) for “covered by Annex I” substitute “listed in Part 1 of the MRLs register in relation to a constituent territory”;
(ii) for “a Member State” substitute “the competent authority for that constituent territory”;
(c) in paragraph 3—

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

4
(ii) omit “for setting, modifying or deleting the MRL”;
(d) in paragraph 4, in the first sentence, for the words from “rapporteur Member States” to the end, substitute “any competent authority”.

(3) In Article 7—
(a) in paragraph 1—
(i) in the first subparagraph, in point (d)—
(aa) for the words from “listed in” to “Directive 91/414/EEC” substitute “required under Article 8(4) of Regulation (EC) No 1107/2009”;
(bb) after “pesticides” insert “in relation to the constituent territory to which the application relates”;
(ii) in the second subparagraph—
(bb) for “Member State” substitute “competent authority”;
(b) in paragraph 2, for “Member State” in both places it occurs substitute “competent authority”.

(4) In Article 8—
(a) in paragraph 1—
(i) for “Member State” substitute “competent authority”;
(ii) for “forward a copy to the Authority and the Commission” substitute “notify the other competent authorities”;
(b) after paragraph 1 insert—

“1A. A competent authority notified in accordance with paragraph 1 may request from the notifying competent authority a copy of the application received, and where such a request is received the notifying competent authority must provide a copy as soon as reasonably practicable.”;
(c) for paragraphs 2 and 3 substitute—

“2. Applications must be evaluated in accordance with—
(a) principles set by regulations made under paragraph 2A in relation to the constituent territory, or
(b) where there are no such regulations, the uniform principles for the evaluation and authorisation of plant protection products prescribed in accordance with Article 29(6) of Regulation (EC) No 1107/2009 in relation to the constituent territory.

2A. The appropriate authority may, by regulations, set evaluation principles for applications for MRLs.

2B. In paragraph 2A, “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.

2C. 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.

3. A competent authority may, by agreement, transfer the evaluation of an application to another competent authority, provided the relevant principles referred to in paragraph 2 are the same in relation to the constituent territory of each of those competent authorities.

3A. A transfer in accordance with paragraph 3 does not affect anything done by a competent authority prior to transfer.”;

(d) omit paragraph 4.

(5) After Article 8 insert—
“Article 8A

The competent authority’s opinion on applications concerning MRLs

1. An evaluation report under Article 8 must include the competent authority’s reasoned opinion on, in particular, the risks to the consumer and where relevant to animals associated with the setting, modification or deletion of an MRL.

2. The reasoned opinion must include—
   (a) an assessment of whether the analytical method for routine monitoring proposed in the application is appropriate for the intended control purposes;
   (b) the anticipated LOD for the pesticide/product combination;
   (c) an assessment of the risks of the acceptable daily intake or acute reference dose being exceeded as a result of the modification of the MRL;
   (d) the contribution to the acceptable daily intake due to the residues in the product for which the MRL was requested;
   (e) any other element relevant to the risk assessment.

3. The reasoned opinion must clearly define the basis for each conclusion reached.

4. The competent authority may request supplementary information from the applicant where necessary for the giving of a reasoned opinion.”.

(6) For Article 9 substitute—
“Article 9

Notification of evaluated applications

1. After completion of the evaluation report under Article 8 the competent authority must without delay—
   (a) forward the application, evaluation report and supporting dossier to the other competent authorities;
   (b) forward a copy of its reasoned opinion to the applicant;
   (c) make a copy of the reasoned opinion public, subject to paragraphs 2 and 3.

2. The duty in paragraph 1(c) does not apply to third party confidential information received by the competent authority for which confidential treatment has been requested and justified.

3. Paragraph 2 does not apply to—
(a) information which must be made public in order to protect public health;
(b) the conclusions of the reasoned opinion relating to foreseeable health effects.”.

(7) For the heading of Section 2, substitute “Assessment of existing MRLs by the competent authority”.

(8) Omit Articles 10 and 11.

(9) For Article 12 substitute—
“Article 12

Assessment of existing MRLs by the competent authority

1. A competent authority must produce a reasoned opinion within a period of 36 months beginning with the date on which an active substance approval decision is made in respect of an active substance in relation to its constituent territory, except where paragraph 2 applies.

2. Where at the end of the 36 month period described in paragraph 1 there are outstanding renewals of authorisations under Article 43 of Regulation (EC) No 1107/2009 relating to that active substance in relation to its constituent territory, a competent authority must instead produce a reasoned opinion before the end of the period of 6 months beginning with the date on which the last of those outstanding renewals is concluded.

3. The reasoned opinion must be based in particular on the relevant assessment report prepared under Regulation (EC) No 1107/2009, and must include—

(a) existing MRLs for that active substance set out in Part 2 or 3 of the MRLs register in relation to the competent authority’s constituent territory;
(b) the necessity of setting a new MRL for that active substance, or its inclusion in Part 4 of the MRLs register;
(c) specific processing factors as referred to in Article 20(2) that may be needed for that active substance;
(d) MRLs which the competent authority may consider including in Part 2 or 3 of the MRLs register and those MRLs related to that active substance which may be deleted.

4. In paragraph 1, an “active substance approval decision” means a decision by the competent authority under Article 13(1) or 20(1) of Regulation (EC) No 1107/2009.

5. The Secretary of State may produce a reasoned opinion under this Article 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 produces a reasoned opinion in accordance with paragraph 5—

(a) a reference in paragraphs 1 to 3 to the competent authority is to be read as a reference to the Secretary of State;
(b) the Secretary of State must send a copy of the produced reasoned opinion to the competent authority.”.

(10) Omit Article 13.

(11) In Article 14—

(a) in the heading, after “applications” insert “or opinions”;

7
(b) for paragraph 1, substitute—

“1. Within 3 months of completing the evaluation of an application under Article 8 or producing or receiving a reasoned opinion under Article 12, a competent authority must decide to take one of the actions set out in paragraph 1B(a) to (c).

1A. Within 3 months of receiving an evaluation report under Article 9(1)(a), a competent authority may decide to—

(a) take the action outlined in paragraph 1B(a) or (b), or
(b) take no action.

1B. The actions are—

(a) set a new MRL in relation to its constituent territory,
(b) modify or delete an existing MRL, or
(c) reject the application, or take no further action in respect of the reasoned opinion.

1C. A new MRL set under paragraph 1B(a) applies from a date set by the competent authority.

1D. The modification or deletion of an MRL under paragraph 1B(b) applies from a date set by the competent authority in accordance with paragraph 1E.

1E. The date described in paragraph 1D must be at least 6 months after the day on which the decision under paragraph 1 or 1A is made, except where the competent authority considers that an earlier date is necessary to avoid endangering human or animal health.”;

(c) in paragraph 2—

(i) for the words before point (a) substitute—

“In making a decision under paragraphs 1 or 1A, the competent authority must take account of—”;
(ii) in point (e), for “a third” substitute “another”;

(d) in paragraph 3—

(i) for “Commission” in both places it occurs substitute “competent authority”;
(ii) in the first sentence, for “by the Authority” substitute “, where the Secretary of State provided the reasoned opinion to the competent authority in accordance with Article 12(6)(b), the Secretary of State”;
(iii) in the second sentence, for “Member States and the Authority” substitute “other competent authorities”;

(e) after paragraph 3 insert—

“4. As soon as reasonably practicable after making a decision under paragraph 1 or 1A, the competent authority must—

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

5. The Secretary of State may make a decision under paragraph 1 or 1A 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 makes a decision in accordance with paragraph 5, a reference in paragraphs 1C to 4 to the competent authority is to be read as a reference to the Secretary of State.”.

(12) For Article 15 substitute—

“Article 15

Setting of new MRLs

1. This Article applies where the competent authority decides to set a new MRL in accordance with Article 14(1B)(a).

2. The competent authority—

(a) may set a temporary MRL in relation to its constituent territory—

(i) for an active substance which is not approved under Regulation (EC) No 1107/2009 in relation to that territory, or

(ii) in the circumstances described in Article 16(1);

(b) otherwise, must set an MRL in relation to its constituent territory.

3. A temporary MRL set in accordance with paragraph 2(a)(i) expires after 12 months unless—

(a) deleted in accordance with Article 14(1B)(b), or

(b) extended in accordance with paragraphs 4 or 5.

4. A competent authority may extend a temporary MRL set in accordance with paragraph 2(a)(i) by a further 12 months where confirmation is pending that any scientific studies necessary for supporting an application for setting an MRL have been undertaken.

5. Where the confirmation described in paragraph 4 is received, a competent authority may extend the temporary MRL by a further 24 months provided that no unacceptable safety concerns for consumers have been identified.

6. Where the competent authority extends the period of the temporary MRL in accordance with paragraph 4 or 5, the competent authority must update the MRLs register accordingly.

7. Where the Secretary of State makes a decision under Article 14(5) to set a new MRL in accordance with Article 14(1B)(a), a reference to the competent authority in paragraphs 1 and 2 is to be read as a reference to the Secretary of State.

8. The Secretary of State may extend a temporary MRL in accordance with paragraphs 4 or 5 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.

9. Where the Secretary of State extends a temporary MRL in accordance with paragraph 8, a reference in paragraph 6 to the competent authority is to be read as a reference to the Secretary of State.”.

(13) In Article 16—

(a) in paragraph 1—

(i) for the words before point (a), substitute—
“The competent authority may set a temporary MRL in the following circumstances—”;


(iii) in point (e), for the words from “a Decision” to “Directive 91/414/EEC” substitute “the competent authority in deciding to refuse approval or the renewal of approval, or to withdraw approval, for an active substance under Regulation (EC) No 1107/2009”;

(iv) in point (f), for the words from “Annex I” to “so request”, substitute “the list in Part 1 of the MRLs register in relation to its constituent territory”;

(b) in paragraph 2—

(i) in the first subparagraph, for “Authority” substitute “competent authority”;

(ii) in the second subparagraph, omit the words from “and any such” to the end;

(iii) in the third subparagraph, for “Annex III” substitute “Part 3 of the MRLs register”;

(c) after paragraph 2 insert—

“3. Upon reassessment of a temporary MRL in accordance with paragraph 2, the competent authority—

(a) may modify or delete the temporary MRL, and

(b) where the competent authority does so, must update the MRLs register accordingly.

4. Where the Secretary of State makes a decision in accordance with Article 15(2) (a)(ii), a reference to the competent authority in paragraphs 1 and 2 is to be read as a reference to the Secretary of State.

5. The Secretary of State may reassess a temporary MRL in accordance with the second or third subparagraph of paragraph 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.

6. Where the Secretary of State reassesses a temporary MRL in accordance with paragraph 5, a reference in paragraph 3 to the competent authority is to be read as a reference to the Secretary of State.”.

(14) For Article 17 substitute—

“Article 17

Modifications of MRLs following withdrawal of authorisations of plant protection products

1. Where a competent authority withdraws an authorisation for a plant protection product, the competent authority—

(a) may modify or delete a MRL, and

(b) where the competent authority does so, must update the MRLs register accordingly.

2. The Secretary of State may modify or delete an MRL in accordance with paragraph (1) (a) instead of the 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.

3. Where the Secretary of State modifies or deletes an MRL in accordance with paragraph 2, the Secretary of State must update the MRLs register accordingly.

Article 17A

Transitional provision for modified MRLs

1. Paragraph 2 applies where a competent authority modifies an MRL in relation to its constituent territory for a pesticide residue by lowering it, under Article 14(1B)(b), 16, 17 or 18(6).

2. The competent authority may exempt one or more products produced before the relevant date from the application of the modified MRL where—
   (a) the competent authority considers it necessary to allow for the normal marketing, processing or consumption of each product exempted, and
   (b) the competent authority is satisfied that in doing so a high level of consumer protection can be ensured.

3. Where the competent authority exempts a product from the application of a modified MRL for a pesticide residue in accordance with paragraph 2—
   (a) an entry in Parts 2 to 5 of the MRLs register in relation to the competent authority’s constituent territory which immediately before the relevant date applied in respect of that product and pesticide residue continues to apply in respect of that product and pesticide residue on and after the relevant date, and
   (b) the competent authority must update the MRLs register accordingly.

4. Where the Secretary of State modifies an MRL for a pesticide residue by lowering it in accordance with Article 14(5), 16(6) or 17(2), a reference in paragraphs 1 to 3 to competent authority is to be read as a reference to Secretary of State.

5. In this Article, “relevant date” means the date from which the modified MRL applies in accordance with Article 14(1D).”.

Chapter 3

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

(2) In Article 18—
   (a) for paragraph 1 substitute—

   “1. A product listed in Part 1 of the MRLs register in relation to a constituent territory must not contain, from the time it is placed on the market as food or feed, or fed to animals in that constituent territory, any pesticide residue exceeding—
       (a) the MRL for that product listed in Part 2 or 3 of the MRLs register in relation to that constituent territory;
       (b) the level described in paragraphs 1A or 1B, where there is no MRL.

1A. Where there is no MRL for a product listed in Part 2 or 3 of the MRLs register in relation to a constituent territory, the level is the default value for an active substance as listed in Part 5 of the MRLs register in relation to that constituent territory (see Article 18A).

1B. Where in relation to a constituent territory—
       (a) there is no MRL for the product in Part 2 or 3 of the MRLs register,
(b) there is no default value for an active substance listed in Part 5 of the MRLs register, and
(c) the active substance is not listed in Part 4 of the MRLs register, the level applicable is 0.01mg/kg.”;
(b) in paragraph 2—
(i) in the words before point (a)—
(aa) for “Member States” substitute “A competent authority”;
(bb) for “their territories” substitute “its constituent territory”;
(cc) for “covered by Annex I” substitute “listed in Part 1 of the MRLs register in relation to its constituent territory”;
(ii) in point (b), for “Annex IV” substitute “Part 4 of the MRLs register in relation to that constituent territory”;
(c) in paragraph 3—
(i) in the first subparagraph—
(aa) for the words before point (a) substitute—
“By way of derogation from paragraph 1, a competent authority may authorise, further to a post-harvest treatment with a fumigant on its constituent territory, residue levels for an active substance which exceed the limits specified in Part 2 or 3 of the MRLs register in relation to that constituent territory where the active substance/product combinations are listed in Part 7 of the MRLs register in relation to that constituent territory, provided that—”;
(bb) in point (b), for “Annexes II or III” substitute “Part 2 or 3 of the MRLs register”;
(cc) in point (c), for “Member States and the Commission” substitute “competent authorities”;
(ii) omit the second subparagraph;
(d) after paragraph 3 insert—

3A. A competent authority may, in relation to its constituent territory—
(a) define combinations of active substances and products for the purposes of paragraph 3;
(b) modify or withdraw any such combinations.

3B. As soon as reasonably practicable after defining, modifying or withdrawing a combination in accordance with paragraph 3A the competent authority must—
(a) notify the other competent authorities of the defining, modifying or withdrawing of the combination and the reason for that decision, and
(b) update the MRLs register accordingly.”;
(e) in paragraph 4—
(i) in the first sentence—
(bb) after “set out in” insert “the EU-derived domestic legislation which transposed(4)”;
(cc) for “Member State” substitute “competent authority”;
(dd) after “within its” insert “constituent”;
(ii) omit the second, third and fourth sentences;
(f) after paragraph 4 insert—

“5. Where a competent authority grants an authorisation in accordance with paragraph 4, the competent authority must—

(a) notify the other competent authorities of that authorisation;
(b) as soon as reasonably practicable, undertake an appropriate risk assessment with a view to setting a temporary MRL for a specified period, or taking any other necessary measure in relation to the products to which the authorisation relates.

6. After the completion of the risk assessment described in paragraph 5(b) the competent authority may set a temporary MRL, and Article 15(3) to (9) applies to any temporary MRL set.

7. In paragraph 4, “EU-derived domestic legislation” has the meaning given by section 2(2) of the European Union (Withdrawal) Act 2018.”.

(3) After Article 18 insert—

“Article 18A

Setting default values for active substances

1. A competent authority may, in relation to its constituent territory, set a default value for an active substance where—

(a) there is no specific MRL for that active substance listed in Part 2 or 3 of the MRLs register in relation to that constituent territory, and
(b) the active substance is not listed in Part 4 of the MRLs register in relation to that constituent territory.

2. A competent authority may modify or withdraw a default value listed in Part 5 of the MRLs register in relation to its constituent territory.

3. When setting, modifying or withdrawing a default value, the competent authority must take into account the routine analytical methods available.

4. As soon as reasonably practicable after setting, modifying or withdrawing a default value the competent authority must—

(a) notify the other competent authorities of the setting, modifying or withdrawing of the default value and the reason for that decision, and
(b) update the MRLs register accordingly.

5. The Secretary of State may set, modify or withdraw a default value in accordance with 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.

6. Where the Secretary of State sets, modifies or withdraws a default value in accordance with paragraph 5, a reference in paragraph 3 or 4 to the competent authority is to be read as a reference to the Secretary of State.”.

(4) In Article 19—
(a) for “covered by Annex I” substitute “listed in Part 1 of the MRLs register in relation to a constituent territory”;
(b) after “animals” insert “in that constituent territory”.

(5) In Article 20—
(a) in paragraph 1—
   (i) for “Annexes II or III” substitute “Part 2 or 3 of the MRLs register in relation to a constituent territory”;
   (ii) for “covered by Annex I” substitute “listed in Part 1 of the MRLs register in relation to that constituent territory”;
(b) for paragraph 2 substitute—
   “2. A competent authority may, in relation to its constituent territory—
   (a) specify concentration factors or dilution factors for—
      (i) specified processing or mixing operations, or
      (ii) specified processed or composite products;
   (b) modify or withdraw any such factors.

3. As soon as reasonably practicable after specifying, modifying or withdrawing concentration or dilution factors in accordance with paragraph 2 the competent authority must—
   (a) notify the other competent authorities of the specifying, modifying or withdrawing of the factors and the reason for that decision, and
   (b) update Part 6 of the MRLs register accordingly.

4. The Secretary of State may specify, modify or withdraw concentration or dilution factors in accordance with paragraph 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.

5. Where the Secretary of State specifies, modifies or withdraws concentration or dilution factors in accordance with paragraph 4, a reference in paragraph 3 to the competent authority is to be read as a reference to the Secretary of State.”.

Chapter 4

6. Omit Chapter 4.

Chapter 5

7.—(1) Chapter 5 is amended as follows.
(2) In Article 26(1)—
(a) for “Without prejudice to Directive 96/23/EC(5), Member States” substitute “Each competent authority”;

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

(3) In Article 27—

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

(b) for paragraph 2 substitute—

“2. Sampling for the purposes of paragraph 1 must be carried out in accordance with the methods described in the Annex to Commission Directive 2002/63/EC(6).


(a) in Section 1, in the second paragraph, in the first sentence, for the words from “the Annexes” to “Community” there were substituted “relation to a constituent territory in accordance with Regulation (EC) No 396/2005 and, in the absence of such”;

(b) in Section 2, in the first paragraph, “Community” were omitted;

(c) in Section 4.3, in Tables 3, 4 and 5, for table footnote (1) there were substituted—

“(1) Classification of foods: Part 1 of the MRLs register.”.”.

(4) In Article 28—

(a) in paragraph 1, for “Community” substitute “retained EU”;

(b) omit paragraph 2;

(c) for paragraph 3 substitute—

“3. All laboratories analysing samples for the official controls on pesticide residues must—

(a) have regard to any relevant guidance issued under Article 46(1);

(b) participate in any proficiency tests for pesticides organised by a competent authority.”.

(5) In the heading of Section 2, for “Community” substitute “United Kingdom”.

(6) In Article 29—

(a) in the heading, for “Community” substitute “United Kingdom”;

(b) in paragraph 1—

(i) for “Commission shall” substitute “competent authorities may jointly”;

(ii) for “Community” substitute “United Kingdom”;

(iii) for “national” substitute “competent authority”;

(iv) for “set out in this Regulation” substitute “in relation to each constituent territory”;

(c) for paragraph 2 substitute—

“2. The competent authorities must jointly publish a United Kingdom control programme prepared in accordance with paragraph 1—

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(a) in a manner which the competent authorities consider appropriate, and
(b) at least six months before the end of the calendar year before the first year
covered by the control programme.”.

(7) In the heading of Section 3, for “National” substitute “Competent authority”.

(8) In Article 30—
(a) in the heading, for “National” substitute “Competent authority”;
(b) in paragraph 1—
   (i) for the first subparagraph substitute—
   “Each competent authority must establish multiannual control programmes for
pesticide residues in its constituent territory, and must update its multiannual
programme every year.”;
   (ii) in the second subparagraph, in point (d)(iv) for “the Community” substitute “any
United Kingdom”;
(c) for paragraph 2, substitute—
   “2. A competent authority must submit its proposed updated control programme to
the other competent authorities at least three months before the end of each calendar
year.”;
(d) in paragraph 3—
   (i) in the first sentence—
   (aa) for “Member States” substitute “Each competent authority”;
   (bb) for “the Community” substitute “any United Kingdom”;
   (ii) in the second sentence—
   (aa) for “They” substitute “Each competent authority”;
   (bb) for “national” substitute “its”;
   (iii) in the third sentence, for “Member States” substitute “a competent authority”.

(9) In the heading of Section 4, for “Member States” substitute “competent authorities”.

(10) In Article 31—
(a) in the heading, for “Member States” substitute “competent authorities”;
(b) in paragraph 1—
   (i) in the words before point (a)—
   (aa) for “Member States” in the first place it occurs substitute “Each competent
authority”;
   (bb) for “Commission, the Authority and the other Member States” substitute
“other competent authorities”;
(ii) in point (a), at the end insert “, and the results of the analysis of samples tested
in accordance with the competent authority’s control programme and any United
Kingdom control programme”;
(iii) in point (b)—
   (aa) for “national control programmes” substitute “competent authority’s control
programme”;
   (bb) for “the Community” substitute “any United Kingdom”;
(iv) in point (c)—
(aa) omit “Community”;
(b) for “national” substitute “competent authority’s”;
(c) for paragraph 2 substitute—
“2. The competent authorities may jointly issue guidance regarding the format and submission of information in accordance with paragraph 1.

3. The competent authorities must jointly publish any guidance issued under paragraph 2 in a manner which the competent authorities consider appropriate.

4. In submitting information in accordance with paragraph 1, a competent authority must have regard to any guidance issued under paragraph 2.”.

(11) In Article 32—
(a) in paragraph 1—
(i) omit “by the Member States”;
(ii) for “Authority shall” substitute “competent authorities must jointly”;
(b) in paragraph 2—
(i) in the words before point (a), for “Authority” substitute “competent authorities”;
(ii) in point (a), at the end insert “, and of the results of the analysis of samples tested in accordance with each competent authority’s control programme and any United Kingdom control programme”;
(iii) in point (b), for “the” in the second place it occurs substitute “any”;
(iv) in point (d), omit “, including reports submitted under Directive 96/23/EC”;
(c) after paragraph 2 insert—
“2A. For the purpose of the first annual report under paragraph 1, paragraph 2(a) is to be read as if for “in accordance with each competent authority’s control programme and any United Kingdom control programme” there were substituted “by the United Kingdom as an EU member State in accordance with Commission Implementing Regulation (EU) 2017/660 concerning a coordinated multiannual control programme of the Union for 2018, 2019 and 2020 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin(7) as it had effect immediately before exit day”.”;
(d) omit paragraphs 3 to 6;
(e) for paragraph 7 substitute—
“7. The competent authorities must jointly publish the Annual Report by the 31st October of the second year following the year to which the information in the Annual Report relates.”.

(12) Omit Article 33.
(13) Omit Section 5.

Chapters 6 and 8

8. Omit chapters 6 and 8.

(7) OJ No L 94, 7.4.2017, p 12, which was partially repealed by Commission Implementing Regulation (EU) 2018/555 (OJ No L 92, 10.4.2018, p 6).
Chapter 9

9.—(1) Chapter 9 is amended as follows.
(2) For Article 43 substitute—

“Article 43

Scientific advice

1. In fulfilling any obligation or performing any function under this Regulation, a competent authority may obtain independent scientific advice, where the competent authority considers it appropriate to do so.

2. Where independent scientific advice is obtained in accordance with paragraph 1, the competent authority must take that advice into account when fulfilling the obligation or performing the function.”.

(3) Omit Articles 44 and 45.
(4) For Article 46 substitute—

“Article 46

Implementing measures

1. A competent authority may issue guidance to assist in the application of this Regulation in relation to its constituent territory, including (but not limited to)—

(a) guidance on the scientific data required for the setting of MRLs;
(b) guidance regarding the sampling methods other than those described in Article 27(2) which are necessary for carrying out such controls of pesticide residues in products;
(c) guidance regarding the specific validation criteria and quality control procedure in relation to the methods of analysis referred to in Article 28(1).

1A. A competent authority must publish any guidance issued under paragraph 1 in a manner which the competent authority considers appropriate.

1B. The Secretary of State may issue guidance 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.

1C. Where the Secretary of State issues guidance under paragraph 1B, a reference in paragraph 1A to competent authority is to be read as a reference to Secretary of State.

1D. 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.

2. The Secretary of State may, by regulations, amend—

(a) Article 29(2)(b) in respect of the date by which a United Kingdom control programme must be published;
(b) Article 30(2) in respect of the date by which a competent authority must submit its control programme;
(c) the date in Article 31(1) by which a competent authority must submit the information described in that Article;
(d) the date in Article 32(7) by which the Annual Report must be published.
3. The Secretary of State may only make regulations under paragraph 2 with the consent of the Welsh Ministers, the Scottish Ministers and the Department.

Article 46A

MRLs register

1. The competent authorities must jointly establish and maintain a register (“the MRLs register”) in accordance with this Article.

2. The MRLs register must be divided into seven Parts as follows.

3. Part 1 of the MRLs register must contain a list of products, product groups and (where appropriate) parts of products referred to in Article 4(1) in relation to each constituent territory, and each list must be divided into the following—
   (a) Section A for entries relating to products of plant and animal origin;
   (b) Section B for entries relating to other products.

4. An entry for a product in Section A of a list in Part 1 must contain the following information—
   (a) a unique code number,
   (b) the category to which the product relates,
   (c) the group and (where applicable) the subgroup to which the product relates,
   (d) the common name of the product,
   (e) the scientific name of the product, and
   (f) where applicable, the part of the product to which MRLs or temporary MRLs apply.

5. An entry for a product in Section B of a list in Part 1 must contain the following information—
   (a) a unique code number,
   (b) the common name of the product,
   (c) the scientific name of the product, and
   (d) a reference to the product in Section A of the list to which the same MRLs apply, including the information required by paragraph 4(a) to (c) in relation to that product.

6. Part 2 of the MRLs register must contain, in relation to each constituent territory, a list of MRLs set in accordance with Article 15(2)(b).

7. Part 3 of the MRLs register must contain, in relation to each constituent territory, a list of temporary MRLs set in accordance with Article 15(2)(a).

8. An entry on Part 2 or 3 of the MRLs register must contain—
   (a) a maximum residue level expressed in mg/kg for each product, product group and (where appropriate) part of a product listed in a list in Part 1 of the MRLs register to which it relates;
   (b) the date from which the MRL or temporary MRL applies in accordance with Article 14(1C) or (1D);
   (c) where the MRL or temporary MRL continues to apply to a product produced before a certain date by virtue of an exemption under Article 17A, that date.

9. Part 4 of the MRLs register must contain the list of evaluated active substances referred to in Article 5(1) in relation to each constituent territory.
10. Part 5 of the MRLs register must contain a list of default values set in accordance with Article 18A in relation to each constituent territory.

11. An entry on the list—
   (a) in Part 4 or 5 of the MRLs register which continues to apply to a product produced before a certain date by virtue of an exemption under Article 17A, must contain that date;
   (b) in Part 5 of the MRLs register must contain a maximum residue level expressed in mg/kg for each product, product group and (where appropriate) part of a product listed in a list in Part 1 of the MRLs register to which the default values relate.

12. Part 6 of the MRLs register must contain a list of concentration or dilution factors set in accordance with Article 20 in relation to each constituent territory.

13. Part 7 of the MRLs register must contain a list of combinations of active substances and products set for the purposes of Article 18(3) in relation to each constituent territory.

14. An entry on the list in Part 7 of the MRLs register for a combination must contain—
   (a) an active substance,
   (b) each product listed in a list in Part 1 of the MRLs register relating to the combination, and
   (c) for each product included in accordance with point (b), the unique code number for that product as provided in the relevant entry in a list in Part 1 of the MRLs register.

15. Where any information to be contained in a list or entry in a Part of the MRLs register in accordance with this Article is the same in relation to one or more constituent territories, a single list or entry (as the case may be) of that information may be established and maintained instead in the relevant Part.

16. A list or entry of information established and maintained in a Part of the MRLs register in accordance with paragraph 15 must—
   (a) comply with any of the requirements in paragraphs 3 to 14 relevant to that Part, and
   (b) indicate each of the constituent territories to which it relates.

17. The MRLs register must contain a search facility.

18. The competent authorities must make the MRLs register available for inspection by the public on a website jointly maintained by the competent authorities.

Article 46B

**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(8).

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(9).

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(8) 2010 asp 10.
(9) S.I. 1979/1573 (N.I.12).
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(10).

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.”.

(5) Omit Article 47.

Chapter 10


Annexes 1 to 7

11. Omit Annexes 1 to 7.

CHAPTER 2

Commission Implementing Regulation (EU) 2018/555

Commission Implementing Regulation (EU) 2018/555 concerning a coordinated multiannual control programme of the Union for 2019, 2020 and 2021 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin

12.—(1) Commission Implementing Regulation (EU) 2018/555 concerning a coordinated multiannual control programme of the Union for 2019, 2020 and 2021 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin is amended as follows.

(2) In Article 1, in the first paragraph, for “Member States” substitute “The competent authorities”.

(3) In Article 2—
   (a) in paragraph 1, in the second subparagraph, for “Directive 2002/63/EC” substitute “the Annex to Commission Directive 2002/63/EC, as read in accordance with Article 27(3) of Regulation (EC) No 396/2005”;
   (b) after paragraph 3 insert—

   “4. For the purposes of paragraph 3—

(10) 1954 c.33. Section 41(6) was amended by S.I. 1999/663.
(a) **Directive 2006/125/EC**(11) is to be read as if, in Article 2(c) the reference to point 1 of Article 2 of Directive 91/414/EC were a reference to Article 2(1) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market;

(b) **Directive 2006/141/EC**(12) is to be read as if, in Article 2(e) the reference to point 1 of Article 2 of Directive 91/414/EC were a reference to Article 2(1) of Regulation (EC) No 1107/2009.

(4) In Article 3—

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

(b) in the second paragraph, for “Member States” substitute “the competent authorities”.

(5) Omit Articles 4 and 5.

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

(7) In Annex 1—

(a) in Part A, in the table—

(i) in the first column, in the fourth entry (Wine)—

(aa) for “Member States” substitute “The competent authorities”;

(bb) for “National Summary report” substitute “information submitted under Article 31 of Regulation (EC) No 396/2005”;

(ii) in the third column, in the tenth entry (Virgin olive oil)—

(aa) for “Member States” substitute “The competent authorities”;

(bb) for “National Summary report” substitute “information submitted under Article 31 of Regulation (EC) No 396/2005”;

(b) in Part C, in the table, in the fifth column, in the one-hundred-and-fourth entry (Isoprothiolane), omit the second sentence;

(c) in table footnote (1), for “part A of Annex I to Regulation (EC) No 396/2005” substitute “Section A of the list in Part 1 of the MRLs register relating to the relevant constituent territory”;

(d) in table footnote (6), in the second sentence, for “to EFSA” substitute “in the information submitted under Article 31 of Regulation (EC) No 396/2005”.

(8) In Annex 2—

(a) in point (1), for the words from “each Member State” to the end substitute “all of the competent authorities collectively is 71”;

(b) in point (2)—

(i) in the first paragraph—

(aa) for “the table in point (5)” substitute “point (1)”;

(bb) for “each Member State shall” substitute “the competent authorities must collectively”;

(ii) in the second and third paragraphs—

(aa) for “that table” substitute “point (1)”;

(bb) for “each Member State shall” substitute “the competent authorities must collectively”;

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(c) in point (3)—
   (i) omit “In accordance with the table in point (5),”;
   (ii) for “each Member State” substitute “the United Kingdom”;
(d) in point (4)—
   (i) in the first paragraph—
      (aa) for “Member States” substitute “Competent authorities”;
      (bb) for “the table in point (5)” substitute “point (1)”;
      (cc) for “Member State” substitute “competent authority”;
   (ii) in the second paragraph, for “Member States” substitute “a competent authority”;
(e) after point (4), insert—
   “(4A) For the purposes of this Annex, samples taken by the United Kingdom as an EU member State in accordance with this Regulation as it had effect immediately before exit day are deemed to have been taken by the competent authorities collectively in 2019.”;
(f) omit point (5).

PART 3
Consequential amendments, transitional provisions, savings and revocations


   (2) In Annex 2—
      (a) in point 3.6.3, for “Article 18(1)(b) of Regulation (EC) No 396/2005” substitute “Article 18A of Regulation (EC) No 396/2005 in relation to the relevant constituent territory”;
      (b) in point 3.6.4, for “point (b) of Article 18(1) of Regulation (EC) No 396/2005” substitute “Article 18A of Regulation (EC) No 396/2005 in relation to the relevant constituent territory”.

Amendment of the Pesticides (Maximum Residue Levels) (England and Wales) Regulations 2008

14.—(1) The Pesticides (Maximum Residue Levels) (England and Wales) Regulations 2008(13) are amended as follows.
   (2) In regulation 6, in the words after paragraph (b)—
      (a) for “covered by Annex I to Regulation 396/2005” substitute “listed in Section A or B of a list in Part 1 of the MRLs register in relation to England or Wales”;
      (b) for “that Regulation” in the first place it occurs substitute “Regulation 396/2005”.
   (3) The amendments made to regulation 6 of the Pesticides (Maximum Residue Levels) (England and Wales) Regulations 2008 by paragraph (2) do not affect—
      (a) any obligation or liability acquired, accrued or incurred immediately before exit day;

(b) any penalty, forfeiture or punishment incurred in respect of any offence committed before exit day; or
(c) any investigation, legal proceeding or remedy in respect of sub-paragraph (a) or (b).

(4) Any penalty, forfeiture or punishment referred to in paragraph (3)(b) may be imposed as if paragraph (2) had not come into force.

(5) Any investigation, legal proceeding or remedy referred to in paragraph (3)(c) may be instituted, continued or enforced as if paragraph (2) had not come into force.

Transitional provisions and savings

15. Schedule 1 has effect.

Revocation: retained direct EU legislation

16. The retained direct EU legislation listed in Schedule 2 is revoked.

Revocation: the EEA agreement

17. In Annex 2 to the EEA agreement, in Chapter 12, omit points 54zzd and 129.

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

20th March 2019
SCHEDULE 1

Transitional provisions and savings

PART 1

Interpretation

Interpretation

1. In this Schedule—
   “competent authority” and “constituent territory” have the meanings given in Article 3A of Regulation (EC) No 396/2005 (as inserted by regulation 3(5));
   “MRLs register” has the meaning given by Article 3(2)(zb) of Regulation (EC) No 396/2005 (as inserted by regulation 3(4)(c)(i)).

PART 2

Existing MRLs etc. under Regulation (EC) No 396/2005

Existing MRL product list

2. The list of products in Parts A and B of Annex 1 to Regulation (EC) No 396/2005 as it had effect immediately before exit day is taken to be the list of products established by each competent authority in relation to its constituent territory in accordance with Article 4(1) of Regulation (EC) No 396/2005.

Existing MRLs under Annexes 2 and 3 to Regulation (EC) No 396/2005

3.—(1) In accordance with this paragraph, an MRL which immediately before exit day is set out in an entry in a table in Annex 2 or 3 to Regulation (EC) No 396/2005 as it has effect immediately before exit day is taken to have been set by each competent authority in relation to its constituent territory—
   (a) for an MRL set out in an entry in the table in Annex 2, under Articles 14(1B)(a) and 15(2) (b) of Regulation (EC) No 396/2005;
   (b) for an MRL set out in an entry in the table in Part A of Annex 3, under Articles 14(1B) (a) and 15(2)(a)(i) of Regulation (EC) No 396/2005;
   (c) for an MRL set out in an entry in the table in Part B of Annex 3, under Articles 14(1B)(a), 15(2)(a)(ii) and 16 of Regulation (EC) No 396/2005.

(2) An MRL to which sub-paragraph (1) applies is taken to apply from the date which it applied from in accordance with a regulation made under Article 14(1) of Regulation (EC) No 396/2005 as it had effect immediately before exit day, except in accordance with sub-paragraph (3).

(3) For the purposes of Article 15(3) of Regulation (EC) No 396/2005, an MRL to which sub-paragraph (1)(b) applies is taken to apply from exit day.

(4) In sub-paragraph (1), “Annex 2” and “Annex 3” means Annex 2 and 3 respectively to Regulation (EC) No 396/2005 as it has effect immediately before exit day and read in accordance with paragraph 4.
(5) Sub-paragraph (6) applies where an MRL to which sub-paragraph (1) applies is immediately before exit day subject to a requirement for the European Commission—

(a) to take specified information into account when reviewing that MRL if the information is submitted by a specified date, or the lack of that information if it is not submitted by that date; or

(b) to take into account the commercial availability of a specified reference standard when reviewing that MRL by a specified date, or the unavailability of it if it is not commercially available by that date.

(6) Where this sub-paragraph applies, on and after exit day the MRL is taken to be subject to the requirement as modified as follows—

(a) a reference in the requirement to the Commission is to be read as a reference to the competent authority;

(b) if the specified date occurred before exit day and on or before that specified date—

(i) the specified information was submitted to the European Commission, the specified date is to be read as 1st January 2020;

(ii) the specified information was not submitted to the European Commission, the requirement is to be read as a requirement on the competent authority to take the lack of that information into account when reviewing the MRL.

(7) For the purposes of sub-paragraphs (5) and (6), a date, a reference standard or information is “specified” if it is specified in the requirement.

Existing MRLs: modifications of Annexes 2 and 3 to Regulation (EC) No 396/2005

4.—(1) For the purposes of paragraph 3, Annexes 2 and 3 of Regulation (EC) No 396/2005 as they had effect immediately before exit day are to be read as follows.

(2) Annex 2 is to be read as if, in the table—

(a) in table footnote (**), for “Annex III Part B” there were substituted “Part 3 of the MRLs register”;

(b) in table footnote (1)—

(i) in the first sentence, the words from “, pending” to the end were omitted;

(ii) in the second sentence, “, unless modified by a Regulation” were omitted;

(c) in table footnote (2), in the second sentence “unless modified by a Directive or a Regulation” were omitted;

(d) in table footnote (a)—

(i) after “apply” there were inserted “in relation to a constituent territory”;

(ii) for “Annex I” there were substituted “Part 1 of the MRLs register”;

(e) in the column for Chlormequat, in entry 0151010 (Table grapes), in table footnote (+), “by a Regulation” were omitted;

(f) in the column for Fipronil, in entry 0211000 ((a) potatoes), entry 1011020 (Kidney), entry 1011040 (Kidney), entry 1011050 (Edible offal), entry 1011990 (Others), entry 1012010 (Muscle), entry 1012020 (Fat), entry 1012030 (Liver), entry 1012040 (Kidney), entry 1012050 (Edible offal), entry 1012990 (Others), entry 1013010 (Muscle), entry 1013020 (Fat), entry 1013030 (Liver), entry 1013040 (Kidney), entry 1013050 (Edible offal), entry 1013990 (Others), entry 1014010 (Muscle), entry 1014020 (Fat), entry 1014030 (Liver), entry 1014040 (Kidney), entry 1014050 (Edible offal), entry 1014990 (Others), entry 1015010 (Muscle), entry 1015020 (Fat), entry 1015030 (Liver), entry 1015040 (Kidney), entry 1015050 (Edible offal), entry 1015990 (Others), entry
1016010 (Muscle), entry 1016020 (Fat), entry 1016030 (Liver), entry 1017010 (Muscle),
entry 1017020 (Fat), entry 1017030 (Liver), entry 1017040 (Kidney), entry 1017050
(Edible offal), entry 1017990 (Others), entry 1020000 ((ii) Milk), entry 1020010 (Cattle),
entry 1020020 (Sheep), entry 1020030 (Goat), entry 1020040 (Horse), entry 1020990
(Other), entry 1030000 ((iii) Bird eggs), entry 1030010 (Chicken), entry 1030020 (Duck),
entry 1030030 (Goose), entry 1030040 (Quail), and entry 1030990 (Others), in table
footnote (+), “by a Regulation” were omitted;

(g) in the column for Metalaxyl, in entry 0820000 (Fruit spices), entry 0820010 (Allspice/
pimento), entry 0820020 (Sichuan pepper), entry 0820030 (Caraway), entry 0820040
(Cardamom), entry 0820050 (Juniper berry), entry 0820060 (Peppercorn), entry 0820070
(Vanilla), entry 0820080 (Tamarind) and entry 0820090 (Others), in table footnote (+), in
the second sentence, “by a Regulation” were omitted;

(h) in the column for Mepiquat—
   (i) in entry 0280010 (Cultivated fungi), in table footnote (+), in the second sentence,
   the words from “by a Regulation” to the end were omitted;
   (ii) in entry 0401090 (Cotton seeds), in table footnote (+), in the first sentence, “by a
   Regulation” were omitted;
   (i) in the column for Hexachlorobenzene, in entry 0401100 (Pumpkin seeds), in table footnote
   (+), in the second sentence—
      (i) for “Commission” there were substituted “competent authority”;
      (ii) for “within 10 years from the date of publication” there were substituted “on or
      before 20th October 2026”;
(j) in the column for Cyantraniliprole, in entry 0153010 (Blackberries), in table footnote (+),
in the first sentence, “by a Regulation” were omitted.

(3) Annex 3 is to be read as if—

(a) in Part A, in the table—
   (i) in table footnote (a)—
      (aa) after “apply” there were inserted “in relation to a constituent territory”;
      (bb) for “Annex I” there were substituted “Part 1 of the MRLs register”;
   (ii) in table footnote (**), for “Annex III Part B” there were substituted “Part 3 of the
      MRLs register”;
   (iii) in table footnote (****), for “Annex V” there were substituted “Part 5 of the MRLs
      register”;
   (iv) in the column for Chlorantraniliprole, in entry 0700000 (HOPS), in table footnote
      (+), “by a Regulation” were omitted;
   (v) in the column for Diphenylamine, in entry 0130010 (Apples) and entry 0130020
      (Pears), in table footnote (+), in the second sentence—
         (aa) for “Commission” there were substituted “competent authority”;
         (bb) for “within 2 years from the date of publication” there were substituted “on or
      before 21st January 2018”;
   (vi) in the column for Mercury compounds, in entry 0120000 (Tree nuts), entry 0256000
      (Herbs and edible flowers), entry 0280010 (Cultivated fungi), entry 0280020
      (Wild fungi), entry 0401000 (Oilseeds), entry 0610000 (Teas), entry 0620000
      (Coffee beans), entry 0630000 (Herbal infusions from), entry 0640000 (Cocoa
      beans), entry 0800000 (SPICES), entry 1011000 ((a) Tissues from swine), entry
      1012000 ((b) Tissues from bovine), entry 1013000 ((c) Tissues from sheep), entry
      27
1014000 ((d) Tissues from goat), entry 1015000 ((e) Tissues from equine), entry 1016010 (Muscle (poultry)), entry 1016020 (Fat tissue (poultry)), entry 1016030 (Liver (poultry)), entry 1016040 (Kidney (poultry)), entry 1016050 (Edible offals (poultry)), entry 1017000 ((g) Tissues from other farmed terrestrial animals), entry 1020000 (Milk), entry 1040000 (Honey and other apiculture products), and entry 1070000 (Wild terrestrial vertebrate animals), in table footnote (+)—

(aa) for “Commission” there were substituted “competent authority”;  
(bb) for “within 10 years from the date of publication” there were substituted “on or before 17th January 2028”;  

(b) in Part B, in the table, in table footnote (a)—

(i) after “apply” there were inserted “in relation to a constituent territory”;  
(ii) for “Annex I” there were substituted “Part 1 of the MRLs register”.

Existing list of active substances in Annex 4 to Regulation (EC) No 396/2005

5. The list of active substances in Annex 4 to Regulation (EC) No 396/2005 as it had effect immediately before exit day is taken to be the list of active substances established by each competent authority in relation to its constituent territory in accordance with Article 5(1) of Regulation (EC) No 396/2005.

Existing default values for active substances in Annex 5 to Regulation (EC) No 395/2005

6.—(1) In accordance with this paragraph, a default value for an active substance which immediately before exit day is set out in an entry in the table in Annex 5 is taken to have been set by each competent authority in relation to its constituent territory under Article 18A(1) of Regulation (EC) No 396/2005.

(2) Sub-paragraph (3) applies where a default value to which sub-paragraph (1) applies is immediately before exit day subject to a requirement for the European Commission to take specified information into account when reviewing that default value if the information is submitted by a specified date, or the lack of that information if it is not submitted by that date.

(3) Where this sub-paragraph applies, on and after exit day the default value is taken to be subject to the requirement as modified as follows—

(a) a reference in the requirement to the Commission is to be read as a reference to the competent authority;
(b) if the specified date occurred before exit day and on or before that specified date—

(i) the specified information was submitted to the European Commission, the specified date is to be read as 1st January 2020;
(ii) the specified information was not submitted to the European Commission, the requirement is to be read as a requirement on each competent authority to take the lack of that information into account when reviewing the default value.

(4) In sub-paragraph (1), “Annex 5” means Annex 5 to Regulation (EC) No 396/2005 as it has effect immediately before exit day, read as if, in the table—

(a) in table footnote (a)—

(i) after “apply” there were inserted “in relation to a constituent territory”;  
(ii) for “Annex I” there were substituted “Part 1 of the MRLs register”;  
(b) in table footnote (**), for “Annex III Part A” there were substituted “Part 3 of the MRLs register”;
(5) In sub-paragraphs (2) and (3), “specified” means specified in the requirement.

Existing concentration or dilution factors

7. A concentration or dilution factor set out in Annex 6 to Regulation (EC) No 396/2005 as it had effect immediately before exit day is taken to be specified by each competent authority in relation to its constituent territory in accordance with Article 20(2) of Regulation (EC) No 396/2005.

Existing active substance/product combinations

8.—(1) An active substance/product combination set out in the table in Annex 7 to Regulation (EC) No 396/2005 as it had effect immediately before exit day is taken to be defined by each competent authority in relation to its constituent territory in accordance with Article 18(3A) of Regulation (EC) No 396/2005.

(2) For the purposes of sub-paragraph (1), Annex 7 to Regulation (EC) No 396/2005 as it had effect immediately before exit day is to be read as if, in the heading of the second column of the table in that Annex, the reference to Annex 1 were a reference to Part 1 of the MRLs register.

Existing transitional measures for MRLs under Article 49(2) of Regulation (EC) No 396/2005

9.—(1) Sub-paragraph (2) applies where immediately before exit day a Regulation listed in Schedule 2 includes provision which continues to apply Regulation (EC) No 396/2005 as it had effect before that Regulation applied in respect of the pesticide residue of an active substance in or on one or more products lawfully produced before a specified date (a “transitional measure”).

(2) In respect of the pesticide residue and the product or products to which the transitional measure applies, paragraphs 3 to 6 of this Part apply as if a reference in those paragraphs to Regulation (EC) No 396/2005 as it had effect immediately before exit day were a reference to Regulation (EC) No 396/2005 as it had effect before the specified date.

(3) For the purposes of this paragraph, a date is “specified” if it is specified in the transitional measure.

PART 3

Ongoing applications for MRLs

Ongoing applications under Article 7 of Regulation (EC) No 396/2005

10.—(1) This paragraph applies to an application where—

(a) before exit day, that application was submitted under Article 7 of Regulation (EC) No 396/2005 as it had effect immediately before exit day to the United Kingdom for evaluation, and

(b) immediately before exit day, a regulation or decision adopted under Article 14(1) of Regulation (EC) No 396/2005 as it had effect immediately before exit day in relation to that application has not entered into force.

(2) An application to which this paragraph applies is taken as being made under Article 7 of Regulation (EC) No 396/2005 on the date on which it was made, to each competent authority in relation to its constituent territory.

(3) Anything done before exit day in relation to an application to which this paragraph applies—

(a) by the United Kingdom as the evaluating member State;
(b) by the European Food Safety Authority under Article 10 or 11 of Regulation (EC) No 396/2005 as it had effect immediately before exit day; is taken to have been done by the competent authority.

PART 4
Ongoing MRL assessments

Ongoing EFSA assessments under Article 12 of Regulation (EC) No 396/2005

11.—(1) This paragraph applies where—

(a) before exit day, the European Food Safety Authority is required to provide a reasoned opinion in respect of an active substance, in accordance with Article 12(1) of Regulation (EC) No 396/2005 as it had effect immediately before exit day, and

(b) immediately before exit day, either—

(i) such an opinion has not been provided in accordance with Article 12(1) of Regulation (EC) No 396/2005 as it had effect immediately before exit day, or

(ii) such an opinion has been provided, but a regulation or decision made as a result of that reasoned opinion under Article 14(1) of Regulation (EC) No 396/2005 as it had effect immediately before exit day has not come into force.

(2) A competent authority may produce a reasoned opinion within a period of 36 months beginning with 1st April 2019 in respect of that active substance in relation to its constituent territory, except where sub-paragraph (3) applies.

(3) Where at the end of the 36 month period described in sub-paragraph (2) there are outstanding renewals of authorisations under Article 43 of Regulation (EC) No 1107/2009 relating to that active substance in relation to its constituent territory, a competent authority may instead produce a reasoned opinion before the end of the period of 6 months beginning with the date on which the last of those outstanding renewals is concluded.

(4) Articles 12(3) to (6) and 14 of Regulation (EC) No 396/2005 apply to a reasoned opinion under sub-paragraph (2) as they apply to a reasoned opinion under Article 12(1) of that Regulation.

(5) In providing a reasoned opinion under sub-paragraph (2), the competent authority may also consider relevant information provided by an interested person, including (but not limited to)—

(a) the GAP; 

(b) evidence of an authorisation; 

(c) relevant assessments undertaken in other countries; 

(d) data required by regulations made under Article 8(4) of Regulation (EC) No 1107/2009, including, where appropriate, toxicological data and data on routine analytical methods for use in control laboratories, as well and plant and animal metabolism data.

(6) In sub-paragraph (5), “interested person” includes manufacturers, growers, importers and producers of products listed in a list in Part 1 of the MRLs register in relation to the competent authority’s constituent territory.

PART 5

Existing technical guidelines

Existing technical guidelines under Article 28(2) of Regulation (EC) No 396/2005

12.—(1) This paragraph applies to technical guidelines which—

(a) before exit day, were adopted in accordance with Article 28(2) of Regulation (EC) No 396/2005 as it had effect immediately before exit day, and

(b) immediately before exit day had not been withdrawn.

(2) Technical guidelines to which this paragraph applies are taken to have been issued by each competent authority in relation to its constituent territory in accordance with Article 46(1) of Regulation (EC) No 396/2005.

PART 6

Control programmes

Saving for existing EU control programme under Article 29 of Regulation (EC) No 396/2005

13.—(1) Despite the amendment of Article 29 of Regulation (EC) No 396/2005 by regulation 7(6), Commission Implementing Regulation (EU) 2018/555 (as amended by regulation 12) continues to have effect, and for the purposes of Sections 2 to 4 of Chapter 5 of Regulation (EC) No 396/2005 is taken to have been prepared by the competent authorities jointly as the United Kingdom control programme for 2019, 2020 and 2021.

(2) The appropriate authority may, by regulations, amend or revoke Commission Implementing Regulation (EU) 2018/555.

(3) In sub-paragraph (2), “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.

(4) 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.

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

Regulations under paragraph 13(2)

14.—(1) Regulations made by the Secretary of State or Welsh Ministers under paragraph 13(2) are to be made by statutory instrument.

(2) For regulations made under paragraph 13(2) by the Scottish Ministers, see section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010.

(3) The power to make regulations conferred on the Department under paragraph 13(2) is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979.
(4) A statutory instrument containing regulations made by the Secretary of State under paragraph 13(2) 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 paragraph 13(2) is subject to annulment in pursuance of a resolution of the National Assembly for Wales.

(6) Regulations made by the Scottish Ministers under paragraph 13(2) 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 paragraph 13(2) are subject to negative resolution within the meaning of section 41(6) of the Interpretation Act (Northern Ireland) Act 1954.

(8) Such regulations may—

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

SCHEDULE 2

Regulation 16

Revocations


oxide, flufenoxuron, fluopicolide, indoxacarb, ioxynil, mepanipyrim, prothioconazole, pyridalyl, thiacloprid and trifloxystrobin in or on certain products.


biphenyl, deltamethrin, ethofumesate, isopyrazam, propiconazole, pymetrozine, pyrimethanil and tebuconazole in or on certain products.


geraniol, thymol, sucrose, ferric sulphate (iron (III) sulphate), ferrous sulphate (iron (II) sulphate) and folic acid in or on certain products.


1-naphthylacetamide, 1-naphthylacetic acid, chloridazon, fluazifop-P, fuberidazole, mepiquat and tralkoxydim in or on certain products.


116. Commission Implementing Regulation (EU) 2017/660 concerning a coordinated multiannual control programme of the Union for 2018, 2019 and 2020 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin.


119. Commission Regulation (EU) 2017/978 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fluopyram; hexachlorocyclohexane (HCH), alpha-isomer; hexachlorocyclohexane (HCH), beta-isomer; hexachlorocyclohexane (HCH), sum of isomers, except the gamma isomer; lindane (hexachlorocyclohexane (HCH), gamma-isomer); nicotine and profenofos in or on certain products.


EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by section 8(1) of the European Union (Withdrawal) Act 2018 (c. 16) in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(a), (b), (c), (d) and (g)) arising from the withdrawal of the UK from the European Union.

These Regulations make amendments to legislation in the field of pesticides, and in particular, amend legislation relating to the maximum residue levels of pesticides. Part 2 amends Regulation (EC) No 396/2005 of the European Parliament and of the Council on maximum residue levels of pesticides in or on food and feed of plant and animal origin and other supporting retained direct EU legislation. Part 3 makes consequential amendments, contains transitional provisions, and revokes retained direct EU legislation.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private or voluntary sector is foreseen.