DRAFT STATUTORY INSTRUMENTS

2019 No.

The Pesticides (Maximum Residue Levels) (Amendment etc.) (EU Exit) Regulations 2019

PART 2

Amendment of retained direct EU legislation relating to maximum residue levels

CHAPTER 1

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

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

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(**1**)" substitute "Article 2(1) and (2) of Regulation (EC) No 1107/2009";

(c) in paragraph 2—

(i) before point (a) insert—

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

(**1**) OJ No L 230, 19.8.1991, p 1, which was repealed by Regulation (EC) No 1107/2009 of the European Parliament and of the Council (OJ No L 309, 24.11.2009, p 1).

(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 Article 14 of and Annex 3 to Directive 2009/128/EC of the European Parliament and of the Council establishing a framework for Community action to achieve the sustainable use of pesticides(**2**)";

(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—

(**2**) 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).

(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";

(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—

(aa) for "Directive 91/414/EEC" substitute "Regulation (EC) No 1107/2009 in relation to that constituent territory";

(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";

(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—";

(ii) in point (a), for "Article 8(4) of Directive 91/414/EEC" substitute "Article 53 of Regulation (EC) No 1107/2009";

(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—

(aa) for "Article 8(4) of Directive 91/414/EEC" substitute "Article 53 of Regulation (EC) No 1107/2009";

(bb) after "set out in" insert "the EU-derived domestic legislation which transposed(**3**)";

(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

(**3**) See for example: in relation to England, S.I. 2015/610; in relation to Wales, S.I. 2006/1643 (W.158); in relation to Scotland, S.S.I. 2005/613; in relation to Northern Ireland, S.R. 2006 No. 82.

(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(**4**), 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(**5**).

3. In paragraph 2, the "Annex to Commission Directive 2002/63/EC" means the Annex to Commission Directive 2002/63/EC establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin, read as if—

(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—

(**4**) OJ No L 125, 23.5.1996, p 10, as last amended by Council Directive 2013/20/EU (OJ No L 158, 10.6.2013, p 234).
(**5**) OJ No L 187, 16.7.2002, p 30.

(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—

(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";

(bb) 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(**6**) 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.

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.

(**6**) 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).

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(**7**).

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(**8**).

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(**9**).

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

10. Omit Chapter 10.

Annexes 1 to 7

11. Omit Annexes 1 to 7.

(**7**) 2010 asp 10.
(**8**) S.I. 1979/1573 (N.I.12).
(**9**) 1954 c.33. Section 41(6) was amended by S.I. 1999/663.