STATUTORY INSTRUMENTS

2019 No. 557

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

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).".