
DRAFT STATUTORY INSTRUMENTS

2019 No.

The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019

PART 4

Amendment and revocation of retained direct EU legislation

Regulation (EC) No 726/2004 of the European Parliament and of the Council

5. Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency is revoked insofar as it applies to medicinal products for veterinary use.

Regulation (EC) 470/2009 of the European Parliament and of the Council

6.—(1) Regulation (EC) 470/2009 of the European Parliament and of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin is amended as follows.

(2) In Article 1(3)—

- (a) omit “Community”;
- (b) after “for by” insert “the retained EU law which transposed”.

(3) In Article 2—

- (a) renumber the existing text as paragraph 1;
- (b) after that paragraph insert—

“2. In this Regulation, “appropriate authority” is to be read in accordance with Article 4(3) and (4).”.

(4) In Article 3—

- (a) for the heading substitute “Scope”;
- (b) for the first paragraph substitute—

“This Regulation applies to any pharmacologically active substance intended for use in the United Kingdom in veterinary medicinal products which are to be administered to food producing animals.”;

- (c) omit the second paragraph.

(5) In Article 4—

- (a) for the heading substitute “Assessment report”;
- (b) for paragraph 1 substitute—

“1. Where an application for a new or amended maximum residue limit for a substance intended for use in a veterinary medicinal product is made under Article 8, the appropriate authority must produce an assessment report which includes a scientific risk assessment and risk management recommendations for the purposes of establishing maximum residue limits for the substance in question.”;

(c) in paragraph 2, for the second sentence substitute—

“The assessment report must take account of any relevant findings of internationally recognised scientific bodies.”;

(d) after paragraph 2 insert—

“3. In paragraph 1, “appropriate authority” means—

- (a) in relation to England, Wales and Scotland, the Secretary of State;
- (b) in relation to Northern Ireland, the Department of Agriculture, Environment and Rural Affairs.

4. But the appropriate authority is the Secretary of State if consent is given in relation to Northern Ireland by the Department of Agriculture, Environment and Rural Affairs.”.

(6) In Article 5, for the words from “, the Agency” to the end substitute—

“whilst ensuring a high level of protection of human health, the appropriate authority must consider extrapolating maximum residue limits from one species to another or from one foodstuff to another when drafting risk management recommendations”.

(7) In Article 6(1), omit the words from “expressed in terms” to the end.

(8) For Article 11 substitute—

“Article 11

Review of maximum residue limit

Where the appropriate authority considers that a review of the maximum residue limit for a substance is necessary in order to protect human or public health and issues a notice to that effect to the Veterinary Products Committee, that Committee must review the substance in question and report its findings to the appropriate authority, together with any recommendations.”.

(9) In Article 12, for the words from “Agency” to “11” substitute “appropriate authority must publish the assessment report referred to in Article 4”.

(10) Omit Article 13.

(11) Omit Article 15.

(12) In Article 16—

- (a) in paragraph 1, omit the words from “within the” to the end;
- (b) for paragraph 2 substitute—

“2. Paragraph 1 does not apply in the case of clinical trials which are authorised under an Animal Test Certificate.”.

(13) Omit Article 17.

(14) In Article 18—

- (a) in the first paragraph, for “Commission” substitute “appropriate authority”;
- (b) in the second paragraph, for “Article 24” substitute “relevant international decisions”;
- (c) omit the third paragraph.

(15) In Article 19—

(a) for paragraph 1 substitute—

“The reference point for action must be set having taken into account the lowest residue concentration which can be quantified with an analytical method validated in accordance with the Annex to Commission [Decision 2002/657/EC](#). The relevant national reference laboratory must advise the appropriate authority on the performance of analytical methods.”;

(b) omit paragraphs 2 and 3.

(16) Omit Article 20.

(17) For Article 21 substitute—

“Article 21

Analytical methods

The appropriate authority must consult relevant national reference laboratories on appropriate analytical methods for detecting residues of pharmacologically active substances for which maximum residue limits have been determined in accordance with Article 14.”.

(18) Omit Article 22.

(19) In Article 23—

(a) in the first paragraph, in the words after point (b), for “Community legislation” substitute “retained EU law”;

(b) omit the second paragraph.

(20) Omit Articles 24 to 28.

(21) In Article 29, omit the first two paragraphs.

(22) Omit Articles 30 to 32.

(23) After Article 32, omit the words from “This Regulation” to “Member States”.

Commission Regulation (EU) No 37/2010

7. Commission Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin is revoked.

Commission Implementing Regulation (EU) 2017/12

8.—(1) Commission Implementing Regulation (EU) 2017/12 regarding the form and content of the applications and requests for the establishment of maximum residue limits in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council is amended as follows.

(2) In Article 1—

(a) in paragraph 1, for “European Medicines Agency (EMA)” substitute “the appropriate authority”;

(b) after paragraph 2 insert—

“**3.** In this Regulation, “appropriate authority” is to be read in accordance with Article 2(4) and (5).”.

(3) In Article 2—

(a) in paragraph 1, for “EMA” substitute “the appropriate authority”;

(b) in paragraph 3, for “EMA” substitute “The appropriate authority”;

(c) after paragraph 3 insert—

“4. In paragraph 1, “appropriate authority” means—

- (a) in relation to England, Wales and Scotland, the Secretary of State;
- (b) in relation to Northern Ireland, the Department of Agriculture, Environment and Rural Affairs.

5. But the appropriate authority is the Secretary of State if consent is given in relation to Northern Ireland by the Department of Agriculture, Environment and Rural Affairs.”.

(4) After Article 3, omit the words from “This Regulation” to “Member States”.

(5) In the Annex—

- (a) in paragraph 2, for “EMA” substitute “appropriate authority”;
- (b) in paragraph B.3.2 of Chapter 2, for “Commission and the EMA” substitute “appropriate authority”.

Commission Regulation (EU) 2017/880

9.—(1) Commission Regulation (EU) 2017/880 laying down rules on the use of a maximum residue limit established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species and a maximum residue limit established for a pharmacologically active substance in one or more species for other species, in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council is amended as follows.

(2) In Article 2, after paragraph (6) insert—

“(7) ‘appropriate authority’ is to be read in accordance with Article 3(2) and (3).”.

(3) In Article 3—

- (a) renumber the existing text as paragraph 1;
- (b) in that paragraph, for “EMA” substitute “appropriate authority”;
- (c) after that paragraph insert—

“2. In paragraph 1, “appropriate authority” means—

- (a) in relation to England, Wales and Scotland, the Secretary of State;
- (b) in relation to Northern Ireland, the Department of Agriculture, Environment and Rural Affairs.

3. But the appropriate authority is the Secretary of State if consent is given in relation to Northern Ireland by the Department of Agriculture, Environment and Rural Affairs.”.

(4) In Articles 4 to 7 for “EMA”, in each place it occurs, substitute “appropriate authority”.

(5) After Article 8, omit the words from “This Regulation” to “Member States”.

Commission Regulation (EU) 2018/782

10.—(1) Commission Regulation (EU) 2018/782 establishing the methodological principles for the risk assessment and risk management recommendations referred to in Regulation (EC) No 470/2009 is amended as follows.

(2) In Article 1—

- (a) for “Agency” substitute “appropriate authority”;
- (b) for “preparing opinions on the” substitute “producing an assessment report in respect of”.

(3) After Article 3, omit the words from “This Regulation” to “Member States”.

- (4) In Annex 1—
- (a) in paragraph 1.1, for the words from “provisions related” to “Council” substitute “the Good Laboratory Practice Regulations 1999⁽¹⁾”;
 - (b) in paragraph 1.2, for “[Directive 2010/63/EU](#) of the European Parliament and of the Council” substitute “the Animals (Scientific Procedures) Act 1986⁽²⁾”;
 - (c) in paragraph 1.7, in the second subparagraph—
 - (i) for “European Medicines Agency (‘Agency’)” substitute “appropriate authority”;
 - (ii) for “the Agency” substitute “the appropriate authority”;
 - (d) in paragraph 1.8, for the words from “the Agency’s” to the end substitute “guidance issued by the appropriate authority”;
 - (e) in paragraph 2.4.2(l), omit “Agency and other”;
 - (f) in paragraph 2.4.2(m), for “[Directive 2010/63/EU](#)” substitute “the Animals (Scientific Procedures) Act 1986”;
 - (g) in paragraph 2.6.1.3, for “Agency” substitute “appropriate authority”;
 - (h) in paragraph 3.2.2(j), omit “Agency and other”;
 - (i) in paragraph 3.2.2(k), for “[Directive 2010/63/EU](#)” substitute “the Animals (Scientific Procedures) Act 1986”;
 - (j) in paragraph 3.5.5—
 - (i) for “Agency” substitute “appropriate authority”;
 - (ii) for “European Reference Laboratory” substitute “relevant national reference laboratories”;
 - (k) in paragraph 3.5.6—
 - (i) for “Agency’s” substitute “appropriate authority’s”;
 - (ii) omit “other EU and”;
 - (l) in paragraph 3.6.3 for “Agency’s” substitute “the appropriate authority’s”.
- (5) In Annex 2—
- (a) in paragraph 2.1—
 - (i) in the second sentence, for the words from “the Agency’s” to the end substitute “guidance issued by the appropriate authority”;
 - (ii) in the third sentence, omit the words from “as defined” to the end;
 - (b) in paragraph 2.7.2, in the first sentence, for “Agency” substitute “appropriate authority”.

(1) S.I. 1999/3106, amended by S.I. 2004/994, 2005/2114, 2011/1043, 2018/378.

(2) 1986 c.14.