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 3

Amendment of subordinate legislation

The Veterinary Medicines Regulations 2013

3.—(1) The Veterinary Medicines Regulations 2013 are amended as follows.

(2) In regulation 2—

(a) in paragraph (2), omit the definitions of "the Agency" and "Commission Regulation (EU) No 37/2010";

(b) omit paragraph (4).

(3) In regulation 4(1), omit "or the Agency".

(4) In regulation 25—

(a) in paragraph (5), for "member State" substitute "country";

(b) in paragraph (6)(a), omit "member State or a third".

(5) In regulation 26(4), for "member State", in each place it occurs, substitute "country".

(6) In regulation 31—

(a) in paragraph (1), for "member State", in each place it occurs, substitute "country";

(b) in paragraph (2), omit "outside the European Union";

(c) in paragraph (4), for "third" substitute "importing".

(7) In regulation 34—

(a) in paragraph (2)(a), for "EU instrument" substitute "enactment";

(b) for paragraph (5) substitute—

"(5) An inspector may be accompanied by such other persons as the inspector considers necessary.".

(c) omit paragraph (10).

(8) Schedule 1 is amended in accordance with paragraphs (9) to (32).

(9) After paragraph 2(2) insert—

"(2A) The reference in paragraph 2(2) to Annex 1 to Directive 2001/82/EC is to be read subject to the following modifications—

(a) a reference to a member State is to be read as a reference to the United Kingdom;

(b) a reference to the national pharmacopoeia of a member State is to be read as a reference to the national pharmacopoeia of the United Kingdom;

(c) a reference to an application for a marketing authorisation pursuant to Article 12 or 13 is to be read as a reference to an application for a marketing authorisation pursuant to this Schedule;

(d) a reference to the Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via veterinary medicinal products is to be read as a reference to that document as it had effect immediately before exit day;

(e) a reference to Council Directive 87/18/EEC is to be read as a reference to Directive 2004/10/EC of the European Parliament and of the Council on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances(**1**);

(f) a reference to Annex 5 of Council Directive 67/548/EEC is to be read as a reference to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures(**2**);

(e) the following provisions are to be ignored—

(i) in Title 1—

(aa) in Part 1, in Chapter A, the fourth paragraph;

(bb) in Part 2, in Chapter A, paragraph 3.3;

(ii) in Title 2, in Part 5, in Chapter A, the fifth paragraph.".

(10) In paragraph 2(3)—

(a) in paragraph (h), for "specified in" substitute "established by an appropriate authority under";

(b) in paragraph (n)(i)—

(i) omit "member State or in a third";

(ii) for "member States" substitute "countries";

(c) in paragraph (n)(iii), for ", whether in the Community or a third" substitute "in any other";

(d) in paragraph (o), for "either in the Community or in a third" substitute "in another";

(e) for paragraph (p) substitute—

"(p) if the veterinary medicinal product is intended for food-producing species and contains one or more pharmacologically active substances for the species in question for which a maximum residue limit has not yet been established under Regulation (EC) No 470/2009 of the European Parliament and of the Council, a document certifying that a valid application for the establishment of maximum residue limits has been submitted.".

(11) In paragraph 5, omit the words from "in accordance with" to the end.

(12) In paragraph 7(1), omit "in the Community".

(13) In paragraph 10—

(a) in sub-paragraph (1), for "Community" substitute "United Kingdom";

(b) in sub-paragraph (5), before "Agency" insert "European Medicines";

(c) omit sub-paragraph (6).

(**1**) OJ L No 50, 20.2.2004, p.44, as last amended by Regulation (EC) No 219/2009 (OJ L No 87, 31.3.2009, p.109).
(**2**) OJ L No 353, 31.12.2008, p.1, as corrected by Corrigendum to Regulation (EC) No 1272/2008 (OJ L No 349, 21.12.2016, p.1).

(14) Omit paragraph 12.

(15) In paragraph 13—

(a) in sub-paragraph (1), for "member State", in both places it occurs, substitute "country";

(b) omit sub-paragraph (4);

(c) in sub-paragraph (5), for "Community" substitute "United Kingdom".

(16) In paragraph 14, omit sub-paragraph (3).

(17) In paragraph 16, for the words from "by another" to "a third" substitute "in another".

(18) In paragraph 18, for "a member State" substitute "the United Kingdom".

(19) Omit paragraph 20.

(20) In paragraph 23—

(a) in sub-paragraph (1)—

(i) after "unless" insert "maximum residue limits have been established under Regulation (EC) No 470/2009 of the European Parliament and of the Council in respect of";

(ii) omit the words from "appear in" to the end;

(b) in sub-paragraph (2), for the words from "appears in" to the end substitute "has been classified under Article 14 of Regulation (EC) No 470/2009 of the European Parliament and of the Council as prohibited for use in food producing animals.".

(21) In paragraph 24—

(a) in sub-paragraph (2)(d), for the words from "that Regulation" to "complied with" substitute "food safety";

(b) in sub-paragraph (3)(a), omit "Community".

(22) In paragraph 29—

(a) for sub-paragraph (1) substitute—

"(1) Before placing an immunological product on the market the holder of the marketing authorisation must notify the Secretary of State asking for written approval to do so.";

(b) in sub-paragraph (2), for "(1)(a)" substitute "(1)";

(c) in sub-paragraph (3), omit the words from "or" to the end.

(23) In paragraph 39, omit sub-paragraph (3).

(24) In paragraph 41, omit sub-paragraph (3).

(25) Omit Part 6.

(26) In paragraph 55, omit "who resides in a member State".

(27) In paragraph 56(a), omit "at least at one point in a member State".

(28) In paragraph 58—

(a) in the heading, for "a third" substitute "another";

(b) in sub-paragraph (1), for "a third" substitute "another";

(c) in sub-paragraph (3), omit the words from "the competent" to the end;

(d) in sub-paragraph (4), omit the words from ",the competent" to "the Agency,".

(29) In paragraph 61—

(a) in sub-paragraph (1), omit the words from "the Agency" to "member State) and";

(b) in sub-paragraph (2), omit the words from "but must" to the end;

(c) omit sub-paragraphs (3) and (4).

(30) In paragraph 62, omit "or by the competent authority of any member State".

(31) In paragraph 63(3), omit the words from "or, if" to the end.

(32) In paragraph 64—

(a) in sub-paragraph (1)(f), omit "in other member States";

(b) in sub-paragraph (3), for the words from "that appears" to the end substitute "for which a maximum residue limit has been established under Regulation (EC) No 470/2009 of the European Parliament and of the Council.";

(c) omit sub-paragraph (4).

(33) In Schedule 2—

(a) omit paragraph 6(3) to (5);

(b) in paragraph 11(2)—

(i) for "a third" substitute "another";

(ii) omit "including a product manufactured in a member State";

(iii) omit "in a member State";

(c) in paragraph 11(3)—

(i) after "not apply" insert "where the exporting country has demonstrated equivalent standards to those of the United Kingdom or";

(ii) omit "by the European Union".

(34) In Schedule 4—

(a) in paragraph 1—

(i) in sub-paragraph (2)(b)(ii) and (3), for "member State" substitute "country";

(ii) in sub-paragraph (4), for the words from "be listed" to the end substitute "be substances for which a maximum residue limit has been established under Regulation (EC) No 470/2009 of the European Parliament and of the Council";

(b) in paragraph 2—

(i) in sub-paragraph (2), for the words from "specified for" to "No 37/2010" substitute "established for the active substance under Regulation (EC) No 470/2009 of the European Parliament and of the Council";

(ii) in sub-paragraph (3), for the words from "is specified" to "No 37/2010" substitute "has been established";

(c) in paragraph 4, omit the words from "and after" to "of use";

(d) in paragraph 5—

(i) for "a third" substitute "another";

(ii) for "the third" substitute "that other";

(e) in paragraph 6—

(i) in the heading, for "member States" substitute "countries";

(ii) in sub-paragraph (1)—

(aa) in the words before paragraph (a), for "member State" substitute "country with equivalent medicines regulation standards to those of the United Kingdom";

(bb) in paragraph (b), for "member State" substitute "country";

(f) in paragraph 7(1), for "a third" substitute "another".

(35) In Schedule 5—

(a) in paragraph 3(3), for "a third" substitute "another";

(b) omit paragraph 27;

(c) in paragraph 28—

(i) in the heading, for "member States" substitute "countries";

(ii) in the words before sub-paragraph (a), for "member State" substitute "country";

(iii) omit sub-paragraph (a) (together with the final "and");

(d) in paragraph 29(1), omit "member State or third";

(e) in paragraph 31, omit sub-paragraph (w).

(36) In Schedule 6, in paragraph 3—

(a) renumber the existing text as sub-paragraph (1);

(b) in that sub-paragraph, omit paragraphs (b) and (c);

(c) after that sub-paragraph insert—

"(2) Sub-paragraph (1) does not apply where appropriate arrangements have been made with the exporting country to ensure that the manufacturer of the veterinary medicinal product applies standards of good manufacturing practice at least equivalent to those laid down in Commission Directive 91/412/EEC(**3**).".

The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (England and Scotland) Regulations 2015

4.—(1) The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (England and Scotland) Regulations 2015(**4**) are amended as follows.

(2) In regulation 2(1)—

(a) omit the definition for "Regulation 37/2010";

(b) for the definition of "Table 1" (including the definition of "Table 1 substance") substitute—

""Table 1 substance" means a substance classified under Article 14(2)(a), (b) or (c) of Regulation 470/2009;";

(c) for the definition of "Table 2 substance" substitute—

""Table 2 substance" means a substance classified under Article 14(2)(d) of Regulation 470/2009;";

(d) in the definition of "unauthorised substance", for "EU legislation" substitute "retained EU law";

(e) for the definition of "unlicensed substance" substitute—

""unlicensed substance" means a substance—

(a) for which a maximum residue limit has been established under Regulation 470/2009, and

(b) which has been—

(**3**) OJ No L 228, 17.8.1991, p.70.
(**4**) S.I. 2015/787.

(i) administered (or is intended for administration) in the United Kingdom to an animal or a batch of animals, or

(ii) administered to an animal outside the United Kingdom,

where at the time of administration neither that substance, nor any product containing it, was authorised for use in that animal in that country of administration;".

(3) For regulation 2(2) substitute—

"(2) For the purpose of ascertaining whether the maximum residue limit established for a pharmacologically active substance has been exceeded for the purposes of these Regulations—

(a) the presence of the drug or drug metabolite (or combination thereof) as specified in the marker residue for that pharmacologically active substance is to be taken to indicate the presence of that substance in that part of an animal or batch of animals, or in any animal product derived from that part of an animal or batch of animals, as specified in the target tissues for that substance;

(b) the maximum residue limit (if any) corresponding to that substance is to apply in respect of the presence in such part of an animal or batch of animals, or in any animal product derived from such part of an animal or batch of animals, of any such drug or drug metabolite (or combination thereof) as if it were that substance.".

(4) In regulation 2(4)—

(a) for "96/22," substitute "96/22 or";

(b) omit "or Regulation 37/2010".