#### 2018 No. 000

#### **EXITING THE EUROPEAN UNION**

#### ANIMALS

#### ANIMAL HEALTH

### The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2018

Sift requirements satisfied	*:	**
Made	*:	**
Laid before Parliament	*:	**
Coming into force in accordance with	regulation 1	

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(a).

The requirements of paragraph 3(2) of Schedule 7 to the Act (relating to the appropriate Parliamentary procedure for these Regulations) have been satisfied.

#### **Citation and commencement**

**1.** These Regulations may be cited as the Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2018 and come into force on exit day.

## Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies

**2.**—(1) Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies is amended as follows.

(2) In Article 3-

- (a) in paragraph 1—
  - (i) in point (b), omit "in the Community";
  - (ii) in point (e)-
    - (aa) for "Member State" substitute "constituent nation";

<sup>(</sup>**a**) 2018 c.16.

- (bb) omit from the words "it shall" to the end;
- (iii) after point (p), insert-
- "(q) constituent nation: one of the following nations of the United Kingdom: England, Wales, Scotland or Northern Ireland;
- (r) OIE: the World Organisation for Animal Health.";
- (b) after paragraph 1, insert—
  - "1A. In this Regulation, "appropriate authority" means:
  - (a) in relation to England, the Secretary of State;
  - (b) in relation to Wales, Welsh Ministers;
  - (c) in relation to Scotland, Scottish Ministers;
  - (d) in relation to Northern Ireland, the Department of Agriculture, Environment and Rural Affairs.
  - 1B. But the appropriate authority is the Secretary of State if consent is given by:
  - (a) in relation to Wales, the Welsh Ministers;
  - (b) relation to Scotland, Scottish Ministers;
  - (c) in relation to Northern Ireland, the Department of Agriculture, Environment and Rural Affairs.".

(3) In Article 5—

- (a) in paragraph 1—
  - (i) for the first subparagraph substitute—
  - "1. The BSE status of countries and regions as categorised by the OIE is—
  - (a) negligible risk,
  - (b) controlled risk, or
  - (c) undetermined risk,

and, as at exit day, the BSE status for each of the constituent nations is established by Commission Decision 2007/453.";

(ii) omit the third subparagraph;

- (b) omit paragraphs 2 to 5;
- (c) for paragraph 6 substitute-

"6. Exporting countries that are eligible for inclusion in the list of countries or regions approved for the import into the United Kingdom of live animals or of the products covered by this Regulation must be categorised with regard to BSE status that takes into account the criteria and potential risk factors set out in paragraph 1, and any statistical survey of the epidemiological situation regarding TSEs in the country on the basis of the use, in a screening procedure, of rapid tests. The classification criteria used by the OIE must be taken into account.

Eligibility to import from a third country into the United Kingdom live animals or products of animal origin within scope of this Regulation under conditions determined on their established category must be established as soon as possible, once any epidemiological or other evidence which might lead to a change in BSE status has been analysed by the appropriate authorities.";

- (d) in paragraph 8, for "paragraphs 2, 3, 4, 6 and 7" substitute "this Article".
- (4) In Article 6-
  - (a) in paragraph 1, for "Each Member State" substitute "The appropriate authority";

- (b) in paragraph 2, for the words from the beginning to "Committee," substitute "The Secretary of State must inform the OIE";
- (c) in paragraph 4—
  - (i) in the first sentence, for the words from the beginning to "Commission" substitute "The appropriate authority in Wales, Scotland and Northern Ireland must, where possible, submit to their relevant Assembly or Parliament an annual report";
  - (ii) omit the third sentence.
- (5) In Article 6a-
  - (a) in paragraph 1, for "Member States may" substitute "Appropriate authorities may confer together and with expert scientists to";
  - (b) in paragraph 3, omit the first sentence.

(6) In Article 8—

(a) for paragraph 1 to 2 substitute—

"1. Specified risk material, referred to and listed in Annex 5 and including at least the brain, spinal cord, eyes and tonsils of bovine animals aged over 12 months, and the vertebral column of bovine animals aged over 30 months, must—

- (a) be removed and disposed of in accordance with Annex 5 and with Regulation (EC) No 1069/2009;
- (b) not be imported into the United Kingdom from any country other than a member State.

2. Tissues from animals which have undergone one of the alternative tests listed in Annex 10, which is applied under the conditions provided for in Annex 5, and in relation to which the test results are negative, are not to be regarded as specified risk material.";

- (b) in paragraph 3, for "In Member States or regions thereof," substitute "In parts of the United Kingdom";
- (c) in paragraph 4, for "Community's" substitute "United Kingdom's".
- (7) Omit Article 10.
- (8) In Article 11, for the first two paragraphs substitute-

"Any person who suspects an animal of being infected by a TSE must immediately notify the relevant competent authority.".

- (9) In Article 13—
  - (a) in paragraph 4, omit the words from "in accordance" to the end;
  - (b) omit paragraph 5.
- (10) Omit Article 14.
- (11) In Article 15(1)—
  - (a) in the first sentence, after "export" insert "to a member State";
  - (b) in the second sentence, for "Community" substitute "EU retained".
- (12) In Article 16-
  - (a) in paragraph 1, in the words before point (a), after "export" insert "to a member State";
  - (b) in paragraph 2, for "third country" substitute "country or region";
  - (c) in paragraph 3, in the second subparagraph, for the words from "dispatched from" to "country" substitute "imported from a country or region";
  - (d) in paragraph 6, omit "into the Community".
- (13) For Article 17 substitute—

#### "Article 17

#### Health certificates

Appropriate health certificates relating to trade in the semen, embryos and ova of bovine, ovine or caprine animals, and appropriate commercial documents relating to trade in products of animal origin must be supplemented, where necessary, by a reference to the category specifying the BSE classification.".

(14) For Article 18 substitute-

#### "Article 18

#### Supplementation of health certificates

The appropriate health certificates relating to imports must be supplemented in respect of the BSE classification of any country by the specific requirements laid down in Annex 9, as soon as that classification is confirmed.".

(15) For Article 19 substitute—

#### "Article 19

#### National reference laboratory

The functions and duties of the United Kingdom's national reference laboratory at Woodham Lane, New Haw, Addlestone, Surrey KT15 3NB are set down in Annex 10, Chapter A.".

(16) Omit Articles 21, 22 and 25.

(17) After Article 26, omit the words from "This Regulation" to "Member States.".

(18) In Annex 2, in Chapter A, in the first paragraph, omit "Member States or third".

(19) Annex 3 is amended in accordance with paragraphs (20) to (26).

- (20) Chapter A is amended in accordance with paragraphs (21) to (23).
- (21) In Part 1 (monitoring in bovine animals)-
  - (a) in point 5, for the words from "Member States" to "territory" substitute "the appropriate authority may test other bovine animals";
  - (b) omit point 7.
- (22) In Part 2 (monitoring in ovine and caprine animals)-
  - (a) in point 2—
    - (i) in point (a)—
      - (aa) for the words from the beginning to "point 4," substitute "The appropriate authorities shall test";
      - (bb) at the end insert "within the United Kingdom";
    - (ii) omit point (b);
    - (iii) in point (c), in the words before the first indent, for "A Member State" substitute "The Secretary of State, with the consent of the other appropriate authorities,";
  - (b) in point 3—
    - (i) in the words before the first indent, for "Member States" substitute "The appropriate authorities";
    - (ii) in Tables A and B, in the heading of column 1, omit "Member State";
  - (c) in point 6, in the words before the first indent, for "Member States" substitute "the appropriate authority";
  - (d) in point 8, in the first sentence, for "Commission" substitute "appropriate authority, which must immediately notify the other appropriate authorities".
- (23) In Part 3 (monitoring in cervids)-
  - (a) omit chapter A;

(b) for Chapter B substitute—

#### "Monitoring in cervids

The appropriate authority may carry out monitoring for TSEs in cervids.".

- (24) Chapter B is amended in accordance with paragraphs (25) to (26).
- (25) In Part 1-
  - (a) in the heading, for "Member States" substitute "appropriate authorities";
  - (b) in Section A-
    - (i) in the heading, for the words from "Member States" to the end substitute "appropriate authorities in their annual report";
    - (ii) in point 2, for "Article 12(2)" substitute "Article 12";
    - (iii) in point 3, for "Article 12(1) and (2) substitute "Article 12";
    - (iv) omit point 9;
  - (c) omit Section B.
- (26) Omit Part 2 (information to be presented in the Union summary report).

(27) Annex 4 is amended in accordance with paragraphs (28) to (32).

(28) In Chapter 3, in Section C, in the words before point (a), omit "for free circulation in the Union".

- (29) In Chapter 4, in Section E, in point (e), omit "for free circulation in the Union".
- (30) Chapter 5 is amended in accordance with paragraphs (31) to (32).
- (31) In Section A, for "Member States" substitute "The appropriate authority".
- (32) In Section E—
  - (a) in point 1—
    - (i) in point (a), omit the words from "from the Union" to the end;
    - (ii) in point (c), in the last paragraph, for the words from "TRACES, the" to "arrival" substitute "the United Kingdom's Import Control System, the competent authority responsible for the end destination establishment";
    - (iii) in point (d), omit ", through TRACES";
  - (b) in point 3—
    - (i) in point (b)(ii)—
      - (aa) in the first and second indents, omit "from the Union";
      - (bb) in the second indent, omit "in the Union";
      - (ii) in point (c), for "Union legislation", in both places it occurs, substitute "retained EU law";
      - (iii) in point (d), in the first and second paragraphs, omit "from the Union";
  - (c) in point 4(f), omit "third".
- (33) Annex 5 is amended in accordance with paragraphs (34) to (43).

(34) In point 1, in the words before point (a), for the words from "Member State" to "their" substitute "country or a".

- (35) In point 2-
  - (a) in the heading, for "Member States" substitute "countries";
  - (b) for "Member States" substitute "a country".

(36) In point 4, in point 4.3, in the words before point (a), for "Member States" substitute "the appropriate authority".

(37) In point 5, omit "in all member States".

(38) In point 6-

- (a) for "Member States, or regions thereof," substitute "parts of the United Kingdom";
- (b) for the second reference to "Member States" substitute "parts of the United Kingdom".
- (39) In point 7, for "Member States" substitute "parts of the United Kingdom".
- (40) In point 8, in point 8.2-
  - (a) in the first sentence, for "Member States may decide" substitute "nothing in this Regulation prevents the appropriate authority from deciding";
  - (b) omit the second sentence.

(41) In point 9, in the words before point (a), for "Member States may decide" substitute "nothing in this Regulation prevents the appropriate authority from deciding".

- (42) In point 10-
  - (a) in point 10.1—
    - (i) for "Member States" substitute "The appropriate authority";
    - (ii) for "another" substitute "a";
  - (b) in point 10.2, for "from one" to the end, substitute "to a member State provided prior notification is provided to the relevant authority in that member State of the proposal to export material of this description";
  - (c) in point 10.3, for "Community" substitute "European Union".
- (43) In point 11-
  - (a) in points 11.1 and 11.2, for "Member States" substitute "The appropriate authority";
  - (b) in point 11.3(a), omit the sentence beginning "Until 30 June".
- (44) Annex 7 is amended in accordance with paragraphs (45) to (54).
- (45) In Chapter A-
  - (a) in the first paragraph, omit "in a member State";
  - (b) in the second paragraph, for "Member State" substitute "appropriate authority".
- (46) Chapter B is amended in accordance with paragraphs (47) to (53).
- (47) In point 2.1, for "Member State" substitute "appropriate authority".
- (48) In point 2.2.2—
  - (a) in the words before point (a), for "Member State" substitute "appropriate authority";
  - (b) in point (a)—
    - (i) in the second paragraph, for the words from "territory of" to the end substitute "United Kingdom";
    - (ii) in the last paragraph, for "Member State" substitute "appropriate authority";
  - (c) in point (b)—
    - (i) in the fourth paragraph, in the words before point (i), for "Member States may decide" substitute "nothing in this Regulation prevents the appropriate authority from deciding";
    - (ii) in point (i), in the first indent, for the words from "territory of" to the end substitute "United Kingdom";
  - (d) in point (c)—
    - (i) in the first paragraph, in the fourth indent, for "Member State" substitute "appropriate authority";
    - (ii) in the third paragraph, in the words before point (i), for "Member States may decide" substitute "nothing in this Regulation prevents the appropriate authority from deciding";

- (iii) in point (i) in the first indent, for the words from "territory of" to the end substitute "United Kingdom";
- (iv) in point (iii) and in the penultimate paragraph, for "Member State", in each place it occurs, substitute "appropriate authority";
- (e) in point (d)—
  - (i) in the first paragraph—
    - (aa) in the words before point (a), for "A Member State" substitute "The appropriate authority";
    - (bb) in the fourth indent, for "Member State" substitute "appropriate authority";
  - (ii) in the second paragraph, for "Member States" substitute "appropriate authority";
  - (iii) in the third paragraph, for "Member State", in both places it occurs, substitute "appropriate authority".
- (49) In point 2.3—
  - (a) in point (a), for "a Member State" substitute "the appropriate authority";
  - (b) in points (b) and (c), for "Member States" substitute "the appropriate authority".
- (50) In point 3.4-
  - (a) in point (b), for "Member State", in both places it occurs, substitute "appropriate authority";
  - (b) in point (c)—
    - (i) in the words before the first indent, for "Member State" substitute "appropriate authority";
    - (ii) in the second indent, for "territory of the same Member State" substitute "United Kingdom".

(51) In the following provisions, for "a Member State may allow" substitute "nothing in this Regulation prevents the appropriate authority from allowing"—

- (a) point 4.2(b), in the second paragraph, in the words before point (i);
- (b) point 4.3(c), in the second paragraph, in the words before point (i).
- (52) In point 4.4(b)-
  - (a) in the words before point (i), for "Member State" substitute "appropriate authority".
  - (b) in point (ii), for "territory of the same Member State" substitute "United Kingdom".
- (53) In points 4.5 and 4.6, for "Member State" substitute "appropriate authority".
- (54) In Chapter C—
  - (a) in Part 1—
    - (i) in point 1, in the second paragraph, for "Member States" substitute "the appropriate authority";
    - (ii) in point 6, omit "of the Member State";
    - (iii) in point 8-
      - (aa) in the words before point (a), for "Member State" substitute "appropriate authority", and omit "of the Member State";
      - (bb) in point (b), omit "determined by the Member State";
  - (b) in Part 2—
    - (i) in point 3, for "Member States may decide" substitute "Nothing in these Regulations prevents the appropriate authority from deciding";
    - (ii) omit point 4.
  - (c) in Part 4, point (1)(b), in the second paragraph, for "Member States" substitute "The appropriate authority";

- (d) omit Part 5.
- (55) Annex 8 is amended in accordance with paragraphs (56) to (63).
- (56) Chapter A is amended in accordance with paragraphs (57) to (61).
- (57) In the heading, omit "intra-Union".
- (58) Section A is amended in accordance with paragraphs (59) to (60).
- (59) In point 1-
  - (a) in point 1.1—
    - (i) omit "intra-Union";
    - (ii) for "Member States" substitute "the appropriate authority";
  - (b) in point 1.2, in the second paragraph—
    - (i) in point (c)(iv), in the first indent, for the words from "in accordance" to the end substitute "and supervised";
    - (ii) in point (d), omit "from 1 January 2014";
    - (iii) in point (f)—
      - (aa) omit the first paragraph;
      - (bb) in the second paragraph, omit "From 1 January 2014,";
      - (cc) in the third paragraph, for "first and second paragraphs of point (f), Member States may decide" substitute "second paragraph of point (f), nothing in this Regulation prevents the appropriate authority from deciding";
    - (iv) in the words before point (g), omit "from 1 January 2014";
    - (v) in points (g)(i) and (h)(i), for "Member State" substitute "country or region";
  - (c) in point 1.3—
    - (i) in point (c)(iv), in the first indent, for the words from "in accordance" to the end substitute "and supervised";
    - (ii) in point (d), omit "from 1 January 2014";
    - (iii) in point (f)—
      - (aa) omit the first paragraph;
      - (bb) in the second paragraph, omit "From 1 January 2014,";
      - (cc) in the third paragraph, for "first and second paragraphs of point (f), Member States may decide" substitute "second paragraph of point (f), nothing in this Regulation prevents the appropriate authority from deciding";
    - (iv) in the words before point (g), omit "from 1 January 2014";
    - (v) in points (g)(i) and (h)(i), for "Member State" substitute "country or region";
  - (d) in point 1.4, in the second paragraph—
    - (i) for "Member State" substitute "appropriate authority";
    - (ii) for "the other Member States" substitute "other countries";
- (60) Omit points 2 to 4.
- (61) In Section B-
  - (a) for "United Kingdom" substitute "appropriate authority";
  - (b) omit "other".
- (62) In Chapter C, in the heading, omit "intra-Community".
- (63) Omit Chapter D.
- (64) In Annex 9—
  - (a) in Chapter E—
    - (i) in the opening paragraph, for "Union" substitute "United Kingdom";

- (ii) in point 5, in the words before point (a), for "the Union and intended for Member States" substitute "parts of the United Kingdom";
- (iii) in point 6, in the words before point (a), for "the Union and intended for a Member State" substitute "parts of the United Kingdom";
- (b) in Chapter F, in points 1 and 2, for "Union" substitute "United Kingdom";
- (c) in Chapter H, in the words before point (1), for "Union" substitute "United Kingdom".
- (65) Annex 10 is amended in accordance with paragraphs (66) to (74).
- (66) In Chapter A-
  - (a) in point 1—
    - (i) in point (a), omit the second sentence;
    - (ii) in point (c), for "Member State", in each place it occurs, substitute "United Kingdom";
    - (iii) omit point (d);
  - (b) omit point 2;
  - (c) for point 3 substitute—

"3. The national reference laboratory for the United Kingdom is the Weybridge laboratory at Woodham Lane, New Haw, Addlestone, Surrey KT15 3NB.".

- (67) Omit Chapter B.
- (68) Chapter C is amended in accordance with paragraphs (69) to (74).
- (69) In point 1, in the second paragraph—
  - (a) in the first sentence, omit "and the guidelines of the EU reference laboratory";
  - (b) in the second sentence, omit the words from ", and be processed" to the end.
- (70) Point 3 is amended in accordance with paragraphs (71) to (73).
- (71) In point 3.1-
  - (a) in point (a), in the third paragraph, in the words before point (i), omit the words from "according to" to "test)";
  - (b) in point (b) in the fourth paragraph, in the words before point (i), omit the words from "according to" to "test)";
  - (c) in point (c), for the words from "which has" to the end substitute "where they must be further tested by a two-blot method for the provisional classification of bovine TSE isolates".

(72) In point 3.2-

- (a) in point (b), in the second paragraph, in the first sentence, for "an" substitute "the relevant";
- (b) in point (c)-
  - (i) in point (i), omit the words "listed in" to the end;
  - (ii) for point (ii) substitute—

#### "(ii) Secondary molecular testing with additional molecular testing methods

In TSE cases in which the presence of BSE cannot be excluded by the primary molecular testing referred to in point (i), the samples must be submitted to further investigation and confirmation by at least one alternative method, differing immunochemically from the original primary molecular method, depending on the volume and nature of the referred material. These additional tests will be carried out by the national reference laboratory.";

- (iii) in point (iii)—
  - (aa) in the first paragraph, omit the words from ", which will" to the end;

- (bb) omit the second paragraph.
- (73) In point 3.3, omit the second paragraph.
- (74) In point 4-
  - (a) in the penultimate paragraph—
    - (i) in the first sentence, omit "has been approved by the EU reference laboratory and";
    - (ii) omit the second sentence;
  - (b) in the final paragraph—
    - (i) in the first sentence, for the words from "after prior" to "finds that" substitute "if";
    - (ii) omit the second sentence.

### Commission Decision 2007/453/EC establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk

**3.**—(1) Commission Decision 2007/453/EC establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk is amended as follows.

(2) In Article 1-

- (a) the existing text becomes paragraph 1;
- (b) after that paragraph, insert—

"2. However, the official United Kingdom BSE status for England, Northern Ireland, Scotland and Wales is categorised by reference to the website of the OIE, as amended from time to time."

- (3) Omit Article 3.
- (4) In the Annex—
  - (a) in Part A, omit—
    - (i) the sub-heading "Regions of Member States";
    - (ii) the entries for Northern Ireland and Scotland;
  - (b) in Part B, omit the entry for the United Kingdom;
  - (c) in Part C, after "B", insert ", other than the regions of the constituent nations, which have an official BSE risk status determined by their categorisation by the OIE".

### Commission Decision 2009/719/EC authorising certain Member States to revise their annual BSE monitoring programmes

**4.**—(1) Commission Decision 2009/719/EC authorising certain Member States to revise their annual BSE monitoring programmes is amended as follows.

(2) For Article 1 substitute—

"1. The appropriate authority may revise their annual monitoring programmes as provided for in Article 6(1b) of Regulation (EC) No 999/2001.

- 2. In this Decision, "appropriate authority" means:
- (a) in relation to England, the Secretary of State;
- (b) in relation to Wales, the Welsh Ministers;
- (c) in relation to Scotland, the Scottish Ministers;
- (d) in relation to Northern Ireland, the Department of Agriculture, Environment and Rural Affairs.".
- (3) In Article 2-
  - (a) in paragraph 1, in the words before point (a), for "Member States" substitute "countries and territories";

- (b) in paragraph 2—
  - (i) for "Member States" substitute "countries or territories";
  - (ii) for the words from "in another" to "performed" substitute ", the age limits for testing in force in the United Kingdom".
- (c) in paragraph 3, for the words from "from 1 January" to "Annex" substitute "the appropriate authority".
- (4) Omit Articles 3 and 4.
- (5) In the Annex, in the heading, for "Member States" substitute "countries".

## Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption

**5.**—(1) Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption is amended as follows.

(2) In the Regulation, for "Community legislation", in each place it occurs (other than in Articles 5(1) and 34(2)), substitute "retained EU law".

- (3) In Article 2-
  - (a) in paragraph 2—
    - (i) in point (g)(i), for "internationally" substitute "outside the British Islands and the European Union";
    - (ii) in point (h), omit "without prejudice to Community environmental legislation,";
  - (b) omit paragraph 3.
- (4) In Article 3-
  - (a) in paragraph 10, for "Member State" substitute "constituent nation";
  - (b) in each of paragraphs 14, 15 and 16, for "Community" substitute "United Kingdom";
  - (c) in paragraph 21, for "Directive 1999/31/EC" substitute "the Environmental Permitting (England and Wales) Regulations 2016(a), the Pollution Prevention and Control (Scotland) Regulations 2012(b) or the Pollution Prevention and Control (Industrial Emissions) Regulations (Northern Ireland) 2013(c)";
  - (d) after paragraph 27 insert-

"28. 'constituent nation' means England, Wales, Scotland or Northern Ireland;

29. 'third country' means a country other than the British Islands;

30. 'the England Trade Regulations' means the Trade in Animals and Related Products Regulations 2011(d);

31. 'the Wales Trade Regulations' means the Trade in Animals and Related Products (Wales) Regulations 2011(e);

32. 'the Scotland Trade Regulations' means the Trade in Animals and Related Products (Scotland) Regulations 2012(**f**);

<sup>(</sup>a) S.I. 2016/1154, amended by S.I. 2017/1012, 1075, 2018/110, 428, 575 and 721.

<sup>(</sup>b) S.S.I. 2012/360, amended by S.S.I. 2014/267, 469, 2015/100, 101, 188, 438, 2016/39, 2017/446, S.I. 2014/469, 2015/483 and 1973.

<sup>(</sup>c) S.R. 2013 No. 160, amended by S.R. 2018 No. 33, 2016 Nos. 95, 309, 2015 Nos. 14, 325, 2014 No. 304 and S.I. 2015/1973.
(d) S.I. 2011/1197, amended by S.I. 2012/2897, 2013/2996, 2014/3158, 2018/575 and 1037.

<sup>(</sup>e) S.I. 2011/2379 (W. 252), amended by S.I. 2014/3158.

<sup>(</sup>f) S.S.I. 2012/177, amended by S.S.I. 2012/198, 199, 2015/100, 401 and S.I. 2014/3158.

33. 'the Northern Ireland Trade Regulations' means the Trade in Animals and Related Products Regulations (Northern Ireland) 2011(**a**);

34. 'the Trade Regulations' means the England Trade Regulations, the Wales Trade Regulations, the Scotland Trade Regulations or the Northern Ireland Trade Regulations, as the case may be.".

(5) After Article 3 insert—

#### "Article 3A

#### **Definition: appropriate authority**

- 1. In this Regulation "the appropriate authority" means—
- (a) in relation to England, the Secretary of State;
- (b) in relation to Wales, the Welsh Ministers;
- (c) in relation to Scotland, the Scottish Ministers;
- (d) in relation to Northern Ireland, the Department of Agriculture, Environment and Rural Affairs.
- 2. But the appropriate authority is the Secretary of State if consent is given by—
- (a) in relation to Wales, the Welsh Ministers;
- (b) in relation to Scotland, the Scottish Ministers;
- (c) in relation to Northern Ireland, the Department of Agriculture, Environment and Rural Affairs.".
- (6) In Article 4-
  - (a) in each of paragraphs 3 and 4, for "Member States" substitute "The appropriate authority";
  - (b) in paragraph 5—
    - (i) for "Member States", in the first place it occurs, substitute "The appropriate authority";
    - (ii) for "Member States", in the second place it occurs, substitute "appropriate authorities".
- (7) In Article 5(1), in the first subparagraph—
  - (a) omit "Community";
  - (b) for "that Article" substitute "Article 34(1)".

(8) In Article 6(1)(a), for "Community veterinary legislation" substitute "veterinary retained EU law".

- (9) In Article 8—
  - (a) in point (c), at the end insert "in each case, reading those Articles as if for references to "Community legislation" there were substituted references to "retained EU law"";
  - (b) in point (d), after "thereof, by" insert "other";
  - (c) in point (f), for "internationally" substitute "outside the British Islands and the European Union".
- (10) In Article 9—
  - (a) in point (c), for "as referred to in Article 15(3) of Directive 96/23/EC" substitute "set by retained EU law or, in the absence thereof, by other national legislation";
  - (b) in point (e)—
    - (i) in point (i)-

<sup>(</sup>a) S.R. 2011 No. 438, amended by S.R. 2014 No. 196 and 2015 No. 282.

- (aa) for "Community veterinary legislation" substitute "veterinary retained EU law";
- (bb) for "Community", in the second place it occurs, substitute "United Kingdom";
- (cc) at the end of the sentence, omit "or";
- (ii) omit point (ii).
- (11) Omit Article 15(2).
- (12) In Article 19-
  - (a) in paragraph 2, for "Member State concerned" substitute "United Kingdom";
  - (b) in paragraph 3—
    - (i) for "Member States" substitute "The Secretary of State and the devolved authorities";
    - (ii) for "the Commission" substitute "each other".
- (13) In Article 21-
  - (a) in paragraph 2, for "same Member State" substitute "United Kingdom";
  - (b) in paragraph 3, for "Member State", in each place it occurs, substitute "constituent nation";
  - (c) for paragraph 4 substitute—

"4. Operators must collect, transport and dispose of Category 3 catering waste so as to ensure that waste management is carried out without endangering human health, without harming the environment and, in particular:

- (a) without risk to water, air, soil, plants or animals;
- (b) without causing a nuisance through noise or odours; and
- (c) without adversely affecting the countryside or places of special interest.".

(14) In Article 24(1), in each of points (b) and (c), for "Directive 2000/76/EC" substitute "the Environmental Permitting (England and Wales) Regulations 2016, the Pollution Prevention and Control (Scotland) Regulations 2012 or the Pollution Prevention and Control (Industrial Emissions) Regulations (Northern Ireland) 2013".

(15) In Article 26(3), for "Community veterinary legislation" substitute "veterinary retained EU law".

(16) In Article 32(1), in the third subparagraph, for "Member States may adopt or maintain national rules" substitute "Nothing in this Regulation prevents the appropriate authority from".

(17) In Article 33, in point (a), for "Article 1(1) of Directive 76/768/EEC" substitute "Article 2(1)(a) of Regulation 1223/2009/EC".

- (18) In Article 34—
  - (a) in the first subparagraph of paragraph 1, for "the Community legislation referred to in that Article." substitute "the following:";
  - (b) after the first subparagraph of paragraph 1, insert—

"(a) Regulation 1223/2009/EC in the case of cosmetic products;

- (b) the Medical Devices Regulations 2002(**a**) in the case of active implantable medical devices, medical devices and in vitro diagnostic medical devices;
- (c) the Veterinary Medicines Regulations 2013(b) in the case of veterinary medicinal products;
- (d) the Human Medicines Regulations 2012(a) in the case of medicinal products.";

 <sup>(</sup>a) S.I. 2002/618, amended by S.I. 2003/1697, 1400, 2005/2909, 2007/400, 610, 803, 2005/2759, 2008/530, 2936, 2009/383, 2012/1426, 2013/525, 2327 and 2017/207.

<sup>(</sup>**b**) S.I. 2013/2033, amended by S.I. 2014/599 and 2018/761.

- (c) in paragraph 2—
  - (i) omit "Community";
  - (ii) for "Article 33" substitute "paragraph 1(a) to (d)".

(19) In Article 37(1), in point (c), for "Community" substitute "United Kingdom".

(20) In Article 41-

- (a) in paragraph 1, in the first subparagraph—
  - (i) in the words before point (a), for "Community" substitute "United Kingdom";
  - (ii) in point (a), for "Community" substitute "United Kingdom".
  - (iii) in point (b), after "legislation;" omit "or";
  - (iv) in point (c), after "Articles;" insert "or";
  - (v) after point (c), insert—
  - "(d) in the case of Category 1 material, Category 2 material and meat-and-bone meal or animal fat derived from Category 1 and Category 2 materials, from the European Union, the requirements of Article 48.";
- (b) in paragraph 2(c), after "only take place" insert "in accordance with Article 48";
- (c) in paragraph 4, in the last subparagraph, for "Commission and the Member States" substitute "appropriate authority".
- (21) In Article 43-
  - (a) in paragraph 1, after "export" insert "other than to the European Union";
  - (b) in paragraph 2, after "third countries" insert "outside the European Union";
  - (c) in paragraph 4, for "Community" substitute "United Kingdom".
- (22) In Article 47(1)-
  - (a) in the first subparagraph—
    - (i) for "Each Member State" substitute "The appropriate authority";
    - (ii) for "territory" substitute "constituent nation";
  - (b) in the third subparagraph, for "Member States" substitute "The appropriate authority";
  - (c) omit the fourth subparagraph.
  - (d) in the fifth subparagraph—
    - (i) for "Member States", in the first place it occurs, substitute "The appropriate authority";
    - (ii) after "operators" insert "in their constituent nation";
    - (iii) for "other Member States" substitute "the other appropriate authorities".
- (23) In Article 48-
  - (a) in the heading, for "to other Member States" substitute "from the European Union to the United Kingdom";
  - (b) in paragraph 1—
    - (i) in the first subparagraph, for the words from "to another Member State" to the end, substitute "from the European Union to the United Kingdom, it shall inform the competent authority of the constituent nation of destination";
    - (ii) in the second subparagraph, for "Member State" substitute "constituent nation";
  - (c) omit paragraph 3;
  - (d) in paragraph 5—

 <sup>(</sup>a) S.I. 2012/1916, amended by S.I. 2012/1916, 2013/235, 898 (W. 102), 1855, 2593, 2014/323, 324, 490, 1878, 2015/178, 259, 323, 354, 570, 895, 903, 1503, 1862, 1879, 2016/186, 407, 696, 2017/241, 1322, 2018/64, 121, 199 and 378.

- (i) in the first subparagraph—
  - (aa) for "to other Member States" substitute "from the European Union to the United Kingdom";
  - (bb) after "third country" insert "other than a member State";
- (ii) in the second subparagraph—
  - (aa) for "re-enter the Community" substitute "enter the United Kingdom";
  - (bb) for "Article 6 of Directive 89/662/EEC" substitute "the Trade Regulations";
- (e) in paragraph 6, for "to other Member States" substitute "from the European Union to the United Kingdom".
- (24) Omit Article 49.
- (25) In Article 50-
  - (a) in paragraph 1, for "Community" substitute "United Kingdom";
  - (b) in paragraph 3, for "Member States" substitute "the United Kingdom".
- (26) Omit Article 51.
- (27) Omit Article 53.
- (28) In Article 56, omit the third and fourth paragraphs.
- (29) After Article 56, omit the words from "This Regulation" to "Member States.".

# Commission Regulation (EU) No 142/2011 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive

**6.**—(1) Commission Regulation (EU) No 142/2011 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive is amended as follows.

(2) In the Regulation, for "Union legislation", in each place it occurs, substitute "retained EU law".

(3) In Article 3, in the words before point (a), after "imported" insert "from a third country outside the European Union".

- (4) In Article 4-
  - (a) for "Article 1.2.3 of the Terrestrial Animal Health Code, 2010" substitute "Chapter 1.3 of the Terrestrial Animal Health Code, 2018(a)";
  - (b) for "Aquatic Animal Health Code, 2010" substitute "Aquatic Animal Health Code, 2018(b)";
- (5) Omit Article 5(1).
- (6) In Article 6-
  - (a) in paragraph 1, in each of points (a) and (b), for "Directive 2000/76/EC" substitute "the Environmental Permitting (England and Wales) Regulations 2016, the Pollution

<sup>(</sup>a) The Terrestrial Animal Health Code 2018 is freely accessible online (http://www.oie.int/standard-setting/terrestrial-code/access-online) or available to order in hard copy from the OIE online bookshop (at http://web.oie.int/boutique/index.php or). The OIE's address is 12, rue de Prony, 75017 Paris, France). A hard copy version is also available to view on request at the offices of the Future Animal & Plant Health, Endemics & Traceability Team at the Department for Environment, Food and Rural Affairs, Seacole Building, 2 Marsham Street, London SW1P 4DF.

<sup>(</sup>b) The Aquatic Animal Health Code 2018 is freely accessible online (http://www.oie.int/standard-setting/aquatic-code/access-online) or available to order in hard copy from the OIE online bookshop (http://web.oie.int/boutique/index.php). A hard copy version is also available to view on request at the offices of the Aquatic Animal Health Team at the Department for Environment, Food and Rural Affairs, Seacole Building, 2 Marsham Street, London SW1P 4DF.

Prevention and Control (Scotland) Regulations 2012 or the Pollution Prevention and Control (Industrial Emissions) Regulations (Northern Ireland) 2013";

- (b) in paragraph 8(a), for "authorities of the Member States", in each place it occurs, substitute "authority".
- (7) In Article 11(3), for the words before point (a) substitute—

"3. Operators may dispatch research and diagnostic samples which consist of the following animal by-products and derived products from the European Union to the United Kingdom without the competent authority of the constituent nation of destination being informed and agreeing to accept the consignment in accordance with Article 48(1) of Regulation (EC) No 1069/2009:".

(8) In Article 12(3), for the words before point (a) substitute—

"3. Operators may dispatch trade samples which consist of the following animal byproducts and derived products from the European Union to the United Kingdom without the competent authority of the constituent nation of destination being informed and agreeing to accept the consignment in accordance with Article 48(1) of Regulation (EC) No 1069/2009:

(9) In Article 13, omit paragraphs 1(b) and 2(b).

(10) In Article 15, in the second subparagraph, for "Member States may authorise" substitute "nothing in this Regulation prevents the appropriate authority from authorising".

- (11) In Article 16-
  - (a) in paragraph 1, omit "Member States or";
  - (b) in paragraph 2, for "Member States" substitute "The appropriate authority";
  - (c) in paragraph 3, for "Commission" substitute "appropriate authority".

(12) In Article 19(b)(viii), for "Union veterinary legislation" substitute "veterinary retained EU law".

(13) In Article 21, in each of paragraphs 1 and 2, after "import" insert "from a third country outside the European Union".

(14) In Article 22—

- (a) in paragraph 1, after "import" insert "from a third country outside the European Union";
- (b) in paragraph 2—
  - (i) in point (a), for "Union" substitute "British Islands";
  - (ii) in point (b), after "imported" insert "from a third country outside the European Union";
- (c) in paragraph 3, for "Member State" substitute "constituent nation";
- (d) for paragraph 4, substitute—
  - "4. Where—
  - (a) there is an agreement between the United Kingdom and the Republic of Ireland that manure may be dispatched over the common border between farms located in regions of the common border,
  - (b) the agreement contains appropriate conditions for the control of any possible risks to public or animal health, such as obligations for the operators concerned to keep records, as laid down in the agreement, and
  - (c) an operator intends to dispatch manure in accordance with the agreement,

the duty in Article 48(1) of Regulation (EC) No 1069/2009 to inform the competent authority does not apply to the dispatch.";

(e) in paragraph 5, for "authorities of the Member States" substitute "authority".

(15) In Article 23(1), for "Union" substitute "United Kingdom from a third country outside the European Union".

(16) In Article 24-

- (a) in paragraph 2, after "imported" insert "from a third country outside the European Union";
- (b) in each of paragraphs 3 and 4, after "import" insert "from a third country outside the European Union".
- (17) Article 25 is amended in accordance with paragraphs (18) to (22).

(18) In the heading, for ", transit" substitute "and transit from a third country outside the European Union".

(19) In paragraph 1, for "Union" substitute "United Kingdom from a third country outside the European Union".

(20) In paragraph 2—

- (a) in the words before point (a), for "Union" substitute "United Kingdom from a third country outside the European Union";
- (b) in point (e)—
  - (i) in point (i)—
    - (aa) after "third country" insert "United Kingdom kept in the European Union or a third country outside the European Union";
    - (bb) in the first indent, for "Union" substitute "United Kingdom";
  - (ii) in point (iii)—
    - (aa) for "Union" substitute "United Kingdom";
    - (bb) for "Article 4(3) of Directive 97/78/EC" substitute "the Trade Regulations".

(21) In paragraph 3, for "Union" substitute "United Kingdom from a third country outside the European Union".

- (22) In paragraph 4, for "Union" substitute "United Kingdom".
- (23) In Article 26-
  - (a) in the words before point (a), after "Directive 96/23/EC," insert "in both cases, reading those Articles as if for references to "Community legislation" there were substituted references to "retained EU law";
  - (b) in point (b)(iii), in the first indent, for "Article 1(1) of Directive 76/768/EEC" substitute "Article 2(1)(a) of Regulation (EC) No 1223/2009".

(24) In Article 27-

- (a) in the heading, after "transit" insert "from a third country outside the European Union";
- (b) in paragraph 1—
  - (i) in the first subparagraph, after "transit" insert "from a third country outside the European Union";
  - (ii) in point (a), for "Member State" substitute "constituent nation";
  - (iii) in point (b), for "Union" substitute "United Kingdom";
- (c) omit paragraph 2;
- (d) in paragraph 3, after "samples", in the second place it occurs, insert "from a third country outside the European Union".
- (25) In Article 28-
  - (a) in the heading, after "transit" insert "from a third country outside the European Union";
  - (b) in paragraph 1, after "transit" insert "from a third country outside the European Union";
  - (c) in paragraph 2, after "samples", in the first place it occurs, insert "from a third country outside the European Union";

- (d) in paragraph 3, after "transit" insert "from a third country outside the European Union";
- (e) in paragraph 4, after "items", in the first place it occurs, insert "from a third country outside the European Union".
- (26) Omit Articles 29 and 29a.
- (27) In Article 30, in the first subparagraph—
  - (a) for "TRACES system" substitute "Import Control System";
  - (b) for "Commission" substitute "appropriate authority".
- (28) In Article 31—
  - (a) in the heading, after "transit" insert "from a third country outside the European Union";
  - (b) in the text—
    - (i) for "Union", in the first place it occurs, substitute "United Kingdom from a third country outside the European Union";
    - (ii) for "Union", in the second place it occurs, substitute "United Kingdom";
    - (iii) for "Directive 97/78/EC" substitute "the Trade Regulations".
- (29) In Article 32-
  - (a) in paragraph 5—
    - (i) after "competent authority" insert "of each constituent nation";
    - (ii) after "operators" insert "in its constituent nation";
  - (b) in paragraph 6—
    - (i) for "Member State" substitute "constituent nation";
    - (ii) for "one of the official languages of that Member State" substitute "English and may also be submitted in other languages".
- (30) In Article 34(c)-
  - (a) after "products" insert "imported into the United Kingdom from the European Union or in transit through the United Kingdom from one member State to another, or";
  - (b) for "Union" substitute "United Kingdom from a third country outside the European Union".
- (31) Omit Article 36.
- (32) After Article 37, omit the words from "This Regulation" to "Member States.".
- (33) In Annex 1-
  - (a) in paragraph 19(b), after "Directive 96/23/EC," insert "in both cases, reading those Articles as if for references to "Community legislation" there were substituted references to "retained EU law";
  - (b) in paragraph 42, for the words from "an incineration plant" to "Directive 2000/76/EC" substitute "a waste incineration plant, as defined in Articles 3(40) and 42(1) of Directive 2010/75/EC"(a);
  - (c) in paragraph 43, for "point 13 of Article 3 of Directive 2000/76/EC" substitute "Article 43 of Directive 2010/75/EC";
  - (d) omit paragraph 48;
  - (e) in paragraph 55, for "as defined in point 5 of Article 3 of Directive 2000/76/EC" substitute "as covered by Article 3(41) and Article 42(1) of Directive 2010/75/EC";
  - (f) in paragraph 56, for "an incineration plant, as defined in point 4 of Article 3 of Directive 2000/76/EC" substitute "a waste incineration plant, as defined in Article 3(40) and Article 42(1) of Directive 2010/75/EC";

<sup>(</sup>**a**) OJ No L 334, 17.12.2010, p.17.

(g) after paragraph 59, insert—

"60. 'Import Control System' means the electronic trade notification system in the United Kingdom which replaces the TRACES system established under Commission Decision 2004/292/EC.".

- (34) In Annex 2, omit Chapter 1.
- (35) In Annex 3-
  - (a) in Chapter 2, in Section 1, in the first paragraph, for "Directive 2000/76/EC" substitute "the Environmental Permitting (England and Wales) Regulations 2016, the Pollution Prevention and Control (Scotland) Regulations 2012 or the Pollution Prevention and Control (Industrial Emissions) Regulations (Northern Ireland) 2013";
  - (b) in Chapter 3—
    - (i) in the first paragraph, for "Directive 2000/76/EC" substitute "the Environmental Permitting (England and Wales) Regulations 2016, the Pollution Prevention and Control (Scotland) Regulations 2012 or the Pollution Prevention and Control (Industrial Emissions) Regulations (Northern Ireland) 2013";
    - (ii) in point (a)(iii)—
      - (aa) for "subject to health restrictions in accordance with Article 4(5) or 5 of Directive 2009/156/EC" substitute "located in a constituent nation which is not considered to be free of African horse sickness in accordance with the final paragraph of this Chapter";
      - (bb) for "Member State" substitute "appropriate authority";
    - (iii) at the end, insert-

"A constituent nation is not considered free of African horse sickness if:

- (a) clinical, serological (in unvaccinated animals) or epidemiological evidence has revealed the presence of African horse sickness in the past two years; or
- (b) vaccination against African horse sickness has been carried out in the past 12 months.";
- (c) in Chapter 5, in head A.2(c), after "853/2004," insert "(EC) No".
- (36) In Annex 4-
  - (a) in Chapter 1, in Section 1, in paragraph 1(a), omit the second subparagraph after point (iv);
  - (b) in Chapter 3, in head G—
    - (i) in paragraph 1(a), for "Member State" substitute "United Kingdom";
    - (ii) omit paragraph 3;
    - (iii) in paragraph 4, for "points 1 and 3" substitute "point 1";
    - (iv) in paragraph 5-
      - (aa) after "competent authority" insert "of a constituent nation";
      - (bb) for "Member State" substitute "constituent nation";
  - (c) in Chapter 4—
    - (i) in Section 1, in paragraph 2, for "Member State", in each place it occurs, substitute "constituent nation";
    - (ii) in Section 3, in paragraph 2(b)(iii)—
      - (aa) in the second indent, for "Member State" substitute "constituent nation";

- (bb) in the third indent, for "Council Directive 91/271/EEC" substitute "the Urban Waste Water Treatment (England and Wales) Regulations 1994(a), the Urban Waste Water Treatment (Scotland) Regulations 1994(b) or the Urban Waste Water Treatment Regulations (Northern Ireland) 2007(c)".
- (37) In Annex 5, in Chapter 3, in Section 2—
  - (a) in paragraph 1, in the final subparagraph, for "Commission" substitute "appropriate authority";
  - (b) in paragraph 4—
    - (i) in point (a), for "point 1" substitute "points 1, 2 and 3";
    - (ii) omit point (b).
- (38) Annex 6 is amended in accordance with paragraphs (39) to (42).
- (39) In Chapter 1, in Section 2—
  - (a) in paragraph 2—
    - (i) in point (a), after "Member State" insert "or constituent nation";
    - (ii) in point (b), for "Member State or", in each place it occurs, substitute "constituent nation or";
  - (b) in paragraph 3, after "Member State" insert "or constituent nation".
- (40) In Chapter 2-
  - (a) in Section 1, in paragraph 3, for "Member States" substitute "The appropriate authority";
  - (b) in Section 2—
    - (i) in paragraph 1(a)—
      - (aa) omit point (i);
      - (bb) in each of points (ii) and (iii), for "that Directive" insert "the Conservation of Habitats and Species Regulations 2017(d), the Conservation of Offshore Marine Habitats and Species Regulations 2017(e), the Conservation (Natural Habitats, etc.) Regulations (Northern Ireland) 1995(f) or the Conservation (Natural Habitats, &c.) Regulations 1994(g)";
    - (ii) omit paragraph 2.

(41) In Chapter 3, in Section 2, in each of points (a) to (c), for "Member State concerned", in each place it occurs, substitute "United Kingdom".

(42) In Chapter 4, in the words before point (a), for "Member States authorise" substitute "nothing in this Regulation prevents the appropriate authority from authorising".

- (43) In Annex 7-
  - (a) in Chapter 1—
    - (i) in paragraph 1, for "one of the official languages" to the end, substitute "English and may also be submitted in other languages";
    - (ii) omit both subparagraphs of paragraph 2;
  - (b) in Chapter 2, in paragraph 1, for "EFSA" substitute "the appropriate authority".
- (44) Annex 8 is amended in accordance with paragraphs (45) to (49).

<sup>(</sup>a) S.I. 1994/2841, amended by S.I. 2003/1788, 2005/2035, 2010/675, 2011/556, 2013/755, 2016/1154 and 2018/942.

<sup>(</sup>b) S.S.I 1994/2842, amended by S.S.I. 1996/973, 2003/273 and 2011/202.

<sup>(</sup>c) S.R. 2007 No. 187.

<sup>(</sup>d) S.I. 2017/1012, amended by S.I. 2017/1013.

<sup>(</sup>e) S.I. 2017/1013.

<sup>(</sup>f) S.R. 1995 No. 380, amended by the Marine Act (Northern Ireland) 2013 c. 10, S.R. 2012 No. 368 and 2015 No. 182.

 <sup>(</sup>g) S.I. 1994/2716, amended by the Marine and Coastal Access Act 2009 c. 23, S.I. 1996/973, 2000/1973, 2001/3966, 2003/2155, 2005/421, 3389, 2006/1282, 2007/1843, 3538, 2009/6, 1307, 2438, 3160, 2010/489 (W. 55), 490, 2011/202, 2015/249, S.S.I 2000/323, 2004/475, 2006/270, 2007/349, 485, 2008/17, 425, 2009/222, 343, 2011/155, 2012/215, 228 and 360.

- (45) In Chapter 1, in Section 4, for "same Member State" substitute "United Kingdom".
- (46) In Chapter 2-
  - (a) in paragraph 1(c)—
    - (i) in the words before point (i), for "from one Member State to another Member State" substitute "from the European Union to the United Kingdom";
    - (ii) in point (iv)-
      - (aa) after "consignments" insert "from a third country outside the European Union";
      - (bb) after "entry into the" insert "European";
  - (b) in paragraph 2(c)(ii), in the first indent, for "Member State" substitute "constituent nation";
  - (c) in each of paragraphs 3 and 4—
    - (i) for "Member States may establish systems or lay down rules" substitute "Nothing in this Regulation prevents the appropriate authority from establishing systems or laying down rules";
    - (ii) for "on their territory" substitute "in their constituent nation";
  - (d) in paragraph 5—
    - (i) for "Member States may use" substitute "nothing in this Regulation prevents the appropriate authority from using";
    - (ii) for "Member State" substitute "constituent nation";
  - (e) in paragraph 6(b), for "same Member State" substitute "United Kingdom".
- (47) In Chapter 3-
  - (i) in paragraph 1(a), for "same Member State" substitute "United Kingdom";
  - (ii) in paragraph 2, in the second subparagraph—
    - (aa) for "Member States" substitute "The appropriate authority";
    - (bb) for "TRACES system" substitute "Import Control System";
  - (iii) in paragraph 4—
    - (aa) in the first subparagraph, for "Union" substitute "United Kingdom";
    - (bb) in the second subparagraph, for "on its territory" substitute "in its constituent nation";
  - (iv) in paragraph 6(b) for "one of the official languages" to the end of the second subparagraph, substitute "English, and may also be drawn up in other languages".
- (48) In Chapter 4, omit Section 3.
- (49) In Chapter 6—
  - (a) for "to 3" substitute "and 2"
  - (b) for "Member States", in the first place it occurs, substitute "constituent nation";
  - (c) omit "and the use of TRACES";
  - (d) for "another Member State sharing a common border when the Member States" substitute "the United Kingdom and the Republic of Ireland, when the United Kingdom and the Republic of Ireland".

(50) In Annex 9, in Chapter 2, in the words before Section 1, in point (h), for "Union veterinary legislation" substitute "veterinary retained EU law".

- (51) In Annex 9, in Chapter 5, Section 1 is amended in accordance with paragraphs (52) and (53).
- (52) In paragraph 1—
  - (a) for "Member State" substitute "United Kingdom";
  - (b) after "authorised by the" insert "relevant".

(53) In paragraph 2, for "Member State", in each place it occurs, substitute "constituent nation".

(54) In Annex 9, in Chapter 5, Section 2 is amended in accordance with paragraphs (55) and (56).

(55) In head A-

- (a) in paragraph 1—
  - (i) for the heading, substitute "Application";
  - (ii) in the first subparagraph, omit "France, Ireland, Latvia, Portugal and";
  - (iii) in the second subparagraph—
    - (aa) for "competent authority of the Member State concerned" substitute "relevant competent authority";
    - (bb) for "territory of that Member State" substitute "United Kingdom";
- (b) in paragraph 3.2.3, for "Directive 2008/98/EC" substitute "the Control of Pollution (Amendment) Act 1989(a) or the Waste and Contaminated Land (Northern Ireland) Order 1997(b)".
- (56) In head B, in paragraph 1-
  - (a) for the heading, substitute "Application";
  - (b) in the first subparagraph, omit "Ireland, Spain, Latvia, Portugal and";
  - (c) in the second subparagraph, for "same Member State referred to above" substitute "United Kingdom".
- (57) In Annex 10, in Chapter 2, in Section 4-
  - (a) in Part 1, in head B—
    - (i) in each of paragraphs 1.2(b), 1.4(b), 3(b) and 6.2, for "Member State" insert "country";
    - (ii) in paragraph 6.1, after "Directive 64/432/EEC" insert-

"taken with the Annexes to which they refer, reading the relevant provisions as if:

- (a) for references to a "Member State" there were substituted references to a "Member State or constituent nation"; and
- (b) in Annex D, in Chapter 1, in Section B(iv), for the reference to "Directive 72/462/EEC" there were substituted a reference to "the Trade in Animals and Related Products Regulations 2011, the Trade in Animals and Related Products (Wales) Regulations 2011, the Trade in Animals and Related Products (Scotland) Regulations 2012 or the Trade in Animals and Related Products Regulations (Northern Ireland) 2011;";
- (b) in Part 2-
  - (i) in paragraph 3(a)—
    - (aa) for "Member State concerned" substitute "United Kingdom";
    - (bb) for "Member States concerned" substitute "United Kingdom and the Republic of Ireland";
  - (ii) in paragraph 3(b)—
    - (aa) in the words before point (i), for "Member State concerned" substitute "United Kingdom";
    - (bb) in each of points (i) and (ii), for "Member State concerned", in each place it occurs, substitute "appropriate authority";

<sup>(</sup>**a**) 1989 c. 14.

<sup>(</sup>b) S.I. 1997/2778 (N.I. 19), amended by the Waste and Contaminated Land (Amendment) Act (Northern Ireland) 2011 c. 5, the Planning Act (Northern-Ireland) 2011 c. 25, S.R. 2003 No. 489, 2006 Nos. 280, 425, S.I. 2006/3336 (N.I. 21), S.R. 2007 Nos. 194, 294, 611, 2008 Nos. 75, 138, 231, 2009 Nos. 178, 254, 2011 Nos. 127, 239, 240, 312, 2013 Nos. 33, 34, 2015 Nos. 14, 49, 238, 288, 2016 No. 280, S.I. 2009/1941, 2007/1200, 1711 and 2012/1916.

- (cc) in the first and second indents of point (ii), for "same Member State", in each place it occurs, substitute "United Kingdom";
- (iii) in paragraph 4, for "same Member State" substitute "United Kingdom";
- (c) in Part 3—
  - (i) in the second paragraph, for "Member States which" substitute "constituent nations whose appropriate authorities";
  - (ii) in Section 10, in the first paragraph, for "Member States" substitute "the British Islands".
- (58) In Annex 11, Chapter 1 is amended in accordance with paragraphs (59) and (60).
- (59) In Section 1—
  - (a) in paragraph 1—
    - (i) in the words before point (a)—
      - (aa) for "Trade in" substitute "Imports of";
      - (bb) for "between Member States" substitute "from the European Union";
      - (cc) for "Member State" substitute "competent authority of the constituent nation";
    - (ii) in point (a)—
      - (aa) for "Trade in" substitute "Imports of";
      - (bb) in point (ii), for "two Member States" substitute "Northern Ireland and the Republic of Ireland";
    - (iii) in point (b)-
      - (aa) in the first subparagraph, for "Member State" substitute "constituent nation";
      - (bb) in point (ii), omit the words from "provided that" to the end;
  - (b) in paragraph 2—
    - (i) in the words before point (a)—
      - (aa) for "Trade in" substitute "Imports of";
      - (bb) for "between Member States" substitute "from the European Union";
      - (cc) for "Member State" substitute "competent authority of the constituent nation";
    - (ii) omit point (b);
  - (c) in paragraph 4—
    - (i) for "traded between Member States", substitute "imported from the European Union";
    - (ii) for "Member State" substitute "constituent nation";
    - (iii) after "Article 4(5)" insert "(a) or (b)";
  - (d) in paragraph 5—
    - (i) for "Member State" substitute "constituent nation";
    - (ii) for "another Member State" substitute "the European Union".
- (60) In Section 2—
  - (a) in the words before point (a), for "Member State" substitute "competent authority of the constituent nation";
  - (b) in point (c)(v), in the second subparagraph, for "Commission" substitute "appropriate authority".
- (61) In Annex 11, in Chapter 2, in Section 1—
  - (a) in paragraph 2, for "Member State" substitute "constituent nation";
  - (b) in paragraph 3, in the second subparagraph—
    - (i) for "Commission" substitute "appropriate authority,";

- (ii) for "Member States" substitute "appropriate authorities";
- (c) in paragraph 4(b), for "Member State" substitute "constituent nation".

(62) In Annex 12-

- (a) in the words before paragraph 1—
  - (i) for "Union" substitute "United Kingdom";
  - (ii) after "products" insert "from a third country outside the European Union";
- (b) in paragraph 1—
  - (i) in the words before point (a), after "products" insert "from a third country outside the European Union";
  - (ii) in point (b)(i), after "Directive 96/23/EC," insert "in both cases, reading those Articles as if for references to "Community legislation" there were substituted references to "retained EU law"";
  - (iii) in point (f), for the words from "one of the official languages" to "Member States" substitute "English; the appropriate authority";
- (c) in paragraph 2(b)(iii)—
  - (i) after "registered" insert "in its constituent nation";
  - (ii) for "Member State" substitute "appropriate authority";
  - (iii) omit "and to the Member State of destination";
- (d) in paragraph 3, in the words before point (a)—
  - (i) for "Union" substitute "United Kingdom from a third country outside the European Union";
  - (ii) for "Article 4 of Directive 97/78/EC" substitute "the Trade Regulations";
- (e) in paragraph 4—
  - (i) for "Union" substitute "United Kingdom from a third country outside the European Union";
  - (ii) for "Article 11 of Directive 97/78/EC" substitute "regulation 18(1) to (3) of the England Trade Regulations, regulation 18(1) to (3) of the Wales Trade Regulations, regulation 16(1) to (3) of the Scotland Trade Regulations or regulation 18(1) to (3) of the Northern Ireland Trade Regulations";
- (f) in paragraph 5, for "TRACES system" substitute "Import Control System";
- (g) in paragraph 7-
  - (i) for "Directive 97/78/EC" substitute "the Trade Regulations";
  - (ii) for "Member State" substitute "constituent nation";
  - (iii) after "transit" insert "from a third country outside the European Union";
- (h) in paragraph 9, after "transit" insert "from a third country outside the European Union".
- (63) In Annex 13—
  - (a) in Chapter 2—
    - (i) in paragraph 2(b), after "Directive 96/23/EC" insert ", in both cases reading those Articles as if for references to "Community legislation" there were substituted references to "retained EU law";
    - (ii) in paragraph 7—
      - (aa) in each of points (a)(i) and (b)(i), for "Union" substitute "British Islands or European Union";
      - (bb) in each of points (a)(ii) and (b)(ii), for "Directive 97/78/EC at a border inspection post" substitute "the Trade Regulations, at a border inspection post if imported from a third country outside the European Union";
  - (b) in Chapter 4, in paragraph 1(a)—

- (i) in point (i), for "point 4 of Article 1.2.3 of the Terrestrial Animal Health Code of the OIE, 2010" substitute "Chapter 1.3 of the Terrestrial Animal Health Code of the OIE, 2018";
- (ii) in point (ii), after "Article 5 of that Directive" insert ", or in relation to holdings in the United Kingdom, not located in a constituent nation which is not considered to be free of African horse sickness in accordance with paragraph 1A";
- (iii) in point (iii)—
  - (aa) omit "Member State or";
  - (bb) after "Article 5(2) of that Directive" insert ", reading the words before point (a) as if for the reference to a "Member State" there were substituted a reference to a "third country", or a constituent nation which is not considered to be free of African horse sickness, in accordance with paragraph 1A";
- (iv) after paragraph 1, insert—
- "1A. A constituent nation is not considered to be free of African horse sickness if:
- (a) clinical, serological (in unvaccinated animals) or epidemiological evidence has revealed the presence of African horse sickness in the past two years, or
- (b) vaccination against African horse sickness has been carried out in the past 12 months."
- (c) in Chapter 5, in head B, in paragraph 1, for "Directive 2002/99" substitute "the Products of Animal Origin (Disease Control) (England) Regulations 2008(a), the Products of Animal Origin (Disease Control) (Wales) Regulations 2008(b), the Products of Animal Origin (Disease Control) (Scotland) Order 2008(c) or the Products of Animal Origin (Disease Control) Regulations (Northern Ireland) 2008(d) and the Trade Regulations";
- (d) in Chapter 7, in head B, in the second paragraph—
  - (i) for "Member States" substitute "The appropriate authority";
  - (ii) for "on their territory" substitute "in their constituent nation";
- (e) in Chapter 9—
  - (i) in paragraph 1—
    - (aa) in point (a), for "Member State" substitute "constituent nation";
    - (bb) in point (b), for "has obtained additional guarantees in accordance with Article 14(2) of Directive 92/65/EEC" substitute "has been assessed by the appropriate authority on a basis equivalent, *mutatis mutandis*, to the assessment in point (a)";
  - (ii) in paragraph 2, after "provided for in" insert "the first two subparagraphs of".
- (64) In Annex 14, Chapter 1 is amended in accordance with paragraphs (65) to (70).

(65) In the heading, for "Union" substitute "United Kingdom from a third country outside the European Union".

(66) In Section 1—

- (a) in the words before point (a)—
  - (i) omit "imported";
  - (ii) after "therefrom" insert "imported from a third country outside the European Union";
- (b) in each of points (e)(i) and (ii), for "Union" substitute "United Kingdom";
- (c) in Table 1, in the column entitled "third countries' lists", in entry 9-

<sup>(</sup>a) S.I. 2008/465, amended by S.I. 2009/1297, 2012/2897, 2014/1894, 2018/575.

<sup>(</sup>b) S.I. 2008/1275 (W.132), amended by S.I. 2009/1373 (W. 136), 1910 (W. 173), 2014/1894, 2018/806.

<sup>(</sup>c) S.S.I. 2008/158, amended by S.S.I. 2009/174 and S.I. 2014/1894.

<sup>(</sup>d) S.R. 2008 No. 431.

- (i) for "Member States authorise imports" substitute "imports into the United Kingdom";
- (ii) after "products" insert "are authorised".
- (67) In Section 2—
  - (a) in the heading, after "Imports" insert "from a third country outside the European Union";
  - (b) in the words before paragraph 1, after "importation" insert "from a third country outside the European Union";
  - (c) in paragraph 1, for "Union" substitute "United Kingdom";
  - (d) in paragraph 4—
    - (i) in the words before point (a), for "Union" substitute "United Kingdom";
    - (ii) in point (a), for "Article 17(2)(a) of Directive 97/78/EC" insert "regulation 20(1)(b) of the England Trade Regulations, regulation 20(1)(b) of the Wales Trade Regulations, regulation 18(1)(b) of the Scotland Trade Regulations or regulation 20(1)(b) of the Northern Ireland Trade Regulations";
  - (e) in paragraph 5, for "Union" substitute "United Kingdom".
- (68) In Section 3-
  - (a) in the heading, after "Imports" insert "from a third country outside the European Union";
  - (b) in the first paragraph, after "importation" insert "from a third country outside the European Union".
- (69) In Section 4-
  - (a) in the heading, after "Imports" insert "from a third country outside the European Union";
  - (b) in head A—
    - (i) in the words before paragraph 1, after "importation" insert "from a third country outside the European Union";
    - (ii) in paragraph 2(b), for "Union" substitute "United Kingdom";
  - (c) in head B—
    - (i) in paragraph 1(b), for "Union" substitute "United Kingdom";
    - (ii) in paragraph 2—
      - (aa) in point (a), after "Directive 64/432/EEC" insert "taken with the Annexes to which they refer, reading the relevant provisions as if for references to a "Member State" or "Member States" there were substituted references to a "third country" or "third countries" (as the case may be)";
      - (bb) in point (b), after "Directive 64/432/EEC" insert—

"taken with the Annex to which it refers, reading the relevant provisions as if:

- (i) for references to a "Member State" or "Member States" there were substituted references to a "third country" or "third countries" (as the case may be); and
- (ii) in Annex D, in Chapter 1, in Section B(iv), for the reference to "Directive 72/462/EEC" there were substituted a reference to "the Trade in Animals and Related Products Regulations 2011, the Trade in Animals and Related Products (Wales) Regulations 2011, the Trade in Animals and Related Products (Scotland) Regulations 2012 or the Trade in Animals and Related Products (Northern Ireland) Regulations 2011";".
- (70) In Section 5—
  - (a) in the heading, after "Imports" insert "from a third country outside the European Union";
  - (b) in the first paragraph, after "importation" insert "from a third country outside the European Union".
- (71) In Annex 14, Chapter 2 is amended in accordance with paragraphs (72) to (84).

(72) In the heading, for "Union" substitute "United Kingdom from a third country outside the European Union".

(73) In Section 1-

- (a) in the words before point (a)—
  - (i) omit "imported";
  - (ii) after "farmed animals" insert "imported from a third country outside the European Union";
  - (iii) after "transit" insert "from a third country outside the European Union";
- (b) in point (c), after "Table 2" insert "or Svalbard";
- (c) in each of points (e)(i) and (ii), for "Union" substitute "United Kingdom";
- (d) in Table 2, in the column entitled "third countries' lists"—
  - (i) except in entry 6, for "Member States authorise imports", in each place it occurs, substitute "imports into the United Kingdom";
  - (ii) after "same species", in each place it occurs, insert "are authorised";
  - (iii) in entry 3, after "equidae" insert "are authorised";
  - (iv) in entry 5, for "European Union" substitute "United Kingdom";
  - (v) in entry 6—
    - (aa) for "the Member States authorise imports" substitute "imports into the United Kingdom";
    - (bb) after "poultrymeat" insert "are authorised";
  - (vi) in entry 8, for "Union" substitute "United Kingdom";
  - (vii) in entry 13, after "meat" insert "are authorised";
  - (viii) in entry 14, after "poultrymeat" insert "are authorised".
- (74) In Section 2-
  - (a) in the heading, after "Imports," insert "from a third country outside the European Union";
  - (b) in the words before paragraph 1, after "import," insert "from a third country outside the European Union";
  - (c) in each of paragraphs 3.1(b)(ii), 3.2(b) and 3.3(b)—
    - (i) for "Directive 97/78/EC" substitute "the Trade Regulations";
    - (ii) for "Article 8(4) of that Directive" substitute "regulation 17 of the England Trade Regulations, regulation 17 of the Wales Trade Regulations, regulation 15 of the Scotland Trade Regulations or regulation 17 of the Northern Ireland Trade Regulations";
  - (d) in paragraph 4(b)(i), for "2010" substitute "2018".
- (75) In Section 3-
  - (a) in the heading, after "Imports," insert "from a third country outside the European Union";
  - (b) in the words before paragraph 1, after "import," insert "from a third country outside the European Union".
- (76) In Section 4-
  - (a) in the heading, after "Imports" insert "from a third country outside the European Union";
  - (b) in the words before paragraph 1, after "import" insert "from a third country outside the European Union".
- (77) In Section 5-
  - (a) in the heading, after "imports" insert "from a third country outside the European Union";
  - (b) in the words before paragraph 1, after "import" insert "from a third country outside the European Union".

(78) In Section 6-

- (a) in the heading, after "Imports" insert "from a third country outside the European Union";
- (b) in the words before point (a), after "imported" insert "from a third country outside the European Union".
- (79) In Section 7-
  - (a) in the heading, after "Imports" insert "from a third country outside the European Union";
  - (b) in paragraph 1-
    - (i) in the words before point (a), after "imported" insert "from a third country outside the European Union";
    - (ii) in point (a), for "Union" substitute "United Kingdom";
    - (iii) in point (b), for "Union", in each place it occurs, substitute "United Kingdom";
    - (iv) in point (c), for "Directive 97/78/EC" substitute "the Trade Regulations";
  - (c) in paragraph 3, for "Union" substitute "United Kingdom";
  - (d) in paragraph 4—
    - (i) for "Directive 97/78/EC" substitute "the Trade Regulations";
    - (ii) for "Article 8(4) of that Directive" substitute "regulation 17 of the England Trade Regulations, regulation 17 of the Wales Trade Regulations, regulation 15 of the Scotland Trade Regulations or regulation 17 of the Northern Ireland Trade Regulations".
- (80) In Section 8-
  - (a) in the heading, after "Imports" insert "from a third country outside the European Union";
  - (b) in the words before paragraph 1, after "imported" insert "from a third country outside the European Union";
  - (c) in paragraph 4—
    - (i) for "Directive 97/78/EC" substitute "the Trade Regulations";
    - (ii) for "Article 8(4) of that Directive" substitute "regulation 17 of the England Trade Regulations, regulation 17 of the Wales Trade Regulations, regulation 15 of the Scotland Trade Regulations or regulation 17 of the Northern Ireland Trade Regulations";
  - (d) in paragraph 5.1, in each of points (a) and (b), for "Union" substitute "United Kingdom".
- (81) In Section 9-
  - (a) in the heading, after "Imports" insert "from a third country outside the European Union";
  - (b) in the words before point (a), after "imported" insert "from a third country outside the European Union";
  - (c) in point (d), for "Union" substitute "United Kingdom";
  - (d) in point (e)—
    - (i) for "Directive 97/78/EC" substitute "the Trade Regulations";
    - (ii) for "Article 8(4) of that Directive" substitute "regulation 17 of the England Trade Regulations, regulation 17 of the Wales Trade Regulations, regulation 15 of the Scotland Trade Regulations or regulation 17 of the Northern Ireland Trade Regulations".
- (82) In Section 10-
  - (a) in the heading, after "Imports" insert "from a third country outside the European Union";
  - (b) in paragraph 1, after "imported" insert "from a third country outside the European Union";
  - (c) in paragraph 2, for "Union" substitute "United Kingdom";
  - (d) in paragraph 3—

- (i) for "Directive 97/78/EC" substitute "the Trade Regulations";
- (ii) for "Article 8(4) of that Directive" substitute "regulation 17 of the England Trade Regulations, regulation 17 of the Wales Trade Regulations, regulation 15 of the Scotland Trade Regulations or regulation 17 of the Northern Ireland Trade Regulations".
- (83) In Section 11-
  - (a) in the heading, after "Imports" insert "from a third country outside the European Union";
  - (b) in paragraph 1—
    - (i) in the words before point (a), after "imported" insert "from a third country outside the European Union";
    - (ii) in point (a), for "one of the plants of origin indicated in Table 3" substitute "one of the following plants of origin: Nitta Gelatin Inc., 2-22 Futamata Yao-City, Osaka 581-0024 Japan, Eastman Gelatine Corporation, 227 Washington Street, Peabody, MA, 01960 USA, or Gelita North America, 2445 Port Neal Industrial Road Sergeant Bluff, Iowa, 51054 USA";
    - (iii) in point (c), for the words from "one" to the end, substitute "a border inspection post at Liverpool, Felixstowe or Heathrow";
    - (iv) in point (d) for "in an approved photographic factory indicated in Table 3" substitute "in the approved photographic factory at Kodak Ltd., Headstone Drive, Harrow, Middlesex HA4 4TY";
    - (v) omit Table 3;
  - (c) in paragraph 2—
    - (i) for "Member State of destination" substitute "United Kingdom";
    - (ii) for "Member States" substitute "the United Kingdom and European Union";
    - (iii) for "same Member State of destination" substitute "United Kingdom";
  - (d) in paragraph 3—
    - (i) for "Directive 97/78/EC" substitute "the Trade Regulations";
    - (ii) for "Article 8(4) of that Directive" substitute "regulation 17 of the England Trade Regulations, regulation 17 of the Wales Trade Regulations, regulation 15 of the Scotland Trade Regulations or regulation 17 of the Northern Ireland Trade Regulations";
  - (e) in paragraph 6(a), for "European Union" substitute "any place in the United Kingdom".

(84) In Section 12-

- (a) in the heading, after "Imports" insert "from a third country outside the European Union";
- (b) in the words before paragraph 1, after "imported" insert "from a third country outside the European Union";
- (c) in paragraph 2—
  - (i) for "Directive 97/78/EC" substitute "the Trade Regulations";
  - (ii) for "Article 8(4) of that Directive" substitute "regulation 17 of the England Trade Regulations, regulation 17 of the Wales Trade Regulations, regulation 15 of the Scotland Trade Regulations or regulation 17 of the Northern Ireland Trade Regulations".
- (85) In Annex 14, Chapter 3 is amended in accordance with paragraphs (86) to (88).
- (86) In Section 1, in point (c)(ii)—
  - (a) for "Member States authorise imports" substitute "imports into the United Kingdom";
  - (b) after "animals" insert "are authorised".
- (87) In Section 2, in paragraph 1—

- (a) in the words before point (a), after "transit" insert "from a third country outside the European Union";
- (b) in point (c)—
  - (i) for "Directive 97/78/EC" substitute "the Trade Regulations";
  - (ii) for "Article 8(4) of that Directive" substitute "regulation 17 of the England Trade Regulations, regulation 17 of the Wales Trade Regulations, regulation 15 of the Scotland Trade Regulations or regulation 17 of the Northern Ireland Trade Regulations".
- (88) In Section 3-
  - (a) in paragraph 1—
    - (i) in the first subparagraph, after "transit" insert "from a third country outside the European Union";
    - (ii) in point (b), for "Member State" substitute "constituent nation";
    - (iii) in point (c), for "Directive 97/78/EC" substitute "the Trade Regulations";
  - (b) in paragraph 3(b)—
    - (i) for "another Member State or" substitute "a";
    - (ii) after "of the" omit "Member State or".
- (89) In Annex 14, Chapter 4 is amended in accordance with paragraphs (90) and (91).
- (90) In Section 1-
  - (a) in the heading, after "Imports" insert "from a third country outside the European Union";
  - (b) in the words before paragraph 1, after "imported" insert "from a third country outside the European Union".
- (91) In Section 2-
  - (a) in the heading, after "Imports" insert "from a third country outside the European Union";
  - (b) in paragraph 1, after "import" insert "from a third country outside the European Union".
- (92) In Annex 15-
  - (a) in the first paragraph—
    - (i) after "third countries" insert "outside the European Union";
    - (ii) after "transit through the" insert "United Kingdom from third countries outside the";
  - (b) in the Notes-
    - (i) in point (d)—
      - (aa) for "one of the official languages" to "destination" substitute "English";
      - (bb) for "these Member States" substitute "the appropriate authority";
    - (ii) in point (g)—
      - (aa) after "laid down in" insert "Article 3(1) to (4), Article 4(1) and (3) and Article 5(2) of";
      - (bb) after "followed" insert ", reading those Articles as if for references to "veterinary legislation" there were substituted references to "Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption"";
    - (iii) in point (i), omit "EU";
    - (iv) in point (j), for "European Union" substitute "United Kingdom".
- (93) Annex 16 is amended in accordance with paragraphs (94) and (95).

(94) In Chapter 2-

(a) in paragraph 1—

- (i) for "Member States" substitute "each other";
- (ii) omit "other Member States and to";
- (iii) for "the Commission" substitute "the Secretary of State and each devolved authority";
- (iv) for "Member State" substitute "other";
- (b) in paragraph 2—
  - (i) in point (a)—
    - (aa) for "Each Member State" substitute "The Secretary of State and each devolved authority";
    - (bb) for "the Commission" substitute "each other";
    - (cc) for "on its territory" substitute "in their respective constituent nation";
  - (ii) in point (b), for "one or more official languages of the Union" substitute "at least English";
- (c) in paragraph 3, for "Commission" substitute "appropriate authority".

(95) In Chapter 3—

- (a) omit Section 4;
- (b) in Section 8,-
  - (i) for "approved photographic factories", in the first place it occurs, to "Annex XIV" substitute "the approved photographic factory at Kodak Ltd., Headstone Drive, Harrow, Middlesex HA4 4TY";
  - (ii) for "factories", in the second place it occurs, substitute "factory";
- (c) in Section 10—
  - (i) in the heading, for "in intra-Union trade" substitute "for imports from the European Union";
  - (ii) for "Member State" substitute "constituent nation".

#### Amendments to the EEA agreement

7. In Annex 1 to the EEA agreement, in Chapter 1, in Part 7.1-

- (a) in point 9b, omit point (a);
- (b) in point 9c, omit points (a) and (b).

name Parliamentary Under Secretary of State Department for Environment, Food and Rural Affairs

#### **EXPLANATORY NOTE**

(This note is not part of these Regulations)

These Regulations are made in exercise of the powers conferred by 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 section 8(2)(a), (c), (d) and (g)) arising from the withdrawal of the United Kingdom from the European Union.

These Regulations amend retained direct EU legislation in the field of transmissible spongiform encephalopathies and animal by-products.

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