
D R A F T S T A T U T O R Y I N S T R U M E N T S

2019 No. 000

EXITING THE EUROPEAN UNION

AGRICULTURE

FOOD

INTELLECTUAL PROPERTY

MEDICINES

TRIBUNALS AND INQUIRIES

The Food and Drink, Veterinary Medicines and Residues
(Amendment etc.) (EU Exit) Regulations 2019

Made - - - - *****

Coming into force in accordance with regulation 1

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The Secretary of State makes these Regulations in exercise of the powers conferred by section 8 of, and paragraph 1 of Schedule 4 and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018^(a).

In accordance with paragraphs 1(1) and 12(1) of Schedule 7 to that Act, a draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament.

In accordance with paragraph 3(1) of Schedule 4 to that Act, the Treasury have consented to the making of regulations 17 and 18(2), Schedule 8 and Part 1 of Schedule 9.

In relation to Parts 2 and 3 of, and Schedules 1 to 7 to, this instrument, there has been consultation as required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety^(b).

PART 1

Introductory

Citation and commencement

1.—(1) These Regulations may be cited as the Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019.

(2) These Regulations come into force on the later of exit day or the day after the day on which they are made.

PART 2

Amendment of subordinate legislation relating to food and drink

The Spirit Drinks Regulations 2008

2.—(1) The Spirit Drinks Regulations 2008^(c) are amended as follows.

(2) In regulation 10—

(a) 2018 c. 16.

(b) OJ No L 31, 1.2.2002, p. 1, to which there are amendments not relevant to these Regulations.

(c) S.I. 2008/3206, to which there are amendments not relevant to these Regulations.

- (a) for paragraph (2) substitute—
 - “(2) The authorised officer may take with them such other person as they consider necessary.”;
- (b) omit paragraph (14).

The Tribunal Procedure (First-tier Tribunal) (General Regulatory Chamber) Rules 2009

3.—(1) The Tribunal Procedure (First-tier Tribunal) (General Regulatory Chamber) Rules 2009(a) are amended as follows.

- (2) In rule 1(3), insert in the appropriate alphabetical places—
 - ““agricultural product or foodstuff decision” means a decision of the Secretary of State specified in the first column of the table in Annex 3 to Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs;”
 - ““aromatised wine decision” means a decision of the Secretary of State specified in column 1 of the table in Annex 4 to Regulation (EU) No 251/2014 of the European Parliament and of the Council on the definition, description, presentation, labelling and the protection of geographical indications of aromatised wine products;”.
- (3) In rule 22(6), after sub-paragraph (g), insert—
 - “(h) in an appeal against an agricultural product or foodstuff decision, within 28 days of the date on which the decision was published;
 - (i) in an appeal against an aromatised wine decision, within 28 days of the date on which the decision was published.”.

The Wine Regulations 2011

- 4.—**(1) The Wine Regulations 2011(b) are amended as follows.
- (2) In regulation 4—
 - (a) in paragraph (1) omit “, and acts as the Member State for,”;
 - (b) in paragraph (2)(a)(i) omit “or Member State”.
- (3) For regulation 8(4) substitute—
 - “(4) An authorised officer entering any premises by virtue of this regulation or regulation 9 may be accompanied by such other person as the officer considers necessary.”.

The Quality Schemes (Agricultural Products and Foodstuffs) Regulations 2018

- 5.—**(1) The Quality Schemes (Agricultural Products and Foodstuffs) Regulations 2018(c) are amended as follows.
- (2) For regulation 3(2) substitute—
 - “(2) The Secretary of State is responsible for exercising the functions of the designated authority for the purposes of Articles 13(3), 24(2), 34 and 38.”.
- (3) Omit regulation 5(1).
- (4) For regulation 10(8) substitute—
 - “(8) An authorised officer may be accompanied by such other persons as the authorised officer considers necessary.”.
- (5) Omit regulation 21.

(a) S.I. 2009/1976; relevant amending instruments are S.I. 2010/43, 2653, 2012/500, 2017/1168, 2018/1053.
(b) S.I. 2011/2936, amended by S.I. 2013/3235, there are other amending instruments but none is relevant.
(c) S.I. 2018/1275.

PART 3

Amendment and revocation of retained direct EU legislation relating to food and drink

Commission Regulation (EC) No 2870/2000

6.—(1) Commission Regulation (EC) No 2870/2000 laying down Community reference methods for the analysis of spirits drinks is amended as follows.

(2) In Article 3—

(a) in the words before point (a)—

(i) omit “Community”;

(ii) after “down” insert “in retained EU law”;

(b) in point (a), for “the Annex to Directive 85/591/EEC” substitute “Annex 3 to Regulation (EC) No 882/2004 of the European Parliament and of the Council”;

(c) in point (d), in the first indent—

(i) at the beginning insert “in relation to an official control,”;

(ii) for “Member State concerned” substitute “appropriate authority, by administrative decision, on a case by case basis”;

(d) after the existing paragraph insert—

“In this Article ‘the appropriate authority’ means:

(a) in relation to England, the Secretary of State;

(b) in relation to Northern Ireland, the Department of Agriculture, Environment and Rural Affairs;

(c) in relation to Scotland, the Scottish Ministers;

(d) in relation to Wales, the Welsh Ministers.”.

(3) In Article 4, after point (c) insert—

“(d) ‘Regulation 110/2008’: means Regulation (EC) No 110/2008 of the European Parliament and of the Council.”.

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

(5) In the Annex—

(a) in Part 3(1) (general remarks relating to the determination of volatile substances and methanol of spirit drinks)—

(i) in point 1, in the words before point 1, for “Regulation (EEC) No 1576/89” substitute “Regulation 110/2008”;

(ii) in point 2, in the second subparagraph, for “Regulation (EEC) No 1576/89” substitute “Regulation 110/2008”;

(b) in Part 6 (determination of glycyrrhizic acid using high performance liquid chromatography), in point 1, for “Regulation (EEC) No 1576/89” substitute “Regulation 110/2008”;

(c) in Part 7 (high-performance liquid chromatography method for verifying the presence of chalcones in pastis), in point 1, in the second subparagraph, for “Regulation (EEC) No 1576/89” substitute “Regulation 110/2008”.

Regulation (EU) No 1151/2012 of the European Parliament and of the Council

7.—(1) Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs is amended as follows.

(2) In Article 1—

- (a) at the end of point (b) insert “and”;
 - (b) at the end of point (c) omit “and”;
 - (c) omit point (d).
- (3) In Article 2—
- (a) in paragraph 1, in the second subparagraph, for the words from “Commission” to “Article 56,” substitute “Secretary of State may make regulations”;
 - (b) in paragraph 2, for “Annex XIb to Regulation (EC) No 1234/2007” substitute “Part 2 of Annex 7 to Regulation 1308/2013”;
 - (c) in paragraph 3—
 - (i) for “Union provisions” substitute “provisions in retained EU law”;
 - (ii) for “the single common organisation of the markets, and” substitute “provisions in, or under, Regulation 1308/2013 and provisions relating”;
 - (d) omit paragraph 4.
- (4) In Article 3—
- (a) in point (6), for “Union” substitute “United Kingdom”;
 - (b) after point (8) insert the points in Part 1 of Schedule 1.
- (5) In Article 4(b), for “Union” substitute “United Kingdom”.
- (6) In Article 5(4)—
- (a) in the first subparagraph, for the words from “Commission” to “Article 56,” substitute “Secretary of State may make regulations”;
 - (b) in the second subparagraph, for the words from “Commission” to “Article 56,” substitute “Secretary of State may make regulations”.
- (7) In Article 7—
- (a) in paragraph 1(e) omit the words from “, taking into account” to the end of that point;
 - (b) in paragraph 2—
 - (i) in the first subparagraph, for the words from “Commission” to “Article 56,” substitute “Secretary of State may make regulations”;
 - (ii) in the second subparagraph—
 - (aa) for “Commission may adopt implementing acts” substitute “Secretary of State may make regulations”;
 - (bb) omit the second sentence.
- (8) In Article 8—
- (a) in paragraph 1, in the words before point (a), for “49(2) or (5)” substitute “49”;
 - (b) omit paragraph 2.
- (9) Omit Article 9.
- (10) In Article 10—
- (a) in paragraph 1, in the words before point (a), for “Commission” substitute “Secretary of State”;
 - (b) in paragraph 2, for “Union” substitute “United Kingdom”.
- (11) In Article 11—
- (a) for paragraph 1, for the words from “Commission” to “maintaining” substitute “Secretary of State must establish and maintain”;
 - (b) in paragraph 2, for “Union”, in both places it occurs, substitute “United Kingdom”;
 - (c) in paragraph 3—
 - (i) for “Commission may adopt implementing acts” substitute “Secretary of State may make regulations”;

- (ii) omit the second sentence;
 - (d) in paragraph 4, for “Commission” substitute “Secretary of State”.
- (12) In Article 12—
- (a) in paragraph 2 omit “Union”;
 - (b) in paragraph 4, for “Member State” substitute “United Kingdom or third country, as relevant, in which that geographical area of origin is located”;
 - (c) in paragraph 5, for the words from “Directive 2000/13/EC” to “Directive 2008/95/EC” substitute “Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, the collective geographical marks registered under the Trade Marks Act 1994(a)”;
 - (d) in paragraph 6 omit “Union”;
 - (e) in paragraph 7—
 - (i) in the first subparagraph—
 - (aa) for the words from “Commission” to “Article 56,” substitute “Secretary of State may make regulations”;
 - (bb) omit “Union”;
 - (ii) in the second subparagraph—
 - (aa) for “Commission may adopt implementing acts” substitute “Secretary of State may make regulations”;
 - (bb) omit “Union”;
 - (cc) omit the second sentence.
- (13) In Article 13(3)—
- (a) in the first subparagraph—
 - (i) for “Member States” substitute “The designated authority”;
 - (ii) for “that Member State” substitute “the United Kingdom”;
 - (b) omit the second subparagraph.
- (14) In Article 14(1)—
- (a) in the first subparagraph, for “Commission” substitute “Secretary of State”;
 - (b) in the third subparagraph, for “Directive 2008/95/EC” substitute “the Trade Marks Act 1994”.
- (15) In Article 15—
- (a) in paragraph 1—
 - (i) in the first subparagraph, in the words before point (a)—
 - (aa) for the words from “Commission” to “five years” substitute “Secretary of State may, by regulations, make provision for a transitional period of up to five years to apply”;
 - (bb) omit “originating in a Member State or a third country”;
 - (cc) for “on condition” substitute “if the Secretary of State is satisfied”;
 - (dd) omit “Article 49(3) or”;
 - (ii) omit the second subparagraph;
 - (b) in paragraph 2—
 - (i) in the first subparagraph—

(a) 1994 c. 26.

- (aa) in the words before point (a), for the words from “the Commission” to “shown” substitute “an application may be made to the Secretary of State to extend the transitional period mentioned in paragraph 1 to 15 years in duly justified cases and the Secretary of State may, by regulations, make provision for such a transitional provision if the Secretary of State is satisfied”;
 - (bb) in point (a), for “Commission” substitute “Secretary of State”;
 - (ii) omit the second subparagraph;
 - (c) in paragraph 4—
 - (i) in the first subparagraph—
 - (aa) for the words from “a Member State may” to “10 years” substitute “nothing in this Regulation prevents the Secretary of State from using any power the Secretary of State has to make regulations to provide for a transitional period of up to 10 years to apply”;
 - (bb) for “Commission” substitute “Secretary of State”;
 - (cc) omit “to the authorities of the Member State”;
 - (dd) omit “national”;
 - (ee) for “49(3)” substitute “51”;
 - (ii) in the third subparagraph, for “dossier referred to in Article 8(2)” substitute “submitted under Article 8(1)”.
- (16) In Article 16—
- (a) in paragraph 1—
 - (i) for the words from the beginning to “entered in”, in the second place it occurs, substitute “The Secretary of State must enter the names of established protected designations of origin and established protected geographical indications on”;
 - (ii) after “such registrations” insert “under EU Regulation 1151/2012(a)”;
 - (b) in paragraph 2, for the words from “Commission” to “Article 56,” substitute “Secretary of State may make regulations”;
 - (c) in paragraph 3—
 - (i) at the beginning insert “In relation to established protected designations of origin and established protected geographical indications,”;
 - (ii) after “Regulation (EC) No 510/2006” insert “, as that Regulation had effect in the United Kingdom immediately before it was repealed by EU Regulation 1151/2012,”;
 - (d) after paragraph 3 insert—

“4. In paragraph 1, in relation to an established protected designation of origin and an established protected geographical indication, ‘corresponding specifications’ means the product specification for the relevant designation of origin or geographical indication as the specification stood immediately before exit day.”.
- (17) In Article 18—
- (a) in paragraph 3 omit “Member State or in a third”;
 - (b) in paragraph 4, for “Union legislation” substitute “retained EU law”;
 - (c) in paragraph 5, for the words from “Commission” to “Article 56,” substitute “Secretary of State may make regulations”.
- (18) In Article 19—
- (a) in paragraph 1(a) omit “, in the appropriate language versions”;
 - (b) in paragraph 2—

(a) OJ No. L 343, 14.12.2012, p. 1, to which there are amendments not relevant to these Regulations.

- (i) in the first subparagraph, for the words from “Commission” to “Article 56,” substitute “Secretary of State may make regulations”;
 - (ii) in the second subparagraph—
 - (aa) for “Commission may adopt implementing acts” substitute “Secretary of State may make regulations”;
 - (bb) omit the second sentence.
- (19) In Article 20—
 - (a) in paragraph 1, in the words before point (a), for “49(2) or (5)” substitute “49”;
 - (b) omit paragraph 2.
- (20) In Article 21—
 - (a) in paragraph 1, in the words before point (a), for “Commission” substitute “Secretary of State”;
 - (b) in paragraph 2, for “Union” substitute “United Kingdom”.
- (21) In Article 22—
 - (a) in paragraph 1, for the words from “Commission” to “maintaining” substitute “Secretary of State must establish and maintain”;
 - (b) in paragraph 2—
 - (i) for “Commission may adopt implementing acts” substitute “Secretary of State may make regulations”;
 - (ii) omit the second sentence.
- (22) In Article 23—
 - (a) in paragraph 2 omit “Union”;
 - (b) in paragraph 4—
 - (i) in the first subparagraph—
 - (aa) for the words from “Commission” to “Article 56,” substitute “Secretary of State may make regulations”;
 - (bb) omit “Union”;
 - (ii) in the second subparagraph—
 - (aa) for “Commission may adopt implementing acts” substitute “Secretary of State may make regulations”;
 - (bb) omit “Union”;
 - (cc) omit the words from “, including” to the end.
- (23) In Article 24—
 - (a) in paragraph 2—
 - (i) for “Member States” substitute “The designated authority”;
 - (ii) for “at national level” substitute “in the United Kingdom”;
 - (b) in paragraph 3—
 - (i) for “Commission may adopt implementing acts” substitute “Secretary of State may make regulations”;
 - (ii) omit the second sentence.
- (24) In Article 25—
 - (a) in paragraph 1—
 - (i) for the words from the beginning to “entered in” substitute “The Secretary of State must enter the names of established protected traditional specialities guaranteed on”;
 - (ii) after “such registrations” insert “under EU Regulation 1151/2012 as it had effect in the United Kingdom immediately before exit day”;

- (b) omit paragraph 2;
 - (c) in paragraph 3—
 - (i) for the words from “Commission” to “Article 56,” substitute “Secretary of State may make regulations”;
 - (ii) at the end insert “relating to the entries to be made on the register referred to in Article 22 under paragraph 1”;
 - (d) after paragraph 3 insert—

“4. In paragraph 1, in relation to an established protected traditional speciality guaranteed, ‘corresponding specifications’ means the product specification for the traditional speciality guaranteed as the specification stood immediately before exit day.”.
- (25) Omit Article 26.
- (26) In Article 27, for “internal market” substitute “United Kingdom”.
- (27) For Article 28 substitute the Article in Part 2 of Schedule 1.
- (28) In Article 29—
- (a) in paragraph 1(c), for “European” substitute “United Kingdom”;
 - (b) in paragraph 4, for the words from “Commission” to “Article 56,” substitute “Secretary of State may make regulations”;
 - (c) in paragraph 5—
 - (i) for “Commission may adopt implementing acts” substitute “Secretary of State may make regulations”;
 - (ii) omit the second sentence;
 - (d) in paragraph 6—
 - (i) for “adopting delegated and implementing acts” substitute “making regulations”;
 - (ii) for “Commission” substitute “Secretary of State”.
- (29) In Article 30—
- (a) in paragraph 1, for the words from “Commission” to “Article 56,” substitute “Secretary of State may make regulations”;
 - (b) in paragraph 2, for the words from “Commission” to “Article 56,” substitute “Secretary of State may make regulations”.
- (30) In Article 31—
- (a) in paragraph 2—
 - (i) for “Union” substitute “United Kingdom”;
 - (ii) for “Article 18(1) of Regulation (EC) No 1257/1999”, in the first place it occurs, substitute “Article 32 of Regulation (EU) No 1305/2013 of the European Parliament and of the Council on support for rural development by the European Agricultural Fund for Rural Development (EAFRD)”;
 - (iii) for “Article 18(1) of Regulation (EC) No 1257/1999”, in the second place it occurs, substitute “Article 32 of Regulation (EU) No 1305/2013 of the European Parliament and of the Council”;
 - (b) in paragraph 3—
 - (i) for the words from “Commission”, in the first place it occurs, to “Article 56,” substitute “Secretary of State may make regulations”;
 - (ii) for the words from “Commission”, in the second place it occurs, to “delegated act” substitute “Secretary of State may make regulations”;
 - (c) in paragraph 4, for the words from “Commission” to “Article 56,” substitute “Secretary of State may make regulations”.
- (31) Omit Article 32.

- (32) In Article 33(2)—
- (a) for “Commission may adopt implementing acts” substitute “Secretary of State may make regulations”;
 - (b) omit the second sentence.
- (33) In Article 34, for “Member States” substitute “The designated authority”.
- (34) In Article 36—
- (a) for the heading substitute—
 - “**Official controls**”;
 - (b) in paragraph 1 omit the first subparagraph;
 - (c) in paragraph 2 omit “referred to in paragraph 1”.
- (35) In Article 37—
- (a) in paragraph 1—
 - (i) in the first subparagraph—
 - (aa) in the words before point (a), for “Union” substitute “United Kingdom”;
 - (bb) in point (a), for the words from the beginning to “Regulation” substitute “the competent authority”;
 - (ii) in the second subparagraph, for “Member States” substitute “Secretary of State”;
 - (b) in paragraph 3—
 - (i) in the first subparagraph, for “Member States” substitute “The Secretary of State”;
 - (ii) in the second subparagraph, for “Commission” substitute “the Secretary of State”;
 - (iii) after the second subparagraph insert—

“The Secretary of State may make the information specified in the first and second subparagraphs public, and update that information periodically, in such manner as appears appropriate to the Secretary of State from time to time.”;
 - (c) omit paragraph 4.
- (36) In Article 38—
- (a) omit the first paragraph;
 - (b) in the second paragraph—
 - (i) for “Member States”, in the first place it occurs, substitute “The designated authority”;
 - (ii) for “Member States”, in the second place it occurs, substitute “that authority”.
- (37) In Article 39(3), in both points (a) and (b), for “Union” substitute “United Kingdom”.
- (38) In Article 40(1), for “Member States” substitute “The Secretary of State”.
- (39) In Article 41—
- (a) in paragraph 1, for “Union” substitute “United Kingdom”;
 - (b) for paragraph 2(b) substitute—

“(b) any relevant enactment.”;
 - (c) in paragraph 3, for the words from “Commission” to “Article 56,” substitute “Secretary of State may make regulations”.
- (40) In Article 42(2), for the words from “Commission” to “Article 56,” substitute “Secretary of State may make regulations”.
- (41) In Article 43—
- (a) for “Union rules or to those of Member States” substitute “retained EU law and any other enactments”;

- (b) for “those rules” substitute “such law and those enactments”.
- (42) In Article 44—
- (a) omit paragraph 2;
 - (b) in paragraph 3—
 - (i) for “Commission shall adopt implementing acts” substitute “Secretary of State may make regulations”;
 - (ii) omit the second sentence.
- (43) In Article 45—
- (a) in paragraph 1—
 - (i) in the words before point (a), for “Regulation (EC) No 1234/2007” substitute “Regulation 1308/2013”;
 - (ii) in point (a), for the words from “competent authorities” to “other competent” substitute “the competent authority or any designated”;
 - (b) in paragraph 2—
 - (i) for “Member States”, in the first place it occurs, substitute “The Secretary of State”;
 - (ii) for “on their territories” substitute “in the United Kingdom”;
 - (iii) for the second and third sentences substitute—

“The Secretary of State must publish the names and addresses of the groups referred to in Article 3(2) in such manner as appears appropriate to the Secretary of State from time to time.”.
- (44) In Article 46—
- (a) in paragraph 1, for “Member States” substitute “The Secretary of State”;
 - (b) in paragraph 3, for “Member States” substitute “The Secretary of State”.
- (45) Omit Article 47.
- (46) In Article 49—
- (a) in paragraph 1, in the first subparagraph—
 - (i) after “Article 48” insert “may be submitted to the Secretary of State”. They”;
 - (ii) for “different Member States or third countries” substitute “the United Kingdom and a third country, or from more than one country, as relevant.”;
 - (b) omit paragraphs 2 to 4;
 - (c) in paragraph 5, for “Commission,” substitute “Secretary of State”;
 - (d) in paragraph 6, for “Commission” substitute “Secretary of State”;
 - (e) in paragraph 7—
 - (i) omit the first subparagraph;
 - (ii) in the second subparagraph—
 - (aa) for “Commission may adopt implementing acts” substitute “Secretary of State may make regulations”;
 - (bb) omit the second sentence.
- (47) In Article 50—
- (a) in the heading, for “**Commission**” substitute “**Secretary of State**”;
 - (b) in paragraph 1—
 - (i) in the first subparagraph—
 - (aa) for “Commission”, in both places it occurs, substitute “Secretary of State”;
 - (bb) for “that it receives” substitute “received”;
 - (ii) in the second subparagraph—

- (aa) for “Commission” substitute “Secretary of State”;
 - (bb) after “public” insert “, in such manner as appears appropriate to the Secretary of State from time to time,”;
 - (cc) for “it” substitute “the Secretary of State”;
- (c) in paragraph 2—
- (i) in the words before point (a)—
 - (aa) for “Commission” substitute “Secretary of State”;
 - (bb) for “it” substitute “the Secretary of State”;
 - (cc) for “the *Official Journal of the European Union*” substitute “such manner as appears appropriate to the Secretary of State from time to time”;
 - (ii) in point (a) omit “the reference to the publication of the”.
- (48) In Article 51—
- (a) in paragraph 1—
 - (i) in the first subparagraph—
 - (aa) for “in the *Official Journal of the European Union*” substitute “of the documents published by virtue of Article 50(2)”;
 - (bb) omit “of a Member State or”;
 - (cc) omit “and established in a third country”;
 - (dd) for “Commission” substitute “Secretary of State”;
 - (ii) omit the second subparagraph;
 - (iii) in the last subparagraph, for “Commission” substitute “Secretary of State”;
 - (b) in paragraph 2, for “Commission”, in both places it occurs, substitute “Secretary of State”;
 - (c) in paragraph 3, in the first, second and third subparagraphs, for “Commission”, in each place it occurs, substitute “Secretary of State”;
 - (d) in paragraph 4, for “Commission” substitute “Secretary of State”;
 - (e) in paragraph 5, for “Commission” substitute “Secretary of State”;
 - (f) in paragraph 6—
 - (i) in the first subparagraph, for the words from “Commission” to “Article 56,” substitute “Secretary of State may make regulations”;
 - (ii) in the second subparagraph—
 - (aa) for “Commission may adopt implementing acts” substitute “Secretary of State may make regulations”;
 - (bb) omit the second sentence.
- (49) In Article 52—
- (a) in paragraph 1—
 - (i) for “Commission”, in both places it occurs, substitute “Secretary of State”;
 - (ii) for “it shall adopt implementing acts rejecting” substitute “the Secretary of State must reject”;
 - (iii) omit the second sentence;
 - (b) in paragraph 2—
 - (i) for “Commission” substitute “Secretary of State”;
 - (ii) for the words from “it shall” to “registering” substitute “the Secretary of State must register”;
 - (c) in paragraph 3—

- (i) in the words before point (a)—
 - (aa) for “Commission” substitute “Secretary of State”;
 - (bb) for “it” substitute “the Secretary of State”;
 - (ii) in point (a) omit the words from “by means” to “substantial”;
 - (iii) in point (b), for the words from “adopt” to the end substitute “decide whether to register the name”;
- (d) for paragraph 4 substitute—
- “4. After making a decision under this Article, the Secretary of State must publish in such manner as appears appropriate to the Secretary of State from time to time:
- (a) a notice informing the applicant and the public of the decision made in relation to the application, and
 - (b) where the application is approved, a copy of the approved product specification.”;
- (e) after paragraph 4 insert—
- “5. An implementing act to which paragraph 6 applies is revoked.
6. This paragraph applies to an implementing act adopted by the European Commission under Article 52 of EU Regulation 1151/2012 and incorporated into domestic law by section 3 of the European Union (Withdrawal) Act 2018.”.
- (50) After Article 52 insert the Article in Part 3 of Schedule 1.
- (51) In Article 53—
- (a) in paragraph 2, in the second subparagraph—
 - (i) for “Commission”, in both places it occurs, substitute “Secretary of State”;
 - (ii) for “the *Official Journal of the European Union*” substitute “such manner as appears appropriate to the Secretary of State from time to time”;
 - (b) in paragraph 3—
 - (i) in the first subparagraph, for the words from “Commission” to “Article 56,” substitute “Secretary of State may make regulations”;
 - (ii) in the second subparagraph—
 - (aa) for “Commission may adopt implementing acts” substitute “Secretary of State may make regulations”;
 - (bb) omit the second sentence;
 - (c) after paragraph 3 insert—
- “4. An implementing act to which paragraph 5 applies is revoked.
5. This paragraph applies to an implementing act relating to an amendment to a product specification adopted by the European Commission pursuant to Article 53 of EU Regulation 1151/2012 and incorporated into domestic law by section 3 of the EUWA.”.
- (52) In Article 54—
- (a) in paragraph 1—
 - (i) in the first subparagraph, in the words before point (a)—
 - (aa) for “Commission” substitute “Secretary of State”;
 - (bb) for “its” substitute “the Secretary of State’s”;
 - (cc) omit “adopt implementing acts to”;
 - (ii) in the second subparagraph, for “Commission” substitute “Secretary of State”;
 - (iii) omit the third subparagraph;
 - (b) in paragraph 2—

- (i) in the first subparagraph, for the words from “Commission” to “Article 56” substitute “Secretary of State may make regulations”;
 - (ii) in the second subparagraph—
 - (aa) for “Commission may adopt implementing acts” substitute “Secretary of State may make regulations”;
 - (bb) omit the second sentence.
 - (c) after paragraph 2 insert—
 - “3. An implementing act to which paragraph 4 applies is revoked.
 - 4. This paragraph applies to an implementing act adopted by the European Commission under Article 54 of EU Regulation 1151/2012 and incorporated into domestic law by section 3 of the EUWA.”.
- (53) After Title 5 insert the Title in Part 4 of Schedule 1.
- (54) In Title 6 omit Chapter 1.
- (55) For Article 56 substitute the Article in Part 5 of Schedule 1.
- (56) Omit Article 57.
- (57) In Article 58(1) omit the second subparagraph.
- (58) In Article 59 omit the second paragraph.
- (59) After Article 59 omit the words from “This Regulation” to “Member States.”.
- (60) After Annex 2 insert the Annex in Part 6 of Schedule 1.

Commission Implementing Regulation (EU) No 716/2013

8.—(1) Commission Implementing Regulation (EU) No 716/2013 laying down rules for the application of Regulation (EC) No 110/2008 of the European Parliament and of the Council on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks is amended as follows.

- (2) In Article 2, after point (d) insert—
 - “(e) ‘third country’ means any country, other than the United Kingdom, and includes:
 - (i) the Bailiwick of Guernsey;
 - (ii) the Bailiwick of Jersey;
 - (iii) the Isle of Man.”.
- (3) Article 7 is amended in accordance with paragraphs (4) and (5).
- (4) In paragraph 1—
 - (a) omit the first subparagraph;
 - (b) in the second subparagraph, in the words before point (a), for “Commission” substitute “Secretary of State”;
 - (c) in the third subparagraph—
 - (i) in the words before point (a)—
 - (aa) for “at least one Member State” substitute “the United Kingdom”;
 - (bb) for “Commission by one of the Member States” substitute “Secretary of State by private entities from the United Kingdom”;
 - (ii) in point (b), for “each of the Member States or” substitute “the”.
- (5) In paragraph 2—
 - (a) omit “Member States or the”;
 - (b) omit “from the third country in question”;
 - (c) for “Commission”, in both places it occurs, substitute “Secretary of State”.

- (6) In Article 8—
- (a) in paragraph 1, for “Commission” substitute “Secretary of State”;
 - (b) in paragraph 2, in the words before point (a)—
 - (i) for “Member State or” substitute “Secretary of State must send”;
 - (ii) for the words from “from the third country” to “receive” substitute “as the case may be”.
- (7) Omit Articles 8a and 9.
- (8) In Article 11(2), for “Commission”, in both places it occurs, substitute “Secretary of State”.
- (9) In Article 15—
- (a) in paragraph 1—
 - (i) for “Commission” substitute “Secretary of State”;
 - (ii) omit “the Member State,”;
 - (iii) omit “from the third country in question”;
 - (b) in paragraph 2, for “Commission” substitute “Secretary of State”;
 - (c) in paragraph 3—
 - (i) for “Commission” substitute “Secretary of State”;
 - (ii) for “it” substitute “the Secretary of State”;
 - (d) in paragraph 4, for “Commission”, in both places it occurs, substitute “Secretary of State”.
- (10) In Article 18(1), for “Commission”, in both places it occurs, substitute “Secretary of State”.
- (11) In Article 19—
- (a) in paragraph 2, for “from the Member State or” substitute “, where relevant, from”;
 - (b) in paragraph 3—
 - (i) in the first subparagraph, for “Commission”, in both places it occurs, substitute “Secretary of State”;
 - (ii) in the second subparagraph—
 - (aa) for “Commission” substitute “Secretary of State”;
 - (bb) omit “the Member State,”;
 - (cc) omit “from the third country,”.
- (12) In Article 20—
- (a) in paragraph 1—
 - (i) for “Commission” substitute “Secretary of State”;
 - (ii) for “it” substitute “the Secretary of State”;
 - (iii) omit “the Member State or”;
 - (iv) omit “from the third country,”;
 - (b) in paragraph 2—
 - (i) for “Commission” substitute “Secretary of State”;
 - (ii) omit “Member State,”;
 - (iii) omit “from the third country in question”;
 - (c) in paragraph 4—
 - (i) in the first subparagraph—
 - (aa) for “Commission” substitute “Secretary of State”;
 - (bb) for “it may suspend”, in the second place it occurs, substitute “the Secretary of State may suspend”;

- (cc) for “It” substitute “The Secretary of State”;
- (ii) in the second subparagraph, for “Commission” substitute “Secretary of State”.
- (13) After Article 23 omit the words from “This Regulation” to “Member States.”.
- (14) For Annexes 1 to 5 substitute the Annexes in Schedule 2.
- (15) Omit Annex 6.

Regulation (EU) No 251/2014 of the European Parliament and of the Council

9.—(1) Regulation (EU) No 251/2014 of the European Parliament and of the Council on the definition, description, presentation, labelling and the protection of geographical indications of aromatised wine products is amended as follows.

- (2) In Article 1(3)—
 - (a) for “Union”, in both places it occurs, substitute “United Kingdom”;
 - (b) for “Member States” substitute “United Kingdom”.
- (3) In Article 2—
 - (a) renumber the unnumbered paragraph as paragraph 1;
 - (b) in paragraph 1 as renumbered, after point (3), insert the points (new definitions) in Part 1 of Schedule 3;
 - (c) after paragraph 1 as renumbered insert—
 - “2. In this Regulation, a reference to a competent authority is to be interpreted, as regards the United Kingdom, as a reference to:
 - (1) in relation to England, Northern Ireland and Wales, the Secretary of State,
 - (2) in relation to Scotland, the Scottish Ministers.”.
- (4) In Article 5—
 - (a) in paragraph 1, for “Union” substitute “United Kingdom”;
 - (b) in paragraph 5 omit “Without prejudice to Article 26.”.
- (5) In Article 7 omit “Member State or third”.
- (6) Omit Article 9.
- (7) In Article 10—
 - (a) in paragraph 2(f)—
 - (i) omit the words from “laid down” to “indication”;
 - (ii) for “Union”, in the second place it occurs, substitute “retained EU”;
 - (b) after paragraph 2 insert—
 - “3. In paragraph 2(f), ‘applicable requirements’ means:
 - (a) requirements laid down in law relating to the use of the geographical indication in the country in which the relevant geographical area is located, including, where the geographical area is located in, or partly within, the United Kingdom, requirements contained in any enactment, and
 - (b) where they must be complied with in the country in which the relevant geographical area is located, requirements laid down by an organisation that manages the protected geographical indication.”.
- (8) In Article 11(2), for “Commission” substitute “Secretary of State”.
- (9) Omit Article 13.
- (10) Before Article 14 insert—

“Article 13a

Application for protection relating to a geographical area in the United Kingdom”;

An application for the protection of a geographical indication for an aromatised wine product originating in the United Kingdom must be submitted to the Secretary of State.”.

(11) In Article 14—

- (a) in the heading, for “Commission” substitute “Secretary of State”;
- (b) in paragraph 1, for “Commission” substitute “Secretary of State”;
- (c) in paragraph 2—
 - (i) for “Commission” substitute “Secretary of State”;
 - (ii) for “referred to in Article 13(5)” substitute “submitted to the Secretary of State”;
- (d) in paragraph 3—
 - (i) for “Commission” substitute “Secretary of State”;
 - (ii) for the words from “it shall” to the end substitute “the Secretary of State must publish the product specification referred to in Article 10(1)(c), and the single document referred to in Article 10(1)(d), in such manner as appears appropriate to the Secretary of State from time to time”;
- (e) in paragraph 4—
 - (i) for “Commission” substitute “Secretary of State”;
 - (ii) for the words from “it” to “decide to” substitute “the Secretary of State must”;
 - (iii) omit the second sentence.

(12) In Article 15, in the first paragraph—

- (a) for the words from “Member State or” to “protection or in” substitute “natural or legal person with a legitimate interest, or the authorities of”;
- (b) for “Commission” substitute “Secretary of State”.

(13) In Article 16—

- (a) for “Commission”, in both places it occurs, substitute “Secretary of State”;
- (b) omit “, by means of implementing acts.”;
- (c) for “Union law” substitute “retained EU law by granting the application”;
- (d) omit the second sentence;
- (e) after the existing paragraph insert—

“After making a decision under the first paragraph, the Secretary of State must publish in such manner as appears appropriate to the Secretary of State from time to time:

- (a) a notice informing the applicant and the public of the decision made in relation to the application, and
- (b) where the application is approved, a copy of the approved product specification.”.

(14) In Article 18(1)—

- (a) in the second subparagraph, for “Union” substitute “United Kingdom”;
- (b) in the third subparagraph—
 - (i) in point (a), for “Union” substitute “United Kingdom”;
 - (ii) for point (b) substitute “any relevant enactment or retained direct EU legislation”.

(15) In Article 19—

- (a) in paragraph 1, in the first subparagraph, for “Commission” substitute “Secretary of State”;
- (b) in paragraph 2, in the first subparagraph—

- (i) for the words from “, if that possibility” to “Union” substitute “in the United Kingdom”;
 - (ii) for “Commission” substitute “Secretary of State”;
 - (iii) for the words from “Directive” to the end substitute “Trade Marks Act 1994”.
- (16) In Article 20—
- (a) in paragraph 3, for “Union” substitute “United Kingdom”;
 - (b) omit paragraph 4.
- (17) In Article 21—
- (a) in the first paragraph, for the words from “Commission” to “Article 34(2),” substitute “Secretary of State must”;
 - (b) in the second paragraph, for “Union”, in both places it occurs, substitute “United Kingdom”;
 - (c) after the second paragraph insert—

“Any entry placed on the register by the Secretary of State, and any amendment of such an entry, or cancellation of such entry, takes effect immediately after the expiry of 20 days beginning with the day on which that entry, amendment or cancellation is made.”.
- (18) Omit Article 22.
- (19) In Article 23(1)—
- (a) in the words before point (a), for “Union” substitute “United Kingdom”;
 - (b) in point (a) omit “or authorities referred to in Article 22”.
- (20) In Article 24—
- (a) in paragraph 1, after “may apply” insert “to the Secretary of State”;
 - (b) in paragraph 2—
 - (i) for “13” substitute “14”;
 - (ii) for “Commission shall, by means of implementing acts,” substitute “Secretary of State may”;
 - (iii) omit the words from “and in the case” to the end;
 - (c) after paragraph 2 insert the paragraph in Part 2 of Schedule 3.
- (21) In Article 25—
- (a) in the first paragraph—
 - (i) for “Commission may, on its” substitute “Secretary of State may, on the Secretary of State’s”;
 - (ii) omit “a Member State, of”;
 - (iii) omit “, by means of implementing acts,”;
 - (iv) omit the second sentence;
 - (b) in the second paragraph, for “13” substitute “14”.
- (22) After Article 25 insert the Articles in Part 3 of Schedule 3.
- (23) Omit Articles 26 and 27.
- (24) In Article 28—
- (a) for the heading substitute—

“Power to make regulations”;
 - (b) in paragraph 1, in the words before point (a), for the words from “Commission” to “Article 33” substitute “Secretary of State may make regulations”;

- (c) in paragraph 2, for the words from “Commission” to “Article 33” substitute “Secretary of State may make regulations”;
- (d) in paragraph 3—
 - (i) in the words before point (a), for the words from “Commission” to “Article 33” substitute “Secretary of State may make regulations”;
 - (ii) in point (c), for “Commission” substitute “Secretary of State”;
- (e) in paragraph 4, for the words from “Commission” to “Article 33” substitute “Secretary of State may make regulations”.

(25) In Article 29—

- (a) for the heading substitute—

“Further power to make regulations”;

- (b) in paragraph 1—
 - (i) in the first subparagraph—
 - (aa) in the words before point (a), for the words from “Commission” to “measures” substitute “Secretary of State may make regulations”;
 - (bb) in point (d), for “Member States” substitute “authorities specified in those regulations”;
 - (ii) omit the second subparagraph;
- (c) in paragraph 2—
 - (i) in the first subparagraph, for the words from “Commission” to “adopt” substitute “Secretary of State may, by regulations, make provision for”;
 - (ii) omit the second subparagraph.

(26) In Article 30, for the words from “Commission” to “decide to” substitute “Secretary of State must”.

(27) In Article 31—

- (a) omit paragraph 1;
- (b) in paragraph 2—
 - (i) omit the second subparagraph;
 - (ii) insert as the last subparagraphs—

“The Secretary of State may make regulations concerning the administrative and physical checks to be conducted with regard to the respect of obligations resulting from the application of Chapter 3 of this Regulation.”.

(28) In Article 32—

- (a) in paragraph 1, for “Member States and the Commission” substitute “The authorities specified in paragraph 4”;
- (b) after paragraph 3 insert—

“4. The specified authorities are:

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

(29) For Article 33 substitute the Article in Part 4 of Schedule 3.

(30) Omit Article 34.

(31) In Article 36—

- (a) omit paragraph 1;
 - (b) in paragraph 2—
 - (i) for “have been” substitute “were”;
 - (ii) after “Regulation (EEC) No 1601/91(a)” insert “as it had effect in the United Kingdom immediately”;
 - (c) in paragraph 3—
 - (i) for “have been” substitute “were”;
 - (ii) after “Regulation (EEC) No 1601/91” insert “, as that Regulation had effect in the United Kingdom immediately before it was repealed,”.
- (32) In Article 37 omit the second paragraph.
- (33) After Article 37 omit the words from “This Regulation” to “Member States.”.
- (34) In Annex 1, in point (5)—
- (a) in the second subparagraph, for the words from “Directive 2009/54/EC” to “Directive 98/83/EC” substitute “any relevant water quality legislation”;
 - (b) after the third subparagraph insert the subparagraph in Part 5 of Schedule 3.
- (35) In Annex 2—
- (a) in Part A, in point (5) omit the second and third paragraphs;
 - (b) in Part B—
 - (i) in point (3), in the second paragraph—
 - (aa) for “other Member States” substitute “another country”;
 - (bb) for “Member State” substitute “country”;
 - (ii) in point (4), in the second paragraph—
 - (aa) for “other Member States” substitute “another country”;
 - (bb) for “Member State” substitute “country”;
 - (iii) in point (13), in the second paragraph—
 - (aa) for “other Member States” substitute “another country”;
 - (bb) for “Member States” substitute “country”.
- (36) After Annex 3 insert the Annex in Part 6 of Schedule 3.

Commission Delegated Regulation (EU) No 664/2014

10.—(1) Commission Delegated Regulation (EU) No 664/2014 supplementing Regulation (EU) No 1151/2012 of the European Parliament and of the Council with regard to the establishment of the Union symbols for protected designations of origin, protected geographical indications and traditional specialities guaranteed and with regard to certain rules on sourcing, certain procedural rules and certain additional transitional rules is amended as follows.

(2) Before Article 1 insert—

“Article A1

Definition of ‘third country’

In this Regulation ‘third country’ means any country, other than the United Kingdom, and includes:

- (a) the Bailiwick of Guernsey;
- (b) the Bailiwick of Jersey;

(a) OJ No. L 149, 14.6.1991, p. 1, as last amended before its repeal by Regulation (EC) No 1334/2008 of the European Parliament and of the Council (OJ No. L 354, 31.12.2008, p. 34) and repealed by Regulation (EU) No 251/2014 of the European Parliament and of the Council (OJ No. L 84, 20.3.2014, p. 14).

- (c) the Isle of Man.”.
- (3) Omit Article 4.
- (4) In Article 5—
 - (a) at the beginning insert “In the case of an application to which Article 49(5) of Regulation (EU) No 1151/2012 applies,”;
 - (b) omit “of the Member State or”;
 - (c) for “Commission” substitute “Secretary of State”;
 - (d) omit “of a Member State or”.
- (5) Article 6 is amended in accordance with paragraphs (6) to (9).
- (6) In paragraph 1, in both the third and fourth subparagraphs, for “Commission” substitute “Secretary of State”.
- (7) In paragraph 2—
 - (a) in the first subparagraph—
 - (i) in the first sentence, for the words from “authorities” to “relates to” substitute “Secretary of State”;
 - (ii) in the second sentence, for the words from “authorities” to “established” substitute “Secretary of State”;
 - (iii) in the third sentence—
 - (aa) after “a product specification” insert “concerning products originating in the United Kingdom”;
 - (bb) for “Member State” substitute “Secretary of State”;
 - (iv) for the fourth sentence substitute—

“Applications for a minor amendment to a product specification concerning products originating in the United Kingdom must be submitted by a group having a legitimate interest.”;
 - (v) in the fifth sentence, for “Commission” substitute “Secretary of State”;
 - (b) in both the third and fourth subparagraphs, for “Commission” substitute “Secretary of State”;
 - (c) for the fifth subparagraph substitute—

“After making a decision in relation to an application under this paragraph, the Secretary of State must publish in such manner as appears appropriate to the Secretary of State:

 - (a) a notice informing the applicant and the public of the decision made under this paragraph in relation to the application, and
 - (b) where the application is approved, a copy of the amended product specification.”;
 - (d) after the fifth subparagraph insert—

“The publication obligations imposed on the Secretary of State by the previous subparagraph also apply in the case of an application that is tacitly approved by virtue of the third subparagraph.”.
- (8) In paragraph 3—
 - (a) in the first subparagraph—
 - (i) at the beginning insert—

“This paragraph applies to a temporary amendment to a product specification concerning the production of products originating in a third country.”;
 - (ii) after “public authorities” insert “in a third country”;
 - (iii) at the end insert “in a third country”;

- (b) omit the second subparagraph.
- (9) After paragraph 3 insert the paragraphs in Schedule 4.
- (10) Omit Article 7(2).
- (11) Omit Articles 8 and 9.
- (12) In Article 10 omit the second paragraph.
- (13) After Article 10 omit the words from “This Regulation” to “Member States.”.

Commission Delegated Regulation (EU) No 665/2014

11.—(1) Commission Delegated Regulation (EU) No 665/2014 supplementing Regulation (EU) No 1151/2012 of the European Parliament and of the Council with regard to conditions of use of the optional quality term ‘mountain product’ is amended as follows.

- (2) Omit Article 6(2).
- (3) After Article 7 omit the words from “This Regulation” to “Member States.”.

Commission Implementing Regulation (EU) No 668/2014

12.—(1) Commission Implementing Regulation (EU) No 668/2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs is amended as follows.

- (2) Before Article 1 insert—

“Article 11

Definition of ‘third country’

In this Regulation ‘third country’ means any country, other than the United Kingdom, and includes:

- (a) the Bailiwick of Guernsey;
- (b) the Bailiwick of Jersey;
- (c) the Isle of Man.” .

- (3) Omit Article 1(2).
- (4) In Article 6—
 - (a) in paragraph 1 omit the second subparagraph;
 - (b) in paragraph 3, for “Commission”, in both places it occurs, substitute “Secretary of State”.
- (5) In Article 8—
 - (a) for the words from “as referred to” to “Member States concerned” substitute “by more than one group referred to in the first subparagraph of Article 49(1) of Regulation (EU) No 1151/2012 relating to a trans-border geographical area, or the name of a traditional speciality guaranteed, must be submitted to the Secretary of State by one of the applicant groups or through the authorities of the relevant third country concerned or by the authorities of one of the third countries concerned (where there is more than one of them)”;
 - (b) for “Member States and third” substitute “the”.
- (6) In Article 9(3), for “Commission” substitute “Secretary of State”.
- (7) In Article 10—
 - (a) in paragraph 1, in the first subparagraph, for the words from “The reference” to “lead to the” substitute “The application must be accompanied by”;
 - (b) in paragraph 2—

- (i) in the second subparagraph, for the words from “The reference” to “lead to the” substitute “It must also be accompanied by an”;
 - (ii) in the third subparagraph—
 - (aa) omit the first and second sentences;
 - (bb) omit “the fifth subparagraph of”;
 - (cc) for the words from “the reference” to the end substitute “the updated product specification”;
 - (iii) in the fourth subparagraph omit the second sentence;
 - (c) in paragraph 3, for “Commission” substitute “Secretary of State”;
 - (d) in paragraph 4, for “Commission”, in both places it occurs, substitute “Secretary of State”.
- (8) In Article 11(1) omit the second subparagraph.
- (9) In Article 12—
- (a) for “Commission” substitute “Secretary of State”;
 - (b) for “10, 11, and 15” substitute “10 and 11”.
- (10) In Article 13(3) omit “Union”.
- (11) In Article 14—
- (a) in paragraph 1—
 - (i) in the words before point (a)—
 - (aa) for the words from the beginning to “registering” substitute “Following a decision by the Secretary of State to approve an application to register”;
 - (bb) for “Commission” substitute “Secretary of State”;
 - (cc) at the end insert “and attach a copy of the product specification relating to the designation of origin or geographical indication to the register”;
 - (ii) for point (c) substitute—
 - “(c) the date of the Secretary of State’s decision;”;
 - (b) after paragraph 1 insert—
 - “1a. The entries in the register, and the provisions in the product specification attached to the register, relating to a designation of origin or geographical indication take effect immediately after the expiry of 20 days beginning with the day on which the entries are made in, and the copy of the product specification is attached to, the register, or, if a copy of the product specification is attached to the register at a later date, immediately after the expiry of 20 days beginning with the day on which the copy of the product specification is attached to the register.”;
 - (c) in paragraph 2—
 - (i) in the words before point (a)—
 - (aa) for the words from the beginning to “registering” substitute “Following a decision by the Secretary of State to approve an application to register”;
 - (bb) for “Commission” substitute “Secretary of State”;
 - (cc) at the end insert “and attach a copy of the product specification relating to the traditional speciality guaranteed to the register”;
 - (ii) for point (c) substitute—
 - “(c) the date of the Secretary of State’s decision;”;
 - (iii) omit point (f);
 - (d) after paragraph 2 insert—

“2a. The entries in the register, and the provisions in the product specification attached to the register, relating to a traditional speciality guaranteed take effect immediately after the expiry of 20 days beginning with the day on which the entries are made in, and the copy of the product specification is attached to, the register, or, if a copy of the product specification is attached to the register at a later date, immediately after the expiry of 20 days beginning with the day on which a copy of the product specification is attached to the register.”;

(e) for paragraphs 3 and 4 substitute the paragraphs in Schedule 5.

(12) Omit Article 15.

(13) In Article 16 omit the second, third and fourth paragraphs.

(14) After Article 16 omit the words from “This Regulation” to “Member States.”.

(15) In Annex 1—

(a) for “EU No: [for EU use only]” substitute “UK No: [for official use only]”;

(b) in the heading of paragraph 2, for “**Member State**” substitute “**United Kingdom**”;

(c) at the end for the words from “Reference to publication” to the end substitute—

“Product specification

[attach copy]”.

(16) In Annex 2—

(a) for “EU No: [for EU use only]” substitute “UK No: [for official use only]”;

(b) for “Member State” substitute “United Kingdom”.

(17) In Annex 3—

(a) in paragraph 1, for “*Official Journal (OJ)* publication” substitute “the single document (where relevant) or product specification published under Article 50(2) of Regulation (EU) No 1151/2012”;

(b) in paragraph 2—

(i) for “*Official Journal (OJ)* publication” substitute “in connection with the publication of the single document (where relevant) and product specification relating to the application published under Article 50(2) of Regulation (EU) No 1151/2012”;

(ii) for “Date of *OJ* publication” substitute “Date of publication”;

(c) in paragraph 3, for “*national*” substitute “*third country*”;

(d) in paragraph 5, in the second subparagraph, after “authorities” insert “of a third country”.

(18) In Annex 4—

(a) in paragraph 1, for “*Official Journal (OJ)* publication” substitute “the notice relating to the application published under Article 50(2) of Regulation (EU) No 1151/2012”;

(b) in paragraph 2—

(i) in the heading, for “***Official Journal (OJ)* publication**” substitute “**the notice relating to the application published under Article 50(2) of Regulation (EU) No 1151/2012**”;

(ii) for “Date of *OJ* publication” substitute “Date of publication”.

(19) In Annex 5—

(a) for “EU No: [for EU use only]” substitute “UK No: [for official use only]”;

(b) in paragraph 2, in the heading, for “**Member State**” substitute “**United Kingdom**”.

(20) In Annex 6—

(a) for “EU No: [for EU use only]” substitute “UK No: [for official use only]”;

(b) in paragraph 2, in the heading, for “**Member State**” substitute “**United Kingdom**”.

(21) In Annex 7—

(a) for “EU No: [for EU use only]” substitute “UK No: [for official use only]”;

- (b) in paragraph 2, in the heading, for “**Member State**” substitute “**United Kingdom**”;
 - (c) in paragraph 6, for points (a) and (b) substitute “[insert the proposed updated product specification]”.
- (22) In Annex 8—
- (a) for “EU No: [for EU use only]” substitute “UK No: [for official use only]”;
 - (b) in paragraph 1, in the heading, omit “**Member State or**”.
- (23) In Annex 9—
- (a) for “EU No: [for EU use only]” substitute “UK No: [for official use only]”;
 - (b) in paragraph 2, in the heading, for “**Member State**” substitute “**United Kingdom**”.

Commission Delegated Regulation (EU) 2018/273

13.—(1) Commission Delegated Regulation (EU) 2018/273 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards the scheme of authorisations for vine plantings, the vineyard register, accompanying documents and certification, the inward and outward register, compulsory declarations, notifications and publication of notified information, and supplementing Regulation (EU) No 1306/2013 of the European Parliament and of the Council as regards the relevant checks and penalties is amended as follows.

- (2) In Article 1—
- (a) in the words before point (a), for the words from “Regulations” to “respectively,” substitute “Regulation (EU) No 1308/2013”;
 - (b) omit points (a), (b) and (e);
 - (c) in point (f) omit “and the analytical databank of isotopic data”.
- (3) In Article 2—
- (a) in paragraph 1—
 - (i) in point (a)—
 - (aa) for the words from “Union territory” to “the European Union,” substitute “United Kingdom”;
 - (bb) omit the words from “or for graft” to the end;
 - (ii) omit points (c) and (d);
 - (iii) after point (k) insert—

“(l) ‘third country’ means any country, other than the United Kingdom, and includes:

 - (i) the Bailiwick of Guernsey;
 - (ii) the Bailiwick of Jersey;
 - (iii) the Isle of Man.”;
 - (b) in paragraph 2, for “IV to VIII” substitute “4, 5, 7 and 8”;
 - (c) in paragraph 3 omit the second subparagraph.
- (4) Omit Chapters 2 and 3.
- (5) In Article 8(3), for “Member States” substitute “The Food Standards Agency, in relation to operators operating in England, Northern Ireland or Wales, and Food Standards Scotland, in relation to operators operating in Scotland.”.
- (6) In Article 9(1)—
- (a) in point (a), for the words from “territory” to the end substitute “United Kingdom”;
 - (b) in point (d), for the words from “territory” to the end substitute “United Kingdom”;
 - (c) in point (e), in the words before point (i), for “territory of a Member State” substitute “United Kingdom”.
- (7) In Article 14—

- (a) in paragraph 1—
 - (i) in the first subparagraph—
 - (aa) in point (a), in the words before point (i), for “Union” substitute “United Kingdom”;
 - (bb) in point (b), in the words before point (i), for “Union” substitute “United Kingdom”;
 - (cc) in point (c)(v), for the words from “not listed” to the end substitute “that do not fall within point (a) or (b) of the second subparagraph of Article 81(2) of Regulation (EU) No 1308/2013”;
 - (ii) omit the second subparagraph;
 - (b) omit paragraph 2.
- (8) In Article 15—
- (a) in the heading, for “Union” substitute “United Kingdom”;
 - (b) in paragraph 1—
 - (i) in the first subparagraph, in the words before point (a), for “Union” substitute “United Kingdom”;
 - (ii) in the second subparagraph omit “of the Member States”.
- (9) In Article 17(1), in the first subparagraph, for the words from “the Union” to “thereto” substitute “retained EU law”.
- (10) In Article 20(2)—
- (a) in point (a)—
 - (i) for “Union law” substitute “retained EU law”;
 - (ii) for “Union” substitute “United Kingdom”;
 - (b) in point (c)—
 - (i) for “Union legislation” substitute “retained EU law”;
 - (ii) for “Union” substitute “United Kingdom”.
- (11) In Article 22(1), in the fourth subparagraph, for “Union customs office” substitute “customs office in the United Kingdom”.
- (12) In Article 24, in the first paragraph, in the words before point (a), for “Union”, in both places it occurs, substitute “United Kingdom”.
- (13) In Article 25(2)—
- (a) for “Union legislation” substitute “retained EU law”;
 - (b) for “Union” substitute “United Kingdom”.
- (14) In Article 26(1), for “Union” substitute “United Kingdom”.
- (15) In Article 27—
- (a) in paragraph 2, for “Union” substitute “United Kingdom”;
 - (b) in paragraph 3—
 - (i) for “of the Member State” substitute “in a case”;
 - (ii) after “free circulation” insert “in the United Kingdom”.
- (16) Omit Article 28(2).
- (17) Omit Article 30.
- (18) Omit Chapter 6.
- (19) In Article 36(2) omit the second subparagraph.
- (20) Omit Article 39.
- (21) Omit Articles 43, 44 and 46.

- (22) In Article 47(1) omit “of a Member State”.
- (23) Omit Articles 49 and 50.
- (24) In Article 51—
- (a) in the heading, for “the information notified” substitute “information”;
 - (b) in paragraph 1—
 - (i) in the words before point (a), for “Commission” substitute “Secretary of State”;
 - (ii) in point (d), for “Commission and the Member States” substitute “United Kingdom”.
- (25) After Article 56 omit the words from “This Regulation” to “Member States.”.
- (26) Omit Annexes 1 to 4.
- (27) Annex 5 is amended in accordance with paragraphs (28) to (31).
- (28) In Section A—
- (a) in the fourth paragraph—
 - (i) for “the Member States” substitute “the Secretary of State, by administrative decision.”;
 - (ii) at the end insert—

“The Secretary of State must publish such information in such manner as considered appropriate by the Secretary of State from time to time.”;
 - (b) after the fourth paragraph insert—

“The Secretary of State may not make a decision concerning the order and specific details concerning the layout of the entries on the documents referred to in Article 10 in relation to the use of such documents in Northern Ireland, Scotland or Wales without the consent of:

 - (a) in relation to Northern Ireland, the Department of Agriculture, Environment and Rural Affairs;
 - (b) in relation to Scotland, the Scottish Ministers;
 - (c) in relation to Wales, the Welsh Ministers.”;
 - (c) in the table—
 - (i) in the sixth row (competent authorities at place of dispatch), in the column numbered 1—
 - (aa) omit the words from “in the case” to “Member State or”;
 - (bb) for “Union” substitute “United Kingdom”;
 - (ii) in the twentieth row (date of dispatch etc.), in the column numbered 1, omit the words from “and, where” to the end”.
- (29) In Section B, in paragraph 2.1—
- (a) in point (a), for “Union rules” substitute “rules in retained EU law”;
 - (b) in point (d), in the words before point (i), for “Union provisions” substitute “provisions in retained EU law”;
 - (c) in point (e) (ii), in the wording relating to the use of the figure “12” (other operations), omit the words from “Examples” to “C III(b)(2)”.
- (30) In Section C, in note 1, for “Symbol of Member State” substitute “The symbol ‘UK’”.
- (31) In Section D, for the indications in that Section substitute “In English: Exported: Export declaration No ... of [date]”.
- (32) In Annex 7—
- (a) for Parts 1 and 2 substitute the Parts in Schedule 6;
 - (b) in Part 3, in Section C—
 - (i) in the instruction relating to Box 2, for “EU” substitute “United Kingdom”;

- (ii) in the instruction relating to Box 4, in the first indent, for “EU” substitute “United Kingdom”.

Commission Implementing Regulation (EU) 2018/274

14.—(1) Commission Implementing Regulation (EU) 2018/274 laying down rules for the application of Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards the scheme of authorisations for vine plantings, certification, the inward and outward register, compulsory declarations and notifications, and of Regulation (EU) No 1306/2013 of the European Parliament and of the Council as regards the relevant checks is amended as follows.

(2) In Article 1—

- (a) in the words before point (a), for the words from “Regulations” to “respectively” substitute “Regulation (EU) No 1308/2013”;
- (b) omit points (a), (e) and (f).

(3) Omit Chapter 2.

(4) In Article 12—

- (a) in paragraph 1—
 - (i) omit the second subparagraph;
 - (ii) in the last subparagraph—
 - (aa) at the beginning insert “In relation to wine produced in the United Kingdom,”;
 - (bb) for “Member State in which the wine is produced” substitute “United Kingdom”;
 - (cc) for “different Member States” substitute “the United Kingdom and a third country”;
 - (dd) for “by any of the Member States” substitute “in the United Kingdom or in the relevant third country”;

(b) in paragraph 2, in the second subparagraph, omit “, save where Member States decide otherwise”;

(c) after paragraph 3 insert—

“4. In this Article ‘third country’ means any country, other than the United Kingdom, and includes:

- (a) the Bailiwick of Guernsey;
- (b) the Bailiwick of Jersey;
- (c) the Isle of Man.”.

(5) In Article 13(2)—

- (a) in the first subparagraph, in point (c), after “competent authorities” insert “, by administrative decision, following an application made by an operator”;
- (b) omit the second subparagraph.

(6) In Article 14—

- (a) in paragraph 1(a)(iii), for the words from “of the classification” to “1308/2013” substitute “to the wine grape variety (which must be a wine grape variety that complies with point (a) or (b) of Article 81(2) of Regulation (EU) No 1308/2013)”;
- (b) in paragraph 2, for “Union legislation” substitute “retained EU law”.

(7) In Article 15(1)—

- (a) in point (a), for “under Union or national” substitute “by”;
- (b) in point (d) omit “Union or national”.

(8) In Article 16(1)(b)(v) omit “Union or national”.

- (9) Omit Chapters 5 and 6.
- (10) Omit Articles 33 and 34.
- (11) In Article 35 omit paragraphs 2 and 4.
- (12) After Article 37 omit the words from “This Regulation” to “Member States.”.
- (13) Omit Annexes 1 to 4.

Annex 2 to the EEA Agreement

- 15. In Annex 2 to the EEA Agreement, in Chapter 27, omit points 8, 9, 9a, 9b and 9ba.

Revocations

- 16. The retained direct EU legislation listed in Schedule 7 is revoked.

PART 4

Amendment of subordinate legislation relating to veterinary medicines

The Veterinary Medicines Regulations 2013

- 17.—(1) The Veterinary Medicines Regulations 2013(a) are amended as follows.
- (2) In regulation 4, after paragraph (3) insert—
 - “(4) Schedule 1A (converted EU marketing authorisations) has effect.”.
- (3) After Schedule 1 insert the Schedule in Part 1 of Schedule 8.
- (4) In Schedule 7—
 - (a) in paragraph 1—
 - (i) omit the definition of “national application”;
 - (ii) in the definition of “simultaneous application” omit the text after sub-paragraph (b);
 - (b) in paragraph 7—
 - (i) for the heading substitute “Application for a marketing authorisation for a pharmaceutical veterinary medicinal product”;
 - (ii) in sub-paragraph (a), for “a national application” substitute “an application”;
 - (iii) omit sub-paragraphs (b) and (c);
 - (iv) in the table—
 - (aa) in the heading, in the second column omit “national”;
 - (bb) in the heading, in the third column omit “national”;
 - (cc) for the heading for the fourth column (including the heading which straddles the fourth and fifth columns) substitute “Pharmacologically equivalent application”;
 - (dd) omit the fifth and sixth columns;
 - (c) omit paragraph 8;
 - (d) in paragraph 9—
 - (i) in sub-paragraph (1)—
 - (aa) for “a national application” substitute “an application”;
 - (bb) omit the words from “a decentralised” to “another member State”;

(a) S.I. 2013/2033, amended by S.I. 2014/599, 2018/761.

- (ii) in the table—
 - (aa) in the heading, in the second column omit “National”;
 - (bb) omit the third column;
- (e) omit paragraph 10;
- (f) in paragraph 11—
 - (i) for the heading substitute “Application for a marketing authorisation based on informed consent”;
 - (ii) for “fees” substitute “fee”;
 - (iii) for the text from “are in accordance” to the end (including the table) substitute “is £945 per application.”;
- (g) in paragraph 15, for the table substitute the table in Part 2 of Schedule 8;
- (h) omit paragraph 16;
- (i) in paragraph 17—
 - (i) in the heading omit the words from “dealt with” to the end;
 - (ii) in the table—
 - (aa) omit the heading for the second column;
 - (bb) omit the third and fourth columns;
- (j) in paragraph 18—
 - (i) for sub-paragraph (2) substitute—
“(2) The fees for a worksharing application are specified in the following table.”;
 - (ii) omit sub-paragraphs (3) to (5);
 - (iii) in the table—
 - (aa) omit the heading for the second column;
 - (bb) omit the third, fourth, fifth, sixth, seventh and eighth columns;
- (k) omit paragraphs 19 and 20;
- (l) in paragraph 21 omit the words from “in the case” to the end;
- (m) in paragraph 22, in the heading omit “national”;
- (n) omit paragraph 23;
- (o) in paragraph 24, in the first column of the table omit “or in another member State”;
- (p) in paragraph 48—
 - (i) in sub-paragraph (1), for the words from “£345” to the end substitute “£815”;
 - (ii) omit sub-paragraph (3);
- (q) in paragraph 49(1)—
 - (i) omit sub-paragraph (a);
 - (ii) in sub-paragraph (b), for “a third” substitute “another”.

PART 5

Amendment of retained direct EU legislation relating to veterinary medicines and residues

Regulation (EC) No 470/2009 of the European Parliament and of the Council

18.—(1) Regulation (EC) No 470/2009 of the European Parliament and of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin is amended as follows.

- (2) For Article 8 substitute the Article in Part 1 of Schedule 9.
- (3) For Article 9 substitute the Article in Part 2 of Schedule 9.
- (4) In Article 10—
 - (a) for paragraph 1 substitute the paragraphs in Part 3 of Schedule 9;
 - (b) in paragraph 2—
 - (i) in the first subparagraph—
 - (aa) for “Commission” substitute “Secretary of State”;
 - (bb) for “paragraph 1” substitute “paragraphs 1 and 1A”;
 - (cc) after “Article 14” insert “, subject to the consent requirement in Article 83B of Regulation (EU) 528/2012 (treating this Article as a provision of that Regulation for the purposes of construing Article 83B(1))”;
 - (dd) omit the second sentence;
 - (ii) in the second subparagraph, for “Article 10(2) of Directive 98/8/EC” substitute “Article 19(7) of Regulation (EU) No 528/2012”;
 - (c) omit paragraph 3.
- (5) In Article 14—
 - (a) for paragraph 1 substitute—

“1. The appropriate authority (or, as regards Article 10(2), the Secretary of State) must classify pharmacologically active substances in accordance with this Article.”;
 - (b) in paragraph 3, for the words after “human health” to the end substitute “, and when laying down a limit regard may be had to any international decisions in respect of that substance.”;
 - (c) in paragraph 5 omit the words from “, pursuant to” to “as appropriate,”;
 - (d) in paragraph 6 omit the words from “, pursuant to” to “as appropriate,”.
- (6) After Article 14 insert the Article in Part 4 of Schedule 9.

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

Date

We consent

Name
Name

Date Two of the Lords Commissioners of Her Majesty’s Treasury

SCHEDULE 1

Regulation 7(4)(b), (27), (50),
(53), (55) and (60)

Regulation (EU) No 1151/2012 of the European Parliament and of the Council: new provisions

PART 1

Article 3: new definitions

“(9) ‘the EUWA’ means the European Union (Withdrawal) Act 2018;

(10) ‘EU Regulation 1151/2012’ means Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs as it had effect in EU law immediately before exit day;

(11) ‘Regulation 1308/2013’ means Regulation (EU) No 1308/2013 of the European Parliament and of the Council establishing a common organisation of the markets in agricultural products;

(12) ‘Regulation 664/2014’ means Commission Delegated Regulation (EU) No 664/2014 supplementing Regulation (EU) No 1151/2012 of the European Parliament and of the Council with regard to the establishment of the Union symbols for protected designations of origin, protected geographical indications and traditional specialities guaranteed and with regard to certain rules on sourcing, certain procedural rules and certain additional transitional rules;

(13) ‘the Quality Schemes Regulations’ means the Quality Schemes (Agricultural Products and Foodstuffs) Regulations 2018;

(14) ‘the competent authority’, in relation to the United Kingdom, means the person specified in regulation 3(1) of the Quality Schemes Regulations;

(15) ‘the designated authority’ means:

- (a) unless point (b) or (c) applies, the person specified in regulation 3(2) of the Quality Schemes Regulations as the person responsible for carrying out the relevant function;
- (b) in a case where an official control has been delegated to a control body in accordance with Article 39, the control body to which the function has been delegated;
- (c) in a case where an enforcement authority has been appointed to carry out the function under regulation 6 of the Quality Schemes Regulations, the appointed enforcement authority;

(16) ‘domestic law’ means the means the law of England and Wales, Scotland and Northern Ireland;

(17) ‘enactment’ includes:

- (a) enactments of the type specified in paragraphs (a) to (f) of the definition of “enactment” in section 20(1) of the EUWA, and
- (b) except in Article 28, retained direct EU legislation;

(18) ‘established protected designation of origin’ means a designation of origin shown as a United Kingdom registered designation of origin on the register maintained by the European Commission pursuant to Article 11 of EU Regulation 1151/2012 as that register stood immediately before exit day;

(19) ‘established protected geographical indication’ means a geographical indication shown as a registered United Kingdom geographical indication on the register maintained by the European Commission pursuant to Article 11 of EU Regulation 1151/2012 as that register stood immediately before exit day;

(20) ‘established protected traditional speciality guaranteed’ means a traditional speciality guaranteed shown as a registered United Kingdom traditional speciality guaranteed on the

register maintained by the European Commission pursuant to Article 22 of EU Regulation 1151/2012 as that register stood immediately before exit day;

(21) ‘FTT’ means the First-tier Tribunal;

(22) ‘third country’ means any country, other than the United Kingdom, and includes:

- (a) the Bailiwick of Guernsey;
- (b) the Bailiwick of Jersey;
- (c) the Isle of Man.”

PART 2

Article 28: new Article

“Article 28

Existing enactments

1. Nothing in this Regulation prevents the maintenance of enactments on optional quality terms that are not covered by this Regulation and are in force immediately before exit day, provided that they comply with retained EU law.

2. In paragraph 1, ‘maintenance’ includes repeal and replacement, and revocation and replacement, without, in both cases, any substantive modification.”

PART 3

New Article 52a

“Article 52a

Applications pending on exit day

1. An application made under EU Regulation 1151/2012 before exit day to which paragraph 2 applies is deemed to be an application made under Article 49(1) of this Regulation for which scrutiny under Article 50(1) of this Regulation has not been commenced. Unless requested not to do so in writing by the applicant who submitted the application, the Secretary of State must scrutinise the application under Article 50(1) of this Regulation. The six month period specified in Article 50(1) starts from the day on which exit day falls.

2. This paragraph applies to an application submitted to the Secretary of State on or after 1st January 2019 or the Secretary of State or the Department for Environment Food and Rural Affairs before that date:

- (a) to register:
 - (i) a name of a geographical area in, or partly in, the United Kingdom as a designation of origin,
 - (ii) a name of a geographical area in, or partly in, the United Kingdom as a geographical indication, or
 - (iii) a name as a traditional speciality guaranteed, and
- (b) that has not been scrutinised under Article 49(2) of EU Regulation 1151/2012 before exit day or has been subject to scrutiny under Article 49(2) before exit day but for which no decision has been taken as to whether it meets the relevant conditions of EU Regulation 1151/2012 or is justified.

3. An application made under EU Regulation 1151/2012 before exit day to which paragraph 4 applies is deemed to be an application made under Article 49(1) of this Regulation that has been found by the Secretary of State, for the purpose of Article 50(2), to

fulfil the conditions laid down in this Regulation but for which the documents specified in Article 50(2) have not been published.

In the case of an application to register the name of a designation of origin or geographical indication, the Secretary of State must, unless requested not to do so in writing by the applicant who submitted the application, publish the single document and product specification submitted with the application made under EU Regulation 1151/2012 as soon as reasonably practicable after exit day.

In the case of an application to register the name of a traditional speciality guaranteed, the Secretary of State must, unless requested not to do so in writing by the applicant who submitted the application, publish the product specification submitted with the application made under EU Regulation 1151/2012 as soon as reasonably practicable after exit day.

The publication of the documents specified in the second or third subparagraph by the Secretary of State initiates the opposition procedure to which Article 51 of this Regulation applies in relation to the application.

4. This paragraph applies to an application submitted to the Secretary of State on or after 1st January 2019 or the Secretary of State or the Department for Environment Food and Rural Affairs before that date:

- (a) to register:
 - (i) the name of a geographical area in, or partly in, the United Kingdom as a designation of origin,
 - (ii) the name of a geographical area in, or partly in, the United Kingdom as a geographical indication, or
 - (iii) a name as a traditional speciality guaranteed, and
- (b) that has been scrutinised under Article 49(2) of EU Regulation 1151/2012 and been found by the Secretary of State to meet the conditions of, and to be justified under, EU Regulation 1151/2012 before exit day but for which the Commission has not adopted an implementing act under Article 52 of EU Regulation 1151/2012 before exit day.”

PART 4

New Title 5A

“TITLE 5A

APPEALS

Article 54a

Appeals: general

1. An appeal may be made to the FTT against a decision of the Secretary of State specified in the first column of the table in Annex 3.

2. Such an appeal may be made:

- (a) in all cases, by a person specified in the corresponding entry in the second column of the table in Annex 3;
- (b) in the case of a decision affecting an application submitted by the authorities of a third country, the authorities of that third country.

3. In determining such an appeal the FTT:

- (a) must consider the decision appealed against afresh, and
- (b) may take into account evidence that was not available to the Secretary of State.

4. The FTT may:
 - (a) dismiss the appeal, or
 - (b) if it allows the appeal, exercise any power specified in the corresponding entry in the third column of the table in Annex 3.
5. The Secretary of State may consider a decision specified in the first column of the table in Annex 3 afresh if evidence becomes available to the Secretary of State after making the original decision that was not available to the Secretary of State at the time of the original decision.
6. Paragraph 5 applies even though an appeal has been made to the FTT in respect of the original decision.
7. Where the Secretary of State decides to consider an original decision afresh in a case where an appeal has been made to the FTT in respect of that decision, the appeal to the FTT is suspended until such time as the Secretary of State has made a fresh decision in relation to the matter.
8. If the Secretary of State makes the same decision again, the appeal to the FTT restarts. If the Secretary of State makes a different decision, the appeal to the FTT ceases unless the FTT directs otherwise.

Article 54b

Appeals: applications to register designations of origin, geographical indications and traditional specialities guaranteed

1. Where an appeal is made to the FTT relating to a decision to approve an application to register a designation of origin, geographical indication or traditional speciality guaranteed, and the Secretary of State has made an entry in the relevant register pursuant to Article 52 relating to that registration, the entry in the register is to be maintained but is in suspense and must be marked to indicate that it is in suspense until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State.
2. Where an appeal is made to the FTT relating to a decision to approve an application to register a designation of origin, geographical indication or traditional speciality guaranteed, and the Secretary of State has not made an entry in the register, the Secretary of State must not make an entry in the register until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State.

Article 54c

Appeals: applications to amend product specifications

1. Paragraph 2 applies where an appeal is made to the FTT relating to a decision by the Secretary of State to approve an application of the type specified in Article 53(2) to amend a product specification relating to a protected designation of origin, protected geographical indication or traditional speciality guaranteed and the Secretary of State has not updated the entry in the relevant register relating to it pursuant to Article 14(3) of Commission Implementing Regulation (EU) 668/2014 by replacing the copy of the product specification attached to the relevant register with the amended version of the product specification.
2. Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the existing copy of the product specification attached to the entry in the relevant register relating to the protected designation of origin, protected geographical indication or traditional speciality guaranteed applies without amendment but the entry in the relevant register must be marked to indicate that an appeal relating to the amendment of the product specification is pending.
3. Paragraph 4 applies where an appeal is made to the FTT relating to a decision by the Secretary of State to approve an application of the type specified in Article 53(2) in relation

to the amendment of a product specification relating to a protected designation of origin, protected geographical indication or traditional speciality guaranteed and the Secretary of State has updated the entry in the relevant register relating to the protected designation of origin, protected geographical indication or traditional speciality guaranteed by replacing the copy of the product specification with the approved amended version.

4. Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the previous copy of the product specification attached to the entry in the relevant register is to be restored but the entry in the relevant register must be marked to indicate that an appeal relating to the amendment of the product specification is pending.

5. Paragraph 6 applies where an appeal is made to the FTT relating to a decision by the Secretary of State to reject an application of the type specified in Article 53(2) to amend a product specification relating to a protected designation of origin, protected geographical indication or traditional speciality guaranteed.

6. Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the existing copy of the product specification attached to the entry in the relevant register is to be maintained but the entry in the register must be marked to indicate that an appeal relating to an application to amend the product specification is pending.

7. Paragraph 8 applies where an appeal is made to the FTT relating to a decision by the Secretary of State to approve an application of the type specified in Article 6(4) and (4)(a) of Regulation 664/2014 to amend a product specification relating to a protected designation of origin, protected geographical indication or traditional speciality guaranteed on a temporary basis and the Secretary of State has not included an entry in the relevant register relating to the temporary amendment of the product specification pursuant to Article 14(3b) of Commission Implementing Regulation (EU) 668/2014.

8. Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the existing copy of the product specification attached to the entry in the relevant register applies without amendment but the entry in the register must be marked to indicate that an appeal relating to the temporary amendment of the product specification is pending.

9. Paragraph 10 applies where an appeal is made to the FTT relating to a decision by the Secretary of State to approve an application of the type specified in Article 6(4) of Regulation 664/2014 in relation to the temporary amendment of a product specification relating to a protected designation of origin, protected geographical indication or traditional speciality guaranteed and the Secretary of State has updated the entry in the relevant register by including an entry relating to the temporary amendment of the product specification.

10. Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the copy of the product specification attached to the entry in the relevant register applies and the entry in the relevant register relating to the temporary amendment must be marked to indicate that an appeal relating to the temporary amendment of the product specification is pending.

11. Paragraph 12 applies where an appeal is made to the FTT relating to a decision by the Secretary of State to reject an application of the type specified in Article 6(4) and (4)(a) of Regulation 664/2014 to amend a product specification relating to a protected designation of origin, protected geographical indication or traditional speciality guaranteed on a temporary basis.

12. Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the copy of the product specification attached to the entry in the relevant register applies but the entry in the register must be

marked to indicate that an appeal relating to an application to amend the product specification on a temporary basis is pending.

Article 54d

Appeals: applications to cancel registered designations of origin, geographical indications and traditional specialities guaranteed

1. Paragraph 2 applies where an appeal is made to the FTT relating to a decision of the Secretary of State to cancel the registration of a protected designation of origin, protected geographical indication or traditional speciality guaranteed under Article 54 and the Secretary of State has not removed the entry in the relevant register.
2. Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the entry in the relevant register is to be maintained but must be marked to indicate that an appeal relating to its cancellation is pending.
3. Paragraph 4 applies where an appeal has been made to the FTT relating to a decision of the Secretary of State to cancel the registration of a protected designation of origin, protected geographical indication or traditional speciality guaranteed and the Secretary of State has removed the entry in the relevant register.
4. Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the entry in the register must be restored but must be marked to indicate that an appeal relating to its cancellation is pending.
5. Paragraph 6 applies where an appeal has been made to the FTT relating to a decision of the Secretary of State not to cancel the registration of a protected designation of origin, protected geographical indication or traditional speciality guaranteed.
6. Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the entry in the relevant register relating to the protected designation of origin, protected geographical indication or traditional speciality guaranteed must be marked to indicate that an appeal relating to the cancellation of the entry is pending.”

PART 5

New Article 56

“Article 56

Regulations

1. Any power to make regulations conferred on the Secretary of State by this Regulation is exercisable by statutory instrument.
2. Such regulations may:
 - (a) contain supplementary, incidental, consequential, transitional or saving provision (including provision amending, repealing or revoking enactments);
 - (b) make different provision for different purposes.
3. Except as specified in paragraph 4, a statutory instrument containing regulations under this Regulation is subject to annulment in pursuance of a resolution of either House of Parliament.
4. A statutory instrument containing regulations made under the second subparagraph of Article 2(1) or Article 18(5), 30(1) or 41(3) may not be made unless a draft of the instrument has been laid before, and approved by a resolution of, each House of Parliament.

5. Before making any regulations under this Regulation, the Secretary of State must consult:

- (a) such bodies or persons as appear to the Secretary of State to be representative of the interests likely to be substantially affected by the regulations;
- (b) such other bodies or persons as the Secretary of State may consider appropriate.”

PART 6

New Annex 3

“ANNEX 3

APPEALS

<i>Decision</i>	<i>Persons who may appeal against the decision</i>	<i>FTT powers</i>
Decision of the Secretary of State to approve an application made under Article 49 to register a designation of origin, geographical indication or traditional speciality guaranteed	The persons are: (a) a person who submitted a reasoned statement of opposition under Article 51(2); (b) a person marketing a product that is, or may be, affected by the registration of the designation of origin, geographical indication or traditional speciality guaranteed.	Power to: (a) quash the decision and direct the Secretary of State to reject the application and (if appropriate) restore the register; (b) remit the matter to the Secretary of State with a direction to repeat the scrutiny of the application and (if appropriate) to restore the register in the meantime.
Decision of the Secretary of State to reject an application made under Article 49 to register a designation of origin, geographical indication or traditional speciality guaranteed	The persons are: (a) the person who submitted the application to register the designation of origin, geographical indication or traditional speciality guaranteed; (b) a person marketing a product that is, or may be, affected by the decision not to register the designation of origin, geographical indication or traditional speciality guaranteed.	Power to: (a) quash the decision and direct the Secretary of State to approve the application and register the designation of origin, geographical indication or traditional speciality guaranteed; (b) remit the matter to the Secretary of State with a direction to repeat the scrutiny of the application.
Decision of the Secretary of State to approve an application made under Article 53 to make an amendment to a product specification relating to a protected designation of origin, protected geographical indication or protected traditional speciality guaranteed	The persons are: (a) a person who submitted a reasoned statement of opposition under Article 51(2), as read with the first subparagraph of Article 53(2), in relation to the application; (b) a person marketing a product that is, or may be, affected by the amendment of the product specification.	Power to: (a) quash the decision and direct the Secretary of State to reject the application and (if appropriate) restore the register; (b) remit the matter to the Secretary of State with a direction to repeat the scrutiny of the application and (if appropriate) to restore the register in the meantime.

<i>Decision</i>	<i>Persons who may appeal against the decision</i>	<i>FTT powers</i>
Decision of the Secretary of State to reject an application made under Article 53 to make an amendment to a product specification relating to a protected designation of origin, protected geographical indication or protected traditional speciality guaranteed	The persons are: (a) the person who submitted the application to amend the product specification; (b) a person marketing a product that is, or may be, affected by the decision not to approve the application to amend the product specification.	Power to: (a) quash the decision and direct the Secretary of State to approve the application and attach a copy of the amended product specification to the register; (b) remit the matter to the Secretary of State with a direction to repeat the scrutiny of the application.
Decision of the Secretary of State under Article 54 to cancel the registration of a protected designation of origin, protected geographical indication or protected traditional speciality guaranteed on the Secretary of State's initiative	The persons are: (a) a person who submitted a reasoned statement of opposition under Article 51(2) as read with Article 7(1) and (4) of Regulation 664/2014; (b) a person marketing a product that is, or may be, affected by the cancellation of the registration of the protected designation of origin, protected geographical indication or protected traditional speciality guaranteed.	Power to: (a) quash the decision and direct the Secretary of State (if appropriate) to restore the register; (b) remit the matter to the Secretary of State with a direction to repeat the scrutiny relating to the cancellation and (if appropriate) to restore the register in the meantime.
Decision of the Secretary of State to approve an application made under Article 54 to cancel the registration of a protected designation of origin, protected geographical indication or protected traditional speciality guaranteed	The persons are: (a) a person who submitted a reasoned statement of opposition under Article 51(2) as read with Article 7(1) and (4) of Regulation 664/2014; (b) a person marketing a product that is, or may be, affected by the cancellation of the registration of the protected designation of origin, protected geographical indication or protected traditional speciality guaranteed.	Power to: (a) quash the decision and direct the Secretary of State to (if appropriate) restore the register, or (b) remit the matter to the Secretary of State with a direction to repeat the scrutiny of the application and (if appropriate) to rectify the register in the meantime.
Decision of the Secretary of State to reject an application made under Article 54 to cancel the registration of a protected designation of origin, protected geographical indication or protected traditional speciality guaranteed	The persons are: (a) the person who submitted the application to cancel the registration of the protected designation of origin, protected geographical indication or protected traditional speciality guaranteed; (b) a person marketing a product that is, or may be, affected by the decision not to cancel the registration the	Power to: (a) quash the decision and direct the Secretary of State to cancel the registration; (b) remit the matter to the Secretary of State with a direction to repeat the scrutiny of the application.”

<i>Decision</i>	<i>Persons who may appeal FTT powers against the decision</i>
	protected designation of origin, protected geographical indication or protected traditional speciality guaranteed.

SCHEDULE 2

Regulation 8(14)

Commission Implementing Regulation (EU) No 716/2013: new Annexes 1 to 5

“ANNEX 1

APPLICATION TO REGISTER A GEOGRAPHICAL INDICATION

Date of receipt (DD/MM/YYYY) ...

[for official use]

Number of pages (including this page) ...

File number ...

[for official use]

Geographical indication to be registered ...

Category of the spirit drink

Applicant

Name of legal or natural person ...

Full address (street number and name, town/city and postal code, country) ...

Legal status, size and composition (*in the case of legal persons*) ...

Nationality ...

Tel., e-mail

Intermediary (if applicable)

Third-country authority

Name(s) of intermediary(ies) ...

Full address(es) (street number and name, town/city and postal code, country) ...

Tel., e-mail ...

Proof of protection in third country ...

Technical file

Number of pages ...

Name(s) of signatory(ies) ...

Signature(s) ...

ANNEX 2 **TECHNICAL FILE**

Date of receipt (DD/MM/YYYY) ...

[for official use]

Number of pages (including this page) ...

File number ...

[for official use]

Geographical indication to be registered ...

Category of the spirit drink

Description of the spirit drink

- Physical, chemical and/or organoleptic characteristics
- Specific characteristics (compared to spirit drinks of the same category)

Geographical area concerned

Method for obtaining the spirit drink

Link with the geographical environment or origin

- Details of the geographical area or origin relevant to the link
- Specific characteristics of the spirit drink attributable to the geographical area

National/regional provisions

Applicant

- Third Country or legal/natural person ...
- Full address (street number and name, town/city and postal code, country) ...
- Legal status (in the case of legal persons) ...

Supplement to the geographical indication

Specific labelling rules

ANNEX 3

OBJECTION TO A GEOGRAPHICAL INDICATION

Date of receipt (DD/MM/YYYY) ...

[for official use]

Number of pages (including this page) ...

File number ...

[for official use]

Objector

Name of legal or natural person ...

Full address (street number and name, town/city and postal code, country) ...

Nationality ...

Tel., e-mail ...

Intermediary (if applicable)

Third-country authority (optional)

Name(s) of intermediary(ies) ...

Full address(es) (street number and name, town/city and postal code, country) ...

Objected geographical indication ...

Prior rights

Registered geographical indication (*)

National geographical indication (*)

[() delete as appropriate]*

Name ...

Registration number ...

Date of registration (DD/MM/YYYY) ...

Trademark

Sign ...

List of products and services ...

Registration number ...

Date of registration ...

Country of origin ...

Reputation/renown (*) ...

[() delete as appropriate]*

Grounds for objection

Name of signatory ...

Signature ...

ANNEX 4

APPLICATION TO CANCEL A GEOGRAPHICAL INDICATION

Date of receipt (DD/MM/YYYY) ...

[for official use]

Number of pages (including this page) ...

Author of request of cancellation ...

File number ...

[for official use]

Name of legal or natural person ...

Full address (*street number and name, town/city and postal code, country*) ...

Nationality ...

Tel., e-mail ...

Contested geographical indication ...

Legitimate interest of the author of the request ...

Statement by the third country (where relevant)...

Grounds for cancellation

Name of signatory ...

Signature ...

ANNEX 5

APPLICATION TO AMEND THE TECHNICAL FILE OF A GEOGRAPHICAL INDICATION

Date of receipt (DD/MM/YYYY) ...

[for official use]

Number of pages (including this page) ...

File number ...

[for official use]

Intermediary (if applicable)

Third-country authority (optional)

Name(s) of intermediary(ies) ...

Full address(es) (street number and name, town/city and postal code, country) ...

Tel., e-mail ...

Name of the geographical indication**Specification heading affected by the amendment**

Protected name (*)

Description of product (*)

Geographical area (*)

Link (*)

Names and addresses of control authorities (*)

Other (*)

[(*) delete as appropriate]

Amendment

Amendment to the product specification not entailing an amendment of the main specifications (*)

Amendment to the product specification entailing an amendment to the main specifications (*)

[(*) *delete as appropriate*]

Explanation of the amendment ...**Amended main specifications**

[*on separate sheet*]

Name of signatory ...

Signature ...”

Regulation (EU) No 251/2014 of the European Parliament and of the
Council: new provisions

PART 1

Article 2(1): new definitions

- “(4) ‘constituent nation’ means England, Northern Ireland, Scotland or Wales;
- (5) ‘country’, in relation to the United Kingdom, means the United Kingdom as a whole and does not mean any of the individual constituent nations forming part of the United Kingdom;
- (6) ‘enactment’ includes enactments of the type specified in paragraphs (a) to (f) of the definition of ‘enactment’ in section 20(1) of the European Union (Withdrawal) Act 2018 but does not include enactments of the type specified in paragraphs (g) and (h) of that definition;
- (7) ‘FTT’ means the First-tier Tribunal;
- (8) ‘register’ means the register established and maintained by the Secretary of State pursuant to Article 21;
- (9) ‘third country’ means any country, other than the United Kingdom, and includes:
- (a) the Bailiwick of Guernsey;
 - (b) the Bailiwick of Jersey;
 - (c) the Isle of Man.”

PART 2

Article 24: new paragraph 3

- “3. In a case where the proposed amendment is only minor and the Secretary of State decides not to follow the procedure laid down in Articles 14(2) and 15, the Secretary of State, after making a decision in relation to the application, must publish in such manner as appears appropriate to the Secretary of State from time to time:
- (a) a notice informing the applicant and the public of the decision made in relation to the application, and
 - (b) where the application is approved, a copy of the single document and product specification for the geographical indication incorporating the approved amendment.”

PART 3

New Articles 25a to 25d

“Article 25a

Appeals: general

1. An appeal may be made to the FTT against a decision of the Secretary of State specified in the first column of the table in Annex 4.
2. Such an appeal may be made:
 - (a) in all cases, by a person specified in the corresponding entry in the second column of the table in Annex 4;

- (b) in the case of a decision affecting an application submitted by the authorities of a third country, the authorities of that third country.
- 3. In determining such an appeal, the FTT:
 - (a) must consider the decision appealed against afresh, and
 - (b) may take into account evidence that was not available to the Secretary of State.
- 4. The FTT may:
 - (a) dismiss the appeal, or
 - (b) if it allows the appeal, exercise any power specified in the corresponding entry in the third column of the table in Annex 4.
- 5. The Secretary of State may consider a decision specified in the first column of the table in Annex 4 afresh if evidence becomes available to the Secretary of State after making the original decision that was not available to the Secretary of State at the time of the original decision.
- 6. Paragraph 5 applies even though an appeal has been made to the FTT in respect of the original decision.
- 7. Where the Secretary of State decides to consider an original decision afresh in a case where an appeal has been made to the FTT in respect of that decision, the appeal to the FTT is suspended until such time as the Secretary of State has made a fresh decision in relation to the matter.
- 8. If the Secretary of State makes the same decision again, the appeal to the FTT restarts. If the Secretary of State makes a different decision, the appeal to the FTT ceases unless the FTT directs otherwise.

Article 25b

Appeals: applications to register geographical indications

- 1. Where an appeal is made to the FTT relating to a decision to approve an application to register a geographical indication and the Secretary of State has made an entry in the register relating to that geographical indication, the entry in the register is to be maintained but is in suspense and must be marked to indicate that it is in suspense until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State.
- 2. Where an appeal is made to the FTT relating to a decision to approve an application to register a geographical indication and the Secretary of State has not made an entry in the register relating to that geographical indication, the Secretary of State must not make an entry in the register until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State.

Article 25c

Appeals: applications to amend product specifications

- 1. Paragraph 2 applies where an appeal is made to the FTT relating to a decision by the Secretary of State to approve an application made under Article 24 to amend a product specification for a geographical indication and the Secretary of State has not updated the entry in the register relating to the indication to incorporate the approved amendment.
- 2. Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the existing entry in the register relating to the geographical indication is to be maintained but must be marked to indicate that an appeal relating to the amendment of the product specification is pending.
- 3. Paragraph 4 applies where an appeal is made to the FTT relating to a decision by the Secretary of State to approve an application made under Article 24 in relation to the

amendment of a product specification for a geographical indication and the Secretary of State has updated the entry in the register relating to the geographical indication to incorporate the approved amendment.

4. Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the previous entry in the register for the protected geographical indication is to be restored but the entry in the register must be marked to indicate that an appeal relating to the amendment of the product specification is pending.

5. Paragraph 6 applies where an appeal is made to the FTT relating to a decision by the Secretary of State to reject an application made under Article 24 to amend a product specification for a protected geographical indication.

6. Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the existing entry in the register is to be maintained but the entry in the register must be marked to indicate that an appeal relating to an application to amend the specification is pending.

Article 25d

Appeals: applications to cancel geographical indications

1. Paragraph 2 applies where an appeal is made to the FTT relating to a decision of the Secretary of State to cancel the registration of a protected geographical indication under Article 25 and the Secretary of State has not removed the entry in the register relating to the geographical indication.

2. Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the entry in the register for the geographical indication is to be maintained but must be marked to indicate that an appeal relating to its cancellation is pending.

3. Paragraph 4 applies where an appeal has been made to the FTT relating to a decision of the Secretary of State to cancel the registration of a protected geographical indication and the Secretary of State has removed the entry in the register for the geographical indication.

4. Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the entry in the register must be restored but must be marked to indicate that an appeal relating to its cancellation is pending.

5. Paragraph 6 applies where an appeal has been made to the FTT relating to a decision of the Secretary of State not to cancel the registration of a protected geographical indication.

6. Until the FTT has determined the appeal and any necessary consequent action or decision has been taken by the Secretary of State, the entry in the register relating to the protected geographical indication must be marked to indicate that an appeal relating to the cancellation of the entry is pending.”

PART 4

New Article 33

“Article 33

Provisions relating to regulations

1. Any power to make regulations conferred on the Secretary of State by this Regulation is exercisable by statutory instrument.

2. Such regulations may:

(a) contain supplementary, incidental, consequential, transitional or saving provision (including provision amending, repealing or revoking enactments and retained direct EU legislation);

(b) make different provision for different purposes.

3. Except as specified in paragraph 4, a statutory instrument containing regulations under this Regulation is subject to annulment in pursuance of a resolution of either House of Parliament.

4. A statutory instrument containing regulations under Article 28 may not be made unless a draft of the instrument has been laid before, and approved by a resolution of, each House of Parliament.”

PART 5

Annex 1, point (5): new subparagraph

“In this point, ‘relevant water quality legislation’ means:

(a) in relation to aromatised wine products marketed in England:

(i) the Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2007(a);

(ii) the Water Supply (Water Quality) Regulations 2016(b);

(iii) the Private Water Supplies (England) Regulations 2016(c);

(b) in relation to aromatised wine products marketed in Northern Ireland:

(i) the Natural Mineral Water, Spring Water and Bottled Drinking Water (Northern Ireland) Regulations 2015(d);

(ii) the Private Water Supplies Regulations (Northern Ireland) 2017(e);

(iii) the Water Supply (Water Quality) Regulations (Northern Ireland) 2017(f);

(c) in relation to aromatised wine products marketed in Scotland:

(i) the Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) (No. 2) Regulations 2007(g);

(ii) the Public Water Supplies (Scotland) Regulations 2014(h);

(iii) the Water Intended for Human Consumption (Private Supplies) (Scotland) Regulations 2017(i);

(d) in relation to aromatised wine products marketed in Wales:

(i) the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015(j);

(ii) the Private Water Supplies (Wales) Regulations 2017(k);

(iii) the Water Supply (Water Quality) Regulations 2018(l).”

(a) S.I. 2007/2785, amended by S.I. 2009/1598, 2010/433, 2011/451, 1043, 2014/1855, 2018/352.

(b) S.I. 2016/614, amended by S.I. 2017/506, 2018/706.

(c) S.I. 2016/618, amended by S.I. 2017/506, 2018/707.

(d) S.R. 2015 No 365, amended by S.R. 2017 No 201.

(e) S.R. 2017 No. 211.

(f) S.R. 2017 No. 212.

(g) S.S.I. 2007/483, amended by S.S.I. 2009/273, 2010/89, 127, 2011/94, 2014/312, 2015/100, 363, 2017/287.

(h) S.S.I. 2014/364; relevant amending instruments are S.S.I. 2015/346, 2017/281.

(i) S.S.I. 2017/282, amended by S.S.I. 2017/321.

(j) S.I. 2015/1867 (W. 274), amended by S.I. 2017/935.

(k) S.I. 2017/1041 (W. 270).

(l) S.I. 2018/647 (W. 121).

PART 6

New Annex 4

“ANNEX 4

APPEALS

<i>Decision</i>	<i>Persons who may appeal against the decision</i>	<i>FTT powers</i>
Decision of the Secretary of State to approve an application made under Article 11 or 13a to register a geographical indication	The persons are: (a) a person who lodged a duly substantiated statement of opposition under Article 15; (b) a person marketing a product that is, or may be, affected by the registration of the geographical indication.	Power to: (a) quash the decision and (if appropriate) direct the Secretary of State to reject the application and (if appropriate) restore the register; (b) remit the matter to the Secretary of State with a direction to repeat the scrutiny of the application and (if appropriate) to restore the register in the meantime.
Decision of the Secretary of State to reject an application made under Article 11 or 13a to register a geographical indication	The persons are: (a) the person who submitted the application to register the geographical indication; (b) a person marketing a product that is, or may be, affected by the decision not to register the geographical indication.	Power to: (a) quash the decision and direct the Secretary of State to register the geographical indication; (b) remit the matter to the Secretary of State with a direction to repeat the scrutiny of the application.
Decision of the Secretary of State to approve an application made under Article 24 to amend a product specification for a protected geographical indication	The persons are: (a) in relation to the approval of an application to which the first sentence of Article 24(2) applies, a person who lodged a duly substantiated statement of opposition under Article 15 as read with Article 24(2); (b) in relation to the approval of any application under Article 24(2), a person marketing a product that is, or may be, affected by the amendment of the product specification.	Power to: (a) quash the decision and direct the Secretary of State to reject the application and (if appropriate) restore the register; (b) remit the matter to the Secretary of State with a direction to repeat the scrutiny of the application and (if appropriate) to restore the register in the meantime.
Decision of the Secretary of State to reject an application made under Article 24 to amend a product specification for a protected geographical indication	The persons are: (a) the person who submitted the application to amend the product specification; (b) a person marketing a product that is, or may be, affected by the decision to reject the application to amend the product specification.	Power to: (a) quash the decision and direct the Secretary of State to approve the application and update the register; (b) remit the matter to the Secretary of State with a direction to repeat the scrutiny of the application.

<i>Decision</i>	<i>Persons who may appeal against the decision</i>	<i>FTT powers</i>
Decision of the Secretary of State under Article 25 to cancel the registration of a protected geographical indication on the Secretary of State's initiative	The persons are: (a) a person who lodged a duly substantiated statement of opposition under Article 15 as read with the second paragraph of Article 25; (b) a person marketing a product that is, or may be, affected by the cancellation of the registration of the protected geographical indication.	Power to: (a) quash the decision and (if appropriate) direct the Secretary of State to restore the register; (b) remit the matter to the Secretary of State with a direction to repeat the scrutiny relating to the cancellation of the registration and (if appropriate) to restore the register in the meantime.
Decision of the Secretary of State to approve an application made under Article 25 to cancel the registration of a protected geographical indication	The persons are: (a) a person who lodged a duly substantiated statement of opposition under Article 15 as read with the second paragraph of Article 25; (b) a person marketing a product that is, or may be, affected by the cancellation of the registration of the protected geographical indication.	Power to: (a) quash the decision and direct the Secretary of State to reject the application and (if appropriate) restore the register; (b) remit the matter to the Secretary of State with a direction to repeat the scrutiny of the application and (if appropriate) to restore the register in the meantime.
Decision of the Secretary of State to reject an application made under Article 25 to cancel the registration of a protected geographical indication	The persons are: (a) the person who submitted the application to cancel the registration of the protected geographical indication; (b) a person marketing a product that is, or may be, affected by the decision not to cancel the registration of the protected geographical indication.	Power to: (a) quash the decision and direct the Secretary of State to cancel the registration; (b) remit the matter to the Secretary of State with a direction to repeat the scrutiny of the application.”

SCHEDULE 4

Regulation 10(9)

Commission Delegated Regulation (EU) No 664/2014, Article 6: new paragraphs 3a to 3d and 4 to 4l

“3a. Temporary amendments concerning products originating in third countries must be communicated to the Secretary of State before the end of the period of two weeks beginning with the day after the first day on which the amendments apply in the relevant third country.

3b. The temporary amendments must be communicated to the Secretary of State by a group having a legitimate interest or by the authorities of the relevant third country.

3c. The communication must be accompanied by:

(a) the reasons for the amendments, and

- (b) as appropriate, evidence of the relevant sanitary and phytosanitary measures or a copy of a document issued by the authorities of the relevant third country recognising the natural disaster or adverse weather conditions.

3d. The Secretary of State must make the temporary amendments public in such manner as appears appropriate to the Secretary of State from time to time.

4. Paragraphs 4a to 4l apply to an application for a temporary amendment to a product specification for a protected designation of origin, protected geographical indication or traditional speciality guaranteed ('the temporary amendments application') concerning the production of products originating in the United Kingdom where it is impossible or difficult to comply with a requirement in a product specification in relation to the production of a product in the United Kingdom:

- (a) because of the imposition of an obligatory sanitary or phytosanitary measure in the United Kingdom by a public authority, including the Secretary of State, or
- (b) for reasons linked to a natural disaster or adverse weather conditions recognised by a public authority, including the Secretary of State.

4a. The temporary amendments application may be made to the Secretary of State.

4b. The procedure laid down in Articles 49 to 52 of Regulation (EU) No 1151/2012 does not apply to the temporary amendments application.

4c. The temporary amendments application may be made by a group having a legitimate interest in the relevant protected designation of origin, protected geographical indication or traditional speciality guaranteed. If the application is not made by the group that submitted the application to register the relevant protected designation of origin, protected geographical indication or traditional speciality guaranteed ('the original applicant group'), the Secretary of State must give the original applicant group the opportunity to make comments on the application if that group still exists.

4d. The temporary amendments application must:

- (a) describe the amendment applied for,
- (b) be accompanied by a copy of the product specification annotated in a way to show the proposed temporary amendment,
- (c) compare, for each amendment—
 - (i) the original product specification against the proposed amended product specification, and
 - (ii) where relevant, the original single document against the proposed amended single document,
- (d) provide a summary of the reasons why an amendment is required, explaining how the circumstances specified in point (a) or (b) of paragraph 4 affect the production of products to which the protected designation of origin, protected geographical indication or traditional speciality guaranteed applies,
- (e) be accompanied, as the case may be, by:
 - (i) evidence of the sanitary or phytosanitary measure or a reference to that measure that will enable the Secretary of State to identify the measure, and obtain a copy of it, easily, or
 - (ii) a copy of a document issued by the relevant public authority recognising the natural disaster or adverse weather conditions or a reference to that document that will enable the Secretary of State to identify the document, and obtain a copy of it, easily,
- (f) provide an estimate, where this is possible, of the period during which it is anticipated that the temporary amendment will need to apply, and

(g) be self-sufficient and contain all amendments to the product specification, and, where relevant, to the single document, for which approval is sought.

4e. A temporary amendments application that does not comply with paragraph 4d is not admissible. The Secretary of State must inform the applicant if the application is inadmissible as soon as reasonably practicable after receiving the application.

4f. The Secretary of State may approve a temporary amendments application if the Secretary of State considers that a temporary amendment to the product specification is appropriate.

4g. Where a temporary amendments application is approved, the Secretary of State must specify the period for which the temporary amendment is approved.

4h. That period may be specified by reference to a set period of time or may be specified by reference to the a period expiring on the happening of an event specified in the decision. The Secretary of State, in deciding the period, must take into account the conditions prevailing at the time the decision to approve the application is taken and the period for which the Secretary of State anticipates that those conditions will continue.

4i. The Secretary of State may extend the temporary amendment on one or more occasions if the Secretary of State considers it is appropriate to do so having regard to the conditions prevailing at the time that decision is made.

4j. After making a decision in relation to a temporary amendments application, the Secretary of State must publish in such manner as appears appropriate to the Secretary of State:

(a) a notice informing the applicant and the public of the decision made in relation to the application, and

(b) where the application is approved, details of the temporary amendments made to the product specification and the period during which those temporary amendments apply.

4k. Where a temporary amendments application is approved and the period during which such temporary amendments are to apply is extended, the Secretary of State must, on each occasion the period is extended, publish in such manner as appears appropriate to the Secretary of State a notice informing the applicant and the public of the extension of the period.

4l. In this paragraph ‘public authority’ has the meaning given in section 20(1) of the European Union (Withdrawal) Act 2018.”

SCHEDULE 5

Regulation 12(11)(e)

Commission Implementing Regulation (EU) No 668/2014, Article 14: new paragraphs 3, 3a, 3b and 4

“3. Where the Secretary of State approves an amendment to a product specification and the change in the product specification affects other information recorded in the relevant register, the Secretary of State must delete the original data, record the new data in the register and attach a copy of the approved amended product specification to the register. The new data, and the provisions in the approved amended product specification, take effect immediately after the expiry of 20 days beginning with the day on which the new data is recorded in the register and the copy of the amended product specification is attached to the register or, if a copy of the amended product specification is attached to the register at a later date, immediately after the expiry of 20 days beginning with the day on which the copy of the amended product specification is attached to the register.

4. Means of transport and transport details	5. Place of unloading (if different from 2)
6. Description of the imported product	7. Quantity in l/hl/kg ⁽¹⁾
	8. Number of containers
<p>9. CERTIFICATE</p> <p>The product described above ⁽²⁾ <input type="checkbox"/> is/ <input type="checkbox"/> is not intended for direct human consumption, complies with the United Kingdom definitions or categories of grapevine products and has been product using oenological practices ⁽²⁾ <input type="checkbox"/> recommended and published by the OIV/<input type="checkbox"/> authorised by the United Kingdom.</p> <p>Full name and address of the competent body: Place and date:</p> <p>Stamp: Signature, name and title of the official:</p>	
<p>10. ANALYSIS REPORT (describing the analytical characteristics of the product described above)</p> <p>FOR GRAPE MUST AND GRAPE JUICE</p> <p>— Density:</p> <p>FOR WINE AND GRAPE MUST STILL IN FERMENTATION</p> <p>— Total alcoholic strength: — Actual alcoholic strength:</p> <p>FOR ALL PRODUCTS</p> <p>— Total dry extract: — Total sulphur dioxide</p> <p>— Total acidity: — Volatile acidity: — Citric acidity:</p> <p>Full name and address of the designated body or department (laboratory)</p>	

Stamp:	Place and date:
	Signature, name and title of official:

⁽¹⁾ Delete as appropriate.

⁽²⁾ Put an 'X' in the appropriate box.

Attribution (entry into free circulation and issue of extracts)

Quantity	11. No and date of the customs document of release into free circulation and of the extract	12. Full name and address of consignee (extract)	13. Stamp of the competent authority
Available			
Attributed			
Available			
Attributed			
Available			
Attributed			
Available			
Attributed			
14. Other remarks			

PART 2

Specimen of the VI-2 document referred to in Article 22

UNITED KINGDOM	VI 2 Serial No EXTRACT OF A DOCUMENT FOR THE IMPORT OF WINE, GRAPE JUICE OR GRAPE MUST INTO THE UNITED KINGDOM	
1. Consignor (name and address)		
2. Consignee (name and address)		
3. Extract VI 1 document No Issued by (name of third country): On:	4. Extract of VI 2 extract No Stamped by (full name and address of the customs office within the United Kingdom): On:	
5. Description of the imported product	6. Quantity in l/hl/kg ⁽¹⁾	
	7. Number of containers	
8. CONSIGNOR'S DECLARATION ⁽²⁾ The VI 1 document referred to in box 3 <input type="checkbox"/> /The extract referred to in box 4 <input type="checkbox"/> was completed in respect of the product described above and comprises: <input type="checkbox"/> a CERTIFICATE to the effect that the product described above <input type="checkbox"/> is/ <input type="checkbox"/> is not intended for direct human consumption, complies with the United Kingdom definitions or categories of grapevine products and has been product using oenological practices ⁽²⁾ <input type="checkbox"/> recommended and published by the OIV/ <input type="checkbox"/> authorised by the United Kingdom. <input type="checkbox"/> an ANALYSIS REPORT showing that the product has the following analytical characteristics: FOR GRAPE MUST AND GRAPE JUICE — Density:		

FOR WINE AND GRAPE MUST STILL IN FERMENTATION

— Total alcoholic strength:

— Actual alcoholic strength:

FOR ALL PRODUCTS

— Total dry extract:

— Total sulphur dioxide:

— Total acidity:

— Volatile acidity:

— Citric acidity:

an ENDORSEMENT ⁽²⁾ from the competent authority certifying that:

— the wine covered by this document is certified as having been produced in the wine-growing region and was given the geographical indication shown in box 5 in accordance with the provisions of the country of origin.

— the alcohol added to this wine is certified as being wine alcohol.

9. CUSTOMS

Declaration certified as true
Place and date:

Stamp:

Full name and address of the
customs office concerned:

Signature:

⁽¹⁾ Delete as appropriate.

⁽²⁾ Put an 'X' in the appropriate box.

Attribution (entry into free circulation and issue of extracts)

Quantity	10. No and date of the customs document of release into free circulation and of the extract	11. Full name and address of consignee (extract)	12. Stamp of the competent authority
Available			
Attributed			
Available			
Attributed			
Available			
Attributed			
Available			
Attributed			
13. Other remarks”			

SCHEDULE 7

Regulation 16

Revocations

1. Council Decision 94/184/EC concerning the conclusion of an Agreement between the European Community and Australia on trade in wine.

2. Council Decision 97/361/EC concerning the conclusion of an Agreement between the European Community and the United Mexican States on the mutual recognition and protection of designations for spirit drinks.

3. Commission Decision 2000/192/EC concerning the conclusion of an Agreement amending the Agreement between the European Community and Australia on trade in wine.

4. Commission Decision 2001/339/EC concerning an Exchange of Letters amending point B of the Annex to the Agreement between the European Community and the Republic of Bulgaria on the reciprocal protection and control of wine names.

5. Commission Decision 2001/581/EC concerning the conclusion of an Agreement amending the Agreement between the European Community and Australia on trade in wine.

6. Council Decision 2001/916/EC on the conclusion of an Additional Protocol adjusting the trade aspects of the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the former Yugoslav Republic of Macedonia, of the other part, to take account of the outcome of the negotiations between the parties on reciprocal preferential concessions for certain wines, the reciprocal recognition, protection and control of wine names and the reciprocal recognition, protection and control of designations for spirits and aromatised drinks.

7. Council Decision 2001/917/EC on the conclusion of an Additional Protocol adjusting the trade aspects of the Interim Agreement between the European Community, of the one part, and the former Yugoslav Republic of Macedonia, of the other part, to take account of the outcome of the negotiations between the parties on reciprocal preferential concessions for certain wines, the reciprocal recognition, protection and control of wine names and the reciprocal recognition, protection and control of designations for spirits and aromatised drinks.

8. Council Decision 2001/918/EC on the conclusion of an Additional Protocol adjusting the trade aspects of the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the Republic of Croatia, of the other part, to take account of the outcome of the negotiations between the parties on reciprocal preferential concessions for certain wines, the reciprocal recognition, protection and control of wine names and the reciprocal recognition, protection and control of designations for spirits and aromatised drinks.

9. Council Decision 2001/919/EC on the conclusion of an Additional Protocol adjusting the trade aspects of the Interim Agreement between the European Community, of the one part, and the Republic of Croatia, of the other part, to take account of the outcome of the negotiations between the parties on reciprocal preferential concessions for certain wines, the reciprocal recognition, protection and control of wine names and the reciprocal recognition, protection and control of designations for spirits and aromatised drinks.

10. Council Decision 2001/920/EC on the conclusion of an Additional Protocol adjusting the trade aspects of the Europe Agreement establishing an association between the European Communities and their Member States, acting within the framework of the European Union, of the one part, and the Republic of Slovenia, of the other part, to take account of the outcome of the negotiations between the parties on reciprocal preferential concessions for certain wines, the reciprocal recognition, protection and control of wine names and the reciprocal recognition, protection and control of designations for spirits and aromatised drinks.

11. Council Decision 2002/51/EC on the conclusion of an Agreement between the European Community and the Republic of South Africa on trade in wine.

12. Council Decision 2002/53/EC concerning the provisional application of the Agreement between the European Community and the Republic of South Africa on trade in wine.

13. Council Decision 2002/55/EC on the conclusion of an Agreement in the form of an Exchange of Letters between the European Community and the Republic of South Africa on trade in wine.

14. Commission Decision 2002/650/EC concerning the conclusion of an Agreement amending the Agreement between the European Community and Australia on trade in wine.

15. Commission Decision 2003/898/EC concerning the conclusion of an agreement amending the Agreement between the European Community and Australia on trade in wine.

16. Council Decision 2004/91/EC on the conclusion of the agreement between the European Community and Canada on trade in wines and spirit drinks.

17. Commission Decision 2004/387/EC on the conclusion of an Agreement in the form of an Exchange of Letters between the European Community and the United Mexican States concerning amendments to Annex I to the Agreement between the European Community and the United Mexican States on the mutual recognition and protection of designations for spirit drinks, taking into account the enlargement.

18. Commission Decision 2004/483/EC on the conclusion of an Agreement in the form of an exchange of letters between the European Community and the United Mexican States concerning amendments to Annex I of the Agreement between the European Community and the United Mexican States on the mutual recognition and protection of designations for spirit drinks, taking into account the enlargement.

19. Commission Decision 2004/785/EC on the conclusion of an Agreement in the form of an exchange of letters between the European Community and the United Mexican States concerning amendments to Annex II of the Agreement between the European Community and the United Mexican States on the mutual recognition and protection of designations for spirit drinks.

20. Council Decision 2005/798/EC concerning the conclusion of an Agreement in the form of an Exchange of Letters between the European Community and the United States of America on matters related to trade in wine.

21. Council Decision 2006/136/EC on the conclusion of an Agreement in the form of an Exchange of Letters between the European Community and the Republic of Chile concerning amendments to the Agreement on Trade in Wines annexed to the Agreement establishing an Association between the European Community and its Member States, of the one part, and the Republic of Chile, of the other part.

22. Council Decision 2006/232/EC on the conclusion of the Agreement between the European Community and the United States of America on trade in wine.

23. Commission Decision 2006/567/EC on the conclusion of an Agreement in the form of an Exchange of Letters between the European Community and the Republic of Chile concerning amendments to Appendices I, II, III and IV of the Agreement on Trade in Wines annexed to the Association Agreement between the European Community and its Member States, of the one part, and the Republic of Chile, of the other part.

24. Commission Decision 2006/569/EC on the conclusion of an Agreement in the form of an Exchange of Letters between the European Community and the Republic of Chile concerning amendments to Appendix VI of the Agreement on Trade in Wines annexed to the Association Agreement between the European Community and its Member States, of the one part, and the Republic of Chile, of the other part.

25. Commission Regulation (EC) No 555/2008 laying down detailed rules for implementing Council Regulation (EC) No 479/2008 on the common organisation of the market in wine as regards support programmes, trade with third countries, production potential and on controls in the wine sector.

26. Council Decision 2009/49/EC on the conclusion of the Agreement between the European Community and Australia on trade in wine.

27. Commission Decision 2009/104/EC on the conclusion of an Agreement in the form of an Exchange of Letters between the European Community and the Republic of Chile concerning amendments to Appendix V of the Agreement on Trade in Wines annexed to the Association Agreement between the European Community and its Member States, of the one part, and the Republic of Chile, of the other part.

28. Council Decision 2011/51/EU on the signing of the Agreement between the European Union and the Swiss Confederation on the protection of designations of origin and geographical indications for agricultural products and foodstuffs, amending the Agreement between the European Community and the Swiss Confederation on trade in agricultural products.

29. Council Decision 2011/620/EU on the signing, on behalf of the Union, of the Agreement between the European Union and Georgia on protection of geographical indications of agricultural products and foodstuffs.

30. Council Decision 2011/738/EU on the conclusion of the Agreement between the European Union and the Swiss Confederation on the protection of designations of origin and geographical indications for agricultural products and foodstuffs, amending the Agreement between the European Community and the Swiss Confederation on trade in agricultural products.

31. Commission Implementing Decision 2011/751/EU on the notification of a proposal for amendment to the Annexes to the EC-US Agreement on trade in wine.

32. Council Decision 2012/164/EU on the conclusion of the Agreement between the European Union and Georgia on protection of geographical indications of agricultural products and foodstuffs.

33. Commission Implementing Decision 2012/275/EU on the inclusion of vine varieties in Appendix IV of the Protocol on wine labelling as referred to in Article 8(2) of the EC-US Agreement on trade in wine.

34. Council Decision 2012/292/EU on the signing, on behalf of the Union, of the Agreement between the European Union and the Republic of Moldova on the protection of geographical indications of agricultural products and foodstuffs.

35. Council Decision 2012/533/EU on the position to be taken by the European Union within the Joint Committee set up by Article 11 of the Agreement between the European Union and Georgia on protection of geographical indications of agricultural products and foodstuffs, as regards the adoption of the rules of procedure of the Joint Committee.

36. Council Decision 2013/7/EU on the conclusion of the Agreement between the European Union and the Republic of Moldova on the protection of geographical indications of agricultural products and foodstuffs.

37. Council Decision 2013/482/EU on the position to be taken by the European Union within the Joint Committee set up by Article 11 of the Agreement between the European Union and the Republic of Moldova on protection of geographical indications of agricultural products and foodstuffs, as regards the adoption of the rules of procedure of the Joint Committee.

38. Council Decision 2014/429/EU on the position to be adopted on behalf of the European Union within the Association Council set up by the Agreement establishing an Association between the European Union and its Member States, on the one hand, and Central America, on the other, as regards the adoption of a decision by the Association Council on the inclusion in Annex XVIII of the respective geographical indications protected in the territory of the parties.

39. Commission Delegated Regulation (EU) 2016/1149 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards the national support programmes in the wine sector.

40. Commission Implementing Regulation (EU) 2016/1150 laying down rules for the application of Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards the national support programmes in the wine sector.

41. Council Decision (EU) 2016/2136 on the signing, on behalf of the European Union, of the Agreement between the European Union and Iceland on the protection of geographical indications for agricultural products and foodstuffs.

42. Council Decision (EU) 2017/1912 on the conclusion of the Agreement between the European Union and Iceland on the protection of geographical indications for agricultural products and foodstuffs.

SCHEDULE 8

Regulation 17(3) and (4)(g)

The Veterinary Medicines Regulations 2013: new provisions

PART 1

New Schedule 1A

“SCHEDULE 1A

Regulation 4(4)

Converted EU marketing authorisations

1. In this Schedule—

“converted EU marketing authorisation” means an EU marketing authorisation to which paragraph 2 applies;

“EU marketing authorisation” means a marketing authorisation for a veterinary medicinal product granted by the European Commission in accordance with Title 3 of Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency^(a).

2. This paragraph applies to an EU marketing authorisation which—

- (a) was granted before exit day, and
- (b) remains in force immediately before exit day.

3. A converted EU marketing authorisation has effect on and after exit day for the purposes of these regulations as if it were a marketing authorisation granted by the Secretary of State under these Regulations on the date it was originally granted—

- (a) on the terms which were in force immediately before exit day,
- (b) with the benefit of any periods of data marketing exclusivity from which the holder benefited immediately before exit day, and
- (c) subject to any suspension or post-authorisation obligations which were in force immediately before exit day.

4. Without prejudice to the generality of paragraph 3—

- (a) the holder of a converted EU marketing authorisation is subject to the annual fee as set out in paragraph 26 of Schedule 7;
- (b) a converted EU marketing authorisation is to be treated as having been granted in accordance with regulation 4(3) and Schedule 1 for the purposes of Regulation (EC) No 469/2009.”

(a) OJ No L 136, 30.4.2004, p 1, as last amended by Regulation (EU) No 1027/2012 (OJ No L 316, 14.11.2012, p 38).

PART 2

Schedule 7, paragraph 15: new table

“Parallel imports

<i>Application</i>	<i>Fee (£)</i>
Application where the imported product is identical to the UK authorised product	2,130
Application where the imported product is therapeutically similar to the UK authorised product (can only be applied to imported products for non-food producing species)	4,710”

SCHEDULE 9

Regulation 18(2), (3),
(4)(a) and (6)

Regulation (EC) No 470/2009 of the European Parliament and of the Council: new provisions

PART 1

New Article 8

“Article 8

Application for a maximum residue limit

1. An application under these Regulations for a new or amended maximum residue limit for a substance intended for use in a veterinary medicinal product must be made to the appropriate authority.
2. An application must include all necessary administrative information, and all scientific documentation necessary for demonstrating the safety of the substance.
3. The applicant must pay to the appropriate authority the application fee, which is—
 - (a) for a new maximum residue limit in respect of a substance, £62,300;
 - (b) for an amended maximum residue limit in respect of a substance, £18,850.
4. The appropriate authority must ensure that where a valid application is received, the substance is classified under Article 14 within 210 days.
5. For the purposes of paragraph 4 an application is valid when both the requirements in paragraphs 2 and 3 have been complied with.
6. As soon as practicable after the substance is classified under Article 14, the appropriate authority must publish—
 - (a) a notice setting out the classification;
 - (b) the assessment report that has been prepared, with any commercially confidential or personal information deleted.
7. If the appropriate authority classifies a substance under Article 14(2)(b) or (d), it must notify the applicant accordingly, and the applicant may appeal to the Veterinary Products Committee under regulation 29 of the Veterinary Medicines Regulations 2013.

8. For the purposes of paragraph 7, regulations 29 and 30 of the Veterinary Medicines Regulations 2013 are to be read as if references to the Secretary of State were references to the appropriate authority.”

PART 2

New Article 9

“Article 9

Further power for appropriate authority to classify substances

1. The appropriate authority may classify a substance intended for use in a veterinary medicinal product which is to be administered to food-producing animals under Article 14 without an application having been made under these Regulations.
2. The power in paragraph 1 includes power to classify a substance which has previously been classified under Article 14.”

PART 3

Article 10(1): new paragraphs

“1. An application for the classification of a pharmacologically active substance intended to be used in a biocidal product used in animal husbandry pursuant to Article 19(7) of Regulation (EU) 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products must be made under Article 8, notwithstanding that it is not a substance intended for use in a veterinary medicinal product to be administered to food-producing animals.

1A. The power to classify a substance under Article 9 may be exercised in respect of a pharmacologically active substance intended to be used in a biocidal product used in animal husbandry, notwithstanding that it is not a substance intended for use in a veterinary medicinal product to be administered to food-producing animals, where the Secretary of State considers it appropriate to do so for the purposes of Article 19(1)(e) of Regulation (EU) 528/2012.

1B. Where proposals are made for the classification of a substance under Article 9 in the circumstances described in paragraph 1A by a devolved authority, the Secretary of State must have regard to such proposals when exercising functions under that paragraph.

1C. In this Article, “devolved authority” has the meaning given in section 20(1) of the European Union (Withdrawal) Act 2018.”

PART 4

New Article 14A

“Article 14A

MRL register

1. The appropriate authority must maintain a register (“the MRL register”) in accordance with this Article.
2. The MRL register must contain—
 - (a) a list of substances which have been classified under Article 14;
 - (b) in respect of each such substance—

- (i) any maximum residue limit or other matter established under paragraph 2 of Article 14;
 - (ii) any conditions or restrictions included in the classification pursuant to paragraph 7 of Article 14.
3. The MRL register must be kept up to date.
4. The MRL register must contain a search facility.
5. The appropriate authority must make the MRL register available for inspection by the public on a website maintained by the appropriate authority.”

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by the European Union (Withdrawal) Act 2018 (c. 16) (in particular under section 8(2)(a), (b), (c), (d), (e) and (g)) in order to address failures of retained EU law to operate effectively and other deficiencies arising from the withdrawal of the United Kingdom from the European Union.

These Regulations make amendments to legislation relating to—

- (a) aromatised wine;
- (b) the quality scheme for agricultural products and foodstuffs;
- (c) spirit drinks;
- (d) wine;
- (e) veterinary medicines;
- (f) residues.

Part 2 amends subordinate legislation and Part 3 amends and revokes retained direct EU legislation as regards the subjects in paragraphs (a) to (d). Part 4 amends subordinate legislation as regards the subject in paragraph (e) and Part 5 amends retained direct EU legislation as regards the subjects in paragraphs (e) and (f).

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

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UK201902131030 02/2019 19585

<http://www.legislation.gov.uk/id/ukdsi/2019/9780111181249>