
STATUTORY INSTRUMENTS

2019 No. 865

**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 - - - - 11th April 2019

Coming into force in accordance with regulation 1

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 ^{F1}.

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 ^{F2}.

F1 [2018 c. 16.](#)

F2 OJ No L 31, 1.2.2002, p. 1, to which there are amendments not relevant to these Regulations.

PART 1

Introductory

Citation [^{F3}, commencement and extent]

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.

[^{F4}(3) Regulation 17 and Schedule 8 extend to Great Britain.]

F3 Words in reg. 1 heading substituted (31.12.2020 immediately before IP completion day) by [The Veterinary Medicines and Residues \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1461\)](#), regs. 1(2)(a), **2(2)(a)**

F4 Reg. 1(3) inserted (31.12.2020 immediately before IP completion day) by [The Veterinary Medicines and Residues \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1461\)](#), regs. 1(2)(a), **2(2)(b)**

Commencement Information

I1 Reg. 1 in force on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1(2)

PART 2

Amendment of subordinate legislation relating to food and drink

The Spirit Drinks Regulations 2008

^{F5}2.

F5 Regs. 2-10 omitted (31.12.2020 immediately before IP completion day) by virtue of [The Agricultural Products, Food and Drink \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1637\)](#), regs. 1(6), **6**

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

^{F5}3.

F5 Regs. 2-10 omitted (31.12.2020 immediately before IP completion day) by virtue of [The Agricultural Products, Food and Drink \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1637\)](#), regs. 1(6), **6**

The Wine Regulations 2011

^{F5}4.

F5 Regs. 2-10 omitted (31.12.2020 immediately before IP completion day) by virtue of [The Agricultural Products, Food and Drink \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1637\)](#), regs. 1(6), **6**

The Quality Schemes (Agricultural Products and Foodstuffs) Regulations 2018

^{F5}5.

F5 Regs. 2-10 omitted (31.12.2020 immediately before IP completion day) by virtue of [The Agricultural Products, Food and Drink \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1637\)](#), regs. 1(6), 6

PART 3

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

Commission Regulation (EC) No 2870/2000

^{F5}6.

F5 Regs. 2-10 omitted (31.12.2020 immediately before IP completion day) by virtue of [The Agricultural Products, Food and Drink \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1637\)](#), regs. 1(6), 6

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

^{F5}7.

F5 Regs. 2-10 omitted (31.12.2020 immediately before IP completion day) by virtue of [The Agricultural Products, Food and Drink \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1637\)](#), regs. 1(6), 6

Commission Implementing Regulation (EU) No 716/2013

^{F5}8.

F5 Regs. 2-10 omitted (31.12.2020 immediately before IP completion day) by virtue of [The Agricultural Products, Food and Drink \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1637\)](#), regs. 1(6), 6

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

^{F5}9.

F5 Regs. 2-10 omitted (31.12.2020 immediately before IP completion day) by virtue of [The Agricultural Products, Food and Drink \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1637\)](#), regs. 1(6), 6

Commission Delegated Regulation (EU) No 664/2014

^{F5}10.

Changes to legislation: There are currently no known outstanding effects for the The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019. (See end of Document for details)

F5 Regs. 2-10 omitted (31.12.2020 immediately before IP completion day) by virtue of [The Agricultural Products, Food and Drink \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1637\)](#), regs. 1(6), 6

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.”.

Commencement Information
I2 Reg. 11 in force on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1(2)

Commission Implementing Regulation (EU) No 668/2014

^{F6}**12.**

F6 Regs. 12-14 omitted (31.12.2020 immediately before IP completion day) by virtue of [The Agricultural Products, Food and Drink \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1637\)](#), regs. 1(6), 6

Commission Delegated Regulation (EU) 2018/273

^{F6}**13.**

F6 Regs. 12-14 omitted (31.12.2020 immediately before IP completion day) by virtue of [The Agricultural Products, Food and Drink \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1637\)](#), regs. 1(6), 6

Commission Implementing Regulation (EU) 2018/274

^{F6}**14.**

F6 Regs. 12-14 omitted (31.12.2020 immediately before IP completion day) by virtue of [The Agricultural Products, Food and Drink \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1637\)](#), regs. 1(6), 6

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.

Commencement Information
I3 Reg. 15 in force on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1(2)

Revocations

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

Commencement Information

- I4** Reg. 16 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

PART 4

Amendment of subordinate legislation relating to veterinary medicines

The Veterinary Medicines Regulations 2013

- 17.—(1) The Veterinary Medicines Regulations 2013 ^{F7} 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”;
- (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 ”.

F7 [S.I. 2013/2033](#), amended by [S.I. 2014/599](#), 2018/761.

Commencement Information

I5 Reg. 17 in force on IP completion day (in accordance with [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)), see [reg. 1\(2\)](#)

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 [^{F8}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.

F8 Words in reg. 18(5)(a) substituted (31.12.2020 immediately before IP completion day) by [The Veterinary Medicines and Residues \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1461\)](#), regs. 1(2)(a), 2(3)

Commencement Information

I6 Reg. 18 in force on IP completion day (in accordance with [2020 c. 1, Sch. 5 para. 1\(1\)](#)), see reg. 1(2)

Changes to legislation: There are currently no known outstanding effects for the *The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019*. (See end of Document for details)

Department for Environment, Food and Rural
Affairs

David Rutley
Parliamentary Under Secretary of State

We consent

Craig Whittaker
Mike Freer
Two of the Lords Commissioners of Her
Majesty's Treasury

F⁹SCHEDULE 1

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

.....

<p>F9 Schs. 1-6 omitted (31.12.2020 immediately before IP completion day) by virtue of The Agricultural Products, Food and Drink (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1637), regs. 1(6), 6</p>

F⁹SCHEDULE 2

Regulation 8(14)

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

“ANNEX 1

APPLICATION TO REGISTER A GEOGRAPHICAL INDICATION

.....

ANNEX 2

TECHNICAL FILE

.....

ANNEX 3

OBJECTION TO A GEOGRAPHICAL INDICATION

.....

ANNEX 4

APPLICATION TO CANCEL A GEOGRAPHICAL INDICATION

.....

ANNEX 5

*APPLICATION TO AMEND THE TECHNICAL
FILE OF A GEOGRAPHICAL INDICATION*

.....”

Changes to legislation: There are currently no known outstanding effects for the The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019. (See end of Document for details)

F⁹SCHEDULE 3

Regulation 9(3)(b), (20) (c), (22), (29), (34)(b) and (36)

.....

F⁹SCHEDULE 4

Regulation 10(9)

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

- “**3a.**
- 3b.**
- 3c.**
- 3d.**
- 4.**
- 4a.**
- 4b.**
- 4c.**
- 4d.**
- 4e.**
- 4f.**
- 4g.**
- 4h.**
- 4i.**
- 4j.**
- 4k.**
- 4l.**”

F⁹SCHEDULE 5

Regulation 12(11)(e)

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

- “**3.**
- 3a.**
- 3b.**
- 4.**”

F⁹SCHEDULE 6

Regulation 13(32)(a)

Commission Delegated Regulation (EU) 2018/273, Annex 7, Parts 1 and 2: new Parts

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.

Commencement Information

I7 Sch. 7 para. 1 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I8 Sch. 7 para. 2 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I9 Sch. 7 para. 3 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I10 Sch. 7 para. 4 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I11 Sch. 7 para. 5 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I12 Sch. 7 para. 6 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I13 Sch. 7 para. 7 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I14 Sch. 7 para. 8 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I15 Sch. 7 para. 9 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I16 Sch. 7 para. 10 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I17 Sch. 7 para. 11 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I18 Sch. 7 para. 12 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I19 Sch. 7 para. 13 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I20 Sch. 7 para. 14 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I21 Sch. 7 para. 15 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Changes to legislation: There are currently no known outstanding effects for the The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019. (See end of Document for details)

Commencement Information

I22 Sch. 7 para. 16 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I23 Sch. 7 para. 17 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I24 Sch. 7 para. 18 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I25 Sch. 7 para. 19 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I26 Sch. 7 para. 20 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I27 Sch. 7 para. 21 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I28 Sch. 7 para. 22 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I29 Sch. 7 para. 23 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I30 Sch. 7 para. 24 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I31 Sch. 7 para. 25 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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

Changes to legislation: There are currently no known outstanding effects for the The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019. (See end of Document for details)

Commencement Information

I32 Sch. 7 para. 26 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I33 Sch. 7 para. 27 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I34 Sch. 7 para. 28 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I35 Sch. 7 para. 29 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I36 Sch. 7 para. 30 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I37 Sch. 7 para. 31 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I38 Sch. 7 para. 32 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I39 Sch. 7 para. 33 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I40 Sch. 7 para. 34 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I41 Sch. 7 para. 35 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I42 Sch. 7 para. 36 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

Changes to legislation: There are currently no known outstanding effects for the The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019. (See end of Document for details)

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.

Commencement Information

I43 Sch. 7 para. 37 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I44 Sch. 7 para. 38 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I45 Sch. 7 para. 39 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I46 Sch. 7 para. 40 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I47 Sch. 7 para. 41 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

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.

Commencement Information

I48 Sch. 7 para. 42 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

SCHEDULE 8

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

The Veterinary Medicines Regulations 2013: new provisions

PART 1

New Schedule 1A

Commencement Information

I49 Sch. 8 Pt. 1 in force on IP completion day (in accordance with 2020 c. 1, [Sch. 5 para. 1\(1\)](#)), see [reg. 1\(2\)](#)

“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^{F10}.

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;

Changes to legislation: There are currently no known outstanding effects for the The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019. (See end of Document for details)

- (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.”

F10 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

Commencement Information

I50 Sch. 8 Pt. 2 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

“Parallel imports

<i>Application</i>	<i>Fee (£)</i>
Application where the imported product is identical to [F11] a product which is authorised for sale in the United Kingdom]	2,130
Application where the imported product is therapeutically similar to [F11] a product which is authorised for sale in the United Kingdom] (can only be applied to imported products for non-food producing species)	4,710”

F11 Words in Sch. 8 Pt. 2 substituted (31.12.2020 immediately before IP completion day) by The Veterinary Medicines and Residues (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1461), regs. 1(2)(a), 2(4)

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

Commencement Information

I51 Sch. 9 Pt. 1 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1(2)

“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 [^{F12}Secretary of State].
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 [^{F13}Secretary of State] 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 [^{F14}Secretary of State] 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 [^{F15}Secretary of State] 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 [^{F16}Secretary of State] classifies a substance under Article 14(2)(b) or (d), [^{F17}the Secretary of State] must notify the applicant accordingly, and the applicant may appeal to the Veterinary Products Committee under regulation 29 of the Veterinary Medicines Regulations 2013.

^{F18}8.”

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|------------|---|
| F12 | Words in Sch. 9 Pt. 1 substituted (31.12.2020 immediately before IP completion day) by The Veterinary Medicines and Residues (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1461) , regs. 1(2)(a), 2(5)(a)(i) |
| F13 | Words in Sch. 9 Pt. 1 substituted (31.12.2020 immediately before IP completion day) by The Veterinary Medicines and Residues (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1461) , regs. 1(2)(a), 2(5)(a)(ii) |
| F14 | Words in Sch. 9 Pt. 1 substituted (31.12.2020 immediately before IP completion day) by The Veterinary Medicines and Residues (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1461) , regs. 1(2)(a), 2(5)(a)(iii) |
| F15 | Words in Sch. 9 Pt. 1 substituted (31.12.2020 immediately before IP completion day) by The Veterinary Medicines and Residues (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1461) , regs. 1(2)(a), 2(5)(a)(iv) |
| F16 | Words in Sch. 9 Pt. 1 substituted (31.12.2020 immediately before IP completion day) by The Veterinary Medicines and Residues (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1461) , regs. 1(2)(a), 2(5)(a)(v)(aa) |
| F17 | Words in Sch. 9 Pt. 1 substituted (31.12.2020 immediately before IP completion day) by The Veterinary Medicines and Residues (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1461) , regs. 1(2)(a), 2(5)(a)(v)(bb) |

Changes to legislation: There are currently no known outstanding effects for the The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019. (See end of Document for details)

F18 Words in Sch. 9 Pt. 1 omitted (31.12.2020 immediately before IP completion day) by virtue of [The Veterinary Medicines and Residues \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1461\)](#), regs. 1(2)(a), **2(5)(a)(vi)**

PART 2

New Article 9

Commencement Information

I52 Sch. 9 Pt. 2 in force on IP completion day (in accordance with [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)), see [reg. 1\(2\)](#)

“Article 9

Further power for appropriate authority to classify substances

1. The [^{F19}Secretary of State] 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.”

F19 Words in Sch. 9 Pt. 2 substituted (31.12.2020 immediately before IP completion day) by [The Veterinary Medicines and Residues \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1461\)](#), regs. 1(2)(a), **2(5)(b)**

PART 3

Article 10(1): new paragraphs

Commencement Information

I53 Sch. 9 Pt. 3 in force on IP completion day (in accordance with [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)), see [reg. 1\(2\)](#)

“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” [^{F20}means the Scottish Ministers or the Welsh Ministers].”

F20 Words in Sch. 9 Pt. 3 substituted (31.12.2020 immediately before IP completion day) by [The Veterinary Medicines and Residues \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1461\)](#), regs. 1(2)(a), **2(5)(c)**

PART 4

New Article 14A

Commencement Information

I54 Sch. 9 Pt. 4 in force on IP completion day (in accordance with [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)), see [reg. 1\(2\)](#)

“Article 14A

MRL register

1. The [^{F21}Secretary of State] 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 [^{F22}Secretary of State] must make the MRL register available for inspection by the public on a website maintained by the [^{F22}Secretary of State].”

F21 Words in Sch. 9 Pt. 4 substituted (31.12.2020 immediately before IP completion day) by [The Veterinary Medicines and Residues \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1461\)](#), regs. 1(2)(a), **2(5)(d)(i)**

F22 Words in Sch. 9 Pt. 4 substituted (31.12.2020 immediately before IP completion day) by [The Veterinary Medicines and Residues \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1461\)](#), regs. 1(2)(a), **2(5)(d)(ii)**

Changes to legislation: There are currently no known outstanding effects for the The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019. (See end of Document for details)

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.

Changes to legislation:

There are currently no known outstanding effects for the The Food and Drink, Veterinary Medicines and Residues (Amendment etc.) (EU Exit) Regulations 2019.