

STATUTORY INSTRUMENTS

**2019 No. 865**

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

**PART 1**

Introductory

**Citation [<sup>F1</sup>, 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.

[<sup>F2</sup>(3) Regulation 17 and Schedule 8 extend to Great Britain.]

**Textual Amendments**

**F1** 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)**

**F2** 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**

<sup>F3</sup>2. ....

**Textual Amendments**

**F3** 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**

<sup>F3</sup>3. ....

**Textual Amendments**  
**F3** 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**

<sup>F3</sup>4. ....

**Textual Amendments**  
**F3** 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**

<sup>F3</sup>5. ....

**Textual Amendments**  
**F3** 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**

<sup>F3</sup>6. ....

**Textual Amendments**  
**F3** 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**

<sup>F3</sup>7. ....

**Textual Amendments**

**F3** 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**

**F38.** .....

**Textual Amendments**

**F3** 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**

**F39.** .....

**Textual Amendments**

**F3** 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**

**F310.** .....

**Textual Amendments**

**F3** 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**

<sup>F4</sup>**12.** .....

**Textual Amendments**  
**F4** 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**

<sup>F4</sup>**13.** .....

**Textual Amendments**  
**F4** 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**

<sup>F4</sup>**14.** .....

**Textual Amendments**  
**F4** 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<sup>M1</sup> 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 ”.

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**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)

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**Marginal Citations**

**M1** S.I. 2013/2033, amended by S.I. 2014/599, 2018/761.

## 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 [<sup>F5</sup>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.

#### Textual Amendments

- F5** 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\(2\)](#)

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**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)*

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We consent

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



**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.