

Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (Text with EEA relevance)

## TITLE V

### FINAL PROVISIONS

#### *Article 25*

##### **Standing Committee on Veterinary Medicinal Products**

1 The Commission shall be assisted by the Standing Committee on Veterinary Medicinal Products.

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at one month.

3 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

#### *Article 26*

##### **Standing Committee on the Food Chain and Animal Health**

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at one month.

3 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4 Where reference is made to this paragraph, Article 5a(1),(2),(4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

#### *Article 27*

##### **Classification of pharmacologically active substances under Regulation (EEC) No 2377/90**

1 By 4 September 2009, the Commission shall adopt, in accordance with the regulatory procedure referred to in Article 25(2), a regulation incorporating the pharmacologically active

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**Changes to legislation:** There are outstanding changes not yet made to Regulation (EC) No 470/2009 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

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substances and their classification regarding maximum residues limits as laid down in Annexes I to IV to Regulation (EEC) No 2377/90 without any modification.

2 For any substance referred to in paragraph 1 for which a maximum residue limit has been established under Regulation (EEC) No 2377/90, the Commission or a Member State may also submit to the Agency a request for an opinion on extrapolation to other species or tissues in accordance with Article 5.

Article 17 shall apply.

#### *Article 28*

### **Reporting**

1 By 6 July 2014, the Commission shall submit a report to the European Parliament and to the Council.

2 The report shall, in particular, review the experience gained from the application of this Regulation, including experience with substances classified under this Regulation which have a multiple use.

3 The report shall, if appropriate, be accompanied by relevant proposals.

#### *Article 29*

### **Repeal**

Regulation (EEC) No 2377/90 is hereby repealed.

Annexes I to IV to the repealed Regulation shall continue to apply until the entry into force of the regulation referred to in Article 27(1) of this Regulation, and Annex V to the repealed Regulation shall continue to apply until the entry into force of the measures referred to in Article 13(1) of this Regulation.

References to the repealed Regulation shall be construed as references to this Regulation or, as appropriate, to the regulation referred to in Article 27(1) of this Regulation.

#### *Article 30*

### **Amendments to Directive 2001/82/EC**

Directive 2001/82/EC is hereby amended as follows:

1. Article 10(3) shall be replaced by the following:
3. By way of derogation from Article 11, the Commission shall establish a list of substances:
  - which are essential for the treatment of equidae, or
  - which bring added clinical benefit compared to other treatment options available for equidae,

and for which the withdrawal period shall not be less than six months according to the control mechanisms laid down in Decisions 93/623/EEC and 2000/68/EC.

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Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a).;

2. in Article 11(2), the third subparagraph shall be replaced by the following:

The Commission may modify these withdrawal periods or establish other withdrawal periods. In so doing, the Commission may differentiate between foodstuffs, species, routes of administration and annexes to Regulation (EEC) No 2377/90. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 89(2a)..

#### *Article 31*

### **Amendment to Regulation (EC) No 726/2004**

Article 57(1)(g) of Regulation (EC) No 726/2004 shall be replaced by the following:

- (g) advising on the maximum limits for residues of veterinary medicinal products and biocidal products used in animal husbandry which may be accepted in foodstuffs of animal origin in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin<sup>(1)</sup>..

#### *Article 32*

### **Entry into force**

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

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- (1) [OJ L 152, 16.6.2009, p. 11](#)'.

### Changes to legislation:

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### Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by [S.I. 2019/676 reg. 6\(23\)](#)
- Art. 2(1) Art. 2 renumbered as Art. 2(1) by [S.I. 2019/676 reg. 6\(3\)\(a\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/676, reg. 6(3) omitted immediately before IP completion day by virtue of S.I. 2020/1461, regs. 1(2)(b), 3(4)(a))
- Art. 2(2) inserted by [S.I. 2019/676 reg. 6\(3\)\(b\)](#)
- Art. 4(3)(4) inserted by [S.I. 2019/676 reg. 6\(5\)\(d\)](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/676, reg. 6(5)(d) omitted immediately before IP completion day by virtue of S.I. 2020/1461, regs. 1(2)(b), 3(4)(c)(ii))
- Art. 8(6) words substituted in earlier amending provision S.I. 2019/865, Sch. 9 Pt. 1 by [S.I. 2020/1461 reg. 2\(5\)\(a\)\(iv\)](#)
- Art. 8(7) words substituted in earlier amending provision S.I. 2019/865, Sch. 9 Pt. 1 by [S.I. 2020/1461 reg. 2\(5\)\(a\)\(v\)\(aa\)](#)
- Art. 8(7) words substituted in earlier amending provision S.I. 2019/865, Sch. 9 Pt. 1 by [S.I. 2020/1461 reg. 2\(5\)\(a\)\(v\)\(bb\)](#)
- Art. 8(8) omitted in earlier amending provision by virtue of S.I. 2019/865, Sch. 9 Pt. 1 by [S.I. 2020/1461 reg. 2\(5\)\(a\)\(vi\)](#)
- Art. 10(1)-(1C) Art. 10(1)-(1C) substituted for Art. 10(1) by [S.I. 2019/865 reg. 18\(4\)\(a\)Sch. 9 Pt. 3](#)
- Art. 10(1C) words substituted in earlier amending provision S.I. 2019/865, Sch. 9 Pt. 3 by [S.I. 2020/1461 reg. 2\(5\)\(c\)](#)
- Art. 14A inserted by [S.I. 2019/865 reg. 18\(6\)Sch. 9 Pt. 4](#)
- Art. 14A(1) words substituted in earlier amending provision S.I. 2019/865, Sch. 9 Pt. 4 by [S.I. 2020/1461 reg. 2\(5\)\(d\)\(i\)](#)
- Art. 14A(5) words substituted in earlier amending provision S.I. 2019/865, Sch. 9 Pt. 4 by [S.I. 2020/1461 reg. 2\(5\)\(d\)\(ii\)](#)