

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 II

MAXIMUM RESIDUE LIMITS

CHAPTER I

Risk assessment and risk management

Section 1

Pharmacologically active substances intended for use in veterinary medicinal products in the Community

Article 4

Opinion of the Agency

1 The opinion of the Agency shall consist of a scientific risk assessment and risk management recommendations.

2 The scientific risk assessment and the risk management recommendations shall aim to ensure a high level of human health protection, whilst also ensuring that human health, animal health and animal welfare are not negatively affected by the lack of availability of appropriate veterinary medicinal products. The opinion shall take account of any relevant scientific findings of the European Food Safety Authority (EFSA) established by Article 22 of Regulation (EC) No 178/2002.

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.

[View outstanding changes](#)

Changes and effects yet to be applied to :

- Art. 4 heading substituted by [S.I. 2019/676 reg. 6\(5\)\(a\)](#)
- Art. 4(1) substituted by [S.I. 2019/676 reg. 6\(5\)\(b\)](#)
- Art. 4(1) words substituted in earlier amending provision S.I. 2019/676, reg. 6(5)(b) by [S.I. 2020/1461 reg. 3\(4\)\(c\)\(i\)](#)
- Art. 4(2) words substituted by [S.I. 2019/676 reg. 6\(5\)\(c\)](#)

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\(5\)\(d\)\(ii\)](#)