

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 3

Application for an opinion of the Agency

Except in cases where the Codex Alimentarius procedure referred to in Article 14(3) of this Regulation applies, any pharmacologically active substance intended for use in the Community in veterinary medicinal products which are to be administered to food-producing animals shall be subject to an opinion of the European Medicines Agency (the Agency) established by Article 55 of Regulation (EC) No 726/2004 on the maximum residue limit, formulated by the Committee for Medicinal Products for Veterinary Use (the Committee) established by Article 30 of that Regulation.

To that end, the applicant for a marketing authorisation for a veterinary medicinal product in which such a substance is used, a person intending to apply for such a marketing authorisation or, where appropriate, the holder of such a marketing authorisation, shall submit an application to the Agency.

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

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