

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 8

Applications and procedures

1 The application referred to in Article 3 shall comply with the format and content laid down by the Commission as provided for in Article 13(1) and shall be accompanied by the fee payable to the Agency.

2 The Agency shall ensure that the opinion of the Committee is given within 210 days of receipt of a valid application in accordance with Article 3 and paragraph 1 of this Article. This time limit shall be suspended where the Agency requests the submission of supplementary information on the given substance within a specific time period, and shall remain suspended until such time as the requested supplementary information has been provided.

3 The Agency shall forward the opinion referred to in Article 4 to the applicant. Within 15 days of receipt of the opinion, the applicant may provide written notice to the Agency that he wishes to request a re-examination of the opinion. In that case the applicant shall submit the detailed grounds for his request to the Agency within 60 days of receipt of the opinion.

Within 60 days of receipt of the applicant's grounds for a re-examination request, the Committee shall consider whether its opinion should be revised and adopt the final opinion. The reasons for the conclusion reached on the request shall be annexed to the final opinion.

4 Within 15 days of the adoption of the final opinion, the Agency shall forward it to the Commission and the applicant, stating the grounds for its conclusions.

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. 8 substituted by [S.I. 2019/865 reg. 18\(2\)Sch. 9 Pt. 1](#)
- Art. 8(1) words substituted in earlier amending provision S.I. 2019/865, Sch. 9 Pt. 1 by [S.I. 2020/1461 reg. 2\(5\)\(a\)\(i\)](#)
- Art. 8(3) words substituted in earlier amending provision S.I. 2019/865, Sch. 9 Pt. 1 by [S.I. 2020/1461 reg. 2\(5\)\(a\)\(ii\)](#)
- Art. 8(4) words substituted in earlier amending provision S.I. 2019/865, Sch. 9 Pt. 1 by [S.I. 2020/1461 reg. 2\(5\)\(a\)\(iii\)](#)

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