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 3

Common provisions

Article 11

Review of an opinion

Where the Commission, the applicant under Article 3 or a Member State, as a result of new information, considers that a review of an opinion is necessary in order to protect human or animal health, it may request the Agency to issue a new opinion on the substances in question.

Where a maximum residue limit has been established in accordance with this Regulation for specific foodstuffs or species, Articles 3 and 9 shall apply for the establishment of a maximum residue limit for that substance for other foodstuffs or species.

The request referred to in the first subparagraph shall be accompanied by information explaining the issue to be addressed. Article 8(2) to (4) or Article 9(2) and (3), as appropriate, shall apply to the new opinion.

Article 12

Publication of opinions

The Agency shall publish the opinions referred to in Articles 4, 9 and 11 after deleting any information of a commercially confidential nature.

Article 13

Implementing measures

1 In accordance with the regulatory procedure referred to in Article 25(2), the Commission shall, in consultation with the Agency, adopt measures regarding the form and content of the applications and requests referred to in Articles 3 and 9.

2 The Commission shall, in consultation with the Agency, Member States and interested parties, adopt measures regarding:

a the methodological principles for the risk assessment and risk management recommendations referred to in Articles 6 and 7, including technical requirements in accordance with internationally agreed standards;

b rules on the use of a maximum residue limit established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species, or a maximum residue limit established for a pharmacologically active substance in one or more species for other species, as referred to in Article 5. Those rules shall specify how and under what circumstances scientific data on residues in a particular foodstuff or in a species or more species may be used for setting a maximum residue limit in other foodstuffs, or other species.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 25(3).

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 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)