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 6

Scientific risk assessment

1 The scientific risk assessment shall consider the metabolism and depletion of pharmacologically active substances in relevant animal species, the type of residues and the amount thereof, that may be ingested by human beings over a lifetime without an appreciable health risk expressed in terms of acceptable daily intake (ADI). Alternative approaches to ADI may be used, if they have been laid down by the Commission as provided for in Article 13(2).

2 The scientific risk assessment shall concern the following:

a the type and amount of residue considered not to present a safety concern for human health;

b the risk of toxicological, pharmacological or microbiological effects in human beings;

c residues that occur in food of plant origin or that come from the environment.

3 If the metabolism and depletion of the substance cannot be assessed, the scientific risk assessment may take into account monitoring data or exposure data.

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. 6(1) words omitted by S.I. 2019/676 reg. 6(7)

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)