

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 I

### GENERAL PROVISIONS

#### *Article 1*

##### **Subject matter and scope**

- 1 For the purposes of ensuring food safety, this Regulation lays down rules and procedures in order to establish:
  - a the maximum concentration of a residue of a pharmacologically active substance which may be permitted in food of animal origin (maximum residue limit);
  - b the level of a residue of a pharmacologically active substance established for control reasons in the case of certain substances for which a maximum residue limit has not been laid down in accordance with this Regulation (reference point for action).
- 2 This Regulation shall not apply:
  - a to active principles of biological origin intended to produce active or passive immunity or to diagnose a state of immunity, used in immunological veterinary medicinal products;
  - b to substances falling within the scope of Regulation (EEC) No 315/93.
- 3 This Regulation shall apply without prejudice to Community legislation prohibiting the use in food-producing animals of certain substances having a hormonal or thyrostatic action and of beta-agonists, as provided for by Directive 96/22/EC.

#### *Article 2*

##### **Definitions**

In addition to the definitions laid down in Article 1 of Directive 2001/82/EC, Article 2 of Regulation (EC) No 882/2004 and Articles 2 and 3 of Regulation (EC) No 178/2002, the following definitions shall apply for the purposes of this Regulation:

- (a) ‘residues of pharmacologically active substances’ means all pharmacologically active substances, expressed in mg/kg or µg/kg on a fresh weight basis, whether active substances, excipients or degradation products, and their metabolites which remain in food obtained from animals;
- (b) ‘food-producing animals’ means animals bred, raised, kept, slaughtered or harvested for the purposes of producing food.

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