

COMMISSION REGULATION (EC) No 1231/2006

of 16 August 2006

amending Annexes I and II to Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin, as regards ceftiofur and polyoxyethylene sorbitan monooleate and trioleate

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin ⁽¹⁾, and in particular Articles 2 and 3 thereof,

Having regard to the opinions of the European Medicines Agency formulated by the Committee for Medicinal Products for Veterinary Use,

Whereas:

- (1) All pharmacologically active substances used in the Community in veterinary medicinal products intended for food-producing animals should be evaluated in accordance with Regulation (EEC) No 2377/90.
- (2) The substance Ceftiofur is currently included in Annex I to Regulation (EEC) No 2377/90 for bovine and porcine for muscle, fat, liver and kidney and for bovine for milk. The entry for Ceftiofur in that Annex should be modified to include ovine and extended to all mammalian food-producing species for muscle, fat, liver, kidney and milk.
- (3) The substance polyoxyethylene sorbitan monooleate is currently included in Annex II to Regulation (EEC) No 2377/90 for all food-producing species. The entry in that Annex for polyoxyethylene sorbitan monooleate should be replaced by polyoxyethylene sorbitan monooleate and

trioleate covering polyoxyethylene sorbitan trioleate for all food-producing species.

- (4) Regulation (EEC) No 2377/90 should therefore be amended accordingly.
- (5) An adequate period should be allowed before the applicability of this Regulation in order to enable Member States to make any adjustment which may be necessary in the light of this Regulation to the authorisations to place the veterinary medicinal products concerned on the market which have been granted in accordance with Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products ⁽²⁾ to take account of the provisions of this Regulation.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I and II to Regulation (EEC) No 2377/90 are amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the third day following its publication in the *Official Journal of the European Union*.

It shall apply from 16 October 2006.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 16 August 2006.

For the Commission

Günter VERHEUGEN

Vice-President

⁽¹⁾ OJ L 224, 18.8.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1055/2006 (OJ L 192, 13.7.2006, p. 3).

⁽²⁾ OJ L 311, 28.11.2001, p. 1. Directive as last amended by Directive 2004/28/EC (OJ L 136, 30.4.2004, p. 58).

ANNEX

A. The following substance is inserted in Annex I to Regulation (EEC) No 2377/90 (List of pharmacologically active substances for which maximum residue limits have been fixed):

1. Anti-infectious agents
- 1.2. Antibiotics
- 1.2.2. Cephalosporins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
Ceftiofur	Sum of all residues retaining the betalactam structure expressed as desfuroy/ceftiofur	All mammalian food-producing species	1 000 µg/kg 2 000 µg/kg 2 000 µg/kg 6 000 µg/kg 100 µg/kg	Muscle Fat (1) Liver Kidney Milk

(1) For porcine species this MRL relates to "skin and fat in natural proportions".

B. The following substance is inserted in Annex II to Regulation (EEC) No 2377/90 (List of substances not subject to maximum residue limits):

3. Substances generally recognised as safe

Pharmacologically active substance(s)	Animal species
Polyoxyethylene sorbitan monooleate and trioleate	All food-producing species'