COMMISSION REGULATION (EC) No 1356/2005

of 18 August 2005

amending Annex I 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 oxolinic acid and morantel

(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 Article 2 thereof,

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

Whereas:

(1) All pharmacologically active substances which are used within the Community in veterinary medicinal products intended for administration to food-producing animals should be evaluated in accordance with Regulation (EEC) No 2377/90.

(2) Oxolinic acid has been included in Annex I to Regulation (EEC) No 2377/90 for chicken and porcine for muscle, skin and fat, liver and kidney, for muscle and skin in natural proportions for fin fish and excluding animals from which eggs are produced for human consumption. The entry should be extended to all food-producing species excluding animals from which milk or eggs are produced for human consumption, for fin fish, this entry relates only to 'muscle and skin in natural proportions' and for porcine and poultry species the maximum residue limit concerning fat relates to 'skin and fat in natural proportions'.

(3) Morantel has been included in Annex I to Regulation (EEC) No 2377/90 for bovine and ovine for muscle, fat, liver, kidney and milk. That entry should be extended to all ruminants.

(4) Regulation (EEC) No 2377/90 should 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 marketing authorisations 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].

(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

Annex I to Regulation (EEC) No 2377/90 is amended in accordance with the Annex to this Regulation.

[1] OJ L 224, 18.8.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1299/2005 (OJ L 206, 9.8.2005, p. 4).

[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).

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 18 October 2005.

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

Done at Brussels, 18 August 2005.

For the Commission
Günter VERHEUGEN
Vicepresident

ANNEX

A. The following substances are inserted in Annex I (List of pharmacologically active substances for which maximum residue limits have been fixed)

1. Anti-infectious agents

1.2. Antibiotics

1.2.3. Quinolones

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
Oxolinic acid	Oxolinic acid	All food-producing species (1)	100 µg/kg	Muscle (2)
			50 µg/kg	Fat (3)
			150 µg/kg	Liver
			150 µg/kg	Kidney

(1) Not for use in animals from which milk or eggs are produced for human consumption; MRLs for fat, liver and kidney do not apply to fin fish
(2) For fin fish this MRL relates to 'muscle and skin in natural proportions';
(3) For porcine and poultry species this MRL relates to 'skin and fat in natural proportions'.

2. Antiparasitic agents

2.1. Agents acting against endoparasites

2.1.7. Tetrahydropyrimides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
Morantel	Sum of residues which may be hydrolysed to N-methyl-1,3-propanediamine and expressed as morantel equivalents	All ruminants	100 µg/kg	Muscle
			100 µg/kg	Fat
			800 µg/kg	Liver
			200 µg/kg	Kidney
			50 µg/kg	Milk