COMMISSION REGULATION (EC) No 75/2005

of 18 January 2005

amending Annexes I, II and III 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 moxidectin, linear alkyl benzene sulphonic acids with alkyl chain lengths ranging from C_9 to C_{13}, containing less than 2,5 % of chains longer than C_{13} and Acetylisovaleryltylosin

(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, 3 and 4 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 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) Moxidectin has been included in Annex I for bovine, ovine and equidae for muscle, fat, liver and kidney and for milk but only for bovine. The entry should be extended to milk for ovine species.

(3) Linear alkyl benzene sulphonic acids with alkyl chain lengths ranging from C_9 to C_{13}, containing less than 2,5 % of chains longer than C_{13} has been included in Annex II for bovine for topical use only. The entry should be extended to cover ovine species.

(4) The substance acetylisovaleryltylosin is included in Annex I for porcine species. In order to allow for the completion of scientific studies for the extension to cover poultry species, acetylisovaleryltylosin should be included in Annex III, excluding animals from which eggs are produced for human consumption.

(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 THE FOLLOWING REGULATION:

Article 1

Annexes I, II and III 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 20 March 2005.

[1] OJ L 224, 18.8.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 2232/2004 (OJ L 379, 24.12.2004, p. 71).

[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).

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

Done at Brussels, 18 January 2005.

For the Commission
Günter VERHEUGEN
Vice-President

ANNEX

A. The following substance is inserted in Annex I to Regulation (EEC) No 2377/90:

2. Antiparasitic agents

2.3. Agents acting against endo- and ectoparasites

2.3.1. Avermectins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
'**Moxidectin**	Moxidectin	Ovine	40 µg/kg	Milk'

B. The following substance is inserted in Annex II to Regulation (EEC) No 2377/90:

2. Organic compounds

Pharmacologically active substance(s)	Animal species
'**Linear alkyl benzene sulphonic acids with alkyl chain lengths ranging from C_9 to C_{13}, containing less than 2,5 % of chains longer than C_{13}**	Ovine [1]

[1] For topical use only.'

C. The following substance is inserted in Annex III to Regulation (EEC) No 2377/90:

1. Anti-infectious agents

1.2. Antibiotics

1.2.2. Macrolides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
'**Acetylisovaleryltylosin** [1]	Sum of acetyl-isovaleryltylosin and 3-O-acetyltylosin	Poultry [2]	50 µg/kg	Skin and fat
			50 µg/kg	Liver

[1] Provisional MRLs expire on 1 July 2006.
[2] Not for use in animals from which eggs are produced for human consumption.'