COMMISSION REGULATION (EC) No 1353/2007

of 20 November 2007

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 Monensin, Lasalocid and Tylvalosin

(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 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) An application for establishing maximum residue limits for Monensin, an antibiotic and anticoccidial belonging to the group of ionophores, has been submitted to the European Medicines Agency. On the basis of the recommendation of the Committee for Medicinal Products for Veterinary Use, this substance should be added in Annex I to Regulation (EEC) No 2377/90 for bovine species (muscle, fat, liver, kidney and milk).

(3) The substance Lasalocid is currently included in Annex I to Regulation (EEC) No 2377/90 for poultry for muscle, skin and fat, liver and kidney and in Annex III to Regulation (EEC) No 2377/90 for poultry from which eggs are produced for human consumption, awaiting validation of analytical method. Those scientific studies have been now completed and the analytical method has been validated by the Committee for Medicinal Products for Veterinary Use. Lasalocid belongs to the group of antibiotic ionophores having anticoccidial properties. Consequently, Lasalocid should be added in Annex I to Regulation (EEC) No 2377/90 for poultry from which eggs are produced for human consumption, under the new point 1.2.16, while the Lasalocid entry under point 2.4.4 of Annex I to Regulation (EEC) No 2377/90 should be deleted.

(4) The substance Acetylisovaleryltylosin, an antibiotic belonging to the group of macrolides is currently included in Annex I to Regulation (EEC) No 2377/90 for porcine and poultry species. A change to the International Non-proprietary Name (INN) of this active substance has been notified to the European Medicines Agency. The substance's name Acetylisovaleryltylosin should be replaced by the new INN, Tylvalosin.

(5) Regulation (EEC) No 2377/90 should therefore be amended accordingly.

(6) 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.

(7) 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 1323/2007 (OJ L 294, 13.11.2007, p. 11).

[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 20 January 2008.

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

Done at Brussels, 20 November 2007.

For the Commission
Günter VERHEUGEN
Vice-President

ANNEX

Annex I to Regulation (EEC) No 2377/90 is amended as follows:

(1) in point 1.2.4, the entry for 'Acetylisovaleryltylosin' is replaced by the following:

1.2.4. Macrolides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
'**Tylvalosin**	Sum of tylvalosin and 3-O-acetyltylosin	Porcine	50 µg/kg	Muscle
			50 µg/kg	Fat (1)
			50 µg/kg	Liver
			50 µg/kg	Kidney
		Poultry (2)	50 µg/kg	Fat (3)
			50 µg/kg	Liver

(1) For porcine species, this MRL relates to "skin and fat in natural proportions".
(2) Not for use in animals from which eggs are produced for human consumption.
(3) For poultry species, this MRL relates to "skin and fat in natural proportions".'

(2) the following point 1.2.16 is added:

'1.2.16. Ionophores

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
Monensin	Monensin A	Bovine	2 µg/kg	Muscle
			10 µg/kg	Fat
			30 µg/kg	Liver
			2 µg/kg	Kidney
			2 µg/kg	Milk
Lasalocid	Lasalocid A	Poultry	20 µg/kg	Muscle
			100 µg/kg	Fat (1)
			100 µg/kg	Liver
			50 µg/kg	Kidney
			150 µg/kg	Eggs

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

(3) in point 2.4.4, the entry for 'Lasalocid' is deleted.