COMMISSION REGULATION (EC) No 1299/2005

of 8 August 2005

amending Annexes I 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 phenoxymethylpenicillin, phoxim, norgestomet and thiamphenicol

(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 and the third paragraph of Article 4 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) Phenoxymethylpenicillin has been included in Annex I to Regulation (EEC) No 2377/90 for porcine for muscle, liver and kidney. The entry should be extended for these target tissues and in addition for skin and fat to poultry excluding animals from which eggs are produced for human consumption.

(3) Phoxim has been included in Annex I to Regulation (EEC) No 2377/90 for muscle, kidney and fat for ovine excluding animals from which milk is produced for human consumption and for porcine for muscle, liver, kidney and for skin and fat. That substance has also been included in Annex III to that Regulation for chicken awaiting completion of scientific studies. These studies have now been completed and phoxim should therefore be inserted in Annex I to that Regulation.

(4) Norgestomet has been included in Annex III to Regulation (EEC) No 2377/90 for bovine awaiting completion of scientific studies. These studies have now been completed and norgestomet should therefore be inserted in Annex I to that Regulation.

(5) The substance thiamphenicol is included in Annex I to Regulation (EEC) No 2377/90 for bovine and chicken excluding animals from which eggs are produced for human consumption. In order to allow for the completion of scientific studies for the extension to cover porcine species, thiamphenicol should be included in Annex III to that Regulation.

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

(7) 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].

(8) 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 III to Regulation (EEC) No 2377/90 are 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 1148/2005 (OJ L 185, 16.7.2005, p. 20).

[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 8 October 2005.

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

Done at Brussels, 8 August 2005.

For the Commission
Günter VERHEUGEN
Vice-President

ANNEX

A. The following substance(s) is(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

1.2.1. Penicillins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
'**Phenoxymethylpenicillin**	Phenoxymethylpenicillin	Poultry ([1])	25 µg/kg	Muscle
			25 µg/kg	Skin + fat
			25 µg/kg	Liver
			25 µg/kg	Kidney

([1]) Not for use in animals from which eggs are produced for human consumption.'

2. Antiparasitic agents

2.2. Agents acting against ectoparasites

2.2.1. Organophosphates

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
'**Phoxim**	Phoxim	Chicken	25 µg/kg	Muscle
			550 µg/kg	Skin + fat
			50 µg/kg	Liver
			30 µg/kg	Kidney
			60 µg/kg	Eggs'

6. Agents acting on the reproductive system

6.1. Progestagens

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
'**Norgestomet** (1)	Norgestomet	Bovine	0,2 µg/kg	Muscle
			0,2 µg/kg	Fat
			0,2 µg/kg	Liver
			0,2 µg/kg	Kidney
			0,12 µg/kg	Milk

(1) For therapeutic and zootechnical purposes only.'

C. The following substance(s) is(are) inserted in Annex III (List of pharmacologically active substances used in veterinary medicinal products for which provisional maximum residue limits have been fixed).

1. Anti-infectious agents

1.2. Antibiotics

1.2.11. Florfenicol and related compounds

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
'**Thiamphenicol** (1)	Thiamphenicol	Porcine	50 µg/kg	Muscle
			50 µg/kg	Skin + fat
			50 µg/kg	Liver
			50 µg/kg	Kidney

(1) Provisional MRLs expire on 1 January 2007.'