COMMISSION REGULATION (EC) No 581/2009

of 3 July 2009

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 gamithromycin

(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) The substance gamithromycin is included in Annex III to Regulation (EEC) No 2377/90 for bovine species, applicable to fat, liver and kidney, excluding animals producing milk for human consumption. The provisional maximum residue limits (hereinafter MRLs) for that substance set out in that Annex will expire on 1 July 2009. Additional data were provided and assessed leading the Committee for Medicinal Products for Veterinary Use to recommend that the provisional MRLs for gamithromycin should be set as definitive and consequently included in Annex I to Regulation (EEC) No 2377/90 for bovine species, applicable to fat, liver and kidney, excluding animals producing milk for human consumption.

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

(4) It is necessary to provide for an adequate period before this Regulation becomes applicable, in order to enable the Member States to make any necessary adjustments with respect to the existing authorisations to place the veterinary medicinal products concerned 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] on the market.

(5) 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 as set out in 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 60 days after publication.

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

Done at Brussels, 3 July 2009.

For the Commission
Günter VERHEUGEN
Vice-President

[1] OJ L 224, 18.8.1990, p. 1.

[2] OJ L 311, 28.11.2001, p. 1.

ANNEX

In point 1.2.4 of Annex I (List of pharmacologically active substances for which maximum residue limits have been fixed) to Regulation (EEC) No 2377/90 the following entry for 'Gamithromycin' is inserted after erythromycin:

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Gamithromycin	Gamithromycin	Bovine	20 µg/kg 200 µg/kg 100 µg/kg	Fat Liver Kidney	Not for use in animals producing milk for human consumption.'