Commission Regulation (EC) No 203/2008 of 4 March 2008 amending Annex 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 gamithromycin (Text with EEA relevance)

COMMISSION REGULATION (EC) No 203/2008

of 4 March 2008

amending Annex 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 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 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 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 (hereinafter MRLs) for gamithromycin, an antibiotic belonging to the group of macrolides, has been submitted to the European Medicines Agency. In its first opinion the Committee for Medicinal Products for Veterinary Use (hereinafter CVMP) established an overall acceptable daily intake (hereinafter ADI) of 370 μg/person as the basis for the MRL calculation. It was based on the microbiological ADI. MRLs for kidney and liver were fixed at 100 respectively 200 μg/kg. The applicant introduced an appeal against the first opinion, disagreeing with the established microbiological ADI as well as with the MRLs set by the CVMP for liver and kidney. He requested to change the overall ADI to 600 μg/person, which corresponded to the toxicological ADI. Furthermore, he requested that, if the overall ADI should not be changed to 600 μg/person, the CVMP consider reducing the MRLs for kidney and liver by half. Having considered the appeal, the CVMP agreed in its final opinion to change the microbiological ADI and, thus, to amend the overall ADI for gamithromycin to 600 μg/person. CVMP decided that provisional maximum residue limits should be established for gamithromycin. As a consequence, it is found appropriate to insert that substance in Annex III to Regulation (EEC) No 2377/90 for

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 203/2008. (See end of Document for details)*

bovine species, for fat, liver and kidney, excluding animals producing milk for human consumption. The provisional maximum residue limits will expire on 1 July 2009.

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

(4) An adequate period should be allowed before the applicability of this Regulation in order to enable Member States to make any necessary adjustment 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)].

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

Article 2

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 5 May 2008.

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

Done at Brussels, 4 March 2008.

For the Commission

Günter VERHEUGEN

Vice-President