Commission Regulation (EC) No 1323/2007 of 12 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 firocoxib (Text with EEA relevance)

COMMISSION REGULATION (EC) No 1323/2007

of 12 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 firocoxib

(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 firocoxib is included in Annex III to Regulation (EEC) No 2377/90 for *Equidae* for muscle, fat, liver and kidney. These provisional maximum residue limits (hereinafter MRLs) expired on 1 July 2007. Additional data were provided and assessed leading the Committee for Medicinal Products for Veterinary Use (hereinafter CVMP) to recommend that MRLs for Firocoxib should be set as definitive and consequently included in Annex I to Regulation (EEC) No 2377/90 for *Equidae* for muscle, fat, liver and kidney.

(3) The CVMP's recommendation is based on a provisional estimation of the substance and its residues that can be ingested daily over a lifetime without any appreciable health risk to exposed individuals (hereinafter 'ADI'). The established temporary Acceptable Daily Intake (ADI) has been determined by applying a different methodology to the usual approach used for establishing ADI of veterinary medicine. However a higher safety factor has been applied to compensate for this use in order to ensure that there are no grounds for supposing that the residues of Firocoxib at the level proposed for use present a hazard for the health of the consumer.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 1323/2007. (See end of Document for details)*

(4) It is therefore proposed to include Firocoxib in Annex I of Regulation (EEC) No 2377/90 accordingly.

(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 THIS REGULATION:

Article 1

Annex I 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 its publication in the *Official Journal of the European Union*.

It shall apply from 12 January 2008.

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

Done at Brussels, 12 November 2007.

For the Commission

Günter VERHEUGEN

Vice-President