COMMISSION REGULATION (EC) No 485/2009

of 9 June 2009

amending Annex II 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 tiludronic acid and iron fumarate

(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 3 thereof,

Having regard to the opinions 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 tiludronic acid in the form of disodium salt is currently included in Annex II to Regulation (EEC) No 2377/90 only for *Equidae* species for intravenous use.

(3) The Committee for Medicinal Products for Veterinary Use (hereinafter 'CVMP') has received an application for the extension of the existing entry for tiludronic acid in the form of disodium salt to include poultry. Having examined the available data on the residue studies for poultry, the CVMP concluded that there is no need to establish maximum residue limits (hereinafter 'MRLs') for tiludronic acid in the form of disodium salt for poultry.

(4) However, given the fact that residue studies were conducted only after subcutaneous administration and taking into account that with 12 to 24 hours after administration residues intake from tissues, including injection site would represent 88 % of the estimated acceptable daily intake, the CVMP concluded that the extension was possible only for parenteral use and for use in laying and breeder birds. Therefore, the current entry in Annex II to Regulation (EEC) No 2377/90 for tiludronic acid in the form of disodium salt should be amended so that this substance could be used for parenteral use in poultry species (laying and breeder birds).

(5) The substance iron fumarate is currently not included in the Annexes to Regulation (EEC) No 2377/90.

(6) The CVMP has received an application to consider whether the substance iron fumarate should be covered by assessments performed for other iron salts with existing entries in Annex II to Regulation (EEC) No 2377/90, for use in all food producing species.

(7) Having examined the assessments performed and considering that fumaric acid is a permitted food additive under European Parliament and Council Directive 95/2/EC [2], the CVMP concluded that the assessments performed for the substances with existing entries in Annex II to Regulation (EEC) No 2377/90, should also apply to iron fumarate. The CVMP considered that no further assessment for iron fumarate is necessary and that there is no need to establish MRLs for iron fumarate. It recommended the inclusion of that substance in Annex II for all food producing species. Therefore this substance should be inserted in Annex II to Regulation (EEC) No 2377/90 for all food producing species.

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

(9) 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 [3].

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

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

[2] OJ L 61, 18.3.1995, p. 1.

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

HAS ADOPTED THIS REGULATION:

Article 1

Annex II 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 9 August 2009.

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

Done at Brussels, 9 June 2009.

For the Commission
Günter VERHEUGEN
Vice-President

ANNEX

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

(a) In point 2, the entry for 'Tiludronic acid (in the form of disodium salt)' is replaced by the following:

2. Organic compounds

Pharmacologically active Substance(s)	Animal species	Other provisions
'Tiludronic acid (in the form of disodium salt)	Equidae	For intravenous use only
	Poultry	For parenteral use only and for use in laying and breeder birds only'

(b) In point 3, the new entry for 'Iron fumarate' is inserted after the entry for Iron dextran as follows:

3. Substances generally recognised as safe

Pharmacologically active Substance(s)	Animal species	Other provisions
'Iron fumarate	All food producing species'	