COMMISSION REGULATION (EC) No 2232/2004

of 23 December 2004

amending Annexes I, II 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 altrenogest, beclomethasone dipropionate, cloprostenol, r-cloprostenol, sorbitan sesquioleate and toltrazuril

(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 Articles 2 and 3 and the third paragraph of Article 4 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 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) The substance altrenogest was included, in accordance with Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC [2], in Annex III to Regulation (EEC) No 2377/90 for porcine species and equidae for zootechnical use only pending completion of scientific studies. These studies have now been completed and altrenogest should therefore be inserted in Annex I to that Regulation.

(3) The substance beclomethasone dipropionate should be included in Annex II to Regulation (EEC) No 2377/90 for equidae but only for inhalation use.

(4) The substances cloprostenol and r-cloprostenol have been included in Annex II to Regulation (EEC) No 2377/90 for bovine, porcine and equine species. Those entries should be extended to cover caprine species.

(5) The substance sorbitan sesquioleate is closely related to sorbitan trioleate, which is included in Annex II to Regulation (EEC) No 2377/90 for all food producing species. Other sorbitan esters are authorised as food additives under Directive 95/2/EC of the European Parliament and Council of 20 February 1995 on food additives other than colours and sweeteners [3] and are therefore included in Annex II to Regulation (EEC) No 2377/90 for all food producing species. The sorbitan esters concerned are sorbitan monostearate (E491), sorbitan tristearate (E492), sorbitan monolaurate (E493), sorbitan monooleate (E494) and sorbitan monopalmitate (E495). sorbitan sesquioleate should therefore also be included in that Annex II for all food producing species.

(6) The substance toltrazuril is included in Annex I to Regulation (EEC) No 2377/90 for chickens, turkeys, and porcine species. In order to allow for the completion of scientific studies for the extension to cover bovine species, toltrazuril should be included in Annex III to that Regulation, but not for animals from which milk is produced for human consumption.

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

(8) 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 [4].

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

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[1] OJ L 224, 18.8.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1875/2004 (OJ L 326, 29.10.2004, p. 19).

[2] OJ L 125, 23.5.1996, p. 3. Directive as last amended by Directive 2003/74/EC of the European Parliament and of the Council (OJ L 262, 14.10.2003, p. 17).

[3] OJ L 61, 18.3.1995, p. 1. Directive as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

[4] 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).

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I, II and III to Regulation (EEC) No 2377/90 are 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 22 February 2005.

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

Done at Brussels, 23 December 2004.

For the Commission
Günter VERHEUGEN
Vice-President

ANNEX

A. **The following substance(s) is(are) inserted in Annex I to Regulation (EEC) No 2377/90**

6. **Agents acting on the reproductive system**

6.1. **Progestagens**

Pharmacologically active substance(s)	*Marker residue*	*Animal species*	*MRLs*	*Target tissues*
'**Altrenogest** (1)	Altrenogest	Porcine	1 µg/kg	Skin and fat
			0,4 µg/kg	Liver
		Equidae	1 µg/kg	Fat
			0,9 µg/kg	Liver

(1) Only for zootechnical use and in accordance with the provisions of Directive 96/22/EC.'

B. **The following substance(s) is(are) inserted in Annex II to Regulation (EEC) No 2377/90**

2. **Organic compounds**

Pharmacologically active substance(s)	*Animal species*
'**Beclomethasone dipropionate**	Equidae (1)
Cloprostenol	Caprine
R-cloprostenol	Caprine
Sorbitan sesquioleate	All food producing species

(1) For inhalation use only.'

C. **The following substance(s) is(are) inserted in Annex III to Regulation (EEC) No 2377/90**

2. **Antiparasitic agents**

2.4. **Agents acting against protozoa**

2.4.3. **Triazinetrione derivatives**

Pharmacologically active substance(s)	*Marker residue*	*Animal species*	*MRLs*	*Target tissues*
'**Toltrazuril** (1)	Toltrazuril sulfone	Bovine	100 µg/kg	Muscle
			150 µg/kg	Fat
			500 µg/kg	Liver
			250 µg/kg	Kidney

(1) Provisional MRLs expire on 1 July 2006. Not for use in animals from which milk is produced for human consumption.'