COMMISSION REGULATION (EC) No 2593/1999

of 8 December 1999

amending Annexes I, II and III of 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

(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], as last amended by Commission Regulation (EC) No 2393/1999 [2], and in particular Articles 6 and 8 thereof,

(1) Whereas, in accordance with Regulation (EEC) No 2377/90, maximum residue limits must be established progressively for all pharmacologically active substances which are used within the Community in veterinary medicinal products intended for administration to food-producing animals;

(2) Whereas maximum residue limits should be established only after the examination within the Committee for Veterinary Medicinal Products of all the relevant information concerning the safety of residues of the substance concerned for the consumer of foodstuffs of animal origin and the impact of residues on the industrial processing of foodstuffs;

(3) Whereas, in establishing maximum residue limits for residues of veterinary medicinal products in foodstuffs of animal origin, it is necessary to specify the animal species in which residues may be present, the levels which may be present in each of the relevant meat tissues obtained from the treated animal (target tissue) and the nature of the residue which is relevant for the monitoring of residues (marker residue);

(4) Whereas, for the control of residues, as provided for in appropriate Community legislation, maximum residue limits should usually be established for the target tissues of liver or kidney; whereas, however, the liver and kidney are frequently removed from carcasses moving in international trade, and maximum residue limits should therefore also always be established for muscle or fat tissues;

(5) Whereas, in the case of veterinary medicinal products intended for use in laying birds, lactating animals or honey bees, maximum residue limits must also be established for eggs, milk or honey;

(6) Whereas novobiocin, betamethasone, spiramycin, diflubenzuron and enrofloxacin should be inserted into annex I to Regulation (EEC) No 2377/90;

(7) Whereas *calendulae flos*, *cimicifugae racemosae rhizoma*, ergometrine maleate, 1-methyl-2-pyrrolidone, mepivacaine, xylazine hydrochloride, novobiocin, piperazine dihydrochloride, poyoxyl castor oil with 30 to 40 oxyethylene units and *jecoris oleum* should be inserted into Annex II to Regulation (EEC) No 2377/90;

(8) Whereas, in order to allow for the completion of scientific studies, piperazine, cyromazine, tilmicosin and toltrazuril should be inserted into Annex III to Regulation (EEC) No 2377/90;

(9) Whereas a period of 60 days should be allowed before the entry into force of this Regulation in order to allow Member States to make any adjustment which may be necessary to the authorisations to place the veterinary medicinal products concerned on the market which have been granted in accordance with Council Directive 81/851/EEC [3], as last amended by Directive 93/40/EEC [4], to take account of the provisions of this Regulation,

(10) Whereas 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

Annexes I, II and III of Regulation (EEC) No 2377/90 are hereby amended as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on the 60th day following its publication in the *Official Journal of the European Communities*.

[1] OJ L 224, 18.8.1990, p. 1.
[2] OJ L 290, 12.11.1999, p. 5.
[3] OJ L 317, 6.11.1981, p. 1.
[4] OJ L 214, 24.8.1993, p. 31.

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

Done at Brussels, 8 December 1999.

For the Commission
Erkki LIIKANEN
Member of the Commission

ANNEX

A. Annex I to Regulation (EEC) No 2377/90 is amended as follows:

1. Anti-infectious agents

1.2. Antibiotics

1.2.3. Quinolones

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Enrofloxacin	Sum of enrofloxacin and ciprofloxacin	Ovine	100 µg/kg 100 µg/kg 300 µg/kg 200 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption'

1.2.4. Macrolides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Spiramycin	Spiramycin 1	Porcine	250 µg/kg 2 000 µg/kg 1 000 µg/kg	Muscle Liver Kidney'	

1.2.11. Other antibiotics

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Novobiocin	Novobiocin	Bovine	50 µg/kg	Milk'	

2. Antiparasitic agents

2.2. Agents actings against ectoparasites

2.2.4. Acyl urea derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Diflubenzuron	Diflubenzuron	Salmonidae	1 000 µg/kg	Muscle and skin in natural proportions'	

5. Corticoides

5.1. Glucocorticoids

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Betamethasone	Betamethasone	Bovine	0,75 µg/kg	Muscle	
			2,0 µg/kg	Liver	
			0,75 µg/kg	Kidney	
			0,3 µg/kg	Milk	
		Porcine	0,75 µg/kg	Muscle	
			2,0 µg/kg	Liver	
			0,75 µg/kg	Kidney'	

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

2. Organic compounds

Pharmacologically active substance(s)	Animal species	Other provisions
'1-methyl-2-pyrrolidone	All food-producing species	
Ergometrine maleate	All mammalian food-producing species	For use in parturient animals only
Jecoris oleum	All food-producing species	For topical use only
Mepivacaine	Equidae	For intra-articular and epidural use as local anaesthetic only
Novobiocin	Bovine	For intrammary use only and for all tissues except milk
Piperazine dihydrochloride	Chicken	For all tissues except eggs
Polyoxyl castor oil with 30 to 40 oxyethylene units	All food-producing species	For use as excipient
Polyoxyl hydrogenated castor oil with 40 to 60 oxyethylene units	All food-producing species	For use as excipient
Xylazine hydrochloride	Bovine, equidae	Not for use in animals from which milk is produced for human consumptiom'

6. Substances of vegetable origin

Pharmacologically active substance(s)	Animal species	Other provisions
'*Calendulae flos*	All food-producing species	For topical use only
Cimicifugae racemosae rhizoma	All food-producing species	Not for use in animals from which milk is produced for human consumptiom'

C. Annex III to Regulation (EEC) No 2377/90 is amended as follows:

1. Anti-infectious agents

1.2. Antibiotics

1.2.2. Macrolides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Tilmicosin	Tilmicosin	Bovine	40 µg/kg	Milk	Provisional MRLs expire on 1.1.2001'

2. Antiparasitic agents

2.1. Agents actings against endoparasites

2.1.5. Piperazine derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Piperazine	Piperazine	Porcine	400 µg/kg	Muscle	Provisional MRLs expire on 1.7.2001'
			800 µg/kg	Skin and fat	
			2 000 µg/kg	Liver	
			1 000 µg/kg	Kidney	
		Chicken	2 000 µg/kg	Eggs	

2.2. Agents acting against ectoparasites

2.2.7. Triazine derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Cyromazine	Cyromazine	Ovine	300 µg/kg	Muscle	Provisional MRLs expire on 1.7.2001
			300 µg/kg	Fat	Not for use in animals from which milk is produced for human consumption'
			300 µg/kg	Liver	
			300 µg/kg	Kidney	

2.4. Agents acting against protozoa

2.4.3. Triazinetrione derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Toltrazuril	Toltrazuril sulfone	Porcine	100 µg/kg 150 µg/kg 500 µg/kg 250 µg/kg	Muscle Skin and fat Liver Kidney	Provisional MRLs expire on 1.1.2001'