COMMISSION REGULATION (EC) No 1838/97

of 24 September 1997

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

(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 749/97 [2], and in particular Articles 6, 7 and 8 thereof,

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;

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;

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);

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 carcases moving in international trade, and maximum residue limits should therefore also always be established for muscle or fat tissues;

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;

Whereas, baquiloprim, tylosin and tolfenamic acid should be inserted into Annex I to Regulation (EEC) No 2377/90;

Whereas bismuth subcarbonate, bismuth subgallate, bismuth subnitrate, bismuth subsalicylate, cloprostenol, r-cloprostenol and luprostiol should be inserted into Annex II to Regulation (EEC) No 2377/90;

Whereas, in order to allow for the completion of scientific studies, apramycin should be inserted into Annex III to Regulation (EEC) No 2377/90;

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 authorizations 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;

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 to 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 110, 26. 4. 1997, p. 24.
[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, 24 September 1997.

For the Commission
Martin BANGEMANN
Member of the Commission

ANNEX

The Annexes to Regulation (EEC) No 2377/90 are hereby amended as follows:

A. Annex I is amended as follows:

1. Anti-infectious agents

1.1. Chemotherapeutics

1.1.2. Diamino pyrimidine derivates

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'1.1.2.1. Baquiloprim	Baquiloprim	Bovine	10 µg/kg	Fat	
			300 µg/kg	Liver	
			150 µg/kg	Kidney	
			30 µg/kg	Milk	
		Porcine	40 µg/kg	Skin + fat	
			50 µg/kg	Liver, kidney'	

1.2. Antibiotics

1.2.4. Macrolides

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'1.2.4.3. Tylosin	Tylosin A	Bovine	100 µg/kg	Muscle, fat, liver, kidney	
			50 µg/kg	Milk	
		Porcine	100 µg/kg	Muscle, skin + fat, liver, kidney	
		Poultry	100 µg/kg	Muscle, skin + fat, liver, kidney	Not for use in hens producing eggs for human consumption'

4. Anti-inflammatory agents

4.1. Nonsteroidal anti-inflammatory agents

4.1.2. Fenamate group derivatives

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'4.1.2.1. Tolfenamic acid	Tolfenamic acid	Bovine	50 µg/kg	Muscle	
			400 µg/kg	Liver	
			100 µg/kg	Kidney	
			50 µg/kg	Milk	
		Porcine	50 µg/kg	Muscle	
			400 µg/kg	Liver	
			100 µg/kg	Kidney'	

B. Annex II is amended as follows:

1. Inorganic compounds

Pharmacologically active substance(s)	Animal species	Other provisions
'1.30. Bismuth subcarbonate	All food-producing species	For oral use only
1.31. Bismuth subgallate	All food-producing species	For oral use only
1.32. Bismuth subnitrate	All food-producing species	For oral use only
1.33. Bismuth subsalicylate	All food-producing species	For oral use only'

2. Organic compounds

Pharmacologically active substance(s)	Animal species	Other provisions
'2.79. Cloprostenol	Bovine, porcine, equidae	
2.80. R-Cloprostenol	Bovine, porcine, equidae	
2.81. Luprostiol	All mammalian species'	

C. Annex III is amended as follows:

1. Anti-infectious agents

1.2. Antibiotics

1.2.5. Aminoglycosides

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'1.2.5.7. Apramycin	Apramycin	Bovine	1 000 µg/kg	Muscle, fat	For use in non-lactating cattle only Provisional MRLs expire on 1. 7. 1999
			10 000 µg/kg	Liver	
			20 000 µg/kg	Kidney	
		Porcine	1 000 µg/kg	Muscle, skin + fat, liver	Provisional MRLs expire on 1. 7. 1999'
			5 000 µg/kg	Kidney	