COMMISSION REGULATION (EC) No 17/97

of 8 January 1997

amending Annexes I, II, III and IV 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

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 2034/96 [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 carcasses 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, eprinomectin should be inserted into Annex I to Regulation (EEC) No 2377/90;

Whereas zinc acetate, zinc chloride, zinc gluconate, zinc oleate, zinc stearate, chlorhexidine, glycerol formal, hesperidin, hesperidin methyl chalcone, menbutone and quatresin should be inserted into Annex II to Regulation (EEC) No 2377/90;

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

Whereas it appears that maximum residue limits cannot be established for chlorpromazine because residues, at whatever limit, in foodstuffs of animal origin constitute a hazard to the health of the consumer; whereas chlorpromazine should therefore be inserted into Annex IV 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 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;

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, III and IV 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 sixtieth day following its publication in the *Official Journal of the European Communities.*

[1] OJ No L 224, 18. 8. 1990, p. 1.
[2] OJ No L 272, 25. 10. 1996, p. 2.
[3] OJ No L 317, 6. 11. 1981, p. 1.
[4] OJ No 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 January 1997.

For the Commission
Martin BANGEMANN
Member of the Commission

ANNEX

Regulation (EEC) No 2377/90 is modified as follows:

A. Annex I is modified as follows:

2. Anti-parasitic agents

2.3. Agents acting against endo- and ectoparasites

2.3.1. Avermectins

Pharmacologically active substance	Marker residue	Animal Species	MRLs	Target tissues	Other provisions
'2.3.1.4. Eprinomectin	Eprinomectin B1a	Bovine	30 µg/kg	Muscle	
			30 µg/kg	Fat	
			600 µg/kg	Liver	
			100 µg/kg	Kidney	
			30 µg/kg	Milk'	

B. Annex II is modified as follows:

1. Inorganic chemicals

Pharmacologically active substance(s)	Animal Species	Other provisions
'1.24. Zinc acetate	All food producing species	
1.25. Zinc chloride	All food producing species	
1.26. Zinc gluconate	All food producing species	
1.27. Zinc oleate	All food producing species	
1.28. Zinc stearate	All food producing species'	

2. Organic compounds

Pharmacologically active substance(s)	Animal Species	Other provisions
'2.69. Chlorhexidine	All food producing species	For topical use only
2.70. Glycerol formal	All food producing species	
2.71. Hesperidin	Equidae	
2.72. Hesperidin methyl chalcone	Equidae	
2.73. Menbutone	Bovine, ovine, caprine, porcine, equidae	
2.74. Quatresin	All food producing species	For use as preservative only at concentrations of up to 0,5 %'

C. Annex III is modified as follows:

1. Anti-infectious agents

1.2. Antibiotics

1.2.6. Quinolones

Pharmacologically active substance	Marker residue	Animal Species	MRLs	Target tissues	Other provisions
'1.2.6.4. Flumequine	Flumequine	Bovine, ovine, porcine, chicken	50 µg/kg	Muscle, fat or fat/skin	Provisional MRLs expire on 1. 1. 2000'
			100 µg/kg	Liver	
			300 µg/kg	Kidney	
		Salmonidae	150 µg/kg	Muscle/skin	

1.2.8. Tetracyclines

Pharmacologically active substance	Marker residue	Animal Species	MRLs	Target tissues	Other provisions
'1.2.8.1. Doxycycline	Sum of parent drug and its 4-epimer	Porcine, poultry	600 µg/kg	Kidney	Provisional MRLs expire on 1. 1. 1998'
			300 µg/kg	Liver, skin/fat	
			100 µg/kg	Muscle	
		Bovine	600 µg/kg	Kidney	
			300 µg/kg	Liver	
			100 µg/kg	Muscle	

2. Antiparasitic agents

2.1. Agents acting against endoparasites

2.1.1. Benzimidazoles and pro-benzimidazoles

Pharmacologically active substance	Marker residue	Animal Species	MRLs	Target tissues	Other provisions
'2.1.1.10. Albendazole sulphoxide	Sum of albendazole, albendazole sulphoxide, albendazole sulphone, and albendazole 2-amino sulphone, expressed as albendazole	Bovine, ovine, pheasant	1 000 µg/kg	Liver	Provisional MRLs expire on 1. 1. 1998'
			500 µg/kg	Kidney	
			100 µg/kg	Muscle, fat	
		Bovine, ovine	100 µg/kg	Milk	

D. Annex IV is modified as follows:

List of pharmacologically active substances for which no maximum levels can be fixed:

'8. Chlorpromazine'