COMMISSION REGULATION (EC) No 1837/97

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 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, febentel, fenbendazole, oxfendazole and dexamethasone should be inserted into Annex I to Regulation (EEC) No 2377/90;

Whereas bromide, sodium salt should be inserted into Annex II to Regulation (EEC) No 2377/90;

Whereas, in order to allow for the completion of scientific studies, ceftiofur, danofloxacin and netobimin 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:

2. Antiparasitic agents

2.1. Agents acting against endoparasites

2.1.3. Benzimidazoles and pro-benzoimidazoles

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'2.1.3.1. Febantel	Sum of extractable residues which may be oxidized to oxfendazole sulphone	Bovine, ovine, porcine, equidae	50 µg/kg	Muscle	
			50 µg/kg	Fat	
			500 µg/kg	Liver	
			50 µg/kg	Kidney	
		Bovine, ovine	10 µg/kg	Milk	
2.1.3.2. Fenbendazole	Sum of extractable residues which may be oxidized to oxfendazole sulphone	Bovine, ovine, porcine, equidae	50 µg/kg	Muscle	
			50 µg/kg	Fat	
			500 µg/kg	Liver	
			50 µg/kg	Kidney	
		Bovine, ovine	10 µg/kg	Milk	
2.1.3.3. Oxfendazole	Sum of extractable residues which may be oxidized to oxfendazole sulphone	Bovine, ovine, porcine, equidae	50 µg/kg	Muscle	
			50 µg/kg	Fat	
			500 µg/kg	Liver	
			50 µg/kg	Kidney	
		Bovine, ovine	10 µg/kg	Milk'	

5. Corticoids

5.1. Glucocorticoids

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'5.1.1. Dexamethasone	Dexamethasone	Bovine, porcine, equidae	0,75 µg/kg	Muscle	
			2,0 µg/kg	Liver	
			0,75 µg/kg	Kidney	
		Bovine	0,3 µg/kg	Milk'	

B. Annex II is amended as follows:

1. Inorganic compounds

Pharmacologically active substance(s)	Animal species	Other provisions
'1.29. Bromide, sodium salt	All food producing mammals	For topical use only'

C. Annex III is amended as follows:

1. Anti-infectious agents

1.2. Antibiotics

1.2.4. Cephalosporins

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'1.2.4.1. Ceftiofur	Sum of all residues retaining the betalactam structure expressed as desfuroylceftiofur	Bovine	2 000 µg/kg 200 µg/kg 600 µg/kg 100 µg/kg	Liver, kidney Muscle Fat Milk	Provisional MRLs expire on 1. 1. 1999'
		Porcine	4 000 µg/kg 3 000 µg/kg 500 µg/kg 600 µg/kg	Kidney Liver Muscle Fat	

1.2.6. Quinolones

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'1.2.6.1. Danofloxacin	Danofloxacin	Bovine	900 µg/kg 500 µg/kg 300 µg/kg 200 µg/kg	Liver Kidney Muscle Fat	Provisional MRLs expire on 1. 1. 1999'
		Chicken	1 200 µg/kg 600 µg/kg 300 µg/kg	Liver, kidney Skin + fat Muscle	

2. Antiparasitic agents

2.1. Agents acting against endo-parasites

2.1.1. Benzimidazoles and pro-benzoimidazoles

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'2.1.1.9. Netobimin	Sum of netobimin and albendazole and metabolites of albendazole measured as 2-aminobenzimidazole sulphone	Bovine, ovine, caprine	100 µg/kg 1 000 µg/kg 500 µg/kg 100 µg/kg	Muscle, fat Liver Kidney Milk	Provisional MRLs expire on 31. 7. 1999'