COMMISSION REGULATION (EC) No 997/1999

of 11 May 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 954/1999 [2], and in particular Articles 6, 7 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 Nitroxinil should be inserted into Annex I to Regulation (EEC) No 2377/90;

(7) Whereas pyrantel embonate, bromhexine, mercaptamine hydrochloride, biotin, Praziquantel, vitamin E, sodium glycerophosphate, vitamin B1, vitamin B2, vitamin B3, vitamin B5, vitamin B6 and vitamin B12 should be inserted into Annex II to Regulation (EEC) No 2377/90;

(8) Whereas, in order to allow for the completion of scientific studies, morantel, halofuginone, diflubenzuron, difloxacin and Oxyclozanide 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,

[1] OJ L 224, 18.8.1990, p. 1.
[2] OJ L 118, 6.5.1999, p. 28.
[3] OJ L 317, 6.11.1981, p. 1.
[4] OJ L 214, 24.8.1993, p. 31.

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

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

Done at Brussels, 11 May 1999.

For the Commission

Martin BANGEMANN

Member of the Commission

ANNEX

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

2. Antiparasitic agents

2.1. Agents acting against endoparasites

2.1.4. Phenol derivatives including salicylanides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Nitroxinil	Nitroxinil	Bovine, ovine	400 µg/kg 200 µg/kg 20 µg/kg 400 µg/kg	Muscle Fat Liver Kidney'	

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

1. Inorganic chemicals

Pharmacologically active substance(s)	Animal species	Other provisions
'Sodium glycerophosphate	All food producing species'	

2. Organic compounds

Pharmacologically active substance(s)	Animal species	Other provisions
'Biotin	All food producing species	
Bromhexine	Bovine Not for use in animals from which milk is produced for human consumption Porcine Poultry Not for use in animals from which eggs are produced for human consumption	

Pharmacologically active substance(s)	Animal species	Other provisions
Mercaptamine hydrochloride	All mammalian food-producing species	
Praziquantel	Ovine	
Pyrantel embonate	Equidae	
Vitamin B1	All food-producing species	
Vitamin B12	All food-producing species	
Vitamin B2	All food-producing species	
Vitamin B3	All food-producing species	
Vitamin B5	All food-producing species	
Vitamin B6	All food-producing species	
Vitamin E	All food-producing species'	

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

1. Anti-infectious agents

1.2. Antibiotics

1.2.6. Quinolones

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Difloxacin	Difloxacin	Bovine	400 µg/kg	Muscle	Provisional MRLs expire on 1.1.2001'
		Not for use in animals from which milk is produced for human consumption	100 µg/kg	Fat	
			1 400 µg/kg	Liver	
			800 µg/kg	Kidney	
		Porcine	400 µg/kg	Muscle	
			100 µg/kg	Skin and fat	
			800 µg/kg	Liver	
			800 µg/kg	Kidney	

2. Antiparasitic agents

2.1. Agents acting against endoparasites

2.1.1. Phenol derivatives including salicylanides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Oxyclozanide	Oxyclozanide	Bovine	20 µg/kg	Muscle	Provisional MRLs expire on 1.7.2000'
			20 µg/kg	Fat	
			500 µg/kg	Liver	
			100 µg/kg	Kidney	
			10 µg/kg	Milk	
		Ovine	20 µg/kg	Muscle	
			20 µg/kg	Fat	
			500 µg/kg	Liver	
			100 µg/kg	Kidney	

2.1.3. Tetrahydropyrimides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Morantel	Sum of residues which may be hydrolysed to N-Methyl-1,3-propanediamine and expressed as morantel equivalents	Bovine, ovine	100 µg/kg	Muscle	Provisional MRLs expire on 1.7.2001'
			100 µg/kg	Fat	
			800 µg/kg	Liver	
			200 µg/kg	Kidney	
			100 µg/kg	Milk	
		Porcine	100 µg/kg	Muscle	
			100 µg/kg	Skin and fat	
			800 µg/kg	Liver	
			200 µg/kg	Kidney	

2.2. Agents acting against ectoparasites

2.2.5. Acyl urea derivates

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	Provisional MRLs expire on 1.7.2000'

2.4. Agents acting against protozoa

2.4.2. Quinazolone derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Halofuginone	Halofuginone	Bovine	10 µg/kg 25 µg/kg 30 µg/kg 30 µg/kg	Muscle Fat Liver Kidney	Provisional MRL's expire on 1.1.2001'