COMMISSION REGULATION (EC) No 2728/98

of 17 December 1998

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 2692/98 [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 enrofloxacin and ivermectin should be inserted into Annex I to Regulation (EEC) No 2377/90;

Whereas *hyperici oleum, eucalypti aetheroleum,* sodium 2-methyl-2-phenoxy-propanoate, nonivamide, nicoboxil, methyl nicotinate, mecillinam, 8-hydroxyquinoline and diethylene glycol monoethyl ether should be inserted into Annex II to Regulation (EEC) No 2377/90;

Whereas, in order to allow for the completion of scientific studies, the duration of the validity of the provisional maximum residue limits previously defined in Annex III to Regulation (EEC) No 2377/90 should be extended for enrofloxacin;

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 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 338, 15. 12. 1998, 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, 17 December 1998.

For the Commission
Martin BANGEMANN
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	Bovine	100 µg/kg	Muscle	
			100 µg/kg	Fat	
			300 µg/kg	Liver	
			200 µg/kg	Kidney	
			100 µg/kg	Milk	
		Rabbits	100 µg/kg	Muscle	
			100 µg/kg	Fat	
			200 µg/kg	Liver	
			300 µg/kg	Kidney	
		Porcine	100 µg/kg	Muscle	
			100 µg/kg	Skin + fat	
			200 µg/kg	Liver	
			300 µg/kg	Kidney	
		Poultry	100 µg/kg	Muscle	
		Not for use in animals from which eggs are produced for human consumption	100 µg/kg	Skin + fat	
			200 µg/kg	Liver	
			300 µg/kg	Kidney	

2. Antiparasitic agents

2.3. Agents acting against endo- and ectoparasites

2.3.1. Avermectins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Ivermectin	22,23-Dihydro-avermectin B1a	Deer, including reindeer	20 µg/kg	Muscle	
			100 µg/kg	Fat	
			50 µg/kg	Liver	
			20 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
8-Hydroxyquinoline	All mammalian food producing species	For topical use in new-born animals only
Diethylene glycol monoethyl ether	Bovine, porcine	
Mecillinam	Bovine	For intra-uterine use only
Methyl nicotinate	Bovine, equidae	For topical use only
Nicoboxil	Equidae	For topical use only
Nonivamide	Equidae	For topical use only
Sodium 2-methyl-2-phenoxy-propanoate	Bovine, porcine, caprine, equidae	

6. Substances of vegetable origin

Pharmacologically active substance(s)	Animal species	Other provisions
Eucalypti aetheroleum	All food producing species	
Hyperici oleum	All food producing species	For topical use only

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

1. Anti-infectious agents

1.2. Antibiotics

1.2.06. 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	Provisional MRLs expire on 1 July 1999