COMMISSION REGULATION (EC) No 1942/1999

of 10 September 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 1931/1999 [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 clorsulon, danofloxacin, florfenicol and moxidectin should be inserted into Annex I to Regulation (EEC) No 2377/90;

(7) Whereas levomethadone, fenpipramide hydrochloride, *apocynum cannabinum*, hydrochlorothiazide, *virola sebifera*, *selenicereus grandiflorus*, *thuja occidentalis*, tricaine mesilate, trichlormethiazide, vincamine and *harunga madagascariensis* should be inserted into Annex II to Regulation (EEC) No 2377/90;

(8) Whereas, in order to allow for the completion of scientific studies, deltamethrin 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;

HAS ADOPTED THE FOLLOWING 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 Regulation shall enter into force on the sixtieth day following its publication in the *Official Journal of the European Communities*.

[1] OJ L 224, 18.8.1990, p. 1.
[2] OJ L 240, 10.9.1999, p. 3.
[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, 10 September 1999.

For the Commission
Karel VAN MIERT
Member of the Commission

ANNEX

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
'Danofloxacin	Danofloxacin	Porcine	100 µg/kg 50 µg/kg 200 µg/kg 200 µg/kg	Muscle Skin and fat Liver Kidney'	

1.2.5. Florfenicol and related compounds

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Florfenicol	Sum of florfenicol and its metabolites measured as florfenicol-amine	Porcine	300 µg/kg 500 µg/kg 2 000 µg/kg 500 µg/kg	Muscle Skin and fat Liver Kidney'	

2. Antiparasitic agents

2.1. Agents acting against endoparasites

2.1.5. Benzenesulphonamides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Clorsulon	Clorsulon	Bovine	35 µg/kg 100 µg/kg 200 µg/kg	Muscle Liver Kidney'	

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
'Moxidectin	Moxidectin	Equidae	50 µg/kg 500 µg/kg 100 µg/kg 50 µg/kg	Muscle Fat Liver Kidney'	

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

2. Organic compounds

Pharmacologically active substance(s)	Animal species	Other provisions
'Fenpipramide hydrochloride	Equidae	For intravenous use only
Hydrochlorothiazide	Bovine	
Levomethadone	Equidae	For intravenous use only
Tricaine mesilate	Fin fish	For water borne use only
Trichlormethiazide	All mammalian food producing species	Not for use in animals from which milk is produced for human consumption
Vincamine	Bovine	For use in newborn animals only'

4. Substances and in homeopathic veterinary medicinal products

Pharmacologically active substance(s)	Animal species	Other provisions
'*Apocynum cannabinum*	All food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias, at concentrations in the products not exceeding one part per hundred only. For oral use only.
Harunga madagascariensis	All food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias, at concentrations in the products not exceeding one part per hundred only.

Pharmacologically active substance(s)	Animal species	Other provisions
Selenicereus grandiflorus	All food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias, at concentrations in the products not exceeding one part per hundred only.
Thuja occidentalis	All food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias, at concentrations in the products not exceeding one part per hundred only.
Virola sebifera	All food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias, at concentrations in the products not exceeding one part per thousand only.'

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

2. Antiparasitic agents

2.2. Agents acting against ectoparasites

2.2.3. Pyrethroids

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Deltamethrin	Deltamethrin	Bovine	10 µg/kg	Muscle	Provisional MRLs expire on 1 July 2001'
			50 µg/kg	Fat	
			10 µg/kg	Liver	
			10 µg/kg	Kidney	
			20 µg/kg	Milk	
		Ovine	10 µg/kg	Muscle	
		Not for use in animals from which milk is produced for human consumption	50 µg/kg	Fat	
			10 µg/kg	Liver	
			10 µg/kg	Kidney	
		Chicken	10 µg/kg	Muscle	
			50 µg/kg	Skin + fat	
			10 µg/kg	Liver	
			10 µg/kg	Kidney	
			50 µg/kg	Eggs	