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(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 1568/98

of 17 July 1998

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

(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 1191/98 [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 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 sarafloxacin should be inserted into Annex I to Regulation (EEC) No 2377/90;

Whereas pyrethrum extract, *hamamelis virginiana, chrysanthemi cinerariifolii flos, echinacea purpurea, tanninum* and natamycin should be inserted into Annex II to Regulation (EEC) No 2377/90;

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

Whereas it appears that maximum residue limits cannot be established for *aristolochia* spp. and preparations thereof because residues, at whatever limit, in foodstuffs of animal origin might constitute a hazard to the health of the consumer; whereas *aristolochia* spp. and preparations thereof should 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,

[1] OJ L 224, 18. 8. 1990, p. 1.
[2] OJ L 165, 10. 6. 1998, p. 6.
[3] OJ L 317, 6. 11. 1981, p. 1.
[4] OJ L 214, 24. 8. 1993, p. 31.

HAS ADOPTED THE FOLLOWING 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 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, 17 July 1998.

For the Commission
Martin BANGEMANN
Member of the Commission

ANNEX I

List of pharmacologically active substances for which maximum residue limits have been fixed

1. Anti-infectious agents

1.2. Antibiotics

1.2.3. Quinolones

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Sarafloxacin	Sarafloxacin	Salmonidae	30 µg/kg	Muscle and skin in natural proportions'	

ANNEX II

List of substances not subject to maximum residue limits

2. Organic compounds

Pharmacologically active substance(s)	Animal species	Other provisions
'2-Aminoethyl dihydrogenphosphate	All food-producing species	
Natamycin	Bovine, equidae	For topical use only'
Parconazole	Guinea fowl	
Tanninum	All food-producing species	

6. Substances of vegetable origin

Pharmacologically active substance(s)	Animal species	Other provisions
'Chrysanthemi cinerariifolii flos	All food-producing species	For topical use only
Echinacea purpurea	All food-producing species	For topical use only
Hamamelis virginiana	All food-producing species	For topical use only
Pyrethrum extract	All food-producing species	For topical use only'

ANNEX III

List of pharmacologically active substances used in veterinary medicinal products for which provisional maximum residue limits have been fixed

1. Anti-infectious agents
1.2. Antibiotics
1.2.5. Aminoglycosides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Spectinomycin	Spectinomycin	Bovine	200 µg/kg	Milk	Provisional MRLs expire on 1. 7. 2000'
		Bovine, porcine, poultry	300 µg/kg	Muscle	
			500 µg/kg	Fat	
			2 000 µg/kg	Liver	
			5 000 µg/kg	Kidney	

1.2.6. Quinolones

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Marbofloxacin	Marbofloxacin	Bovine	150 µg/kg	Muscle	Provisional MRLs expire on 1. 7. 2000'
			50 µg/kg	Fat	
			150 µg/kg	Liver	
			150 µg/kg	Kidney	
			75 µg/kg	Milk	
		Porcine	150 µg/kg	Muscle	
			50 µg/kg	Skin and fat	
			150 µg/kg	Liver	
			150 µg/kg	Kidney	

ANNEX IV

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

Pharmacologically active substance(s)
'*Aristolochia* spp. and preparations thereof'