COMMISSION REGULATION (EC) No 1931/1999

of 9 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 1308/1999 [2], and in particular Articles 6 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 carprofen, emamectin, cefquinome, teflubenzuron and apramycin should be inserted into Annex I to Regulation (EEC) No 2377/90;

(7) Whereas histidine, adenosine, its 5′-mono-, 5′-di-, 5′-triphosphates, glycine, glutamine, glutamic acid, alanine, doxapram, cytidine, its 5′-mono-, 5′-di- and 5′-triphosphates, cysteine, choline, chymotrypsin, arginine, hyaluronic acid, carnitine, apramycin, bromide, potassium salt, azamethiphos, aspartic acid, asparagine, citrulline, pepsin, valine, uridine, its 5′-mono-, 5′-di-, 5′-triphosphates, tyrosine, tryptophan, trypsin, thymidine, threonine, thioctic acid, sulfogaiacol, serine, proline, guanosine, its 5′-mono-, 5′-di- and 5′-triphosphates, phenylalanine, vetrabutine hydrochloride, orotic acid, ornithine and methionine and lysine and leucine and isoleucine and inositol and inosine and its 5′-mono-, 5′-di- and 5′-triphosphates and piperonyl butoxide should be inserted into Annex II to Regulation (EEC) No 2377/90;

(8) Whereas, in order to allow for the completion of scientific studies, coumafos, cymiazole and kanamycin 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 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 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 156, 23.6.1999, p. 1.
[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, 9 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

1.2.02. Cephalosporins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Cefquinome	Cefquinome	Porcine	50 µg/kg 50 µg/kg 100 µg/kg 200 µg/kg	Muscle Skin + fat Liver Kidney'	

1.2.10. Aminoglycosides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Apramycin	Apramycin	Bovine	1 000 µg/kg 1 000 µg/kg 10 000 µg/kg 20 000 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption'

2. Antiparasitic agents

2.2. Agents acting against ectoparasites

2.2.4. Acyl urea derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Teflubenzuron	Teflubenzuron	Salmonidae	500 µg/kg	Muscle and skin in natural proportions'	

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
'Emamectin	Emamectin B1a	Salmonidae	100 µg/kg	Muscle and skin in natural proportions'	

4. Anti-inflammatory agents

4.1. Nonsteroidal anti-inflammatory agents

4.1.1. Arylpropionic acid derivative

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Carprofen	Carprofen	Bovine	500 µg/kg	Muscle	
		Not for use in animals from which milk is produced for human consumption	1 000 µg/kg	Fat	
			1 000 µg/kg	Liver	
			1 000 µg/kg	Kidney	
		Equidae	500 µg/kg	Muscle	
			1 000 µg/kg	Fat	
			1 000 µg/kg	Liver	
			1 000 µg/kg	Kidney'	

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

1. Inorganic chemicals

Pharmacologically active substance(s)	Animal species	Other provisions
'Bromide, potassium salt	All food producing species'	

2. Organic compounds

Pharmacologically active substance(s)	Animal species	Other provisions
'Apramycin	Porcine, rabbits Ovine Not for use in animals from which milk is produced for human consumption Chicken Not for use in animals from which eggs are produced for human consumption	For oral use only
Azamethiphos	Salmonidae	
Doxapram	All mammalian food producing species	
Piperonyl butoxide	Bovine, ovine, caprine, equidae	For topical use only'
Sulfogaiacol	All food producing species	
Vetrabutine hydrochloride	Porcine	

3. Substances generally recognised as safe

Pharmacologically active substance(s)	Animal species	Other provisions
'Adenosine and its 5′-mono-, 5′-di- and 5′-triphosphates	All food producing species	
Alanine	All food producing species	
Arginine	All food producing species	
Asparagine	All food producing species	
Aspartic acid	All food producing species	
Carnitine	All food producing species	
Choline	All food producing species	
Chymotrypsin	All food producing species	

Pharmacologically active substance(s)	Animal species	Other provisions
Citrulline	All food producing species	
Cysteine	All food producing species	
Cytidine and its 5′-mono-, 5′-di- and 5′-triphosphates	All food producing species	
Glutamic acid	All food producing species	
Glutamine	All food producing species	
Glycine	All food producing species	
Guanosine and its 5′-mono-, 5′-di- and 5′-triphosphates	All food producing species	
Histidine	All food producing species	
Hyaluronic acid	All food producing species	
Inosine and its 5′-mono-, 5′-di- and 5′-triphosphates	All food producing species	
Inositol	All food producing species	
Isoleucine	All food producing species	
Leucine	All food producing species	
Lysine	All food producing species	
Methionine	All food producing species	
Ornithine	All food producing species	
Orotic acid	All food producing species	
Pepsin	All food producing species	
Phenylalanine	All food producing species	
Proline	All food producing species	
Serine	All food producing species	
Thioctic acid	All food producing species	
Threonine	All food producing species	
Thymidine	All food producing species	

Pharmacologically active substance(s)	Animal species	Other provisions
Trypsin	All food producing species	
Tryptophan	All food producing species	
Tyrosine	All food producing species	
Uridine and its 5′-mono-, 5′-di- and 5′-triphosphates	All food producing species	
Valine	All food producing species'	

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

1. Anti-infectious agents

1.2. Antibiotics

1.2.05. Aminoglycosides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Kanamycin	Kanamycin	Rabbits	100 µg/kg	Muscle	Provisional MRLs expire on 1.1.2002'
			100 µg/kg	Fat	
			600 µg/kg	Liver	
			2 500 µg/kg	Kidney	
		Bovine, ovine	100 µg/kg	Muscle	
			100 µg/kg	Fat	
			600 µg/kg	Liver	
			2 500 µg/kg	Kidney	
			150 µg/kg	Milk	
		Porcine, chicken	100 µg/kg	Muscle	
			100 µg/kg	Skin + fat	
			600 µg/kg	Liver	
			2 500 µg/kg	Kidney	

2. Antiparasitic agents

2.2. Agents acting against ectoparasites

2.2.2. Iminophenyl thiazolidine derivative

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Cymiazole	Cymiazole	Bees	1 000 µg/kg	Honey	Provisional MRLs expire on 1.7.2001'

2.2.4. Organophosphates

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Coumafos	Coumafos	Bees	100 µg/kg	Honey	Provisional MRLs expire on 1.7.2001'