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COMMISSION REGULATION (EC) No 807/2001

of 25 April 2001

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 750/2001 (2), and in particular Articles 6, 7 and 8 thereof,

Whereas:

- In accordance with Regulation (EEC) No 2377/90, (1)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.
- Maximum residue limits should be established only after (2) 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.
- In establishing maximum residue limits for residues of (3) 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) 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. 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.
- In the case of veterinary medicinal products intended for (5) use in laying birds, lactating animals or honey bees,

maximum residue limits must also be established for eggs, milk or honey.

- (6) Cefoperazone, cyhalothrin, lincomycin, nafcillin, netobimin, phoxim, tiamulin and cyfluthrin should be inserted into Annex I to Regulation (EEC) No 2377/90.
- 'Linear alkyl benzene sulphonic acids with alkyl chain (7) lengths ranging from C_9 to C_{13} , containing less than 2,5 % of chains longer than C_{13} ' should be inserted into Annex II to Regulation (EEC) No 2377/90.
- In order to allow for the completion of scientific studies, (8) 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 cefacetrile, oxolinic acid and permethrin.
- An adequate period should be allowed before the entry (9) 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 Commission Directive 2000/37/EC (⁴), to take account of the provisions of this Regulation.
- (10)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 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 third day following its publication in the Official Journal of the European Communities.

It shall apply from the 60th day following its publication.

^{(&}lt;sup>1</sup>) OJ L 224, 18.8.1990, p. 1. (²) OJ L 109, 19.4.2001, p. 35.

^{(&}lt;sup>3</sup>) OJ L 317, 6.11.1981, p. 1. (⁴) OJ L 139, 10.6.2000, p. 25.

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

Done at Brussels, 25 April 2001.

For the Commission Erkki LIIKANEN Member of the Commission

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

- 1. Anti-infectious agents
- 1.2. Antibiotics
- 1.2.1. Penicillins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Nafcillin	Nafcillin	Bovine	300 μg/kg 300 μg/kg 300 μg/kg 300 μg/kg 30 μg/kg	Muscle Fat Liver Kidney Milk	For intramammary use only'

ANNEX

1.2.2. Cephalosporins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Cefoperazone	Cefoperazone	Bovine	50 μg/kg	Milk'	

1.2.8. Pleuromutilines

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Tiamulin	Sum of metabolites that may be hydrolysed to 8-α- hydroxymutilin		100 µg/kg 100 µg/kg 300 µg/kg	Muscle Skin and fat Liver'	

1.2.9. Lincosamides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Lincomycin	Lincomycin	Ovine	100 μg/kg 50 μg/kg 500 μg/kg 1 500 μg/kg 1 500 μg/kg 1 50 μg/kg	Muscle Fat Liver Kidney Milk	

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
		Porcine	100 µg/kg 50 µg/kg 500 µg/kg 1 500 µg/kg	Muscle Skin and fat Liver Kidney	
		Chicken	100 μg/kg 50 μg/kg 500 μg/kg 1 500 μg/kg 50 μg/kg	Muscle Skin and fat Liver Kidney Eggs'	

Antiparasitic agents 2.

Agents acting against endoparasites 2.1.

2.1.3. Benzimidazoles and pro-benzimidazoles

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Netobimin	Sum of albendazole oxide, albendazole sulphone and albendazole 2-aminosul- phone, expressed as alben- dazole		100 μg/kg 100 μg/kg 1 000 μg/kg 500 μg/kg 100 μg/kg	Muscle Fat Liver Kidney Milk	For oral use only'

Agents acting against ectoparasites 2.2.

2.2.1. Organophosphates

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Phoxim	Phoxim	Ovine Porcine	50 μg/kg 400 μg/kg 50 μg/kg 20 μg/kg 700 μg/kg 20 μg/kg 20 μg/kg	Muscle Fat Kidney Muscle Skin and fat Liver Kidney	Not for use in animals from which milk is produced for human consumption'

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2.2.3. Pyrethroids

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Cyhalothrin	Cyhalothrin (sum of isomers)	Bovine	500 μg/kg 50 μg/kg 50 μg/kg 10 μg/kg	Fat Kidney Milk Muscle	Further provisions in Council Directive 94/29/EC are to be observed'
Cyfluthrin	Cyfluthrin (sum of isomers)	Bovine	50 μg/kg 10 μg/kg 10 μg/kg 20 μg/kg	Fat Liver Kidney Milk	

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

2. Organic compounds

Pharmacologically active substance(s)	Animal species	Other provisions
Linear alkyl benzene sulphonic acids with alkyl chain lengths ranging from C_9 to C_{13} , containing less than 2,5 % of chains longer than C_{13}	Bovine	For topical use only'

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

- 1. Anti-infectious agents
- 1.2. Antibiotics
- 1.2.4. Cephalosporins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Cefacetrile	Cefacetrile	Bovine	125 μg/kg	Milk	Provisional MRLs expire on 1.1.2002 For intramammary use only'

1.2.6. Quinolones

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Oxolinic acid	Oxolinic acid	Bovine	100 μg/kg 50 μg/kg 150 μg/kg 150 μg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1.1.2003 Not for use in animals from which milk is produced for human consumption'

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Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
		Porcine	100 µg/kg 50 µg/kg 150 µg/kg 150 µg/kg	Muscle Skin and fat Liver Kidney	
		Chicken	100 µg/kg 50 µg/kg 150 µg/kg 150 µg/kg 50 µg/kg	Muscle Skin and fat Liver Kidney Eggs	
		Fin fish	300 μg/kg	Muscle and skin in natural proportions	

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
'Permethrin	Permethrin isomers)	(sum of	of	Chicken, porcine	50 μg/kg 500 μg/kg 50 μg/kg 50 μg/kg	Muscle Skin and fat Liver Kidney	Provisional MRLs expire on 1.1.2003
				Bovine, caprine	50 μg/kg 500 μg/kg 50 μg/kg 50 μg/kg 50 μg/kg	Muscle Fat Liver Kidney Milk	Provisional MRLs expire on 1.1.2003 Further provisions in Commission Directive 98/82/EC are to be observed (OJ L 290, 29.10.1998, p. 25)
				Chicken	50 μg/kg	Eggs	Provisional MRLs expire on 1.1.2003'