

COMMISSION REGULATION (EC) No 1181/2002

of 1 July 2002

amending Annex I 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 869/2002 ⁽²⁾ and in particular Articles 6, 7 and 8 thereof,

Whereas:

- (1) 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) 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) 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) In view of the reduced availability of veterinary medicinal products for certain food-producing species ⁽³⁾, maximum residue limits may be established by methods of extrapolation from maximum residue limits set for other species on a strictly scientific basis.
- (5) 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.

- (6) 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.
- (7) Trimethoprim, Neomycin (including framycetin), Paromomycin, Spectinomycin, Colistin, Danofloxacin, Difloxacin, Enrofloxacin, Flumequine, Erythromycin, Tilmicosin, Tylosin, Florfenicol, Lincomycin and Oxytetracycline should be inserted into Annex I to Regulation (EEC) No 2377/90.
- (8) An adequate period 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 Directive 2001/82/EC ⁽⁴⁾ of the European Parliament and of the Council to take account of the provisions of this Regulation.
- (9) 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

Annex I of Regulation (EEC) No 2377/90 is 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 sixtieth day following its publication.

⁽¹⁾ OJ L 224, 18.8.1990, p. 1.

⁽²⁾ OJ L 137, 25.5.2002, p. 10.

⁽³⁾ Availability of veterinary medical products Communication from the Commission to the Council and the European Parliament COM(2000) 806 final.

⁽⁴⁾ OJ L 311, 28.11.2001, p. 1.

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

Done at Brussels, 1 July 2002.

For the Commission
Erkki LIIKANEN
Member of the Commission

ANNEX

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

1. Anti-infectious agents
 - 1.1. Chemotherapeutics
 - 1.1.2. Diamino pyrimidine derivatives

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Trimethoprim	Trimethoprim	All food producing species except equidae	50 µg/kg	Fat ⁽¹⁾	Not for use in animals from which eggs are produced for human consumption
			50 µg/kg	Muscle ⁽²⁾	
			50 µg/kg	Liver	
			50 µg/kg	Kidney	
			50 µg/kg	Milk	
		Equidae	100 µg/kg	Muscle	
			100 µg/kg	Fat	
			100 µg/kg	Liver	
			100 µg/kg	Kidney	
			100 µg/kg	Kidney	

⁽¹⁾ For porcine and poultry species this MRL relates to "skin and fat in natural proportions".⁽²⁾ For fin fish this MRL relates to "muscle and skin in natural proportions".

- 1.2. Antibiotics
 - 1.2.3. Quinolones

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Danofloxacin	Danofloxacin	All food producing species except bovine, ovine, caprine and poultry	100 µg/kg	Muscle ⁽¹⁾	Not for use in animals from which eggs are produced for human consumption
			50 µg/kg	Fat ⁽²⁾	
			200 µg/kg	Liver	
			200 µg/kg	Kidney	
			200 µg/kg	Muscle	
		Bovine, ovine, caprine	100 µg/kg	Fat	
			400 µg/kg	Liver	
			400 µg/kg	Kidney	
			30 µg/kg	Milk	
			Poultry	200 µg/kg	
		100 µg/kg		Skin and fat	
		400 µg/kg		Liver	
		400 µg/kg		Kidney	

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	
Difloxacin	Difloxacin	All food producing species except bovine, ovine, caprine and poultry	300 µg/kg	Muscle (1)	Not for use in animals from which milk is produced for human consumption	
			100 µg/kg	Fat		
			800 µg/kg	Liver		
			600 µg/kg	Kidney		
		Bovine, ovine, caprine	400 µg/kg	Muscle		
			100 µg/kg	Fat		
			1 400 µg/kg	Liver		
			800 µg/kg	Kidney		
		Porcine	400 µg/kg	Muscle		
			100 µg/kg	Skin and fat		
			800 µg/kg	Liver		
			800 µg/kg	Kidney		
		Poultry	300 µg/kg	Muscle		Not for use in animals from which eggs are produced for human consumption
			400 µg/kg	Skin and fat		
			1 900 µg/kg	Liver		
			600 µg/kg	Kidney		
Enrofloxacin	Sum of enrofloxacin and ciprofloxacin	All food producing species except bovine, ovine, caprine, porcine, rabbits and poultry	100 µg/kg	Muscle (1)	Not for use in animals from which eggs are produced for human consumption	
			100 µg/kg	Fat		
			200 µg/kg	Liver		
			200 µg/kg	Kidney		
		Bovine, ovine, caprine	100 µg/kg	Muscle		
			100 µg/kg	Fat		
			300 µg/kg	Liver		
			200 µg/kg	Kidney		
			100 µg/kg	Milk		
		Porcine, rabbits	100 µg/kg	Muscle		
			100 µg/kg	Fat (2)		
			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 and fat		
			200 µg/kg	Liver		
			300 µg/kg	Kidney		

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Flumequine	Flumequine	All food producing species except bovine, ovine, caprine, porcine, poultry and fin fish	200 µg/kg	Muscle	Not for use in animals from which eggs are produced for human consumption
			250 µg/kg	Fat	
			500 µg/kg	Liver	
			1 000 µg/kg	Kidney	
		Bovine, porcine, ovine, caprine	200 µg/kg	Muscle	
			300 µg/kg	Fat (?)	
			500 µg/kg	Liver	
			1 500 µg/kg	Kidney	
			50 µg/kg	Milk	
		Poultry	400 µg/kg	Muscle	
			250 µg/kg	Skin and fat	
			800 µg/kg	Liver	
			1 000 µg/kg	Kidney	
Fin fish	600 µg/kg	Muscle and skin in natural proportion			

(?) For fin fish this MRL relates to "muscle and skin in natural proportions".

(!) For porcine species this MRL relates to "skin and fat in natural proportions".

1.2.4. Macrolides

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Erythromycin	erythromycin A	All food producing species	200 µg/kg	Muscle (!)	Not for use in animals from which eggs are produced for human consumption
			200 µg/kg	Fat (?)	
			200 µg/kg	Liver	
			200 µg/kg	Kidney	
			40 µg/kg	Milk	
			150 µg/kg	Eggs	
Tilmicosin	Tilmicosin	All food producing species except poultry	50 µg/kg	Muscle (!)	Not for use in animals from which eggs are produced for human consumption
			50 µg/kg	Fat (?)	
			1 000 µg/kg	Liver	
			1 000 µg/kg	Kidney	
		Poultry	50 µg/kg	Milk	
			75 µg/kg	Muscle	
			75 µg/kg	Sin and fat	
			1 000 µg/kg	Liver	
250 µg/kg	Kidney				

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Tylosin	Tylosin A	All food producing species	100 µg/kg 100 µg/kg 100 µg/kg 100 µg/kg 50 µg/kg 200 µg/kg	Fat ⁽³⁾ Muscle ⁽¹⁾ Liver Kidney Milk Eggs	

⁽¹⁾ For fin fish this MRL relates to a "muscle and skin in natural proportions".

⁽²⁾ For porcine species this MRL relates to "skin and fat in natural proportions".

⁽³⁾ For porcine and poultry species this MRL relates to "skin and fat in natural proportions".

1.2.5. Florfenicol and related compounds

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Florfenicol	Sum of florfenicol and its metabolites measured as florfenicol-amine	All food producing species except bovine, ovine, caprine, porcine, poultry and fin fish	100 µg/kg 200 µg/kg 2 000 µg/kg 300 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption
		Bovine, ovine, caprine	200 µg/kg 3 000 µg/kg 300 µg/kg	Muscle Fat Kidney	
		Porcine	300 µg/kg 500 µg/kg 2 000 µg/kg 500 µg/kg	Muscle Skin and fat Liver Kidney	Not for use in animals from which eggs are produced for human consumption
		Poultry	100 µg/kg 200 µg/kg 2 500 µg/kg 750 µg/kg	Muscle Skin and fat Liver Kidney	
		Fin fish	1 000 µg/kg	Muscle and skin in natural proportions'	

1.2.9. Lincosamides

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Lincomycin	Lincomycin	All food producing species	50 µg/kg 100 µg/kg 500 µg/kg 1 500 µg/kg 150 µg/kg 50 µg/kg	Fat ⁽¹⁾ Muscle ⁽²⁾ Liver Kidney Milk Eggs	

⁽¹⁾ For porcine and poultry species this MRL relates to "skin and fat in natural proportions".

⁽²⁾ For fin fish this MRL relates to "muscle and skin in natural proportions".

1.2.10. Aminoglycosides

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Neomycin (including framycetin)	Neomycin B	All food producing species	500 µg/kg 500 µg/kg 500 µg/kg 5 000 µg/kg 1 500 µg/kg 500 µg/kg	Fat ⁽¹⁾ Muscle ⁽²⁾ Liver Kidney Milk Eggs	
Paromomycin	Paromomycin	All food producing species	500 µg/kg 1 500 µg/kg 1 500 µg/kg	Muscle ⁽²⁾ Liver Kidney	Not for use in animals from which milk or eggs are produced for human consumption
Spectinomycin	Spectinomycin	All food producing species except ovine	500 µg/kg 300 µg/kg 1 000 µg/kg 5 000 µg/kg 200 µg/kg	Fat ⁽¹⁾ Muscle ⁽²⁾ Liver Kidney Milk	Not for use in animals from which eggs are produced for human consumption

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
		Ovine	300 µg/kg 500 µg/kg 2 000 µg/kg 5 000 µg/kg 200 µg/kg	Muscle Fat Liver Kidney Milk	

(¹) For porcine and poultry species this MRL relates to "skin and fat in natural proportions".

(²) For fin fish this MRL relates to "muscle and skin in natural proportions".

1.2.14. Polymyxins

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Colistin	Colistin	All food producing species	150 µg/kg 150 µg/kg 150 µg/kg 200 µg/kg 50 µg/kg 300 µg/kg	Fat (¹) Muscle (²) Liver Kidney Milk Eggs	

(¹) For porcine and poultry species this MRL relates to "skin and fat in natural proportions".

(²) For fin fish this MRL relates to "muscle and skin in natural proportions".

2. Antiparasitic agents

2.1. Agents acting against endoparasites

2.1.4. Phenol derivatives including salicylanides

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Oxyclozanide	Oxyclozanide	Bovine	20 µg/kg 20 µg/kg 500 µg/kg 100 µg/kg 10 µg/kg	Muscle Fat Liver Kidney Milk	Not for use in animals from which milk is produced for human consumption'
		Ovine	20 µg/kg 20 µg/kg 500 µg/kg 100 µg/kg	Muscle Fat Liver Kidney	