

## COMMISSION REGULATION (EC) No 121/98

of 16 January 1998

**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<sup>(1)</sup>, as last amended by Commission Regulation (EC) No 1850/97<sup>(2)</sup> 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 danofloxacin, cefazolin and trimethoprim should be inserted into Annex I to Regulation (EEC) No 2377/90;

Whereas lini oleum, folic acid, betain and cefazolin should be inserted into Annex II to Regulation (EEC) No 2377/90;

Whereas, in order to allow for the completion of scientific studies, 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 penethamate;

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<sup>(3)</sup>, as last amended by Directive 93/40/EEC<sup>(4)</sup>, 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,

HAS ADOPTED THIS 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 60th day following its publication in the *Official Journal of the European Communities*.

<sup>(1)</sup> OJ L 224, 18. 8. 1990, p. 1.

<sup>(2)</sup> OJ L 264, 26. 9. 1997, p. 12.

<sup>(3)</sup> OJ L 317, 6. 11. 1981, p. 1.

<sup>(4)</sup> 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, 16 January 1998.

*For the Commission*  
Martin BANGEMANN  
*Member of the Commission*

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## ANNEX

## A. Annex I is modified as follows:

## 1. Anti-infectious agents

## 1.1. Chemotherapeutics

## 1.1.2. Diamino pyrimidine derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions	
Trimethoprim	Trimethoprim	Bovine	50 µg/kg	Muscle, fat, liver, kidney, milk		
		Porcine	50 µg/kg	Muscle, skin and fat, liver, kidney		
		Poultry	50 µg/kg	Muscle, skin and fat, liver, kidney	Not for use in animals from which eggs are produced for human consumption	
		Equidae	100 µg/kg	Muscle, fat, liver, kidney		
		Fin Fish	50 µg/kg	Muscle and skin in natural proportions		
1.2. Antibiotics						
1.2.2. Cephalosporins						
Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions	
Cefazolin	Cefazolin	Ovine, caprine	50 µg/kg	Milk		
		1.2.3. Quinolones				
Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions	
Danofloxacin	Danofloxacin	Bovine	200 µg/kg	Muscle	Not for use in animals from which milk is produced for human consumption	
			100 µg/kg	Fat		
			400 µg/kg	Liver, kidney		
		Chicken	200 µg/kg	Muscle		Not for use in animals from which eggs are produced for human consumption
			100 µg/kg	Skin and fat		
400 µg/kg	Liver, kidney					

## B. Annex II is modified as follows:

## 2. Organic compounds

Pharmacologically active substance(s)	Animal species	Other provisions
Cefazolin	Ovine, caprine	For intramammary use only (except if the udder may be used as food for human consumption)
Betaine	All food producing species	
Folic acid	All food producing species	
Lini oleum	All food producing species	

## C. Annex III is modified as follows:

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

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Penethamate	Benzylpenicillin	Ovine	50 µg/kg	Muscle, fat, liver, kidney	Provisional MRLs expire on 1 January 2000
			4 µg/kg	Milk	
		Porcine	50 µg/kg	Muscle, fat, liver, kidney	