COMMISSION REGULATION (EC) No 281/96

of 14 February 1996

amending Annexes I 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 2804/95 [2], and in particular Articles 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 level 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 carcases 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 tetracycline, oxytetracycline, chlortetracycline and all substances belonging to the sulfonamide group should be inserted into Annex I to Regulation (EEC) No 2377/90;

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

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 authorizations to place the veterinary medicinal products concerned on the market which have been granted in accordance with Council Directive 81/851/EEC [3], as 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,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I 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 No L 224, 18. 8. 1990, p. 1.
[2] OJ No L 291, 6. 12. 1995, p. 8.
[3] OJ No L 317, 6. 11. 1981, p. 1.
[4] OJ No 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, 14 February 1996.

For the Commission
Martin BANGEMANN
Member of the Commission

ANNEX

A. Annex I is amended as follows:

1. Anti-infectious agents
1.1. Chemotherapeutics
1.1.1. Sulfonamides

Pharmacologically active substance	Marker residue	Animal Species	MRLs	Target tissues	Other provisions
'All substances belonging to the sulfonamide group	Parent drug	Bovine Ovine Caprine	100 µg/kg	Milk	The combined residues of all substances in the sulfonamide group should not exceed 100 µg/kg'

1.2. Antibiotics
1.2.6. Tetracylines

Pharmacologically active substance	Marker residue	Animal Species	MRLs	Target Tissues	Other provisions
'1.2.6.1. Tetracycline	Sum of parent drug and its 4-epimer	All food producing species	600 µg/kg	Kidney	
			300 µg/kg	Liver	
			100 µg/kg	Muscle	
			100 µg/kg	Milk	
			200 µg/kg	Eggs	
1.2.6.2. Oxytetracycline	Sum of parent drug and its 4-epimer	All food producing species	600 µg/kg	Kidney	
			300 µg/kg	Liver	
			100 µg/kg	Muscle	
			100 µg/kg	Milk	
			200 µg/kg	Eggs	
1.2.6.3. Chlortetracycline	Sum of parent drug and its 4-epimer	All food producing species	600 µg/kg	Kidney	
			300 µg/kg	Liver	
			100 µg/kg	Muscle	
			100 µg/kg	Milk	
			200 µg/kg	Eggs'	

B. Annex III is amended as follows:

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

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'1.1.2.1. Trimethoprim	Trimethoprim	All food producing species	50 µg/kg	Muscle, liver, kidney, fat, milk	Provisional MRLs expire on 1 January 1998'