COMMISSION REGULATION (EC) No 1286/2000

of 19 June 2000

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 2758/1999 [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) 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 carcases moving in international trade, and maximum residue limits should therefore also always be established for muscle or fat tissues.

(5) 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) Phenoxymethylpenicillin should be inserted into Annex I to Regulation (EEC) No 2377/90.

(7) Calcium aspartate, *rhei radix*, standardised extracts, preparations thereof, *matricaria recutita*, preparations thereof, zinc aspartate, sodim salicylate, sodium acetylsalicylate, salicylic acid, methyl salicylate, carbasalate calcium and bismuth subnitrate and aluminium salicylate, basic and Acetylsalicylic acid DL-lysine should be inserted into Annex II to Regulation (EEC) No 2377/90.

(8) In order to allow for the completion of scientific studies, methylprednisolone and acetylisovaleryltylosin should be inserted into Annex III to Regulation (EEC) No 2377/90.

(9) 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 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) 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 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 third day following its publication in the *Official Journal of the European Communities*.

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

[1] OJ L 224, 18.8.1990, p. 1.
[2] OJ L 331, 23.12.1999, p. 49.
[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, 19 June 2000.

For the Commission
Erkki LIIKANEN
Member of the Commission

ANNEX

A. The following substance is inserted in Annex I to Regulation (EEC) No 2377/90 (List of pharmacologically active substances for which maximum residue limits have been fixed)

1. Anti-infectious agents

1.2. Antibiotics

1.2.1. Penicillins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Phenoxymethylpenicillin	Phenoxymethylpenicillin	Porcine	25 µg/kg 25 µg/kg 25 µg/kg	Muscle Liver Kidney'	

B. The following substances are inserted in Annex II to Regulation (EEC) No 2377/90 (List of substances not subject to maximum residue limits)

2. Organic compounds

Pharmacologically active substance(s)	Animal species	Other provisions
'Aluminium salicylate, basic	All food producing species except fish For topical use only	
Bismuth subnitrate	Bovine	For intramammary use only
Calcium aspartate	All food producing species	
Methyl salicylate	All food producing species except fish	For topical use only
Salicylic acid	All food producing species except fish	For topical use only
Sodium salicylate	All food producing species except fish	For topical use only'
Zinc aspartate	All food producing species	

6. Substances of vegetable origin

Pharmacologically active substance(s)	Animal species	Other provisions
'*Matricaria recutita* and preparations thereof	All food producing species	
Rhei radix, standardised extracts and preparations thereof	All food producing species'	

C. The following substances are inserted in Annex III to Regulation (EEC) No 2377/90 (List of pharmacologically active substances used in veterinary medicinal products for which provisional maximum residue limits have been fixed)

1. Anti-infectious agents

1.2. Antibiotics

1.2.2. Macrolides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Acetylisovaleryltylosin	Sum of acetylisovaleryltylosin and 3-O-acetyltylosin	Porcine	100 µg/kg 100 µg/kg 100 µg/kg 100 µg/kg	Muscle Skin and fat Liver Kidney	Provisional MRLs expire on 1.7.2001'

7. Corticoids

7.1. Glucocorticoids

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Methylprednisolone	Methylprednisolone	Bovine	10 µg/kg 10 µg/kg 10 µg/kg 10 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1.7.2001. Not for use in animals from which milk is produced for human consumption'