COMMISSION REGULATION (EEC) No 675/92

of 18 March 1992

amending Annexes I 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

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic 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), 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 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 tissue 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 the sulfonamide group of substances (in respect of residues in meat), ivermectin, benzylpenicillin, ampicillin, amoxicillin, oxacillin, cloxacillin and dicloxacillin should be inserted into Annex I to Regulation (EEC) No 2377/90;

Whereas dimetridazole, ronidazole, chloramphenicol, azaperone and carazolol, the nitrofurans group, trimethoprim, dapsone, compounds belonging to the tetracyclines group, spiramycin, febantel, fenbendazole, oxfendazole, levamisol and sulfonamide group (in respect of residues in milk) should be inserted into Annex III to Regulation (EEC) No 2377/90; whereas it is necessary to define the duration of the provisional maximum residue limits;

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/CEE (2) 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 Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector,

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 60 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 317, 6. 11. 1981, p. 1.

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

Done at Brussels, 18 March 1992.

For the Commission
Martin BANGEMANN
Vice-President

ANNEX

A. Annex I is hereby replaced by the following:

'ANNEX I

List of pharmacologically active substances for which maximum residue limits have been fixed

1. *Anti-infectious agents*

1.1. Chemotherapeutics

1.1.1. Sulfonamides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
All substances belonging to the sulfonamide group	Parent drug	All food producing species	100 µg/kg	Muscle, liver, kidney, fat	The combined total residues of all substances within the sulfonamide group should not excced 100 µg/kg

1.2. Antibiotics

1.2.1. Penicillins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
1.2.1.1. Benzylpenicillin	Parent drug	All food producing species	50 µg/kg	Muscle, liver, kidney, fat	
			4 µg/kg	milk	
1.2.1.2. Ampicillin	Parent drug	All food producing species	50 µg/kg	Muscle, liver, kidney, fat	
			4 µg/kg	milk	
1.2.1.3. Amoxicillin	Parent drug	All food producing species	50 µg/kg	Muscle, liver, kidney, fat	
			4 µg/kg	milk	
1.2.1.4. Oxacillin	Parent drug	All food producing species	300 µg/kg	Muscle, liver, kidney, fat	
			30 µg/kg	milk	
1.2.1.5. Cloxacillin	Parent drug	All food producing species	300 µg/kg	Muscle, liver, kidney, fat	
			30 µg/kg	milk	
1.2.1.6. Dicloxacillin	Parent drug	All food producing species	300 µg/kg	Muscle, liver, kidney, fat	
			30 µg/kg	milk	

2. *Antiparasitic agents*

2.1. Agents acting against endoparasites

2.1.1. Avermectins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
2.1.1.1. Ivermectin	H2B1a – metabolite	Bovine, ovine, porcine, equine	15 µg/kg 20 µg/kg	Liver fat	The MRLs for liver and fat apply to all four species mentioned'

B. Annex III is hereby replaced by the following:

'ANNEX III

List of pharmacologically active substances used in veterinary medicinal products for which provisional maximum residue limits have been fixed

1. *Anti-infectious agents*

1.1. Chemotherapeutics

1.1.1. Sulfonamides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
All substances belonging to the sulfonamide group	Parent drug	Cattle, sheep, goats	100 µg/kg	milk	Provisional MRL expires on 1 January 1994. The combined total residues of all substances within the sulfonamide group should not exceed 100 µg/kg.

1.1.2. Diamino pyrimidine derivates

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
1.1.2.1. Trimethoprim	Parent drug	All food producing species	50 µg/kg	Muscle, liver, kidney, fat milk	Provisional MRL expires on 1 January 1996

1.1.3. Nitrofurans

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
All substances belonging to the nitrofuran group	All residues with intact 5-nitro structure	All food producing species	5 µg/kg	Muscle, liver, kidney, fat	Provisional MRL expires on 1 July 1993 The combined total residues of all substances within this group should not exceed 5 µg/kg

1.1.4. Nitroimidazoles

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
1.1.4.1. Dimetridazole	All residues with intact nitroimidazole structure	All food producing species	10 µg/kg	Muscle, liver, kidney, fat	Provisional MRL expires on 1 January 1994
1.1.4.2. Ronidazole	All residues with intact nitroimidazole structure	All food producing species	2 µg/kg	Muscle, liver, kidney, fat	Provisional MRL expires on 1 January 1994

1.1.n. Other chemotherapeutics

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
1.1.n.1. Dapsone	Parent drug	All food producing species	25 µg/kg 25 µg/kg	Muscle, liver, kidney, fat milk	Provisional MRL expires on 1 January 1994

1.2. Antibiotics

1.2.2. Tetracyclines

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
All substances belonging to the tetracycline group	Parent drug	All food producing species	600 µg/kg 300 µg/kg 200 µg/kg 100 µg/kg 100 µg/kg	Kidney, liver eggs, muscle, milk	Provisional MRLs expires on 1 January 1994. The combined total residues of all substances within the tetracycline group should not exceed the limits indicated

1.2.3. Macrolides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
1.2.3.1. Spiramycin	Parent drug	Bovine, porcine	300 µg/kg 200 µg/kg 50 µg/kg	Liver kidney muscle	Provisional MRLs expire on 1 July 1995
		bovine	150 µg/kg	milk	The MRLs for liver, kidney and muscle apply to both the bovine and porcine species

1.2.4. Chloramphenicol and related compounds

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
1.2.4.1. Chloramphenicol	Parent drug	All food producing species	10 µg/kg	Muscle, liver, kidney, fat	Provisional MRL expires on July 1994

2. *Antiparasitic agents*

2.1. Agents acting against endo-parasites

2.1.1. Benzimidazoles and pro-benzimidazoles

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
2.1.1.1. Febantel 2.1.1.2. Fenbendazole 2.1.1.3. Oxfendazole	combined residues of oxfendazole, oxfendazole sulfone and fenbendazole	All food producing species	1 000 µg/kg 10 µg/kg 10 µg/kg	Liver muscle, kidney, fat milk	Provisional MRLs expire on 1 July 1995 The MRLs cover all residues of febantel, fenbendazole and oxfendazole

2.1.2. Tetra-hydro-imidazoles (imidazolthiazoles)

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
2.1.2.1. Levamisol	Parent drug	All food producing species	10 µg/kg	Muscle, liver, kidney, fat, milk	Provisional MRL expires on 1 January 1995

3. *Agents acting on the nervous system*

3.1. Agents acting on the central nervous system

3.1.1. Butyrofenone tranquillizers

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
3.1.1.1. Azaperone	Azaperol	All food producing species	100 µg/kg 50 µg/kg	kidney liver, muscle, fat	Provisional MRLs expire on 1 January 1996

3.2. Agents acting on the autonomic nervous system

3.2.1. Anti-adrenergics

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
3.2.1.1. Carazolol	Parent drug	All food producing species	30 µg/kg 5 µg/kg	Liver, kidney muscle, fat	Provisional MRLs expire on 1 July 1995'