COMMISSION REGULATION (EC) No 1478/2001

of 18 July 2001

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 1322/2001 [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 Community 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 taget 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.

(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) Bacitracin (bovine, milk), rafoxanide, coumafos, cyromazine and doramectin (deer including reindeer) should be inserted into Annex I to Regulation (EEC) No 2377/90.

(7) Amprolium and tiludronic acid, disodium salt should be inserted into Annex II to Regulation (EEC) No 2377/90.

(8) 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 piperazine.

(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 Commission Directive 2000/37/EC [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 THIS REGULATION:

Article 1

Annexes I, II and III to Regulation (EEC) No 2377/90 are hereby amended as se 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 177, 30.6.2001, p. 52.
[3] OJ L 317, 6.11.1981, p. 1.
[4] OJ L 139, 10.6.2000, p. 25.

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

Done at Brussels, 18 July 2001.

For the Commission
Erkki LIIKANEN
Member of the Commission

ANNEX

A. Annex I to Regulation (EC) No 2377/90 is amended as follows:

1. Anti-infectious agents

1.2. Antibiotics

1.2.12. Polypeptides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Bacitracin	Sum of bacitracin A, bacitracin B, and bacitracin C	Bovine	100 µg/kg	Milk'	

2. Antiparasitic agents

2.1. Agents acting against endoparasites

2.1.1. Salicylanilides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Rafoxanide	Rafoxanide	Bovine	30 µg/kg	Muscle	Not for use in animals from which milk is produced for human consumption'
			30 µg/kg	Fat	
			10 µg/kg	Liver	
			40 µg/kg	Kidney	
		Ovine	100 µg/kg	Muscle	
			250 µg/kg	Fat	
			150 µg/kg	Liver	
			150 µg/kg	Kidney	

2.2. Agents acting against ectoparasites

2.2.1. Organophosphates

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Coumafos	Coumafos	Bees	100 µg/kg	Honey'	

2.2.6. Triazine derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Cyromazine	Cyromazine	Ovine	300 µg/kg 300 µg/kg 300 µg/kg 300 µg/kg	Muscle Fat Liver Kidney	Not for use in animals from which milk is produced for human consumption'

2.3. Agents acting against endo- and ectoparasites

2.3.1. Avermectins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Doramectin	Doramectin	Deer, including reindeer	20 µg/kg 100 µg/kg 50 µg/kg 30 µg/kg	Muscle Fat Liver Kidney'	

B. Annex II to Regulation (EEC) No 2377/90 is amended as follows:

2. Organic compounds

Pharmacologically active substance(s)	Animal species	Other provisions
'Amprolium	Poultry	For oral use only
Tiludronic acid, disodium salt	Equidae	For intravenous use only'

C. Annex III to Regulation (EEC) No 2377/90 is amended as follows:

2. Antiparasitic agents

2.1. Agents acting against endoparasites

2.1.5. Piperazine derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Piperazine	Piperazine	Porcine	400 µg/kg 800 µg/kg 2 000 µg/kg 1 000 µg/kg	Muscle Skin and fat Liver Kidney	Provisional MRLs expire on 1.7.2003'
		Chicken	2 000 µg/kg	Eggs	