COMMISSION REGULATION (EC) No 2338/2000

of 20 October 2000

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 [1], as last amended by Commission Regulation (EC) No 1960/2000 [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) Erythromycin, flumequine, marbofloxacin, paromomycin, pirlimycin, tiamulin and tilmicosin should be inserted into Annex I to Regulation (EEC) No 2377/90.

(7) *Anisi stellati fructus*, standardised extracts and preparations thereof, *Cinchonae cortex*, standardised extracts and preparations thereof, *Cinnamoni cassiae cortex*, standardised extracts and preparations thereof, *Cinnamomi ceylanici cortex*, standardised extracts and preparations thereof, *Condurango cortex*, standardised extracts and preparations thereof, decoquinate, *Frangulae cortex*, standardised extracts and preparations thereof, *Gentianae radix*, standardised extracts and preparations thereof, sodium boroformiate and sodium propionate 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 colistin, josamycin and oxyclozanide.

(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 amended as set out in the Annex.

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 sixtieth day following its publication.

[1] OJ L 224, 18.8.1990, p. 1.
[2] OJ L 234, 16.9.2000, p. 5.
[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, 20 October 2000.

For the Commission
Erkki LIIKANEN
Member of the Commission

ANNEX

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

1. Anti-infectious agents

1.2. Antibiotics

1.2.3. Quinolones

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Flumequine	Flumequine	Bovine	50 µg/kg	Milk	
		Turkey	400 µg/kg	Muscle	
			250 µg/kg	Skin and fat	
			800 µg/kg	Liver	
			1 000 µg/kg	Kidney	
Marbofloxacin	Marbofloxacin	Bovine	150 µg/kg	Muscle	
			50 µg/kg	Fat	
			150 µg/kg	Liver	
			150 µg/kg	Kidney	
			75 µg/kg	Milk	
		Porcine	150 µg/kg	Muscle	
			50 µg/kg	Skin and fat	
			150 µg/kg	Liver	
			150 µg/kg	Kidney'	

1.2.4. Macrolides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Erythromycin	Erythromycin A	Chiken	200 µg/kg	Muscle	
			200 µg/kg	Skin and fat	
			200 µg/kg	Liver	
			200 µg/kg	Kidney	
			150 µg/kg	Eggs	
		Bovine	200 µg/kg	Muscle	
			200 µg/kg	Fat	
			200 µg/kg	Liver	
			200 µg/kg	Kidney	
			40 µg/kg	Milk	
		Ovine	200 µg/kg	Muscle	Not for use in animals from which milk is produced for human consumption
			200 µg/kg	Fat	
			200 µg/kg	Liver	
			200 µg/kg	Kidney	
		Porcine	200 µg/kg	Muscle	
			200 µg/kg	Skin and fat	
			200 µg/kg	Liver	
			200 µg/kg	Kidney	
Tilmicosin	Tilmicosin	Rabbits	50 µg/kg	Muscle	
			50 µg/kg	Fat	
			1 000 µg/kg	Liver	
			1 000 µg/kg	Kidney'	

1.2.8. Pleuromutilines

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Tiamulin	Sum of metaboilites that may be hydrolysed to 8-α-hydroxymutilin	Rabbits	100 µg/kg	Muscle	
			500 µg/kg	Liver'	

1.2.9. Lincosamides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Pirlimycin	Pirlimycin	Bovine	100 µg/kg 100 µg/kg 1 000 µg/kg 400 µg/kg 100 µg/kg	Muscle Fat Liver Kidney Milk'	

1.2.10. Aminoglycosides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Paromomycin	Paromomycin	Bovine	500 µg/kg 1 500 µg/kg 1 500 µg/kg	Muscle Liver Kidney	Not for use in animals from which milk is produced for human consumption
		Porcine, rabbits	500 µg/kg 1 500 µg/kg 1 500 µg/kg	Muscle Liver Kidney	
		Chicken	500 µg/kg 1 500 µg/kg 1 500 µg/kg	Muscle Liver Kidney	Not for use in animals from which eggs are produced for human consumption'

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

1. Inorganic chemicals

Pharmacologically active substance(s)	Animal species	Other provisions
'Sodium propionate	All food producing species'	

2. Organic compounds

Pharmacologically active substance(s)	Animal species	Other provisions
'Decoquinate	Bovine, ovine	For oral use only. Not for use in animals from which milk is produced for human consumption'
Sodium boroformiate	All food producing species	

6. Substances of vegetable origin

Pharmacologically active substance(s)	Animal species	Other provisions
'*Anisi stellati fructus*, standardised extracts and preparations thereof	All food producing species	
Cinchonae cortex, standardised extracts and preparations thereof	All food producing species	
Cinnamomi cassiae cortex, standardised extracts and preparations thereof	All food producing species	
Cinnamomi ceylanici cortex, standardised extracts and preparations thereof	All food producing species	
Condurango cortex, standardised extracts and preparations thereof	All food producing species	
Frangulae cortex, standardised extracts and preparations thereof	All food producing species	
Gentianae radix, standardised extracts and preparations thereof	All food producing species'	

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

1. Anti-infectious agents

1.2. Antibiotics

1.2.2. Macrolides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Josamycin	Josamycin	Chicken	200 µg/kg 200 µg/kg 200 µg/kg 400 µg/kg 200 µg/kg	Muscle Fat Liver Kidney Eggs	Provisional MRLs expire on 1.7.2002'

1.2.9. Polymyxins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Colistin	Colistin	Bovine, ovine	50 µg/kg	Milk	Provisional MRLs expire on 1.7.2002'
		Bovine, ovine, porcine, chicken, rabbits	150 µg/kg	Muscle	
			150 µg/kg	Fat	
			150 µg/kg	Liver	
			200 µg/kg	Kidney	
		Chicken	300 µg/kg	Eggs	

2. Antiparasitic agents

2.1. Agents acting against endoparasites

2.1.1. Phenol derivatives including salicylanides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Oxyclozanide	Oxyclozanide	Bovine	20 µg/kg	Muscle	Provisional MRLs expire on 1.7.2002'
			20 µg/kg	Fat	
			500 µg/kg	Liver	
			100 µg/kg	Kidney	
			10 µg/kg	Milk	
		Ovine	20 µg/kg	Muscle	
			20 µg/kg	Fat	
			500 µg/kg	Liver	
			100 µg/kg	Kidney	