COMMISSION REGULATION (EC) No 1442/95

of 26 June 1995

amending Annexes I, II, III and IV 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 1441/95 [2], and in particular Article 6, 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 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 carazolol, diazinon and spiramycin (applicable to the species cattle and chicken) should be inserted into Annex I to Regulation (EEC) No 2377/90;

Whereas lecirelin, sodium dichloroisocyanurate, dinoprost tromethamine, hydrochloric acid, malic acid, l-tartaric acid and its mono- and di-basic salt of sodium, potassium and calcium, benzylalcohol, ethanol, n-butanol should be inserted into Annex II to Regulation (EEC) No 2377/90;

Whereas, in order to allow for the completion of scientific studies, danofloxacin and erythromycin should be inserted into Annex III to Regulation (EEC) No 2377/90;

Whereas, 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 of Regulation (EEC) No 2377/90 should be extended for tylosin and spiramycin (applicable to the species pigs);

Whereas it appears that maximum residue limits cannot be established for furazolidone because residues, at whatever limit, in foodstuffs of animal origin constitute a hazard to the health of the consumer; whereas furazolidone should therefore be inserted into Annex IV to Regulation (EEC) No 2377/90;

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

[1] OJ No L 224, 18. 8. 1990, p. 1.
[2] See page 22 of this Official Journal.

81/851/EEC (1), as last amended by Directive 93/40/EEC (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, II, III and IV 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 sixtieth day following its publication in the *Official Journal of the European Communities.*

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

Done at Brussels, 26 June 1995.

For the Commission

Martin BANGEMANN

Member of the Commission

(1) OJ No L 317, 6. 11. 1981, p. 1.
(2) OJ No L 214, 24. 8. 1993, p. 31.

ANNEX

Regulation (EEC) No 2377/90 is amended as follows:

A. Annex I is modified as follows:

1. Anti-infectious agents

1.2. Antibiotics

1.2.4. Macrolides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'1.2.4.3. Spiramycin	Sum of spiramycin and neospiramycin	Bovine	300 µg/kg 200 µg/kg 200 µg/kg	Liver, kidney, fat Muscle Milk	
		Chicken	400 µg/kg 300 µg/kg 200 µg/kg	Liver Fat + skin Muscle'	

2. Antiparasitic agents

2.2. Agents acting against ectoparasites

2.2.3. Organophosphates

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'2.2.3.1. Diazinon	Diazinon	Bovine, ovine, caprine, porcine	700 µg/kg 20 µg/kg	Fat Kidney, liver, muscle	
		Bovine, ovine, caprine	20 µg/kg	Milk'	

3. Agents acting on the nervous system

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	Carazolol	Porcine	25 µg/kg 5 µg/kg	Liver, kidney Muscle, fat, + skin'	

B. In Annex II the following headings are added:

1. Inorganic chemicals

Pharmacologically Active Substance(s)	Animal Species	Other provisions
'1.6. Hydrochloric acid	All food producing species	For use as excipient
1.7. Sodium dichloroisocyanurate	Bovine, ovine, caprine	For topical use only'

2. Organic chemicals

Pharmacologically Active Substance(s)	Animal Species	Other provisions
'2.20. Lecirelin	Bovine, equidae, rabbit	
2.21. Dinoprost tromethamine	All mammalian species	
2.22. Malic acid	All food producing species	For use as excipient
2.23. L-tartaric acid and its mono- and di-basic salt of sodium, potassium and calcium	Al food producing species	For use as excipient
2.24. Benzylalcohol	All food producing species	For use as excipient
2.25. Ethanol	All food producing species	For use as excipient
2.26. N-butanol	All food producing species	For use as excipient'

C. Annex III is modified 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
'1.2.2.1. Spiramycin	Spiramycin	Porcine	600 µg/kg 300 µg/kg 200 µg/kg	Liver Kidney, muscle Fat	Provisional MRLs expire on 1 July 1997 MRLs apply to all microbiological active residues expressed as Spiramycin-equivalent
1.2.2.2. Tylosin	Tylosin	Bovine, Porcine, Poultry Bovine	100 µg/kg 50 µg/kg	Muscle, liver, kidney Milk	Provisional MRLs expire on 1 July 1997

Pharmacologically Active substance(s)	Marker Residue	Animal Species	MRLs	Target Tissues	Other provisions
1.2.2.3. Erythromycin	Erythromycin	Bovine, ovine, porcine, poultry Bovine, ovine Poultry	400 µg/kg 40 µg/kg 200 µg/kg	Liver, kidney, muscle, fat Milk Eggs	Provisional MRLs expire on 1 June 2000 MRLs apply to all microbiological active residues expressed as Erythromycin-equivalent'

1.2.4. Quinolones

Pharmacologically Active substance(s)	Marker Residue	Animal Species	MRLs	Target Tissues	Other provisions
'1.2.4.1. Danofloxacin	Danofloxacin	Bovine	900 µg/kg 500 µg/kg 300 µg/kg 200 µg/kg	Liver Kidney Muscle Fat	Provisional MRLs expire on 1 July 1997'
		Chicken	1 200 µg/kg 600 µg/kg 300 µg/kg	Liver, kidney Fat + skin Muscle	

D. Annex IV is modified as follows:

List of pharmacologically active substances for which no maximum residue limits can be fixed

'5. Furazolidon'