COMMISSION REGULATION (EC) No 1916/98

of 9 September 1998

amending Annexes I and II 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 1570/98 [2], and in particular Articles 6 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 toltrazuril and amitraz should be inserted into Annex I to Regulation (EEC) No 2377/90;

Whereas clazuril, aluminium distearate, aluminium hydroxide acetate, aluminium phosphate, aluminium tristearate, ammonium chloride, cobalt carbonate, cobalt dichloride, cobalt gluconate, cobalt oxide, cobalt sulphate, cobalt trioxide, iron sulphate, *terebinthinae laricina,* coco alkyl dimethyl betaines, diprophylline, hexetidine, polyethylene glycol 15 hydroxystearate, polyethylene glycol 7 glyceryl cocoate, polyethylene glycol stearates with 8-40 oxyethylene units, prethcamide (crotethamide, cropropamide), terpin hydrate, *balsamum peruvianum,* oxidation products of *terebinthinae oleum, ricini oleum* and *terebinthinae aetheroleum rectificatum* and iron dichloride should be inserted into Annex II 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 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;

Whereas 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 and II to 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 60th day following its publication in the *Official Journal of the European Communities.*

[1] OJ L 224, 18. 8. 1990, p. 1.
[2] OJ L 205, 22. 7. 1998, p. 10.
[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, 9 September 1998.

For the Commission
Martin BANGEMANN
Member of the Commission

ANNEX

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

2. Anti-parasitic agents

2.2. Agents acting against ectoparasites

2.2.2. Formamidines

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Amitraz	Sum of amitraz and all metabolites containing the 2,4-DMA moeity, expressed as amitraz	Bovine	200 µg/kg	Fat	
			200 µg/kg	Liver	
			200 µg/kg	Kidney	
			10 µg/kg	Milk	
		Ovine	400 µg/kg	Fat	
			100 µg/kg	Liver	
			200 µg/kg	Kidney	
			10 µg/kg	Milk'	

2.4. Agents acting against protozoa

2.4.1. Triazinetrione derivative

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Toltrazuril	Toltrazuril sulfone	Chicken	100 µg/kg	Muscle	Not for use in animals from which eggs are produced for human consumption'
			200 µg/kg	Skin + fat	
			600 µg/kg	Liver	
			400 µg/kg	Kidney	
		Turkey	100 µg/kg	Muscle	
			200 µg/kg	Skin + fat	
			600 µg/kg	Liver	
			400 µg/kg	Kidney	

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

1. Inorganic chemicals

Pharmacologically active substance(s)	Animal species	Other provisions
‘Aluminium distearate	All food producing species	
Aluminium hydroxide acetate	All food producing species	
Aluminium phosphate	All food producing species	
Aluminium tristearate	All food producing species	
Aluminium chloride	All food producing species	
Cobalt carbonate	All food producing species	
Cobalt dichloride	All food producing species	
Cobalt gluconate	All food producing species	
Cobalt oxide	All food producing species	
Cobalt sulphate	All food producing species	
Cobalt trioxide	All food producing species	
Iron dichloride	All food producing species	
Iron sulphate	All food producing species’	

2. Organic compounds

Pharmacologically active substance(s)	Animal species	Other provisions
‘Clazuril	Pigeon	
Coco alkyl dimethyl betaines	All food producing species	For use as excipient
Diprophylline	All food producing species	
Hexetidine	Equidae	For topical use only
Polyethylene glycol 15 hydroxystearate	All food producing species	For use as excipient

Pharmacologically active substance(s)	Animal species	Other provisions
Polyethylene glycol 7 glyceryl cocoate	All food producing species	For topical use only
Polyethylene glycol stearates with 8-40 oxyethylene units	All food producing species	For use as excipient'
Prethcamide (crotethamide and cropropamide)	All mammalian food producing species	
Terpin hydrate	Bovine, porcine, ovine, caprine	

6. Substances of vegetable origin

Pharmacologically active substance(s)	Animal species	Other provisions
'Balsamum peruvianum	All food producing species	For topical use only
Oxidation products of *terebinthinae oleum*	Bovine, porcine, ovine, caprine	
Ricini oleum	All food producing species	For use as excipient
Terebinthinae aetheroleum rectificatum	All food producing species	For topical use only
Terebinthinae laricina	All food producing species	For topical use only'