Commission Regulation (EC) No 1311/96 of 8 July 1996 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)

COMMISSION REGULATION (EC) No 1311/96

of 8 July 1996

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 1147/96[(2)], and in particular Articles 5, 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 level 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 carcasses 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, difloxacin should be inserted into Annex I to Regulation (EEC) No 2377/90;

Whereas dimethyl phthalate, diethyl phthalate, ethyl lactate, heptaminol, menthol, phloroglucinol and trime-thylphloroglucinol should be inserted into Annex II to Regulation (EEC) No 2377/90;

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

Whereas, in order to allow for the completion of the scientific studies in progress, 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 thiabendazole;

Whereas it appears that maximum residue limits cannot be established for colchicine because residues, at whatever limit, in foodstuffs of animal origin constitute a hazard to the health of the consumer; whereas colchicine 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 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, 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 60th 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, 8 July 1996.

For the Commission

Martin BANGEMANN

Member of the Commission

ANNEX

A. Annex I is modified as follows:

1. Anti-infectious agents

1.2. Antibiotics

1.2.3. Quinolones

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
‘ 1.2.3.3. Difloxacin	Difloxacin	Chicken, turkey	200 µg/kg	Liver	
			150 µg/kg	Kidney	
			50 µg/kg	Muscle	
			200 µg/kg	Skin and fat’	

B. Annex II is modified as follows:

2. Organic compounds

Pharmacologically active substance(s)		Animal species	Other provisions
‘ 2.44.	Dimethyl phthalate	All food producing species	
2.45.	Diethyl phthalate	All food producing species	
2.46.	Ethyl lactate	All food producing species	
2.47.	Heptaminol	All food producing species	
2.48.	Menthol	All food producing species	
2.49.	Phloroglucinol	All food producing species	
2.50.	Trimethylphloroglucinol	All food producing species’	

C. Annex III is modified as follows:

1. Anti-infectious agents

1.2. Antibiotics

1.2.9. Penicillins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
‘ 1.2.9.1.	Benzylpenicillin Penethamate	Ovine	50 µg/kg	Muscle, liver, kidney, fat	Provisional MRLs expire on 1.1.1998’
			4 µg/kg	Milk	
		Porcine	50 µg/kg	Muscle, liver, kidney, fat	

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	Oher provisions
‘2.1.1.5.	Sum of thiabendazole and 5-hydroxythiabendazole	Bovine, ovine, caprine	100 µg/kg	Muscle, liver, kidney, fat, milk	Provisional MRLs expire on 1. 1. 1998’

5. Anti-inflammatory agents

5.1. Nonsteroidal anti-inflammatory agents

5.1.1. Arylpropionic acid derivative

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
‘ 5.1.1.2.	Carprofen Carprofen	Bovine	1 000 µg/kg	Liver, kidney	Provisional MRLs expire on 1.1.1998’
			500 µg/kg	Muscle, fat	
		Equine	1 000 µg/kg	Liver, kidney	

			50 µg/kg	Muscle	
			100 µg/kg	Fat	

D. Annex IV is modified as follows:

List of pharmacologically active substances for which no maximum levels can be fixed:

7. Colchicine.

(**1**) OJ No L 224, 18. 8. 1990, p. 1.

(**2**) OJ No L 151, 26. 6. 1996, p. 26.

(**3**) OJ No L 317, 6. 11. 1981, p. 1.

(**4**) OJ No L 214, 24. 8. 1993, p. 31.

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EC) No 1311/96.