Commission Regulation (EC) No 749/97 of 25 April 1997 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

COMMISSION REGULATION (EC) No 749/97

of 25 April 1997

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

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 748/97[(2)], and in particular Articles 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 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 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 and vedaprofen should be inserted into Annex I to Regulation (EEC) No 2377/90;

Whereas thiomersal and timerfonate should be inserted into Annex II to Regulation (EEC) No 2377/90;

Whereas, in order to allow for the completion of scientific studies, clavulanic acid 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 dexamethasone;

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, II and III 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, 25 April 1997.

For the Commission

Martin BANGEMANN

Member of the Commission

ANNEX

The Annexes to Regulation (EEC) No 2377/90 are amended as follows:

A. Annex I is amended 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	1 900 µg/kg	Liver	
			600 µg/kg	Kidney	
			300 µg/kg	Muscle	
			400 µg/kg	Skin/fat’	

4. Anti-inflammatory agents

4.1. Nonsteroidal anti-inflammatory agents

4.1.1. Arylpropionic acid derivative

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
‘4.1.1.1. Vedaprofen	Vedaprofen	Equidae	1 000 µg/kg	Kidney	
			100 µg/kg	Liver	
			50 µg/kg	Muscle	
			20 µg/kg	Fat’	

B. Annex II is amended as follows:

2. Organic compounds

Pharmacologically active substance(s)	Animal species	Other provisions
‘2.82. Thiomersal	All food producing species	For use only as preservatives in multidose vaccines at

			a concentration not exceeding 0,02 %
2.83.	Timerfonate	All food producing species	For use only as preservatives in multidose vaccines at a concentration not exceeding 0,02 %’

C. Annex III is amended as follows:

1. Anti-infectious agents

1.2. Antibiotics

1.2.10. Beta-lactamase inhibitors

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
‘1.2.10.1.	Clavulanic acid	Bovine, ovine, porcine	200 µg/kg	Muscle, liver, kidney, fat	Provisional MRLs expire on 1. 7. 1999’
		Bovine, ovine	200 µg/kg	Milk	

4. Corticoids

4.1. Glucocorticoids

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
‘4.1.1.	Dexamethasone	Bovine, porcine, equidae	2,5 µg/kg	Liver	Provisional MRLs expire on 1. 7. 1997’
			0,5 µg/kg	Muscle, kidney	
		Bovine	0,3 µg/kg	Milk	

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

(**2**) See page 21 of this Official Journal.

(**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 749/97.