

COMMISSION REGULATION (EC) No 804/1999
of 16 April 1999

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 508/1999 ⁽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 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 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 lincomycin and ceftiofur should be inserted into Annex I to Regulation (EEC) No 2377/90;

Whereas *melissae aetheroleum*, *centellae asiaticae extractum*, strychnine, 1-methyl-2-pyrrolidone, etamsylate, enilconazole and cefacetrile should be inserted into Annex II to Regulation (EEC) No 2377/90;

Whereas, in order to allow for the completion of scientific studies, oxolinic acid, cefacetrile and thiamphenicol 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 to Regulation (EEC) No 2377/90 should be extended for nafcillin and cephalirin;

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 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 60, 9.3.1999, p. 16.

⁽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, 16 April 1999.

For the Commission

Martin BANGEMANN

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
 - 1.2.2. Cephalosporins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Ceftiofur	Sum of all residues retaining the betalactam structure expressed as desfuroylceftiofur	Bovine	1 000 µg/kg 2 000 µg/kg 2 000 µg/kg 6 000 µg/kg 100 µg/kg	Muscle Fat Liver Kidney Milk, not for intramammary use	
		Porcine	1 000 µg/kg 2 000 µg/kg 2 000 µg/kg 6 000 µg/kg	Muscle Fat Liver Kidney'	

- 1.2.9. Lincosamides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Lincomycin	Lincomycin	Bovine	100 µg/kg 50 µg/kg 500 µg/kg 1 500 µg/kg 150 µg/kg	Muscle Fat Liver Kidney Milk'	

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

2. Organic compounds

Pharmacologically active substance(s)	Animal species	Other provisions
'1-Methyl-2-pyrrolidone	Equidae	
Cefacetrile	Bovine	For intramammary use only and for all tissues except milk
Enilconazole	Bovine, equidae	For topical use only
Etamsylate	All food producing species	
Strychnine	Bovine	For oral use only at dose to 0,1 mg/kg bw'

6. Substances of vegetable origin

Pharmacologically active substance(s)	Animal species	Other provisions
' <i>Centellae asiaticae extractum</i>	All food producing species	For topical use only'
<i>Melissae aetheroleum</i>	All food producing species	

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

1. Anti-infectious agents
- 1.2. Antibiotics
- 1.2.4. Cephalosporins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Cefacetrile	Cefacetrile	Bovine	125 µg/kg	Milk	Provisional MRLs expire on 1.1.2001 For intramammary use only
Cephapirin	Sum of cephapirin and desacetylcephapirin	Bovine	50 µg/kg 50 µg/kg 50 µg/kg 100 µg/kg 10 µg/kg	Muscle Fat Liver Kidney Milk	Provisional MRLs expire on 1.1.2001'

1.2.6. Quinolones

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Oxolinic acid	Oxolinic acid	Bovine	100 µg/kg	Muscle	Provisional MRLs expire on 1.1.2001'
			50 µg/kg	Fat	
			150 µg/kg	Liver	
			150 µg/kg	Kidney	
		Porcine	100 µg/kg	Muscle	
			50 µg/kg	Skin + fat	
			150 µg/kg	Liver	
			150 µg/kg	Kidney	
		Chicken	100 µg/kg	Muscle	
			50 µg/kg	Skin + fat	
			150 µg/kg	Liver	
			150 µg/kg	Kidney	
		Fin fish	50 µg/kg	Eggs	
			300 µg/kg	Muscle and skin in natural proportions	

1.2.10. Penicillins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Nafcillin	Nafcillin	Bovine	300 µg/kg	Muscle	Provisional MRLs expire on 1.1.2001'
			300 µg/kg	Fat	
			300 µg/kg	Liver	
			300 µg/kg	Kidney	
			30 µg/kg	Milk	

1.2.11. Florfenicol and related compounds

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Thiamphenicol	Thiamphenicol	Ovine	50 µg/kg	Muscle	Provisional MRLs expire on 1.1.2001'
			50 µg/kg	Fat	
			50 µg/kg	Liver	
			50 µg/kg	Kidney	
		Porcine	50 µg/kg	Muscle	
			50 µg/kg	Skin + fat	
			50 µg/kg	Liver	
			50 µg/kg	Kidney	
		Fin fish	50 µg/kg	Muscle and skin in natural proportions	

1.2.13. Lincosamides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Lincomycin	Lincomycin	Ovine	100 µg/kg	Muscle	Provisional MRLs expire on 1.1.2001'
			50 µg/kg	Fat	
			500 µg/kg	Liver	
			1 500 µg/kg	Kidney	
			150 µg/kg	Milk	
		Porcine	100 µg/kg	Muscle	
			50 µg/kg	Skin + fat	
			500 µg/kg	Liver	
			1 500 µg/kg	Kidney	
		Chicken	100 µg/kg	Muscle	
			50 µg/kg	Skin + fat	
			500 µg/kg	Liver	
			1 500 µg/kg	Kidney	
			50 µg/kg	Eggs	