COMMISSION REGULATION (EC) No 2393/1999

of 11 November 1999

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

(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 2385/1999 [2], and in particular Articles 6 and 8 thereof,

(1) 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;

(2) Whereas maximum residue limits should be established only after 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;

(3) 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);

(4) 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;

(5) 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;

(6) Whereas meloxicam, amitraz and albendazole oxide should be inserted into Annex I to Regulation (EEC) No 2377/90;

(7) Whereas tosylchloramide sodium, paracetamol, humic acids, their sodium salts, chlorphenamine, bituminosulfonates, ammonium and sodium salts and betaine glucuronate and 2-aminoethanol glucuronate should be inserted into Annex II to Regulation (EEC) No 2377/90;

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

(9) 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;

(10) 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 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 288, 11.11.1999, p. 14.
[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, 11 November 1999.

For the Commission
Erkki LIIKANEN
Member of the Commission

ANNEX

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

2. Antiparasitic agents

2.1. Agents acting against endoparasites

2.1.3. Benzimidazoles and pro-benzimidazoles

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Albendazole oxide	Sum of albendazole oxide, albendazole sulphone and albendazole 2-aminosulphone, expressed as albendazole	Bovine, ovine	100 µg/kg 100 µg/kg 1 000 µg/kg 500 µg/kg 100 µg/kg	Muscle Fat Liver Kidney Milk'	

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-dimethylaniline moiety, expressed as amitraz	Bees (honey)	200 µg/kg	Honey'	

4. Anti-inflammatory agents

4.1. Nonsteroidal anti-inflammatory agents

4.1.4. Oxican derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Meloxicam	Meloxicam	Bovine	25 µg/kg 60 µg/kg 35 µg/kg	Muscle Liver Kidney'	

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

2. Organic compounds

Pharmacologically active substance(s)	Animal species	Other provisions
'2-aminoethanol glucuronate	All food-producing species	
Betaine glucuronate	All food-producing species	
Bituminosulfonates, ammonium and sodium salts	All mammalian food-producing species	For topical use only Not for use in animals from which milk is produced for human consumption
Chlorphenamine	All mammalian food-producing species	
Humic acids and their sodium salts	All food-producing species	For oral use only
Paracetamol	Porcine	For oral use only
Tosylchloramide sodium	Fin fish	For water-borne use only'

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

2. Antiparasitic agents

2.2. Agents acting against ectoparasites

2.2.6. Pyrimidines derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Dicyclanil	Sum of dicyclanil and 2,4,6-triamino-pyrimidine-5-carbonitrile	Ovine	200 µg/kg 50 µg/kg 400 µg/kg 400 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1 July 2000; Not for use in animals from which milk is produced for human consumption'