

COMMISSION REGULATION (EC) No 2034/96

of 24 October 1996

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 2010/96⁽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, penethamate (applicable to bovine tissues) should be inserted in Annex I to Regulation (EEC) No 2377/90;

Whereas, based on the currently authorized use in veterinary practice, boric acid and borates, polysulphated glycosaminoglycan, rifaximin and tau fluvalinate should be inserted into Annex II to Regulation (EEC) No 2377/90;

Whereas, some substances were previously evaluated through European Union procedures, such as the Scientific Committee for Food; whereas, some of these substances were considered to be acceptable for addition to human foodstuffs and granted an E number; whereas, their administration to food producing animals as part of veterinary medicinal products is unlikely to result in residues in food of animal origin either significantly different from the additive or in concentrations exceeding those of the additive where it has been added directly to the food; whereas, based on the currently authorized use in veterinary practice, those substances approved as additives in foodstuffs for human consumption, with a valid E number, should be included in Annex II of Regulation (EEC) No 2377/90;

Whereas, in order to allow for the completion of scientific studies, rifaximin (applicable to bovine milk) should be inserted in Annex III 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,

⁽¹⁾ OJ No L 224, 18. 8. 1990, p. 1.

⁽²⁾ OJ No L 269, 22. 10. 1996, p. 5.

⁽³⁾ OJ No L 317, 6. 11. 1981, p. 1.

⁽⁴⁾ OJ No L 214, 24. 8. 1993, p. 31.

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 that of 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, 24 October 1996.

For the Commission

Martin BANGEMANN

Member of the Commission

ANNEX

Regulation (EEC) No 2377/90 is amended as follows:

A. Annex I is modified as follows:

1. Anti-infectious agents
- 1.2. Antibiotics
- 1.2.1. Penicillins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'1.2.1.7. Penethamate	Benzylpenicillin	Bovine	50 µg/kg	Kidney, liver, muscle, fat	
			4 µg/kg	Milk'	

B. Annex II is modified as follows:

1. Inorganic chemicals

Pharmacologically active substance(s)	Animal species	Other provisions
'1.8. Boric acid and borates	All food producing species'	

2. Organic compounds

Pharmacologically active substance(s)	Animal species	Other provisions
'2.34. Polysulphated glycosaminoglycan	Horses	
2.35. Rifaximin	Bovine	For intramammary use — except if the udder may be used as food for human consumption — and intrauterine use only
2.36. Tau fluvalinate	Honey bees'	

5. Substances used as food additives in foodstuffs for human consumption

Pharmacologically active substance(s)	Animal species	Other provisions
'5.1. Substances with an E number	All food producing species	Only substances approved as additives in foodstuffs for human consumption, with the exception of preservatives listed in part C of Annex III to Council Directive 95/2/CE(*)
(*) OJ No L 61, 18. 3. 1995, p. 1.		

C. Annex III is modified as follows:

- 1. Anti-infectious agents
- 1.2. Antibiotics
- 1.2.7. Naphtalene-ringed ansamycin

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'1.2.7.1. Rifaximin	Rifaximin	Bovine	60 µg/kg	Milk	Provisional MRL expires on 1. 6. 1998'