COMMISSION REGULATION (EC) No 1102/95

of 16 May 1995

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 3059/94 [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 tilmicosin should be inserted into Annex I to Regulation (EEC) No 2377/90;

Whereas based on the current use in veterinary practice romifidine, detomidine, human chorion gonadotrophin, brotizolam, calcium hypophosphite, calcium acetate, calcium propionate, calcium benzoate, calcium malate, calcium chloride, calcium sulphate, calcium hydroxide, calcium oxide, calcium phosphate, calcium polyphosphates, calcium silicate, calcium gluconate, calcium carbonate and calcium stearate should be inserted into Annex II to Regulation (EEC) No 2377/90;

Whereas human chorion gonadotrophin, calcium hypophosphite, calcium acetate, calcium propionate, calcium benzoate, calcium malate, calcium chloride, calcium sulphate, calcium hydroxide, calcium oxide, calcium phosphate, calcium polyphosphates, calcium silicate, calcium gluconate, calcium carbonate and calcium stearate should be inserted into Annex II to Regulation (EEC) No 2377/90 : by extrapolation of scientific data this classification into Annex II shall apply to all food-producing animals;

Whereas, in order to allow for the completion of scientific studies, netobimin should be inserted into 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 Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector,

[1] OJ No L 224, 18. 8. 1990, p. 1.
[2] OJ No L 323, 16. 12. 1994, p. 15.
[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 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, 16 May 1995.

For the Commission

Martin BANGEMANN

Member of the Commission

ANNEX

A. Annex I is modified as follows:

1. Anti-infectious agents

1.2.4. Macrolides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
1.2.4.2. Tilmicosin	Tilmicosin	Ovine Porcine Ovine	1 000 µg/kg 50 µg/kg 50 µg/l	Liver, kidney, Muscle, fat Milk	

B. In Annex II, point '1. Inorganic compounds' the following heading added:

1. Inorganic chemicals

Pharmacologically Active Substances(s)	Animal Species	Other provisions
1.5. Calcium acetate Calcium benzoate Calcium carbonate Calcium chloride Calcium gluconate Calcium hydroxide Calcium hypophosphite Calcium malate Calcium oxide Calcium phosphate Calcium polyphosphates Calcium propionate Calcium silicate Calcium stearate Calcium sulphate	All food producing species	

In Annex II, point '2. Organic compounds' the following heading added:

2. Organic compounds

Pharmacologically active substances(s)	Animal Species	Other provisions
2.12. Romifidine	Equidae	For therapeutic uses only
2.13. Detomidine	Bovine, equidae	For therapeutic uses only
2.14. Brotizolam	Bovine	For therapeutic uses only
2.15. Human chorion gonadotrophin (HCG)	All food producing species	

C. Annex III is modified as follows:

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	Other provisions
2.1.1.7. Netobimin	Sum of netobimin and albendazole and metabolites of albendazole measured as 2-amino-benzimidazole sulphone	Bovine, ovine, caprine	1 000 µg/kg 500 µg/kg 100 µg/kg 100 µg/kg	Liver Kidney Muscle, fat Milk	Provisional MRLs expire on 31 July 1997