COMMISSION REGULATION (EC) No 3426/93

of 14 December 1993

amending Annexes III and IV 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

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 3425/93 (2) and in particular Articles 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, 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 all substances belonging to the tetracyclines and the sulphonamides group;

Whereas, in order to allow for the assessment of new scientific information, 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 dimetridazole;

Whereas ronidazole and dapsone should be inserted in Annex IV 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 amended by Directive 90/676/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,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes III and IV 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 sixtieth day following its publication in the *Official Journal of the European Communities*.

(1) OJ No L 224, 18. 8. 1990, p. 1.
(2) See page 12 of this Official Journal.
(3) OJ No L 317, 6. 11. 1981, p. 1.
(4) OJ No L 373, 31. 12. 1990, p. 15.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 December 1993.

For the Commission
Martin BANGEMANN
Member of the Commission

ANNEX

A. Annex III is modified as follows:

'ANNEX III

List of pharmacologically active substances used in veterinary medicinal products for which provisional maximum residue limits have been fixed

1. Anti-infectious agents

1.1. Chemotherapeutics

1.1.1. Sulfonamides

Pharmacologically active substances(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
All substances belonging to the sulfonamide group	Parent drug	Cattle Sheep Goats	100 µg/kg	Milk	Provisional MRL expires on 1. 1. 1996. The combined total residues of all substances within the sulfonamide group should not exceed 100 µg/kg

1.1.4. Nitroimidazoles

Pharmacologically active substances(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
1.1.4.1. Dimetridazole	All residues with intact nitroimidazole structure	All food-producing species	10 µg/kg	Muscle, liver, kidney, fat	Provisional MRL expires on 1. 1. 1995

1.2. Antibiotics

1.2.2. Tetracyclines

Pharmacologically active substances(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
All substances belonging to the tetracycline group	Parent drug	All food-producing species	600 µg/kg 300 µg/kg 200 µg/kg 100 µg/kg 100 µg/kg	Kidney Liver Eggs Muscle Milk	Provisional MRL expires on 1. 1. 1996. The combined total residues of all substances within the tetracycline group should not exceed the limits indicated.'

B. In Annex IV, the following substances are added:

'2. Ronidazole

3. Dapsone'.