# COMMISSION REGULATION (EC) No 749/97

## of 25 April 1997

## 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 748/97 [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 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, difloxacin and vedaprofen should be inserted into Annex I to Regulation (EEC) No 2377/90;

Whereas thiomersal and timerfonate should be inserted into Annex II to Regulation (EEC) No 2377/90;

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

Whereas, in order to allow for the completion of the scientific studies in progress, the duration of the validity of the provisional maximum residue limits previously defined in Annex III of Regulation (EEC) No 2377/90 should be extended for dexamethasone;

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 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.*

[1] OJ No L 224, 18. 8. 1990, p. 1.
[2] See page 21 of this Official Journal.
[3] OJ No L 317, 6. 11. 1981, p. 1.
[4] OJ No 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, 25 April 1997.

*For the Commission*

Martin BANGEMANN

*Member of the Commission*

*ANNEX*

The Annexes to Regulation (EEC) No 2377/90 are amended as follows:

A. Annex I is amended as follows:

1. Anti-infectious agents

1.2. Antibiotics

1.2.3. Quinolones

| Pharmacologically active substance | Marker residue | Animal species | MRLs | Target tissues | Other provisions |
|---|---|---|---|---|---|
| '1.2.3.3. Difloxacin | Difloxacin | Chicken, turkey | 1 900 µg/kg | Liver | |
| | | | 600 µg/kg | Kidney | |
| | | | 300 µg/kg | Muscle | |
| | | | 400 µg/kg | Skin/fat' | |

4. Anti-inflammatory agents

4.1. Nonsteroidal anti-inflammatory agents

4.1.1. Arylpropionic acid derivative

| Pharmacologically active substance | Marker residue | Animal species | MRLs | Target tissues | Other provisions |
|---|---|---|---|---|---|
| '4.1.1.1. Vedaprofen | Vedaprofen | Equidae | 1 000 µg/kg | Kidney | |
| | | | 100 µg/kg | Liver | |
| | | | 50 µg/kg | Muscle | |
| | | | 20 µg/kg | Fat' | |

B. Annex II is amended as follows:

2. Organic compounds

| Pharmacologically active substance(s) | Animal species | Other provisions |
|---|---|---|
| '2.82. Thiomersal | All food producing species | For use only as preservatives in multidose vaccines at a concentration not exceeding 0,02 % |
| 2.83. Timerfonate | All food producing species | For use only as preservatives in multidose vaccines at a concentration not exceeding 0,02 %' |

C. Annex III is amended as follows:

1. Anti-infectious agents

1.2. Antibiotics

1.2.10. Beta-lactamase inhibitors

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs | Target tissues | Other provisions |
|---|---|---|---|---|---|
| '1.2.10.1. Clavulanic acid | Clavulanic acid | Bovine, ovine, porcine | 200 µg/kg | Muscle, liver, kidney, fat | Provisional MRLs expire on 1. 7. 1999' |
| | | Bovine, ovine | 200 µg/kg | Milk | |

4. Corticoids

4.1. Glucocorticoids

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs | Target tissues | Other provisions |
|---|---|---|---|---|---|
| '4.1.1. Dexamethasone | Dexamethasone | Bovine, porcine, equidae | 2,5 µg/kg | Liver | Provisional MRLs expire on 1. 7. 1997' |
| | | | 0,5 µg/kg | Muscle, kidney | |
| | | Bovine | 0,3 µg/kg | Milk | |