Commission Regulation (EC) No 2703/94 of 7 November 1994 amending Annexes I, II and III 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 (Text with EEA relevance)

# COMMISSION REGULATION (EC) No 2703/94

## of 7 November 1994

amending Annexes I, II and III 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

(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<sup>(1)</sup>, as last amended by Commission Regulation (EC) No 2701/94<sup>(2)</sup>, 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 carcases 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 florfenicol should be inserted into Annex I to Regulation (EEC) No 2377/90;

Whereas gonadotrophin releasing hormone should be inserted into Annex II to Regulation (EEC) No 2377/90; whereas by extrapolation of scientific data this classification into Annex II shall apply to all food-producing animals;

Whereas moxidectin, should be inserted into Annex III to Regulation (EEC) No 2377/90 in order to allow for the establishment of the specificity of the analytical method against Doramectin for which a standard must become publicly available;

Whereas ceftiofur should be inserted into Annex III to Regulation (EEC) No 2377/90 in order to allow for the completion of the validation of the analytical method for bovine and porcine liver and fat tissues; whereas surveillance of residues of ceftiofur is assured by monitoring bovine and porcine muscle and kidney tissues;

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<sup>(3)</sup>, as last amended by Directive 93/40/EEC<sup>(4)</sup> 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 Directives on the removal of technical barriers to trade in the veterinary medicinal products sector,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I, II and III 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 60th 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, 7 November 1994.

For the Commission

Martin BANGEMANN

Member of the Commission

## **ANNEX**

- A. Annex I is amended as follows:
  - 1. Anti-infectious agents
    - 1.2. Antibiotics
      - 1.2.5. Florfenicol and related compounds

| Pharma<br>active<br>substan |   | ll <b>A</b> nimal<br>species | MRLs                                     | Target<br>tissues          | Other provisions |
|-----------------------------|---|------------------------------|--|----------------------------|------------------|
| <b>'1.2.5.1</b> .           | Sum of florente and its metaboli measure as florfenic amine | tes<br>d                     | 200 µg/kg<br>300 µg/kg<br>3 000<br>µg/kg | Muscle<br>Kidney<br>Liver' |                  |

- B. In Annex II, point 2. 'Organic compounds' the following headings are added:
  - 2. Organic compounds

| Pharmacologically active substance(s) |                                 | Animal species              | Other provisions |  |  |
|---------------------------------------|---------------------------------|-----------------------------|------------------|--|--|
| <b>'</b> 2.9.                         | Gonadotrophin releasing hormone | All food producing species' |                  |  |  |

- C. Annex III is amended as follows:
  - 1. Anti-infectious agents
    - 2. Antibiotics
      - 1.2.4. Cephalosporins

| residue   |  | MRLs  | Target<br>tissues  | Other provisions  |
|---|--|---|--|---|
| Sum<br>Certijofur<br>residues<br>retaining<br>the<br>betalacta<br>structure<br>expresse | m<br>d   | 2 000<br>µg/kg<br>200 µg/<br>kg<br>600 µg/<br>kg<br>100 µg/<br>kg                           | Kidney,<br>liver<br>Muscle<br>Fat<br>Milk  | Provisional<br>MRLs<br>expire<br>on 1<br>July<br>1997'  |
|   | residue<br>ce(s)<br>Sum<br>Ceffiofur<br>residues<br>retaining<br>the<br>betalacta<br>structure<br>expresse | residue species  Sum Bovine Geffiofur residues retaining the betalactam structure expressed | Sum Bovine 2 000  Getijofur 2000  µg/kg residues retaining kg the 600 µg/ betalactam kg structure 100 µg/ kg | residue species  Sum Geftiofur Bovine Ceftiofur Presidues retaining the betalactam structure expressed as desfurovlecefficial at the specific and the specific |

| 3 000   Muscle               |  |
|------------------------------|--|
| 3 000   Muscle   μg/kg   Fat |  |
| 500 μg/<br>  kg              |  |
| kg                           |  |
| 600 μg/                      |  |
| 600 μg/                      |  |

#### Antiparasitic agents 2.

#### 2.3. Agents acting against endo- and ectoparasites

#### 2.3.1. Avermectins

| Pharma<br>active<br>substan |                    | llyAnimal<br>species | MRLs          | Target<br>tissues | Other provisions                                       |
|-----------------------------|--------------------|----------------------|---------------|-------------------|--|
| 2.3.1.1.                    | Moxideo<br>Moxideo |                      | 200 μg/<br>kg | Fat               | Provisional<br>MRLs<br>expire<br>on 1<br>July<br>1997' |
| Ovine                       | 20 μg/<br>kg       | Kidney,<br>liver     |               |                   |  |

- (1) OJ No L 224, 18. 8. 1990, p. 1.
- (2) See page 7 of this Official Journal.
- (**3**) OJ No L 317, 6. 11. 1981, p. 1.
- (4) OJ No L 214, 24. 8. 1993, p. 31.