# COMMISSION REGULATION (EC) No 2385/1999

## of 10 November 1999

## 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 1943/1999 [2], and in particular Articles 6 and 8 thereof,

(1) 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;

(2) Whereas maximum residue limits should be established only after 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;

(3) 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);

(4) 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;

(5) 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;

(6) Whereas flubendazole and florfenicol should be inserted into Annex I to Regulation (EEC) No 2377/90;

(7) Whereas *strychni semen*, *ruta graveolens*, *ruscus aculeatus*, *lauri fructus*, *lauri folii aetheroleum*, *juniperi fructus*, *hippocastani semen* and *capsici fructus acer* should be inserted into Annex II to Regulation (EEC) No 2377/90;

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

(9) Whereas a period of 60 days should be allowed before the entry 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;

(10) 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 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*.

[1] OJ L 224, 18.8.1990, p. 1.
[2] OJ L 241, 11.9.1999, p. 9.
[3] OJ L 317, 6.11.1981, p. 1.
[4] OJ 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, 10 November 1999.

*For the Commission*
Erkki LIIKANEN
*Member of the Commission*

*ANNEX*

A. Annex I to Regulation (EEC) No 2377/90 is amended as follows:

1. Anti-infectious agents

1.2. Antibiotics

1.2.5. Florfenicol and related compounds

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs | Target tissues | Other provisions |
|---|---|---|---|---|---|
| 'Florfenicol | Sum of florfenicol and its metabolites measured as florfenicol-amine | Chicken | 100 µg/kg<br>200 µg/kg<br>2 500 µg/kg<br>750 µg/kg | Muscle<br>Skin and fat<br>Liver<br>Kidney | Not for use in animals from which eggs are produced for human consumption' |

2. Antiparasitic agents

2.1. Agents acting against endoparasites

2.1.3. Benzimidazoles and pro-benzimidazoles

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs | Target tissues | Other provisions |
|---|---|---|---|---|---|
| 'Flubendazole | Sum of flubendazole and (2-amino 1H-benzimidazol-5-yl) (4fluorophenyl) methanone | Turkey | 50 µg/kg<br>50 µg/kg<br>400 µg/kg<br>300 µg/kg | Muscle<br>Skin and fat<br>Liver<br>Kidney' | |

B. Annex II to Regulation (EEC) No 2377/90 is amended as follows:

4. Substances used in homeopathic veterinary medicinal products

| Pharmacologically active substance(s) | Animal species | Other provisions |
|---|---|---|
| '*Ruta graveolens* | All food-producing species | For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias, at concentrations in the products not exceeding one part per thousand only.<br>Not for use in animals from which milk is produced for human consumption' |

6. Substances of vegetable origin

| Pharmacologically active substance(s) | Animal species | Other provisions |
|---|---|---|
| *'Capsici fructus acer* | All food-producing species | |
| *Hippocastani semen* | All food-producing species | For topical use only |
| *Juniperi fructus* | All food-producing species | |
| *Lauri folii aetheroleum* | All food-producing species | |
| *Lauri fructus* | All food-producing species | |
| *Ruscus aculeatus* | All food-producing species | For topical use only |
| *Strychni semen* | Bovine, ovine, caprine | For oral use only at doses up to the equivalent of 0,1 mg strychnine/kg bw' |

C. Annex III to Regulation (EEC) No 2377/90 is amended as follows:

2. Antiparasitic agents

2.2. Agents acting against ectoparasites

2.2.4. Organophosphates

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs | Target tissues | Other provisions |
|---|---|---|---|---|---|
| 'Phoxim | Phoxim | Porcine | 20 µg/kg<br>700 µg/kg<br>20 µg/kg<br>20 µg/kg | Muscle<br>Skin and fat<br>Liver<br>Kidney | Provisional MRLs expire on 1 January 2001' |