# Commission Regulation (EC) No 807/2001 of 25 April 2001 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 807/2001

## of 25 April 2001

## 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[(1)], as last amended by Commission Regulation (EC) No 750/2001[(2)], and in particular Articles 6, 7 and 8 thereof,

Whereas:

(1) 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) 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.

(3) 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) 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. 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.

(5) 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) Cefoperazone, cyhalothrin, lincomycin, nafcillin, netobimin, phoxim, tiamulin and cyfluthrin should be inserted into Annex I to Regulation (EEC) No 2377/90.

(7) 'Linear alkyl benzene sulphonic acids with alkyl chain lengths ranging from $C_9$ to $C_{13}$, containing less than 2,5 % of chains longer than $C_{13}$' should be inserted into Annex II to Regulation (EEC) No 2377/90.

(8) 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 cefacetrile, oxolinic acid and permethrin.

(9) An adequate period 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 Commission Directive 2000/37/EC[(4)], to take account of the provisions of this Regulation.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THE FOLLOWING 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 third day following its publication in the *Official Journal of the European Communities*.

It shall apply from the 60th day following its publication.

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

ANNEX

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

1. Anti-infectious agents

1.2. Antibiotics

1.2.1. Penicillins

| **Pharmacologically active substance(s)** | **Marker residue** | **Animal species** | **MRLs** | **Target tissues** | **Other provisions** |
|---|---|---|---|---|---|
| Nafcillin | Nafcillin | Bovine | 300 µg/kg | Muscle | For intramammary use only |
| | | | 300 µg/kg | Fat | |
| | | | 300 µg/kg | Liver | |
| | | | 300 µg/kg | Kidney | |
| | | | 30 µg/kg | Milk | |

1.2.2. Cephalosporins

| **Pharmacologically active substance(s)** | **Marker residue** | **Animal species** | **MRLs** | **Target tissues** | **Other provisions** |
|---|---|---|---|---|---|
| Cefoperazone | Cefoperazone | Bovine | 50 µg/kg | Milk | |

1.2.8. Pleuromutilines

| **Pharmacologically active substance(s)** | **Marker residue** | **Animal species** | **MRLs** | **Target tissues** | **Other provisions** |
|---|---|---|---|---|---|
| Tiamulin | Sum of metabolites that may be hydrolysed to 8-α-hydroxymutilin | Turkey | 100 µg/kg | Muscle | |
| | | | 100 µg/kg | Skin and fat | |
| | | | 300 µg/kg | Liver | |

1.2.9. Lincosamides

| **Pharmacologically active substance(s)** | **Marker residue** | **Animal species** | **MRLs** | **Target tissues** | **Other provisions** |
|---|---|---|---|---|---|
| Lincomycin | Lincomycin | Ovine | 100 µg/kg | Muscle | |
| | | | 50 µg/kg | Fat | |
| | | | 500 µg/kg | Liver | |

| | | | | | |
|---|---|---|---|---|---|
| | | | 1 500 µg/kg | Kidney | |
| | | | 150 µg/kg | Milk | |
| | | Porcine | 100 µg/kg | Muscle | |
| | | | 50 µg/kg | Skin and fat | |
| | | | 500 µg/kg | Liver | |
| | | | 1 500 µg/kg | Kidney | |
| | | Chicken | 100 µg/kg | Muscle | |
| | | | 50 µg/kg | Skin and fat | |
| | | | 500 µg/kg | Liver | |
| | | | 1 500 µg/kg | Kidney | |
| | | | 50 µg/kg | Eggs | |

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 |
|---|---|---|---|---|---|
| Netobimin | Sum of albendazole oxide, albendazole sulphone and albendazole 2-aminosulphone, expressed as albendazole | [X1Bovine, ovine] | 100 µg/kg | Muscle | For oral use only |
| | | | 100 µg/kg | Fat | |
| | | | 1 000 µg/kg | Liver | |
| | | | 500 µg/kg | Kidney | |
| | | | 100 µg/kg | Milk | |

**Editorial Information**

**X1** Substituted by Corrigendum to Commission Regulation (EC) No 807/2001 of 25 April 2001 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 (Official Journal of the European Communities L 118 of 27 April 2001).

2.2. Agents acting against ectoparasites

2.2.1. Organophosphates

| Pharmacologically active substance(s) | Marker residue | Animal species | MRLs | Target tissues | Other provisions |
|---|---|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| Phoxim | Phoxim | Ovine | 50 µg/kg | Muscle | Not for use in animals from which milk is produced for human consumption |
| | | | 400 µg/kg | Fat | |
| | | | 50 µg/kg | Kidney | |
| | | Porcine | 20 µg/kg | Muscle | |
| | | | 700 µg/kg | Skin and fat | |
| | | | 20 µg/kg | Liver | |
| | | | 20 µg/kg | Kidney | |

2.2.3. Pyrethroids

| **[X1Pharmacologically active substance(s)** | **Marker residue** | **Animal species** | **MRLs** | **Target tissues** | **Other provisions** |
|---|---|---|---|---|---|
| Cyhalothrin | Cyhalothrin (sum of isomers) | Bovine | 500 µg/kg | Fat | Further provisions in Council Directive 94/29/EC are to be observed |
| | | | 50 µg/kg | Kidney | |
| | | | 50 µg/kg | Milk | |
| [X2Cyfluthrin | Cyfluthrin (sum of isomers) | Bovine, caprine | 50 µg/kg | Fat | |
| | | | 10 µg/kg | Liver | |
| | | | 10 µg/kg | Kidney | |
| | | | 20 µg/kg | Milk | Further provisions in Council Directive 94/29/EC are to be observed]] |

**Editorial Information**

**X2** Substituted by Corrigendum to Commission Regulation (EC) No 807/2001 of 25 April 2001 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 (Official Journal of the European Union L 118 of 27 April 2001).

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

2. Organic compounds

| **Pharmacologically active substance(s)** | **Animal species** | **Other provisions** |
|---|---|---|

| | | |
|---|---|---|
| Linear alkyl benzene sulphonic acids with alkyl chain lengths ranging from $C_9$ to $C_{13}$, containing less than 2,5 % of chains longer than $C_{13}$ | Bovine | For topical use only |

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

1. Anti-infectious agents

1.2. Antibiotics

1.2.4. Cephalosporins

| **Pharmacologically active substance(s)** | **Marker residue** | **Animal species** | **MRLs** | **Target tissues** | **Other provisions** |
|---|---|---|---|---|---|
| Cefacetrile | Cefacetrile | Bovine | 125 µg/kg | Milk | Provisional MRLs expire on 1.1.2002 For intramammary use only |

1.2.6. Quinolones

| **Pharmacologically active substance(s)** | **Marker residue** | **Animal species** | **MRLs** | **Target tissues** | **Other provisions** |
|---|---|---|---|---|---|
| Oxolinic acid | Oxolinic acid | Bovine | 100 µg/kg | Muscle | Provisional MRLs expire on 1.1.2003 Not for use in animals from which milk is produced for human consumption |
| | | | 50 µg/kg | Fat | |
| | | | 150 µg/kg | Liver | |
| | | | 150 µg/kg | Kidney | |
| | | Porcine | 100 µg/kg | Muscle | |
| | | | 50 µg/kg | Skin and fat | |
| | | | 150 µg/kg | Liver | |
| | | | 150 µg/kg | Kidney | |
| | | Chicken | 100 µg/kg | Muscle | |
| | | | 50 µg/kg | Skin and fat | |
| | | | 150 µg/kg | Liver | |
| | | | 150 µg/kg | Kidney | |
| | | | 50 µg/kg | Eggs | |

| | | | | | |
|---|---|---|---|---|---|
| | | Fin fish | 300 µg/kg | Muscle and skin in natural proportions | |

2. Antiparasitic agents

2.2. Agents acting against ectoparasites

2.2.3. Pyrethroids

| **Pharmacologically active substance(s)** | **Marker residue** | **Animal species** | **MRLs** | **Target tissues** | **Other provisions** |
|---|---|---|---|---|---|
| Permethrin | Permethrin (sum of isomers) | Chicken, porcine | 50 µg/kg | Muscle | Provisional MRLs expire on 1.1.2003 |
| | | | 500 µg/kg | Skin and fat | |
| | | | 50 µg/kg | Liver | |
| | | | 50 µg/kg | Kidney | |
| | | Bovine, caprine | 50 µg/kg | Muscle | Provisional MRLs expire on 1.1.2003 |
| | | | 500 µg/kg | Fat | |
| | | | 50 µg/kg | Liver | |
| | | | 50 µg/kg | Kidney | |
| | | | 50 µg/kg | Milk | Further provisions in Commission Directive 98/82/EC are to be observed (OJ L 290, 29.10.1998, p. 25) |
| | | Chicken | 50 µg/kg | Eggs | Provisional MRLs expire on 1.1.2003 |

(**1**) OJ L 224, 18.8.1990, p. 1.

(**2**) OJ L 109, 19.4.2001, p. 35.

(**3**) OJ L 317, 6.11.1981, p. 1.

(**4**) OJ L 139, 10.6.2000, p. 25.

**Changes to legislation:**
There are currently no known outstanding effects for the Commission Regulation (EC) No 807/2001.