

**COMMISSION REGULATION (EC) No 2728/1999
of 20 December 1999**

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 2593/1999 ⁽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 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) Whereas, in establishing maximum residue limits for 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 carcasses 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 flunixin, cefalexin, flumequine, meloxicam and tiamulin should be inserted into Annex I to Regulation (EEC) No 2377/90;
- (7) Whereas butafosfan, *eucalyptus globulus*, furosemide, *echinacea*, *cupressi aetheroleum*, *crataegus*, cefalonium, *carlinae radix*, *cardiospermum halicacabum*, *turnera diffusa*, *calendula officinalis*, *euphrasia officinalis*, *boldo folium*, *bellis perennis*, *artemisia abrotanum*, *arnicae radix*, *arnica montana (arnicae flos, arnicae planta tota)*, aloes, Barbados, Capae, their standardised dry extract, preparations thereof, *allium cepa*, *ailanthus altissima*, *agnus Castus*, *aesculus hippocastanum*, *camphora*, *lobaria pulmonaria*, *syzygium cumini*, *solidago virgaurea*, *silybum marianum*, *serenoa repens*, *prunus laucerasus*, *okoubaka aubrevillei*, *viscum album*, *symphyti radix*, lidocaine, *hamamelis virginiana*, *lachnanthes tinctoria*, *hypericum perforatum* and *ginkgo biloba* and *harpagophytum procumbens* and *lavandulae aetheroleum* and ginseng should be inserted into Annex II to Regulation (EEC) No 2377/90;
- (8) Whereas, in order to allow for the completion of scientific studies, tiamulin, spectinomycin, doramectin, mebendazole, propetamphos, metamizole, abamectin, cefalonium and rafoxanide 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 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;
- (10) Whereas the measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

⁽¹⁾ OJ L 224, 18.8.1990, p. 1.
⁽²⁾ OJ L 315, 9.12.1999, p. 26.

⁽³⁾ OJ L 317, 6.11.1981, p. 1.
⁽⁴⁾ OJ L 214, 24.8.1993, p. 31.

HAS ADOPTED THE FOLLOWING REGULATION:

Article 2

Article 1

Annexes I, II and III to Regulation (EEC) No 2377/90 are hereby amended as set out in the Annex hereto.

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.

Done at Brussels, 20 December 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

1.2.2. Quinolones

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Cefalexin	Cefalexin	Bovine	200 µg/kg 200 µg/kg 200 µg/kg 1 000 µg/kg 100 µg/kg	Muscle Fat Liver Kidney Milk'	

1.2.3. Quinolones

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Flumequine	Flumequine	Bovine, ovine Not for use in animals from which milk is produced for human consumption Porcine Chicken Not for use in animals from which eggs are produced for human consumption Salmonidae	200 µg/kg 300 µg/kg 500 µg/kg 1 500 µg/kg 200 µg/kg 300 µg/kg 500 µg/kg 1 500 µg/kg 400 µg/kg 250 µg/kg 800 µg/kg 1 000 µg/kg 600 µg/kg	Muscle Fat Liver Kidney Muscle Skin and fat Liver Kidney Muscle Skin and fat Liver Kidney Muscle and skin in natural proportions'	

1.2.8. Pleuromutlilines

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Tiamulin	Sum of metabolites that may be hydrolysed to 8- α -hydroxymutlilin	Porcine	100 $\mu\text{g}/\text{kg}$ 500 $\mu\text{g}/\text{kg}$	Muscle Liver	
	Tiamulin	Chicken	100 $\mu\text{g}/\text{kg}$ 100 $\mu\text{g}/\text{kg}$ 1 000 $\mu\text{g}/\text{kg}$ 1 000 $\mu\text{g}/\text{kg}$	Muscle Skin and fat Liver Eggs'	

4. Anti-inflammatory agents

4.1. Nonsteroidal anti-inflammatory agents

4.1.2. Fenamate group derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Flunixin	Flunixin	Bovine	20 $\mu\text{g}/\text{kg}$ 30 $\mu\text{g}/\text{kg}$ 300 $\mu\text{g}/\text{kg}$ 100 $\mu\text{g}/\text{kg}$ 40 $\mu\text{g}/\text{kg}$	Muscle Fat Liver Kidney Milk	
	5-Hydroxyflunixin Flunixin	Porcine	50 $\mu\text{g}/\text{kg}$ 10 $\mu\text{g}/\text{kg}$ 200 $\mu\text{g}/\text{kg}$ 30 $\mu\text{g}/\text{kg}$	Muscle Skin and fat Liver Kidney'	

4.1.4. Oxicam derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Meloxicam	Meloxicam	Bovine	20 $\mu\text{g}/\text{kg}$ 65 $\mu\text{g}/\text{kg}$ 65 $\mu\text{g}/\text{kg}$ 15 $\mu\text{g}/\text{kg}$	Muscle Liver Kidney Milk'	

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

2. Organic compounds

Pharmacologically active substance(s)	Animal species	Other provisions
'Butafosfan	Bovine	For intravenous use only and not for use in animals from which milk is produced for human consumption
Cefalonium	Bovine	For intramammary use and eye treatment only, and for all tissues except milk
Furosemide	Bovine, equidae	For intravenous administration only
Lidocaine	Equidae	For local-regional anaesthesia only

4. Substances used in homeopathic veterinary medicinal products

Pharmacologically active substance(s)	Animal species	Other provisions
' <i>Aesculus hippocastanum</i>	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 ten only
<i>Agnus castus</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Ailanthus altissima</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Allium cepa</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Arnica radix</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding in the products not exceeding one part per ten only

Pharmacologically active substance(s)	Animal species	Other provisions
<i>Artemisia abrotanum</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Bellis perennis</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Calendula officinalis</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding in the products not exceeding one part per ten only
<i>Camphora</i>	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 hundred only.
<i>Cardiospermum halicacabum</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Crataegus</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Echinacea</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only For topical use only.
<i>Eucalyptus globulus</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding in the products not exceeding one part per ten only

Pharmacologically active substance(s)	Animal species	Other provisions
<i>Euphrasia officinalis</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Ginkgo biloba</i>	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.
Ginseng	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Hamamelis virginiana</i>	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 ten only
<i>Harpagophytum procumbens</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Hypericum perforatum</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Lachnanthes tinctoria</i>	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.
<i>Lobelia pulmonaria</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Okoubaka aubrevillei</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only

Pharmacologically active substance(s)	Animal species	Other provisions
<i>Prunus laurocerasus</i>	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.
<i>Serenoa repens</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Silybum marianum</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Solidago virgaurea</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Syzygium cumini</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Turnera diffusa</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only
<i>Viscum album</i>	All-food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only

6. Substances of vegetable origin

Pharmacologically active substance(s)	Animal species	Other provisions
'Aloes, Barbados and Capae, their standardised dry extract and preparations thereof	All food-producing species	
<i>Arnica montana (arnicae flos and arnicae planta tota)</i>	All food-producing species	For topical use only
<i>Boldo folium</i>	All food-producing species	
<i>Carlinae radix</i>	All food-producing species	For topical use only
<i>Cupressi aetheroleum</i>	All food-producing species	For topical use only
<i>Lavandulae aetheroleum</i>	All food-producing species	For topical use only
<i>Symphyti radix</i>	All food-producing species	For topical use on intact skin 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
'Cefalonium	Cefalonium	Bovine	10 µg/kg	Milk	Provisional MRLs expire on 1.7.2001'

1.2.5. Aminoglycosides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Spectinomycin	Spectinomycin	Ovine Not for use in animals from which milk is produced for human consumption Chicken	300 µg/kg 500 µg/kg 2 000 µg/kg 5 000 µg/kg 200 µg/kg	Muscle Fat Liver Kidney Eggs	Provisional MRLs expire on 1.1.2002'

1.2.1.4. Pleuromutilines

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Tiamulin	Sum of metabolites that may be hydrolysed to 8-a-hydroxymutilin	Turkey	100 µg/kg 100 µg/kg 300 µg/kg	Muscle Skin and fat Liver	Provisional MRLs expire on 1.7.2001'

2. Antiparasitic agents

2.1. Agents acting against endoparasites

2.1.2. Benzimidazoles and pro-benzimidazoles

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Mebendazole	Sum of mebendazole methyl (5-(1-hydroxy, 1-phenyl) methyl-1H-benzimidazol-2-yl) carbamate and (2-amino-1H-benzimidazol-5-yl) phenylmethanone, expressed as mebendazole equivalents	Ovine, caprine, equidae Not for use in animals from which milk is produced for human consumption	60 µg/kg 60 µg/kg 400 µg/kg 60 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1.1.2002'

2.1.6. Salicylanilides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Rafoxanide	Rafoxanide	Bovine Not for use in animals from which milk is produced for human consumption Ovine Not for use in animals from which milk is produced for human consumption	30 µg/kg 30 µg/kg 10 µg/kg 40 µg/kg 100 µg/kg 250 µg/kg 150 µg/kg 150 µg/kg	Muscle Fat Liver Kidney Muscle Fat Liver Kidney	Provisional MRLs expire on 1.7.2001'

2.2. Agents acting against ectoparasites

2.2.4. Organophosphates

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Propetamphos	Sum of residues of propetamphos and desisopropyl-propetamphos	Ovine Not for use in animals from which milk is produced for human consumption	90 µg/kg 90 µg/kg	Fat Kidney	Provisional MRLs expire on 1.1.2001'

2.3. Agents acting against endo- and ectoparasites

2.3.1. Avermectins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
'Abamectin	Avermectin B1a	Ovine	20 µg/kg 50 µg/kg 25 µg/kg 20 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1.1.2001
Doramectin	Doramectin	Deer, including reindeer	20 µg/kg 100 µg/kg 50 µg/kg 30 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1.7.2001'

5. Anti-inflammatory agents
 5.1. Nonsteroidal anti-inflammatory agents
 5.1.3. Pyrazolone derivatives

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Metamizole	4-Methylaminoantipyrin	Bovine, porcine, equidae Not for use in animals from which milk is produced for human consumption	200 µg/kg 200 µg/kg 200 µg/kg 200 µg/kg	Muscle Fat Liver Kidney	Provisional MRLs expire on 1.7.2001