

**COMMISSION REGULATION (EC) No 2686/98**

of 11 December 1998

**amending Annexes I and II 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<sup>(1)</sup>, as last amended by Commission Regulation (EC) No 2560/98<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 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 flumethrin should be inserted into Annex I to Regulation (EEC) No 2377/90;

Whereas oleylolate, calcium glucoheptonate, calcium glucono glucoheptonate, calcium gluconolactate, calcium glutamate, nickel gluconate, nickel sulphate, sodium hypophosphite, bacitracin, bronopol, cetostearyl alcohol, menadione, phytomenadione, 2-pyrrolidone, sodium cetostearyl sulphate, wool alcohols, *lespedeza capitata*, *majoranae herba*, *medicago sativa extractum*, *sinapis nigrae semen* and flumethrin should be inserted into Annex II to Regulation (EEC) No 2377/90;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<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 Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THE FOLLOWING REGULATION:

*Article 1*

Annexes I and II 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 60th day following its publication in the *Official Journal of the European Communities*.<sup>(1)</sup> OJ L 224, 18. 8. 1990, p. 1.<sup>(2)</sup> OJ L 320, 28. 11. 1998, p. 28.<sup>(3)</sup> OJ L 317, 6. 11. 1981, p. 1.<sup>(4)</sup> 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, 11 December 1998.

*For the Commission*  
Martin BANGEMANN  
*Member of the Commission*

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ANNEX

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

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
'Flumethrin	Flumethrin (sum of trans-Z isomers)	Bovine	10 µg/kg 150 µg/kg 20 µg/kg 10 µg/kg 30 µg/kg	Muscle Fat Liver Kidney Milk'	

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

1. Inorganic chemicals

Pharmacologically active substance(s)	Animal species	Other provisions
'Calcium glucoheptonate	All food-producing species	
Calcium glucono glucoheptonate	All food-producing species	
Calcium gluconolactate	All food-producing species	
Calcium glutamate	All food-producing species	
Nickel gluconate	All food-producing species	
Nickel sulphate	All food-producing species	
Sodium hypophosphite	All food-producing species'	

## 2. Organic compounds

Pharmacologically active substance(s)	Animal species	Other provisions
'2-Pyrrolidone	All food-producing species	At parenteral doses up to 40 mg/kg bw
Bacitracin	Bovine	For intramammary use in lactating cows only and for all tissues except milk
Bronopol	Salmonidae	For use only on farmed fertilised eggs
Cetostearyl alcohol	All food-producing species	
Flumethrin	Honey bees	
Menadione	All food-producing species	
Oleyloleate	All food-producing species	For topical use only
Phytomenadione	All food-producing species	
Sodium cetostearyl sulphate	All food-producing species	For topical use only
Wool alcohols	All food-producing species	For topical use only'

## 6. Substances of vegetable origin

Pharmacologically active substance(s)	Animal species	Other provisions
<i>Lespedeza capitata</i>	All food-producing species	
<i>Majoranae herba</i>	All food-producing species	
<i>Medicago sativa extractum</i>	All food-producing species	For topical use only
<i>Sinapis nigrae semen</i>	All food-producing species'	