

## COMMISSION REGULATION (EC) No 1798/96

of 17 September 1996

amending Annex 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

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 1742/96<sup>(2)</sup> and in particular Articles 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, scientific data to address outstanding questions on safety and residues have been provided, these were considered insufficient to conclude the assessment on albendazole, thiamphenicol, oxibendazole, flubendazole and azaperone, so that they can be inserted into Annex I to Council Regulation (EC) No 2377/90;

Whereas additional information has now been provided in respect of albendazole, thiamphenicol, oxibendazole, flubendazole and azaperone; the duration of validity of the provisional maximum residue limits previously defined in Annex III to Regulation (EC) No 2377/90 for the above-mentioned substances shall be extended in order that completion of the scientific evaluation in progress may be achieved;

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 Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex III to Regulation (EEC) No 2377/90 is 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 No L 224, 18. 8. 1990, p. 1.

<sup>(2)</sup> OJ No L 226, 7. 9. 1996, p. 5.

<sup>(3)</sup> OJ No L 317, 6. 11. 1981, p. 1.

<sup>(4)</sup> OJ No 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, 17 September 1996.

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

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## ANNEX

Annex III to Regulation (EEC) No 2377/90 is modified as follows:

## 1. Anti-infectious agents

## 1.2. Antibiotics

## 1.2.3. Thiamphenicol and related compounds

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
1.2.3.1. Thiamphenicol	Thiamphenicol	Bovine, poultry	40 µg/kg	Muscle, liver, kidney, fat	Provisional MRLs expire on 1. 1. 1988'

## 2. Antiparasitic agents

## 2.1. Agents acting against endo-parasites

## 2.1.1. Benzimidazoles and pro-benzimidazoles

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
2.1.1.4. Albendazole	Sum of albendazole and metabolites which are measured as 2-amino-benzimidazole sulphone	Bovine, ovine	100 µg/kg	Muscle, fat, milk	Provisional MRLs expire on 1. 1. 1998.
			500 µg/kg	Kidney	
			1 000 µg/kg	Liver	
2.1.1.7. Flubendazole	Flubendazole	Poultry and game birds	500 µg/kg	Liver	Provisional MRLs expire on 1. 1. 1998
			200 µg/kg	Muscle	
			400 µg/kg	Eggs	
			10 µg/kg	Muscle, liver, kidney, fat	
		Porcine			

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions
2.1.1.8. Oxibendazole	Oxibendazole	Bovine, ovine, porcine, <i>equidae</i>	100 µg/kg	Muscle, liver, kidney, fat	Provisional MRLs expire on 1. 1. 1998 <sup>1</sup> .
		Bovins, ovine	50 µg/kg	Milk	
3. Agents acting on the nervous system					
3.1. Agents acting on the central nervous system					
3.1.1. Butyrofenone tranquilizers					
Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
3.1.1.1. Azaperone	Azaperol	All food producing species	100 µg/kg	Kidney	Provisional MRLs expire on 1. 1. 1998 <sup>1</sup> .
			50 µg/kg	Liver, muscle, fat	