

Commission Regulation (EC) No 869/2005 of 8 June 2005 amending Annexes I and II 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 as regards ivermectin and carprofen (Text with EEA relevance)

COMMISSION REGULATION (EC) No 869/2005

of 8 June 2005

amending Annexes I and II 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 as regards ivermectin and carprofen

(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>, and in particular Articles 2 and 3 thereof,

Having regard to the opinions of the European Medicines Agency formulated by the Committee for Medicinal Products for Veterinary Use,

Whereas:

- (1) All pharmacologically active substances which are used within the Community in veterinary medicinal products intended for administration to food-producing animals should be evaluated in accordance with Regulation (EEC) No 2377/90.
- (2) Ivermectin has been included in Annex I to Regulation (EEC) No 2377/90 for bovine, porcine, ovine and *Equidae* for liver and fat and for deer including reindeer for liver, fat, muscle and kidney. That entry should be modified and extended to all mammalian food producing species excluding animals from which milk is produced for human consumption.
- (3) Carprofen has been included in Annex I to Regulation (EEC) No 2377/90 with carprofen as marker residue for bovine and *Equidae* for muscle, fat, liver and kidney excluding bovine from which milk is produced for human consumption. That marker residue should be replaced by the sum of carprofen and carprofen glucuronide conjugate. Carprofen should be included in Annex II to that Regulation for bovine milk only.
- (4) Regulation (EEC) No 2377/90 should be amended accordingly.
- (5) An adequate period should be allowed before the applicability of this Regulation in order to enable Member States to make any adjustment which may be necessary in the light of this Regulation to the marketing authorisations granted in accordance with

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*Status: Point in time view as at 08/06/2005.*

*Changes to legislation: There are currently no known outstanding effects for the  
Commission Regulation (EC) No 869/2005. (See end of Document for details)*

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Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products<sup>(2)</sup>.

- (6) 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 and II to Regulation (EEC) No 2377/90 are amended in accordance with the Annex to this Regulation.

*Article 2*

This Regulation shall enter into force on the third day following its publication in the *Official Journal of the European Union*.

It shall apply from 8 August 2005.

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

Done at Brussels, 8 June 2005.

*For the Commission*  
Günter VERHEUGEN  
*Vice-President*

*Status: Point in time view as at 08/06/2005.**Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EC) No 869/2005. (See end of Document for details)*

## ANNEX

A. The following substance(s) is(are) inserted in Annex I to Regulation (EEC) No 2377/90

2. Antiparasitic agents
- 2.3. Agents acting against endo- and ectoparasites
- 2.3.1. Avermectins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
'Ivermectin	22,23-Dihydro-avermectin B1a	All mammalian food-producing species <sup>a</sup>	100 µg/kg	Fat
			100 µg/kg	Liver
			30 µg/kg	Kidney

<sup>a</sup> Not for use in animals from which milk is produced for human consumption.'

4. Anti-inflammatory agents
- 4.1. Nonsteroidal anti-inflammatory agents
- 4.1.1. Arylpropionic acid derivative

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues
'Carprofen	Sum of carprofen and carprofen glucuronide conjugate	Bovine, equidae	500 µg/kg	Muscle
			1 000 µg/kg	Fat
			1 000 µg/kg	Liver
			1 000 µg/kg	Kidney'

B. The following substance(s) is(are) inserted in Annex II to Regulation (EEC) No 2377/90

8. Anti-inflammatory agents

Pharmacologically active substance(s)	Animal species
'Carprofen	Bovine <sup>a</sup>

<sup>a</sup> For bovine milk only.'

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- (1) [OJ L 224, 18.8.1990, p. 1](#). Regulation as last amended by Commission Regulation (EC) No 712/2005 ([OJ L 120, 12.5.2005, p. 3](#)).
- (2) [OJ L 311, 28.11.2001, p. 1](#). Directive as last amended by Directive 2004/28/EC ([OJ L 136, 30.4.2004, p. 58](#)).

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