COMMISSION REGULATION (EC) No 545/2006

of 31 March 2006

amending Regulation (EC) No 1464/2004 as regards the conditions for authorisation of the feed additive 'Monteban', belonging to the group of coccidiostats and other medicinal substances

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition [1], and in particular Article 13(3) thereof,

Whereas:

(1) The additive narasin (Monteban, Monteban G 100), belonging to the group of coccidiostats and other medicinal substances, was authorised under certain conditions in accordance with Council Directive 70/524/EEC [2]. Commission Regulation (EC) No 1464/2004 [3] authorised that additive for 10 years for use for chickens for fattening, linking the authorisation to the person responsible for putting that additive into circulation. That additive was notified as an existing product on the basis of Article 10 of Regulation (EC) No 1831/2003. Since all the information required under that provision was submitted, that additive was entered into the Community Register of Feed Additives.

(2) Regulation (EC) No 1831/2003 provides for the possibility to modify the authorisation of an additive further to a request from the authorisation holder and an opinion of the European Food Safety Authority ('the Authority').

(3) In its opinion adopted on 27 July 2004, the Authority proposed to establish a maximum residue limit (MRL) of 50 µg/kg for all wet tissues in chickens for fattening. Consequently a withdrawal time of one day before the slaughter was considered sufficient. It may be necessary to review the maximum residue limit mentioned in the Annex of this Regulation in light of the results of any evaluation by the European Medicines Agency concerning the active substance.

(4) The holder of the authorisation of the additive narasin (Monteban, Monteban G 100) proposed changing the terms of the authorisation by submitting an application to the Commission requesting to introduce MRL as evaluated by the Authority.

(5) Regulation (EC) No 1464/2004 should therefore be amended accordingly.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EC) No 1464/2004 is replaced by the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 31 March 2006.

For the Commission
Markos KYPRIANOU
Member of the Commission

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[1] OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).
[2] OJ L 270, 14.12.1970, p. 1. Directive repealed by Regulation (EC) No 1831/2003.
[3] OJ L 270, 18.8.2004, p. 8.

ANNEX

Regis-tration number of additive	Name and registration number of person responsible for putting additive into circulation	Additive (Trade name)	Composition, chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation	Maximum residue limits (MRLs) in the relevant foodstuffs of animal origin from species or category of animal concerned
						mg of active substance/kg of complete feedingstuff				
Coccidiostats and other medicinal substances										
'E 765	Eli Lilly and Company Limited	Narasin 100 g/kg (Monteban, Monteban G 100)	Additive composition: Narasin: 100 g activity/kg Soybean oil or mineral oil: 10-30 g/kg Vermiculite: 0-20 g/kg Soybean mill run or rice hulls qs 1 kg Active substance: Narasin, $C_{43}H_{72}O_{11}$ CAS number: 55134-13-9 polyether monocarboxylic acid produced by *Streptomyces aureofaciens* (NRRL 8092), in granular form Narasin A activity: ≥ 90 %	Chickens for fattening	—	60	70	Use prohibited at least one day before slaughter. Indicate in the instructions for use: "Dangerous for equine species, turkeys and rabbits" "This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances (e.g. tiamulin) can be contraindicated"	21.8.2014	50 µg Narasin/kg for all wet tissues from chickens for fattening'