COMMISSION REGULATION (EC) No 496/2007

of 4 May 2007

amending Regulation (EC) No 600/2005 as regards the introduction of a maximum residue limit for the feed additive 'Salinomax 120G', 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 salinomycin sodium (Salinomax 120G) was authorised under certain conditions in accordance with Council Directive 70/524/EEC [2]. Commission Regulation (EC) No 600/2005 [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 entered into the Community Register of Feed Additives.

(2) Regulation (EC) No 1831/2003 provides for the possibility of modifying the authorisation of an additive further to a request from the holder of the authorisation and an opinion of the European Food Safety Authority (the Authority). The holder of the authorisation of the additive salinomycin sodium (Salinomax 120G) has submitted an application which proposes changing the conditions of the authorisation by introducing a maximum residue limit (MRL) as evaluated by the Authority.

(3) In its opinion adopted on 26 January 2005 [4], the Authority proposed to establish an MRL for the active substance concerned. It may be necessary to review that MRL in the light of the results of a future evaluation of that active substance by the European Agency for the Evaluation of Medicinal Products.

(4) Regulation (EC) No 600/2005 should therefore be amended accordingly.

(5) 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 600/2005 is replaced by the text in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 20th day following 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, 4 May 2007.

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 as last amended by Commission Regulation (EC) No 1800/2004 (OJ L 317, 16.10.2004, p. 37).

[3] OJ L 99, 19.4.2005, p. 5. Regulation as amended by Regulation (EC) No 2028/2006 (OJ L 414, 30.12.2006, p. 26).

[4] Update of the Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on a new request from the Commission related to the safety of 'Bio-Cox®120G' based on Salinomycin sodium as a feed additive in accordance with Council Directive 70/524/EEC (Article 4g). Adopted on 26 January 2005, *The EFSA Journal* (2005) 170, p. 1-4.

ANNEX

Registration 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
						mg of active substance/kg of complete feedingstuff				
Coccidiostats and other medicinal substances										
E 766	Alpharma (Belgium) BVBA	Salinomycin sodium 120 g/kg (Salinomax 120G)	**Additive composition:** Salinomycin sodium 120 g/kg Calcium lignosulfonate: 40 g/kg Calcium sulphate dihydrate to 1 000 g/kg **Active substance:** Salinomycin sodium, $C_{42}H_{69}O_{11}Na$, Sodium salt of a polyether monocarboxylic acid produced by fermentation of *Streptomyces albus* (ATCC 21838/US 9401-06), CAS No: 55 721-31-8 Related impurities: < 42 mg elaiophylin/kg salinomycin sodium. < 40 g 17-epi-20 desoxysalinomycin/kg salinomycin sodium	Chickens for fattening	—	50	70	Use prohibited at least one day before slaughter. Indicate in the instructions for use: 'Dangerous for equines and turkeys'; 'This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances (e.g.tiamulin) can be contraindicated'	22.4.2015	5 µg of Salinomycin/kg for all wet tissues