Commission Regulation (EC) No 500/2007 of 7 May 2007 amending Regulation (EC) No 1463/2004 as regards the introduction of a maximum residue limit for the feed additive 'Sacox 120 microGranulate', belonging to the group of coccidiostats and other medicinal substances (Text with EEA relevance)

COMMISSION REGULATION (EC) No 500/2007

of 7 May 2007

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(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 (Sacox 120 microGranulate) was authorised under certain conditions in accordance with Council Directive 70/524/EEC[(2)]. Commission Regulation (EC) No 1463/2004[(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 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 (Sacox 120 microGranulate) 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 30 June 2004[(4)], the Authority proposed to establish an MRL of 5 μg/kg 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 1463/2004 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,

Changes to legislation: Commission Regulation (EC) No 500/2007 is up to date with all changes known to be in force on or before 27 December 2020. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EC) No 1463/2004 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, 7 May 2007.

For the Commission

Markos KYPRIANOU

Member of the Commission

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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	Huvepharma NV Belgium	Salinomycin sodium 120 g/kg (Sacox 120 microGranulate)	Additive composition: Salinomycin sodium ≥ 120 g/kg Silicon dioxide 10-100 g/kg Calcium carbonate 350-700 g/kg Active substance: Salinomycin sodium, $C_{42}H_{69}O_{11}Na$, CAS number: 55721-31-8, Sodium salt of a polyether monocarboxylic acid produced by fermentation of *Streptomyces albus*	—	—	60	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’	21.8.2015	4 µg of Salinomycin/kg for all wet tissues