COMMISSION REGULATION (EC) No 1463/2004

of 17 August 2004

concerning the authorisation for 10 years of the additive 'Sacox 120 microGranulate' in feedingstuffs, 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 Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs [1], and in particular Article 9g(5)(b) thereof,

Whereas:

(1) In accordance with Directive 70/524/EEC, coccidiostats included in Annex I to that Directive before 1 January 1988 were provisionally authorised as from 1 April 1998 and transferred to Chapter I of Annex B with a view to their re-evaluation as additives linked to a person responsible for putting them into circulation. The salinomycin sodium product, Sacox 120 microGranulate, is an additive belonging to the group 'Coccidiostats and other medicinal substances' listed in Chapter I of Annex B to Directive 70/524/EEC.

(2) The person responsible for putting Sacox 120 microGranulate into circulation submitted an application for authorisation and a dossier, according to Article 9g(2) and (4) of that Directive.

(3) Article 9g(6) of Directive 70/524/EEC allows the automatic extension of the period of authorisation of the additives concerned until the Commission takes a decision in cases where, for reasons beyond the control of the authorisation holder, no decision may be taken on the application before the expiry date of the authorisation. This provision is applicable to the authorisation of Sacox 120 microGranulate. The Commission requested a full risk evaluation from the Scientific Committee for Animal Nutrition on 26 April 2001 and this request was consequently transferred to the European Food Safety Authority. Several requests for additional information were made during the re-evaluation process making it impossible to complete the re-evaluation within the time limit required by Article 9g.

(4) The Scientific Panel on Additives and Products or Substances used in Animal Feed attached to the European Food Safety Authority has delivered a favourable opinion with regard to the safety and to the efficacy of Sacox 120 microGranulate for chickens for fattening.

(5) The re-evaluation of Sacox 120 microGranulate carried out by the Commission showed that the relevant conditions laid down in Directive 70/524/EEC are satisfied. Sacox 120 microGranulate should therefore be authorised for 10 years as an additive linked to the person responsible for putting it into circulation and included in Chapter I of the list referred to Article 9t(b) of that Directive.

(6) As the authorisation for the additive is now linked to a person responsible for putting it into circulation, and replaces the previous authorisation which was not linked to any specific person, it is appropriate to delete the latter authorisation.

(7) Since there are no safety reasons for withdrawing the product salinomycin sodium from the market immediately, it is appropriate to allow a transitional period of six months for the disposal of existing stocks of the additive.

(8) 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

Chapter I of Annex B to Directive 70/524/EEC is amended as follows:

The additive salinomycin sodium, belonging to the group 'Coccidiostats and other medical substances', is deleted.

Article 2

The additive Sacox 120 microGranulate belonging to the group 'Coccidiostats and other medical substances' as set out in the Annex to the present Regulation is authorised for use in animal nutrition under the conditions laid down in that Annex.

Article 3

A period of six months from the date of entry into force of this Regulation is permitted to use up the existing stocks of salinomycin sodium.

Article 4

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

[1] OJ L 270, 14.12.1970, p. 1. Directive as last amended by Commission Regulation (EC) No 1289/2004 (OJ L 243, 15.7.2004, p. 15).

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

Done at Brussels, 17 August 2004.

For the Commission
David BYRNE
Member of the Commission

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
						mg of active substance/kg of complete feedingstuff			
Coccidiostats and other medicinal substances									
'E 766	Intervet International bv	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: 53003-10-4, Sodium salt of a polyether onocarboxylic acid produced by fermentation of *Streptomyces albus* (DSM 12217) Related impurities: < 42 mg elaiophylin/kg salinomycin sodium. < 40 g 17-epi-20-desoxy-salinomycin/kg salinomycin sodium	Chickens for fattening	—	60	70	Use prohibited at least five days 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 contra-indicated"	21 August 2014'