COMMISSION REGULATION (EC) No 1356/2004

of 26 July 2004

concerning the authorisation for 10 years of the additive 'Elancoban' 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 monensin sodium product, Elancoban, 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 into circulation Elancoban 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 case of, 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 Elancoban. On 26 April 2001, the Commission requested the Scientific Committee for Animal Nutrition for a full risk evaluation 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 limits 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 Elancoban for chickens for fattening, for chickens reared for laying and for turkeys.

(5) The re-evaluation of Elancoban carried out by the Commission showed that the relevant conditions laid down in Directive 70/524/EEC are satisfied. Elancoban 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 monensin 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 monensin sodium, belonging to the group 'Coccidiostats and other medical substances', shall be deleted.

Article 2

The additive Elancoban 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.

[1] OJ L 270, 14.12.1970, p. 1. Regulation as last amended by Regulation (EC) No 1756/2002 (OJ L 265, 3.10.2002, p. 1).

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 monensin 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*.

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

Done at Brussels, 26 July 2004.

For the Commission
David BYRNE
Member of the Commission

ANNEX

Registration number of additive	Name and registration number of person responsible for putting the additive into circulation	Additive (trade name)	Composition, chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	Period of authorisation
						mg of active substance/kg of complete feedingstuff			
Coccidiostats and other medicinal substances									
'E 757	Eli Lilly and Company Limited	Monensin sodium	***Active substance:*** $C_{36}H_{61}O_{11}Na$ sodium salt of polyether monocarboxylic acid produced by *Streptomyces cinnamonensis*, ATCC 15413 in granular form. Factor composition: Monensin A: not less than 90 % Monensin: A + B: not less than 95 %	Chickens for fattening	—	100	125	Use prohibited at least three days before slaughter. Indicate in the instructions for use: Dangerous for equines. This feedingstuff contains an ionophore: avoid simultaneous administration with tiamulin and monitor for possible adverse reactions when used concurrently with other medicinal substances.	30.7.2014'
		Elancoban G100 Elancoban 100 Elancogran 100	***Additive composition:*** Granular monensin (dried fermentation product) equivalent to Monensin activity 10 % w/w Mineral oil 1-3 % w/w Limestone granular 13-23 % w/w Rice hulls or limestone granular qs 100 % w/w	Chickens reared for laying	16 weeks	100	120	Indicate in the instructions for use: Dangerous for equines. This feedingstuff contains an ionophore: avoid simultaneous administration with tiamulin and monitor for possible adverse reactions when used concurrently with other medicinal substances.	
		Elancoban G200 Elancoban 200	Granular monensin (dried fermentation product) equivalent to Monensin activity 20 % w/w Mineral oil 1-3 % w/w Rice hulls or limestone granular qs 100 % w/w	Turkeys	16 weeks	60	100	Use prohibited at least three days before slaughter. Indicate in the instructions for use: Dangerous for equines. This feedingstuff contains an ionophore: avoid simultaneous administration with tiamulin and monitor for possible adverse reactions when used concurrently with other medicinal substances.	