COMMISSION REGULATION (EC) No 108/2007

of 5 February 2007

amending Regulation (EC) No 1356/2004 as regards the conditions for authorisation of the feed additive Elancoban, 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 monensin sodium (Elancoban G100, Elancoban 100, Elancogran 100, Elancoban G200, Elancoban 200) was authorised under certain conditions in accordance with Council Directive 70/524/EEC [2]. Commission Regulation (EC) No 1356/2004 [3] authorised that additive for 10 years for use for chickens for fattening, chickens reared for laying and turkeys, 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 authorisation holder and an opinion of the European Food Safety Authority (the Authority). The holder of the authorisation of the additive monensin sodium (Elancoban G100, Elancoban 100, Elancogran 100, Elancoban G200, Elancoban 200) has submitted an application which proposes changing the terms of the authorisation by introducing maximum residue limits (MRLs) as evaluated by the Authority.

(3) In its opinion adopted on 21 November 2006, the Authority proposed to establish provisional MRLs for the active substance concerned [4]. It may be necessary to review the MRLs set out in the Annex in the light of the results of a future evaluation of that active substance by the European Medicines Agency.

(4) Regulation (EC) No 1356/2004 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,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EC) No 1356/2004 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, 5 February 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 repealed by Regulation (EC) No 1831/2003.

[3] OJ L 251, 27.7.2004, p. 6.

[4] Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the Maximum Residues Limits for monensin sodium for chicken and turkeys for fattening, adopted on 21 November 2006, The EFSA Journal (2006) 413, p. 1-13. See also Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the request of the Commission on the re-evaluation of coccidiostat Elancoban in accordance with article 9G of Council Directive 70/524/EEC, adopted on 4 March 2004, The EFSA Journal (2004) 42, p. 1-61.

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	Provisional 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 757	Eli Lilly and Company Limited	Monensin sodium (Elancoban G100, Elancoban 100, Elancogran 100, Elancoban G200, Elancoban 200)	***Active substanc:*** $C_{36}H_{61}O_{11}Na$ sodium salt of polyether mono-carboxylic acid produced by Strep-tomyces cinnamonensis, ATCC 15413 in granular form. Factor composition: Monensin A: not less than 90 % Monensin: A + B: not less than 95 % ***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 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	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 adminis-tration with tiamulin and monitor for possible adverse reactions when used concurrently with other medicinal substances"	30.7.2014	25 µg monensin sodium/kg of wet skin + fat. 8 µg monensin sodium/kg of wet liver, kidney and muscle'.
				Chickens reared for laying	16 weeks	100	120			
				Turkeys	16 weeks	60	100			