

COMMISSION REGULATION (EC) No 1096/2008**of 6 November 2008****amending Regulation (EC) No 1356/2004 as regards the terms of the 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 ten 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 in accordance with 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 to modify 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').

(3) The holder of the authorisation of the additive monensin sodium (Elancoban G100, Elancoban 100, Elancogran 100, Elancoban G200, Elancoban 200) has submitted an application with which it proposes changing the terms of the authorisation by reducing the withdrawal period before slaughter.

(4) In its opinion adopted on 18 June 2008 ⁽⁴⁾, the Authority concluded, after re-assessing human exposure, that a one-day withdrawal time for Elancoban G100, Elancoban 100, Elancogran 100, Elancoban G200 and Elancoban 200 for chickens for fattening, chickens reared for laying and turkeys could be set.

(5) Regulation (EC) No 1356/2004 should therefore be amended accordingly.

(6) 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 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, 6 November 2008.

For the Commission

Androulla VASSILIOU

Member of the Commission

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽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⁾ Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) on a request from the European Commission on the withdrawal period for Elancoban for chickens for fattening, chickens reared for laying and turkeys for fattening. *The EFSA Journal* (2008) 730, 1-16.

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/kg of complete feedingsstuff	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 feedingsstuff	Maximum content				
Coccidiostats and other medicinal substances											
E 757	Eli Lilly and Company Limited	Monensin sodium (Elancoban G100, Elancoban 100, Elancogran 100, Elancoban G200, Elancoban 200)	<p><i>Active substance</i> $C_{38}H_{61}O_{11}Na$ sodium salt of polyether monocarboxylic acid produced by <i>Streptomyces cinnamonensis</i>, ATCC 15413 in granular form.</p> <p><i>Factor composition:</i> Monensin A: not less than 90 % Monensin A + B: not less than 95 %</p> <p><i>Additive composition</i> 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</p>	Chickens for fattening Chickens reared for laying Turkeys	— 16 weeks 16 weeks	100 100 60	125 120 100	Use prohibited at least one day before slaughter. Indicate in the instructions for use: 'Dangerous for equines. This feedingsstuff contains an ionophore: avoid simultaneous administration with tiamulin and monitor for possible adverse reactions when used concurrently with other medicinal substances'	30.7.2014	25 µg/kg monensin sodium of wet skin + fat 8 µg/kg monensin sodium of wet liver, wet kidney and wet muscle.	