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)

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

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EC) No 1096/2008. (See end of Document for details)*

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 substance* Monensin 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 % *Additive composition* Granular monensin (dried	Chickens for fattening	—	100	125	Use prohibited at least one day 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	30.7.2012	25 µg/kg monensin sodium of wet skin + fat 8 µg/kg monensin sodium of wet liver, wet kidney and wet muscle.
				Chickens reared for laying	16 weeks	100	120			
				Turkeys	16 weeks	60	100			