Commission Regulation (EC) No 1095/2008 of 6 November 2008 amending Regulation (EC) No 109/2007 as regards the terms of the authorisation of the feed additive monensin sodium (Coxidin) (Text with EEA relevance)

COMMISSION REGULATION (EC) No 1095/2008

of 6 November 2008

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(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 (Coxidin) was authorised under certain conditions in accordance with Regulation (EC) No 1831/2003. Commission Regulation (EC) No 109/2007[(2)] authorised that additive for ten years for use for chickens for fattening and turkey, linking the authorisation to the holder of authorisation for putting that additive into circulation.

(2) Regulation (EC) No 1831/2003 provides for the possibility of modifying 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 feed additive monensin sodium (Coxidin) has submitted an application with which it proposes changing the terms of the authorisation by reducing the withdrawal period before slaughter and by establishing the final Maximum Residue Limits (MRLs).

(4) In its opinion adopted on 18 June 2008[(3)], the Authority concluded, after re-assessing human exposure, that a one-day withdrawal time for Coxidin for chickens for fattening and turkeys could be set. No new data was provided by the holder of the authorisation which would allow the Authority to propose a final MRL.

(5) Regulation (EC) No 109/2007 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:

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 1095/2008. (See end of Document for details)*

Article 1

The Annex to Regulation (EC) No 109/2007 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 1095/2008. (See end of Document for details)*

ANNEX

Identification number of the additive	**Name of the holder of authorisation**	**Additive (Trade name)**	**Composition, chemical formula, description, analytical method**	**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 with a moisture content of 12 %				
Coccidiostats and histomonostats										
5 1701	Huvepharma NV Belgium	Monensin sodium (Coxidin)	*Active substance* $C_{36}H_{61}O_{11}Na$ Sodium salt of polyether monocarboxylic acid produced by *Streptomyces cinnamonensis*, 28682 LMG S-19095 in powder form. Factor composition: Monensin A: not less than 90 % Monensin A + B: not less than 95 %	Chickens for fattening	—	100	125	1. Use prohibited at least one day before slaughter 2. The additive shall be incorporated in compound feedingstuffs in form of a premixture 3. Maximum permitted dose of monensin sodium in complementary feedingstuffs: — 625 mg/kg for chickens for fattening;	6.2.2017	25 µg monensin sodium/kg of wet skin + fat 8 µg monensin sodium/kg of wet liver, wet kidney and wet muscle
				Turkeys	16 weeks	60	100			

a Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives