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)

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:

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

[1] OJ L 268, 18.10.2003, p. 29.
[2] OJ L 31, 6.2.2007, p. 6.
[3] 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 Coxidin for chickens and turkeys for fattening and the re-examination of the provisional Maximum Residue Limit. *The EFSA Journal* (2008) 731, 1-14.

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 1 701	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 % Monensin C: 0,2-0,3 % *Additive composition* Monensin sodium technical substance equivalent to monensin activity: 25 % Perlite: 15-20 % Wheat bran: 55-60 % *Analytical method* (1) Method for determination of the active substance: high performance liquid chromatography (HPLC) with post-column derivatisation and UV detection (λ = 520 nm)	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; — 500 mg/kg for turkeys 4. Monensin sodium shall not be mixed with other coccidiostats 5. 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' 6. Wear suitable protective clothing, gloves and eye/face protection. In case of insufficient ventilation in the premise, wear suitable respiratory equipments	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			

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