COMMISSION REGULATION (EC) No 109/2007

of 5 February 2007

concerning the authorisation of monensin sodium (Coxidin) as a feed additive

(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 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of the preparation set out in the Annex to this Regulation. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) The application concerns authorisation of the substance monensin sodium (Coxidin) as a feed additive for chickens for fattening and turkeys, to be classified in the additive category 'occidiostats and histomonostats'.

(4) The European Food Safety Authority (the Authority) concluded in its opinion of 20 October 2005 that monensin sodium (Coxidin) does not have an adverse effect on animal health, human health or the environment [2]. The Authority further concluded that monensin sodium (Coxidin) does not present any other risk which would, in accordance with Article 5(2) of Regulation (EC) No 1831/2003, exclude authorisation. According to that opinion, the use of that product may be effectively used to prevent coccidiosis. This opinion also verified the report on the method of analysis of that feed additive in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003. The Authority concluded that it was necessary to establish maximum residue limits (MRLs). However, it was unable to propose MRLs since the applicant had not provided the data required. After receiving those data the Authority adopted an opinion proposing provisional MRLs on 21 November 2006 [3]. It may be necessary to review the MRLs set out in the Annex to this Regulation in the light of the results of a future evaluation of the active substance concerned by the European Agency for the Evaluation of Medicinal Products.

(5) The assessment of that preparation shows that the conditions for authorisation, provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised, as specified in the Annex to this Regulation.

(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 substance, specified in the Annex, belonging to the additive category 'coccidiostats and histomonostats', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

[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] Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on a request from the European Commission of the coccidiostat COXIDIN (monensin sodium), adopted on 20 October 2005, The EFSA Journal (2005) 283, p. 1-53.

[3] 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 safety of COXIDIN (monensin sodium), adopted on 12 July 2006, The EFSA Journal (2006) 381, p. 1-10.

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

ANNEX

Registration number of additive	Name and registration number of person responsible for putting additive into circulation	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										
E 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 cinnamonnensis, 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) HPLC method	Chickens for fattening	—	100	125	1. Use prohibited at least three days 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 premises, wear suitable respiratory equipment.	6.2.2017	25 µg monensin sodium/kg of wet skin + fat. 8 µg monensin sodium/kg of wet liver, kidney and muscle.
				Turkeys	16 weeks	90	100			

(1) Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/html/crlfaa/