

COMMISSION REGULATION (EC) No 156/2008
of 21 February 2008
amending Regulation (EC) No 109/2007 as regards the minimum content 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 10 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

which proposes changing the terms of the authorisation by reducing the minimum content of that additive as regards use for turkeys.

- (4) In its opinion adopted on 18 September 2007, the Authority has proposed to reduce the minimum content of the additive for turkeys from 90 mg to 60 mg per kg of complete feedingstuff because it can be considered efficacious in the control of coccidiosis⁽³⁾.
- (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, 21 February 2008.

For the Commission
Markos KYPRIANOU
Member of the Commission

⁽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⁾ OJ L 31, 6.2.2007, p. 6.

⁽³⁾ Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on Efficacy of Coxidin 25 % (monensin sodium) as a feed additive for turkeys. Adopted on 18 September 2007. *The EFSA Journal* (2007) 545, 1-13.

ANNEX

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 food-stuffs of animal origin
						mg of active substance/kg of complete feedstuff with a moisture content of 12 %	mg of active substance/kg of complete feedstuff with a moisture content of 12 %				
Coccidiostats and histomonostats											
5 1 701	Huvepharma NV Belgium	Monensin sodium (Coxidin)	Active substance: $C_{38}H_{61}O_{11}Na$ Sodium salt of polyether monocarboxylic acid produced by <i>Streptomyces cinnamonensis</i> , 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 ($\lambda = 520$ nm).	Chickens for fattening Turkeys	— 16 weeks	100 60	125 100	1. Use prohibited at least three days before slaughter. 2. The additive shall be incorporated in compound feeding-stuffs 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, kidney and muscle.	

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