COMMISSION IMPLEMENTING REGULATION (EU) No 140/2012

of 17 February 2012

concerning the authorisation of monensin sodium as a feed additive for chickens reared for laying (holder of authorisation Huvepharma NV Belgium)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 monensin sodium. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of monensin sodium as a feed additive for chickens reared for laying, to be classified in the additive category 'coccidiostats and histomonostats'.

(4) The use of monensin sodium was authorised for 10 years as a feed additive for use in chickens for fattening and turkeys up to 16 weeks by Commission Regulation (EC) No 109/2007 [2].

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 15 November 2011 [3] that, under the proposed conditions of use, monensin sodium does not have an adverse effect on human health, animal health or the environment, and that its use is efficacious in controlling eimeria infections. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

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

(7) 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 preparation 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 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, 17 February 2012.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 268, 18.10.2003, p. 29.
[2] OJ L 31, 6.2.2007, p. 6.
[3] *EFSA Journal 2011*; 9(12):2442.

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										
51701	Huvepharma NV Belgium	Monensin sodium (Coxidin)	*Additive composition* Monensin sodium technical substance equivalent to monensin activity: 25 % Perlite: 15 %–20 % Calcium carbonate q.s.100 % *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 % *Analytical method* [1] Method for determination of the active substance: high performance liquid chromatography (HPLC) with post-column derivatisation and UV-VIS (EN ISO standard method 14183:2008)	Chickens reared for laying	16 weeks	100	125	1. Use prohibited at least 1 day before slaughter. 2. The additive shall be incorporated in compound feedingstuffs in the form of a premixture. 3. Monensin sodium shall not be mixed with other coccidiostats. 4. 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'. 5. Wear suitable protective clothing, gloves and eye/face protection. In case of insufficient ventilation in the premises, wear suitable respiratory equipment. 6. A post-market monitoring programme on the resistance to *Eimeria* spp. shall be planned and executed by the holder of authorisation.	9 March 2022	25 µg monensin sodium/kg of wet skin + fat 8 µg monensin sodium/kg of wet liver, wet kidney and wet muscle

[1] Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx