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COMMISSION IMPLEMENTING REGULATION (EU) No 388/2011

of 19 April 2011

concerning the authorisation of maduramicin ammonium alpha as a feed additive for chickens for fattening (holder of authorisation Alpharma (Belgium) BVBA) and amending Regulation (EC) No 2430/1999

(Text with EEA relevance)

(OJ L 104, 20.4.2011, p. 3)

Amended by:

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(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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ([2]).

(2) Maduramicin ammonium alpha, CAS number 84878-61-5, was authorised for 10 years in accordance with Directive 70/524/EEC as a feed additive for use on chickens for fattening by Commission Regulation (EC) No 2430/1999 ([3]) and for use on turkeys by Commission Regulation (EC) No 2380/2001 ([4]). That additive was subsequently entered in the Community Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of maduramicin ammonium alpha as a feed additive for chickens for fattening, requesting that additive to be classified in the additive category ‘coccidiostats and histomonostats’. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 9 December 2010 that, under the proposed conditions of use, maduramicin ammonium alpha does not have an adverse effect on animal health, human health or the environment, and that that additive is effective in controlling coccidiosis in chickens for fattening ([5]). The Authority recommends appropriate measures for user safety. It also

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 270, 14.12.1970, p. 1.
([3]) OJ L 296, 17.11.1999, p. 3.
([4]) OJ L 321, 6.12.2001, p. 18.
([5]) EFSA Journal 2011; 9(1):1952.

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verified the report on the method of analysis of the feed additive in feed submitted by the European Union Reference Laboratory for Feed Additives set up by Regulation (EC) No 1831/2003.

(5) The assessment of maduramicin ammonium alpha shows that the conditions for authorisation, as 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) As a consequence of the granting of a new authorisation under Regulation (EC) No 1831/2003, the provisions on maduramicin ammonium alpha in Regulation (EC) No 2430/1999 should be deleted.

(7) Since the modifications on the conditions of the authorisation are not related to safety reasons, it is appropriate to allow a transitional period for the disposal of existing stocks of the premixtures and compound feed.

(8) 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

In Annex I to Regulation (EC) No 2430/1999, the entry under the registration number of additive E 770, concerning Maduramicin ammonium alpha is deleted.

Article 3

Premixtures and compound feed containing maduramicin ammonium alpha labelled in accordance with Directive 70/524/EEC may continue to be placed on the market and used until the existing stocks are exhausted.

Article 4

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.

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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	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 1 770	►**M1** Pfizer Ltd ◄	Maduramicin ammonium alpha 10 g/kg (Cygro 10 G)	*Additive Composition* Maduramicin ammonium alpha: 10 g/kg Carboxymethylcellulose sodium: 20 g/kg Calcium sulphate dihydrate: 970 g/kg *Active substance* Maduramicin ammonium alpha $C_{47}H_{83}O_{17}N$ CAS number: 84878-61-5 (2R, 3S, 4S, 5R, 6S)-6[(1R)-1-[(2S,5R,7S,8R,9S)-2-[2S,2′R,3′S,5R,5′R)-3′-[(2,6-dideoxy-3,4-di-O-methyl-β-L-arabinohexopyranosyl)oxy]-octahydro-2-methyl-5′-[(2S,3S,5R,6S)-tetrahydro-6-hydroxy-3,5,6-trimethyl-2H-pyran-2-yl][2,2′-bifuran]-5-yl]-9-hydroxy-2,8-dimethy-1,6dioxaspirol[4.5]dec-7-yl]ethyl]tetrahydro-2-hydroxy-4,5-dimethoxy-3-	Chickens for fattening	—	5	6	1. The additive shall be incorporated in compound feed in form of a premixture. 2. Maduramicin ammonium alpha shall not be mixed with other coccidiostats. 3. Indicate in the instructions for use: ‘Dangerous for equines’. ‘This feedingstuff contains an ionophore: simultaneous use with certain medicinal substances (e.g. tiamulin) can be contraindicated’. 4. For safety: breathing protection, glasses and gloves shall be used during handling. 5. A post-market monitoring program on the resistance to *Eimeria* spp. shall be planned and executed by the holder of authorisation. 6. The use is prohibited at least 3 days before slaughter	10 May 2021	150 µg of maduramycin ammonium/kg of fresh liver, skin and fat; 100 µg of maduramycin ammonium/kg of fresh kidney; 30 µg of maduramycin ammonium/kg of fresh muscle.

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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	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 %				
			methyl-3H-pyran-2-acetic acid, monoammonium salt produced by a fermentation process by the strain *Actinomadura yumaensis* NRRL 12515: ≥ 90 %. Related impurities: Maduramicin ammonium β: ≤ 1 % *Analytical method* (1) For the determination of maduramicin ammonium alpha in the additive, premixtures and feedingstuffs: reversed-phased high performance liquid chromatography (HPLC) using post-column derivatization with vanillin and detection at 520nm-EN 15781:2009. For the determination of residues of maduramicin ammonium alpha in liver and muscle: reversed-phased high performance liquid chromatography (HPLC) coupled to tandem mass spectrometry.							

(1) Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: www.irmm.jrc.be/eurl-feed-additives