Commission Implementing Regulation (EU) No 406/2011 of 27 April 2011 amending Regulation (EC) No 2380/2001 as regards the composition of the feed additive maduramicin ammonium alpha (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 406/2011

of 27 April 2011

amending Regulation (EC) No 2380/2001 as regards the composition of the feed additive maduramicin ammonium alpha

(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 13(3) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the possibility to modify the authorisation of a feed additive further to a request from the holder of the authorisation and an opinion of the European Food Safety Authority (the Authority).

(2) The use of maduramicin ammonium alpha belonging to the group of coccidiostats and other medicinal substances, was authorised for 10 years in accordance with Council Directive 70/524/EEC[(2)] as a feed additive for the use on chickens for fattening by Commission Regulation (EC) No 2430/1999[(3)] and for turkeys by Commission Regulation (EC) No 2380/2001[(4)].

(3) The holder of the authorisation submitted an application for a modification of the authorisation as regards the composition of the carrier of the feed additive. The holder of the authorisation submitted the relevant data to support its request.

(4) The Authority concluded in its opinion of 8 December 2010[(5)] that the use of this new formulation of the additive on turkeys would not be expected to raise any additional concerns for animal health, human health or the environment and is effective in controlling coccidiosis.

(5) The conditions provided for in Article 5 of Regulation (EC) No 1831/2003 are satisfied.

(6) Regulation (EC) No 2380/2001 should therefore be amended accordingly.

(7) Since the modifications to 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 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 Annex to Regulation (EC) No 2380/2001 is replaced by the Annex to this Regulation.

Article 2

Premixtures and compound feed containing maduramicin ammonium alpha produced in accordance with Regulation (EC) No 2380/2001 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 3

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, 27 April 2011.

For the Commission

The President

José Manuel BARROSO

ANNEX

ANNEX Identification number of the additiveName of the holder of authorisationAdditive(Trade name)Composition, chemical formula, description, analytical methodSpecies or category of animalMaximum ageMinimum contentMaximum contentOther provisionsEnd of period of authorisationmg of active substance/kg of complete feedingstuff with a moisture content of 12 %Coccidiostats and other medicinal substancesE 770Alpharma Belgium BVBAMaduramicin ammoniumalpha 1 g/100 g(Cygro 1 %)Additive compositionMaduramicin ammonium alpha: 1 g/100 gCarboxymethylcellulose sodium: 2 g/100 gCalcium sulphate dihydrate: 97 g/100 gActive substanceMaduramicin ammonium α C47H83O17NCAS number: 84878-61-5, ammonium salt of a polyether monocarboxylic acid produced by a fermentation process by the strain Actinomadura yumaensis (ATCC 31585) (NRRL 12515)Related impurities:Maduramicin ammonium β: < 10 %Turkeys16 weeks551.
Use prohibited at least 5 days before slaughter.
2.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’.
15.12.2011

(**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):1954.

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 406/2011.