COMMISSION REGULATION (EU) No 515/2010

of 15 June 2010

amending Regulation (EC) No 1137/2007 as regards the use of the feed additive *Bacillus subtilis* (O35) in feed containing lasalocid sodium, maduramycin ammonium, monensin sodium, narasin, salinomycin sodium and semduramycin sodium

(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 authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) 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).

(3) The use of the micro-organism preparation of *Bacillus subtilis* DSM 17299 was authorised for 10 years for chickens for fattening by Commission Regulation (EC) No 1137/2007 of 1 October 2007 concerning the authorisation of *Bacillus subtilis* (O35) as a feed additive [2].

(4) The holder of the authorisation submitted an application for a modification of the authorisation of this additive to allow its use in feed containing the coccidiostats lasalocid sodium, maduramycin ammonium, monensin sodium, narasin, salinomycin sodium and semduramycin sodium for chickens for fattening. The holder of the authorisation submitted the relevant data to support its request.

(5) The Authority concluded in its opinion of 10 March 2010 that the additive *Bacillus subtilis* DSM 17299 is compatible with lasalocid sodium, maduramycin ammonium, monensin sodium, narasin, salinomycin sodium and semduramycin sodium [3].

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

(7) Regulation (EC) No 1137/2007 should therefore be amended accordingly.

(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 1137/2007 is replaced by the text in 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, 15 June 2010.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 268, 18.10.2003, p. 29.
[2] OJ L 256, 2.10.2007, p. 5.
[3] *The EFSA Journal* 2010; 8(3):1552 [7 pp.].

ANNEX

'*ANNEX*

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: gut flora stabilisers									
4b1821	Chr. Hansen A/S	*Bacillus subtilis* DSM 17299	Additive composition Preparation of *Bacillus subtilis* DSM 17299 containing a minimum of $1,6 \times 10^9$ CFU/g of additive Characterisation of the active sustance *Bacillus subtilis* DSM 17299 spore concentrate Analytical method (1) Enumeration spread plate method using tryptone soya agar with preheat treatment of feed samples	Chickens for fattening	—	8×10^8	$1,6 \times 10^9$	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. The use is permitted in feed containing the permitted coccidiostats: diclazuril, halofuginone, robenidine, decoquinate, narasin/nicarbazin, lasalocid sodium, maduramycin ammonium, monensin sodium, narasin, salinomycin sodium or semduramycin sodium.	22.10.2017

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