

COMMISSION IMPLEMENTING REGULATION (EU) No 881/2011

of 2 September 2011

amending Regulation (EC) No 1137/2007 as regards the additive composition of the preparation of *Bacillus subtilis* DSM 17299 (holder of authorisation Chr. Hansen A/S) and its use in feed containing formic acid

(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) The preparation of *Bacillus subtilis* DSM 17299, belonging to the additive category of 'zootechnical additives', was authorised for 10 years as a feed additive for use on chickens for fattening by Commission Regulation (EC) No 1137/2007⁽²⁾.
- (2) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, the holder of the authorisation has proposed changing the terms of the authorisation of *Bacillus subtilis* DSM 17299 to modify the additive composition by increasing the minimum concentration and to allow its use in feed for chickens for fattening containing formic acid. The application was accompanied by the relevant supporting data. The Commission forwarded that application to the European Food Safety Authority (hereinafter 'the Authority').

- (3) The Authority concluded in its opinion of 15 March 2011 that the increase of the minimum concentration from $1,6 \times 10^9$ to $1,6 \times 10^{10}$ CFU/g is unlikely to introduce new hazards and that the modified composition is compatible with formic acid. 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.
- (4) The conditions provided for in Article 5 of Regulation (EC) No 1831/2003 are satisfied.
- (5) Regulation (EC) No 1137/2007 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 1137/2007 is amended in accordance with 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, 2 September 2011.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ OJ L 265, 2.10.2007, p. 5.

ANNEX

The Annex to Regulation (EC) No 1137/2007 is replaced by the following:

‘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	<i>Bacillus subtilis</i> DSM 17299	<i>Additive composition:</i> Preparation of <i>Bacillus subtilis</i> DSM 17299 containing a minimum of $1,6 \times 10^{10}$ CFU/g of additive <i>Characterisation of the active substance:</i> <i>Bacillus subtilis</i> DSM 17299 spore concentrate <i>Analytical method</i> ⁽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 one of the following coccidiostats: diclazuril, halo-fuginone, robenidine, decoquinate, narasin/nicarbazin, lasalocid sodium, maduramycin ammonium, monensin sodium, narasin, salinomycin sodium, semduramycin sodium. 3. The compatibility of this additive with formic acid has been shown.	22 October 2017

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx