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COMMISSION REGULATION (EC) No 1137/2007

of 1 October 2007

concerning the authorisation of *Bacillus subtilis* (O35) as a feed additive

(Text with EEA relevance)

(OJ L 256, 2.10.2007, p. 5)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Regulation (EC) No 203/2009 of 16 March 2009	L 71	11	17.3.2009
►M2	Commission Regulation (EU) No 515/2010 of 15 June 2010	L 150	44	16.6.2010
►M3	Commission Implementing Regulation (EU) No 881/2011 of 2 September 2011	L 228	9	3.9.2011
►M4	Commission Implementing Regulation (EU) No 1018/2012 of 5 November 2012	L 307	56	7.11.2012

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COMMISSION REGULATION (EC) No 1137/2007

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concerning the authorisation of *Bacillus subtilis* (O35) as a feed additive

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 the preparation set out in the Annex to this Regulation. 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 the preparation of *Bacillus subtilis* DSM 17299 (O35) as a feed additive for chickens for fattening to be classified in the additive category ‘zootechnical additives’.

(4) The European Food Safety Authority (the Authority) concluded in its opinion of 17 October 2006 that the preparation of *Bacillus subtilis* DSM 17299 (O35) does not have an adverse effect on animal health, human health or the environment ([2]). It further concluded that that preparation does not present any other risk which would, in accordance with Article 5(2) of Regulation (EC) No 1831/2003, exclude authorisation. The opinion of the Authority recommends appropriate measures for user safety. It does not consider that there is a need for specific requirements of post market monitoring. This opinion also verifies the report on the method of analysis of the feed additive in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of that preparation shows that the conditions for authorisation, 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.

([1]) OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).

([2]) Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed and the Scientific Panel on Genetically Modified Organisms on the safety and efficacy of the microbiological product ‘O35’, a preparation of *Bacillus subtilis*, as a feed additive for chickens for fattening in accordance with Regulation (EC) No 1831/2003. Adopted on 17 October 2006. *The EFSA Journal* (2006) 406, p. 1-11.

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(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 preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’, 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.

▼M3

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 $1{,}6 \times 10^{10}$ CFU/g of additive *Characterisation of the active substance:* *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	►M4 —— ◄	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, halofuginone, 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