

COMMISSION IMPLEMENTING REGULATION (EU) 2017/187**of 2 February 2017****concerning the authorisation of a preparation of *Bacillus subtilis* (DSM 28343) as a feed additive for chickens for fattening (holder of authorisation Lactosan GmbH & Co. KG)****(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.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of *Bacillus subtilis* (DSM 28343). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of a preparation of *Bacillus subtilis* (DSM 28343) 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 24 May 2016 ⁽²⁾ that, under the proposed conditions of use, the preparation of *Bacillus subtilis* (DSM 28343) does not have an adverse effect on animal health, human health or the environment, and that it has a potential to improve performance in chickens for fattening. The Authority does not consider that there is a need for specific requirements of post-market monitoring. 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.
- (5) The assessment of the preparation of *Bacillus subtilis* (DSM 28343) 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) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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 twentieth day following that of its publication in the *Official Journal of the European Union*.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2016;14(6):4507.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 2 February 2017.

For the Commission

The President

Jean-Claude JUNKER

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									
4b1825	Lactosan GmbH & Co. KG	Bacillus subtilis (DSM 28343)	<i>Additive composition</i> Preparation of <i>Bacillus subtilis</i> (DSM 28343) containing a minimum of 1 × 10 ¹⁰ CFU/g of additive <i>Solid form</i> <i>Characterisation of the active substance</i> Viable spores of <i>Bacillus subtilis</i> (DSM 28343) <i>Analytical method</i> ⁽¹⁾ Identification and enumeration of <i>Bacillus subtilis</i> (DSM 28343) in the feed additive, premixtures and feedingstuffs — Identification: Pulsed Field Gel Electrophoresis (PFGE) — Enumeration: Spread plate method using tryptone soya agar — EN 15784.	Chickens for fattening	—	1 × 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 following authorised coccidiostats: diclazuril, nicarbazin, decoquinate, lasalocid A sodium, monensin sodium, robenidine hydrochloride, maduramicin ammonium or halofuginone hydrobromide. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection and skin protections.	23 February 2027

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>