COMMISSION IMPLEMENTING REGULATION (EU) 2020/1032

of 15 July 2020

concerning the authorisation of the preparation of *Bacillus subtilis* DSM 28343 as a feed additive for calves for rearing and pigs 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, two applications were submitted for the authorisation of the preparation of *Bacillus subtilis* DSM 28343. Those applications were accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) Those applications concern the authorisation of the preparation of *Bacillus subtilis* DSM 28343 as a feed additive for calves for rearing and pigs for fattening, to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 6 March 2018 ([2]), 4 July 2019 ([3]) and 15 May 2019 ([4]) that, under the proposed conditions of use, the preparation of *Bacillus subtilis* DSM 28343 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive should be considered a potential respiratory sensitiser and no conclusion can be drawn on its potential skin sensitisation. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority concluded that the additive has a significant effect on growth performance in calves for rearing and a potential to increase the body weight gain of pigs 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

Authorisation

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.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2018;16(3):5220.
([3]) *EFSA Journal* 2019;17(7):5793.
([4]) *EFSA Journal* 2019;17(5):5725.

Article 2

Entry into force

This Regulation shall enter into force on the twentieth day following that of 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 July 2020.

For the Commission
The President
Ursula VON DER LEYEN

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	*Additive composition* Preparation of *Bacillus subtilis* DSM 28343 containing a minimum of 1×10^{10} CFU/g of additive Solid form *Characterisation of the active substance* Viable spores of *Bacillus subtilis* DSM 28343 *Analytical method* (1) For identification of *Bacillus subtilis* DSM 28343 in the feed additive, premixtures and feedingstuffs: Pulsed Field Gel Electrophoresis (PFGE) For enumeration of *Bacillus subtilis* DSM 28343 in the feed additive, premixtures and feedingstuffs: Spread plate method using tryptone soya agar – EN 15784	Calves for rearing Pigs for fattening	- -	1×10^9 2×10^8	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The use in calves for rearing shall be restricted to milk replacers. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks from their 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.	5 August 2030

(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