Commission Implementing Regulation (EU) 2018/1079 of 30 July 2018 concerning the authorisation of a preparation of Bacillus subtilis DSM 28343 as a feed additive for weaned piglets (holder of authorisation Lactosan GmbH & Co. KG) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1079

of 30 July 2018

concerning the authorisation of a preparation of *Bacillus subtilis* DSM 28343 as a feed additive for weaned piglets (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) The application concerns the authorisation of a preparation of *Bacillus subtilis* DSM 28343 as a feed additive for weaned piglets to be classified in the additive category ‘zootechnical additives’.

(4) The preparation of *Bacillus subtilis* DSM 28343 belonging to the additive category of ‘zootechnical additives’, was authorised for 10 years as a feed additive for chickens for fattening by Commission Implementing Regulation (EU) 2017/187[(2)].

(5) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 6 March 2018[(3)] 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 the potential to increase the weight, weight gain or feed to gain ratio of weaned piglets. 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.

(6) 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.

(7) 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*.

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

Done at Brussels, 30 July 2018.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1079. (See end of Document for details)*

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*[a] *For identification* of *Bacillus subtilis* DSM 28343	Piglets (weaned)	—	1×10^{9}	—	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For use in weaned piglets up to 35 kg of body weight. 3. For users of the additive and premixtures, feed business operators shall establish	20.8.2028

a 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