Commission Implementing Regulation (EU) 2017/219 of 8 February 2017 concerning the authorisation of a preparation of Bacillus subtilis (DSM 27273) as a feed additive for weaned piglets and weaned minor porcine species (holder of authorisation Chr. Hansen A/S) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/219

of 8 February 2017

concerning the authorisation of a preparation of *Bacillus subtilis* (DSM 27273) as a feed additive for weaned piglets and weaned minor porcine species (holder of authorisation Chr. Hansen A/S)

(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 27273). 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 27273) as a feed additive for weaned piglets and weaned minor porcine species to be classified in the additive category ‘zootechnical additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 20 October 2015[(2)] that, under the proposed conditions of use, the preparation of *Bacillus subtilis* (DSM 27273) does not have an adverse effect on animal health, human health or the environment. It was also concluded that the preparation has a potential to improve performance in weaned piglets. This conclusion can be extrapolated to weaned minor porcine species when the additive is used at the same dose. 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 27273) 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*.

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

Done at Brussels, 8 February 2017.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/219. (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, category of animal**	**Maximum age**	**Minimum content**	**Maximum content**	**Other provisions**	**End of period of authorisation**
						CFU/Units of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: gut flora stabilisers									
4b1826	Chr. Hansen A/S	*Bacillus subtilis* DSM 27273	*Additive composition* Preparation of *Bacillus subtilis* DSM 27273 containing a minimum of $1{,}6 \times 10^9$ CFU/g of additive Solid form *Characterisation of the active substance* Viable spores of *Bacillus subtilis* DSM 27273 *Analytical method*[a] Identification and enumeration of *Bacillus*	Weaned piglets	—	4×10^8	—	1. In the directions for use of the additive and premixtures, indicate the storage temperature, storage life and stability to pelleting. 2. For use in weaned piglets up to 35 kg of body weight. For users of the additive and premixtures, feed business operators shall	1 March 2027
				Weaned minor porcine species	—	4×10^8			

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