Commission Implementing Regulation (EU) 2020/1760 of 25 November 2020 concerning the authorisation of the preparation of Bacillus subtilis DSM 25841 as a feed additive for all porcine species, including sows, other than lactating sows in order to have a benefit in suckling piglets (holder of authorisation Chr. Hansen A/S) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1760

of 25 November 2020

concerning the authorisation of the preparation of *Bacillus subtilis* DSM 25841 as a feed additive for all porcine species, including sows, other than lactating sows in order to have a benefit in suckling piglets (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, two applications were submitted for the authorisation of the preparation of *Bacillus subtilis* DSM 25841. Those applications were accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) The applications concern the authorisation of the preparation of *Bacillus subtilis* DSM 25841 as a feed additive for all porcine species, including sows, other than lactating sows in order to have a benefit in suckling piglets to be classified in the additive category ‘zootechnical additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 20 February 2018[(2)], 4 October 2019[(3)] and 4 October 2019[(4)], under the proposed conditions of use, the preparation of *Bacillus subtilis* DSM 25841 does not have an adverse effect on animal health, consumer safety or the environment. It also stated that this preparation should be considered a potential respiratory sensitiser and that it cannot conclude on its irritancy potential to skin and eyes or its dermal 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 also concluded that the preparation has the potential to be efficacious in improving zootechnical parameters in the target species. 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 25841 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.

(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.

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, 25 November 2020.

For the Commission

The President

Ursula VON DER LEYEN

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1760. (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**	**Minimum content**	**Maximum content**	**Other provisions**	**End of period of authorisation**
						CFU/kg of complete feedingstuff with a moisture content of 12 %		**CFU/l of water for drinking**			
Category of zootechnical additives. Functional group: gut flora stabilisers											
4b1900	Chr. Hansen A/S	*Bacillus subtilis* DSM 25841	*Additive composition* Preparation of *Bacillus subtilis* DSM 25841 containing a minimum of 1,25 × 10^{10} CFU/g of additive Solid form	All porcine species, including sows, other than lactating sows in order to have a benefit in suckling piglets	—	5 × 10^{8}	—	1,7 × 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 additive may be used in water for drinking. 3. For use of the additive in water for	16.12.2030
			Characterisation of the active substance Viable spores of *Bacillus subtilis* DSM 25841								
			Analytical method[a] For identification of *Bacillus*								

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