# Commission Implementing Regulation (EU) 2017/2308 of 13 December 2017 concerning the authorisation of the preparation of Bacillus subtilis (DSM 5750) and Bacillus licheniformis (DSM 5749) as a feed additive for suckling piglets (holder of authorisation Chr. Hansen A/S) (Text with EEA relevance)

## COMMISSION IMPLEMENTING REGULATION (EU) 2017/2308

of 13 December 2017

concerning the authorisation of the preparation of *Bacillus subtilis* (DSM 5750) and *Bacillus licheniformis* (DSM 5749) as a feed additive for 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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[(2)].

(2) The preparation of *Bacillus subtilis* (DSM 5750) and *Bacillus licheniformis* (DSM 5749) was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive, for pigs for fattening and piglets by Commission Regulation (EC) No 2148/2004[(3)]. That preparation was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003. That preparation was authorised for 10 years for weaned piglets, pigs for fattening, sows, calves for rearing and turkeys for fattening by Commission Implementing Regulation (EU) 2017/447[(4)].

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of the preparation of *Bacillus subtilis* (DSM 5750) and *Bacillus licheniformis* (DSM 5749) as a feed additive for piglets. The application was also for the assessment of this preparation for a new use in water for drinking. The applicant requested that additive to be classified in the additive category ‘zootechnical additives’. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 12 July 2016[(5)] that, under the proposed conditions of use, the preparation of *Bacillus subtilis* (DSM 5750) and *Bacillus licheniformis* (DSM 5749) does not have an adverse effect on animal health, human health or the environment. The Authority considered that the additive has the potential to improve weight gain in suckling piglets when used in feed or in water for drinking. 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 5750) and *Bacillus licheniformis* (DSM 5749) 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.

*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, 13 December 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) 2017/2308. (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 | | | | | | | | | | | |
| 4b1700i | Chr. Hansen A/S | *Bacillus subtilis* (DSM 5750) and *Bacillus licheniformis* (DSM 5749) | *Additive composition* Preparation of *Bacillus subtilis* (DSM 5750) and *Bacillus licheniformis* (DSM 5749) containing a minimum of $3,2 \times 10^{10}$ CFU/g of additive (1:1 ratio) Solid form *Characterisation of the active substance* Viable spores of *Bacillus subtilis* (DSM 5750) and *Bacillus licheniformis* | Suckling piglets | — | $1,3 \times 10^{9}$ | — | $6,5 \times 10^{8}$ | — | 1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.<br>2. The additive may be used in water for drinking.<br>3. For use of the additive in water for | 3 January 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