



2023/2647

29.11.2023

COMMISSION IMPLEMENTING REGULATION (EU) 2023/2647

of 28 November 2023

concerning the authorisation of the preparation of *Bacillus subtilis* DSM 5750 and *Bacillus paralicheniformis* DSM 5749 as a feed additive for calves for fattening, lambs for rearing and for fattening and minor ruminant species for rearing and for fattening, and amending Implementing Regulation (EU) 2017/2308 as regards the terms of the authorisation of that preparation 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) and Article 13(3) 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 an authorisation.
- (2) Commission Implementing Regulation (EU) 2017/2308 ⁽²⁾ authorised the use of the preparation of *Bacillus subtilis* (DSM 5750) and *Bacillus licheniformis* (DSM 5749) as a feed additive for suckling piglets for a 10-year period.
- (3) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted on 15 October 2019 for the authorisation of new uses of the preparation of *Bacillus subtilis* DSM 5750 and *Bacillus licheniformis* DSM 5749 as a feed additive for piglets, other minor growing and reproductive porcine species, calves for fattening and other growing ruminants, turkeys for breeding and other minor poultry species, to be classified in the category 'zootechnical additives' and in the functional group 'gut flora stabilisers'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The applicant withdrew the request for authorisation for other minor growing and reproductive porcine species, turkeys for breeding and other minor poultry species. He also clarified that, as regards piglets, the application was actually seeking to allow for an independent use of the preparation in sows and suckling piglets, which consists in a request for modification of the terms of the authorisation granted by Implementing Regulation (EU) 2017/2308.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 31 January 2023 ⁽³⁾ that, under the proposed conditions of use, the preparation of *Bacillus subtilis* DSM 5750 and *Bacillus paralicheniformis* DSM 5749 (previously taxonomically identified as *Bacillus licheniformis* DSM 5749) is considered safe for the target species, consumers and the environment. It also concluded that that preparation should be considered a potential respiratory sensitiser. In the absence of validated assays to assess microorganisms, it could not conclude on the skin sensitisation potential of the preparation. The Authority further established that the conclusions on efficacy of the additive drawn in its opinion of 12 July 2016 ⁽⁴⁾ for weaned piglets and calves for rearing can be extended to suckling piglets, calves for fattening and other growing ruminants. It did not consider that there is a need for specific requirements of post-market monitoring. The Authority also verified the report on the methods of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ 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) (OJ L 331, 14.12.2017, p. 19).

⁽³⁾ EFSA Journal 2023;21(3):7859.

⁽⁴⁾ EFSA Journal 2016;14(9):4558.

- (6) In view of the above, the Commission considers that the preparation of *Bacillus subtilis* DSM 5750 and *Bacillus paralicheniformis* DSM 5749 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003 as regards the new uses of that preparation for calves for fattening, lambs for rearing and for fattening, and minor ruminant species for rearing and for fattening. Accordingly, those uses of the preparation should be authorised. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (7) The Commission also considers that the authorisation of the preparation of *Bacillus subtilis* (DSM 5750) and *Bacillus licheniformis* (DSM 5749) still meets the conditions provided for in Article 5 of Regulation (EC) No 1831/2003 when modifying the terms thereof as regards suckling piglets, by making the simultaneous feeding of sows and suckling piglets with that preparation a recommendation instead of an obligation. Implementing Regulation (EU) 2017/2308 should therefore be amended accordingly. Since safety reasons do not require the immediate application of the modification to the conditions of authorisation of that preparation for suckling piglets, it is appropriate to provide for a transitional period for the interested parties to prepare themselves to meet that modification to the terms of the authorisation.
- (8) 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 for calves for fattening, lambs for rearing and for fattening, and minor ruminant species for rearing and for fattening, subject to the conditions laid down in that Annex.

Article 2

Amendment to Implementing Regulation (EU) 2017/2308

In the Annex to Implementing Regulation (EU) 2017/2308, the provision number 4 in the column 'other provisions' is replaced by the following:

'4. Indicate in the instructions for use:

"It is recommended to feed the additive to lactating sows and suckling piglets simultaneously."

Article 3

Transitional measures concerning the amendment to Implementing Regulation (EU) 2017/2308

1. The preparation of *Bacillus subtilis* (DSM 5750) and *Bacillus licheniformis* (DSM 5749) for use for suckling piglets and premixtures containing that preparation, which are produced and labelled before 19 June 2024 in accordance with the rules applicable before 19 December 2023 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the preparation referred to in paragraph 1 for use for suckling piglets, which are produced and labelled before 19 December 2024 in accordance with the rules applicable before 19 December 2023 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 4

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, 28 November 2023.

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	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 stabiliser											
4b1700i	Chr. Hansen A/S	<i>Bacillus subtilis</i> DSM 5750 and <i>Bacillus paralicheniformis</i> DSM 5749	<i>Additive composition</i> Preparation of <i>Bacillus subtilis</i> DSM 5750 and <i>Bacillus paralicheniformis</i> DSM 5749 containing a minimum of $3,2 \times 10^{10}$ CFU/g of additive (1:1 ratio) <i>Solid form</i> <i>Characterisation of the active substance</i> Viable spores of <i>Bacillus subtilis</i> DSM 5750 and <i>Bacillus paralicheniformis</i> DSM 5749	Calves for fattening Lambs for rearing and for fattening Minor ruminant species for rearing and for fattening	—	$1,3 \times 10^9$	—	$6,5 \times 10^8$	—	<div>1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.</div> <div>2. The additive may be used in water for drinking.</div> <div>3. For use of the additive in water for drinking, a homogeneous dispersion of the additive shall be ensured.</div>	19 December 2033

			<p>Analytical method ⁽¹⁾ Identification and enumeration of <i>Bacillus subtilis</i> DSM 5750 and <i>Bacillus paralicheniformis</i> DSM 5749 in the feed additive, premixtures, compound feed and water:</p> <ul style="list-style-type: none"> — For the identification: Pulsed Field Gel Electrophoresis (PFGE) CEN/TS 17697 or DNA sequencing methods — For the enumeration: Spread plate method using tryptone soya agar EN 15784. 							<p>4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment.</p>	
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⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en