



2025/1468

23.7.2025

**COMMISSION IMPLEMENTING REGULATION (EU) 2025/1468**

**of 22 July 2025**

**concerning the authorisation of a preparation of *Bacillus subtilis* DSM 33862 and *Lentilactobacillus buchneri* DSM 12856 as a feed additive for all animal species**

(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 <sup>(1)</sup>, 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 33862 and *Lentilactobacillus buchneri* DSM 12856. 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 the preparation of *Bacillus subtilis* DSM 33862 and *Lentilactobacillus buchneri* DSM 12856 as a feed additive for all animal species, requesting that additive to be classified in the category 'technological additives' and in the functional group 'silage additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 15 October 2024 <sup>(2)</sup> that the additive consisting of a preparation of *Bacillus subtilis* DSM 33862 and *Lentilactobacillus buchneri* DSM 12856 is safe for all animal species, consumers and the environment. It also concluded that the additive is not an irritant to the skin but should be considered as a potential skin and respiratory sensitiser, and any exposure through skin and respiratory tract is considered a risk. The latter conclusion would apply to any preparations containing the active agents. The Authority further concluded that the addition of the additive at a minimum level of  $1 \times 10^8$  CFU/kg fresh plant material has the potential to improve the aerobic stability of silage from fresh plant material, with a dry matter range between 32 % and 65 %.
- (5) In view of the above, the Commission considers that the preparation of *Bacillus subtilis* DSM 33862 and *Lentilactobacillus buchneri* DSM 12856 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that 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.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

<sup>(2)</sup> EFSA Journal 22(11), e9070. <https://doi.org/10.2903/j.efsa.2024.9070>.

HAS ADOPTED THIS REGULATION:

*Article 1*

**Authorisation**

The preparation specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'silage additives', 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, 22 July 2025.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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ANNEX

Identification number of the feed additive	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 fresh material			
Category: technological additives. Functional group: silage additives								
1k1802	<i>Bacillus subtilis</i> DSM 33862 and <i>Lentilactobacillus buchneri</i> DSM 12856	<i>Additive composition</i>  Preparation of <i>Bacillus subtilis</i> DSM 33862 and <i>Lentilactobacillus buchneri</i> DSM 12856 containing a minimum of 3,6 × 10 <sup>11</sup> CFU/g additive with a ratio 1:4 (7,2 × 10 <sup>10</sup> CFU <i>Bacillus subtilis</i> DSM 33862/g and 2,88 × 10 <sup>11</sup> CFU <i>Lentilactobacillus buchneri</i> DSM 12856/g)  Solid form  <i>Characterisation of the active substance</i>  Viable cells of <i>Bacillus subtilis</i> DSM 33862 and <i>Lentilactobacillus buchneri</i> DSM 12856  <i>Analytical method</i> <sup>(1)</sup>  Identification of <i>Bacillus subtilis</i> DSM 33862 and <i>Lentilactobacillus buchneri</i> DSM 12856:  — DNA sequencing methods or Pulsed Field Gel Electrophoresis (PFGE) (CEN/TS 17697)  — Enumeration of <i>Bacillus subtilis</i> DSM 33862 in the feed additive: Spread plate method on tryptone soya agar (EN 15784)	All animal species	-	-	-	<div><div>1.</div><div>In the directions for use of the additive and premixtures, the storage conditions shall be indicated.</div></div> <div><div>2.</div><div>Minimum dose of the additive when it is not used in combination with other micro-organisms as silage additives: 1 × 10<sup>8</sup> CFU/kg fresh plant material.</div></div> <div><div>3.</div><div>The additive shall only be used with easy and moderately difficult to ensile fresh plant material <sup>(2)</sup>.</div></div> <div><div>4.</div><div>On the label of the additive and premixtures the following shall be indicated: 'It is recommended to use the additive 1k1802 only with fresh plant material with a dry matter range 32-65 %.'</div></div>	12.8.2035

Identification number of the feed additive	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 fresh material			
Category: technological additives. Functional group: silage additives								
		— Enumeration of <i>Lentilactobacillus buchneri</i> DSM 12856 in the feed additive: Spread plate (or pour plate) method on MRS agar (EN 15787)					5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin and breathing protective equipment.	

(<sup>1</sup>) 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](https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en).

(<sup>2</sup>) Easy to ensile forage: > 3 % soluble carbohydrates in fresh material; moderately difficult to ensile forage: 1,5-3,0 % soluble carbohydrates in the fresh material in accordance with Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1, <http://data.europa.eu/eli/reg/2008/429/oj>).