



**COMMISSION IMPLEMENTING REGULATION (EU) 2025/359**

**of 21 February 2025**

**concerning the authorisation of a preparation of *Lactococcus lactis* DSM 34262 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 an authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of *Lactococcus lactis* DSM 34262. 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 *Lactococcus lactis* DSM 34262 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 26 June 2024 <sup>(2)</sup> that *Lactococcus lactis* DSM 34262 and the formulated additive are safe for all animal species, consumers and the environment. Regarding user safety, the additive should be considered as a potential skin and respiratory sensitiser, and any exposure through skin and respiratory tract is considered a risk. One preparation was shown not to be irritant to skin or eyes. The addition of *Lactococcus lactis* DSM 34262 at a minimum level of  $1 \times 10^8$  CFU/kg fresh plant material has the potential to improve the production of silage from fresh material with a DM content ranging from 30 % to 35 %. The Authority 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) In view of the above, the Commission considers that the preparation of *Lactococcus lactis* DSM 34262 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 2024; 22:e8902.

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, 21 February 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 |                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                               |             |                          |                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                |
| 1k2084                                                                | <i>Lactococcus lactis</i> DSM 34262 | <p><i>Additive composition</i></p> <p>Preparation of <i>Lactococcus lactis</i> DSM 34262 containing a minimum of 3 × 10<sup>11</sup> CFU/g additive</p> <p>Solid form</p> <hr/> <p><i>Characterisation of the active substance</i></p> <p>Viable cells of <i>Lactococcus lactis</i> DSM 34262</p> <hr/> <p><i>Analytical method</i> <sup>(1)</sup></p> <p>Enumeration in the feed additive of <i>Lactococcus lactis</i> DSM 34262:</p> <p>— Pour-plate method on MRS agar (ISO 15214)</p> <p>Identification of <i>Lactococcus lactis</i> DSM 34262:</p> <p>— Pulsed Field Gel Electrophoresis (PFGE) – CEN/TS 17697 or DNA sequencing methods</p> | All animal species            | —           | —                        | —               | <p>1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated.</p> <p>2. The additive shall only be used with easy and moderately difficult to ensile fresh plant material <sup>(2)</sup>.</p> <p>3. Minimum dose of the additive when it is not used in combination with other micro-organisms as silage additives: 1x10<sup>8</sup> CFU/kg fresh material.</p> <p>4. If used as a cryoprotectant, polyethylene glycol (PEG 4000) shall be used up to a maximum concentration of 0,025 mg/kg silage.</p> <p>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures</p> | 16 March 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 |          |                                                               |                               |             |                          |                 |                                                                                                                                                                                                                                         |                                |
|                                                                       |          |                                                               |                               |             |                          |                 | to address the 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, eye 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, ELI: <http://data.europa.eu/eli/reg/2008/429/oj>).