



2025/2497

11.12.2025

**COMMISSION IMPLEMENTING REGULATION (EU) 2025/2497
of 10 December 2025**

concerning the authorisation of preparations of *Enterococcus faecium* DSM 33761, *Pediococcus acidilactici* DSM 33758, *Bifidobacterium animalis* DSM 16284, *Limosilactobacillus reuteri* DSM 33751 and *Ligilactobacillus salivarius* DSM 16351 as a feed additive for poultry for fattening and reared for laying or reproduction (holder of authorisation: Biomin GmbH)

(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 an authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of preparations of *Enterococcus faecium* DSM 33761, *Pediococcus acidilactici* DSM 33758, *Bifidobacterium animalis* DSM 16284, *Limosilactobacillus reuteri* DSM 33751 and *Ligilactobacillus salivarius* DSM 16351. 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 preparations of *Enterococcus faecium* DSM 33761, *Pediococcus acidilactici* DSM 33758, *Bifidobacterium animalis* DSM 16284, *Limosilactobacillus reuteri* DSM 33751 and *Ligilactobacillus salivarius* DSM 16351 as a feed additive for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and minor poultry species for fattening and reared for laying or breeding, requesting that additive to be classified in the additive category 'zootechnical additives' and in the functional group 'gut flora stabilisers'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 26 September 2023 ⁽²⁾ that, under the proposed conditions of use, the preparations of *Enterococcus faecium* DSM 33761, *Pediococcus acidilactici* DSM 33758, *Bifidobacterium animalis* DSM 16284, *Limosilactobacillus reuteri* DSM 33751 and *Ligilactobacillus salivarius* DSM 16351 are safe for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and minor poultry species for fattening and reared for laying or breeding, as well as for consumers and the environment. The Authority also concluded that the preparation of *Enterococcus faecium* DSM 33761, *Pediococcus acidilactici* DSM 33758, *Bifidobacterium animalis* DSM 16284, *Limosilactobacillus reuteri* DSM 33751 and *Ligilactobacillus salivarius* DSM 16351 in both formulations is considered respiratory sensitiser but it is not irritant to the skin. No conclusion could be made on the potential of the additive to be an eye irritant or dermal sensitiser. After the assessment of supplementary information submitted by the applicant, the Authority concluded in its opinion of 6 May 2025 ⁽³⁾ that the preparation of *Enterococcus faecium* DSM 33761, *Pediococcus acidilactici* DSM 33758, *Bifidobacterium animalis* DSM 16284, *Limosilactobacillus reuteri* DSM 33751 and *Ligilactobacillus salivarius* DSM 16351 has the potential to be efficacious in all poultry for fattening and reared for laying or breeding at 1×10^8 CFU/kg complete feed and 5×10^7 CFU/L water for drinking. The Authority did not consider that there is a need for specific requirements of post-market monitoring.

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

⁽²⁾ EFSA Journal 2023;21(10):8354. <https://doi.org/10.2903/j.efsa.2023.8354>.

⁽³⁾ EFSA Journal. 2025;23:e9459. <https://doi.org/10.2903/j.efsa.2025.9459>.

- (5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in a previous assessment concerning another application for the authorisation of the same additive and verified by the Authority in its opinion of 26 September 2023² are valid and applicable for the current application. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005 ⁽⁴⁾, an evaluation report of the Reference Laboratory was therefore not required.
- (6) In view of the above, the Commission considers that the preparations of *Enterococcus faecium* DSM 33761, *Pediococcus acidilactici* DSM 33758, *Bifidobacterium animalis* DSM 16284, *Limosilactobacillus reuteri* DSM 33751 and *Ligilactobacillus salivarius* DSM 16351 satisfy the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of these preparations should be authorised for poultry for fattening and reared for laying or reproduction. 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 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 preparations specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', are 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, 10 December 2025.

For the Commission

The President

Ursula VON DER LEYEN

⁽⁴⁾ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

ANNEX

PART I

Identification number of the feed additive	Name of the holder of authorisation	Name of the 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 complete feed with a moisture content of 12 %			
Category: zootechnical additives. Functional group: gut flora stabilisers.									
4b1897	Biomin GmbH	<i>Enterococcus faecium</i> DSM 33761, <i>Pediococcus acidilactici</i> DSM 33758, <i>Bifidobacterium animalis</i> DSM 16284, <i>Limosilactobacillus reuteri</i> DSM 33751 and <i>Ligilactobacillus salivarius</i> DSM 16351	Additive composition Preparation of <i>Enterococcus faecium</i> DSM 33761, <i>Pediococcus acidilactici</i> DSM 33758, <i>Bifidobacterium animalis</i> DSM 16284, <i>Limosilactobacillus reuteri</i> DSM 33751 and <i>Ligilactobacillus salivarius</i> DSM 16351 containing a minimum of: 4 × 10 ¹⁰ CFU/g (total) with a minimum of bacterial concentration of 1,3 x 10 ¹⁰ <i>Enterococcus faecium</i> DSM 33761 1,3 x 10 ¹⁰ <i>Pediococcus acidilactici</i> DSM 33758 1,2 x 10 ¹⁰ <i>Bifidobacterium animalis</i> DSM 16284; 1,0 x 10 ⁹ <i>Limosilactobacillus reuteri</i> DSM 33751 and 1,0 x 10 ⁹ <i>Ligilactobacillus salivarius</i> DSM 16351.	Poultry for fattening and reared for laying or reproduction	-	1 × 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 simultaneously with the following coccidiostats, in accordance with their respective conditions of authorisation as feed additives: nicarbazin, diclazuril, decoquinone or halofuginone. 3. 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 breathing, eye and skin protective equipment.	31 December 2035

Identification number of the feed additive	Name of the holder of authorisation	Name of the 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 complete feed with a moisture content of 12 %			
			Solid coated form <i>Characterisation of the active substance</i> Viable cells of <i>Enterococcus faecium</i> DSM 33761, <i>Pediococcus acidilactici</i> DSM 33758, <i>Bifidobacterium animalis</i> DSM 16284, <i>Limosilactobacillus reuteri</i> DSM 33751 and <i>Ligilactobacillus salivarius</i> DSM 16351. <i>Analytical method ⁽¹⁾</i> For the identification of <i>Enterococcus faecium</i> DSM 33761, <i>Pediococcus acidilactici</i> DSM 33758, <i>Bifidobacterium animalis</i> DSM 16284, <i>Limosilactobacillus reuteri</i> DSM 33751 and <i>Ligilactobacillus salivarius</i> DSM 16351: — DNA sequencing methods or Pulsed-Field Gel Electrophoresis (PFGE)-CEN/TS 17697 For the enumeration of <i>Enterococcus faecium</i> DSM 33761 in the feed additive, premixtures and compound feed: — Spread plate (or pour plate) method on bile esculin azide agar or on Slanetz and Bartley agar (EN 15788)						

Identification number of the feed additive	Name of the holder of authorisation	Name of the 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 complete feed with a moisture content of 12 %			
			For the enumeration of <i>Pediococcus acidilactici</i> DSM 33758 in the feed additive, premixtures and compound feed: — Spread plate (or pour plate) method on MRS agar (EN 15786) For the enumeration of <i>Bifidobacterium animalis</i> DSM 16284 in the feed additive, premixtures and compound feed: — Spread plate (or pour plate) method on MRS agar (EN 15785) For the enumeration of <i>Limosilactobacillus reuteri</i> DSM 33751 and <i>Ligilactobacillus salivarius</i> DSM 16351 in the feed additive, premixtures and compound feed: — Spread plate (or pour plate) method on MRS agar (EN 15787)						

(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.

PART II

Identification number of the feed additive	Name of the holder of authorisation	Name of the 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/l of water for drinking			
Category: zootechnical additives. Functional group: gut flora stabilisers.									
4b1897i	Biomin GmbH	<i>Enterococcus faecium</i> DSM 33761, <i>Pediococcus acidilactici</i> DSM 33758, <i>Bifidobacterium animalis</i> DSM 16284, <i>Limosilactobacillus reuteri</i> DSM 33751 and <i>Ligilactobacillus salivarius</i> DSM 16351	Additive composition Preparation of <i>Enterococcus faecium</i> DSM 33761, <i>Pediococcus acidilactici</i> DSM 33758, <i>Bifidobacterium animalis</i> DSM 16284, <i>Limosilactobacillus reuteri</i> DSM 33751 and <i>Ligilactobacillus salivarius</i> DSM 16351 containing a minimum of: 1 × 10 ¹¹ CFU/g (total) with a minimum of bacterial concentration of 3,25 × 10 ¹⁰ <i>Enterococcus faecium</i> DSM 33761 3,25 × 10 ¹⁰ <i>Pediococcus acidilactici</i> DSM 33758 3,0 × 10 ¹⁰ <i>Bifidobacterium animalis</i> DSM 16284; 2,0 × 10 ⁹ <i>Limosilactobacillus reuteri</i> DSM 33751 and 2,0 × 10 ⁹ <i>Ligilactobacillus salivarius</i> DSM 16351. Solid (non coated) form	Poultry for fattening and reared for laying or reproduction	-	5 × 10 ⁷	-	1. In the directions for use of the additive, the storage conditions and the stability in water for drinking shall be indicated. 2. The additive shall be used via water for drinking. 3. The additive may be used simultaneously with the following coccidiostats, in accordance with their respective conditions of authorisation as feed additives: nicarbazin, diclazuril, decoquinate or halofuginone. 4. 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	31 December 2035

Identification number of the feed additive	Name of the holder of authorisation	Name of the 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/l of water for drinking			
			<i>Characterisation of the active substance</i> Viable cells of <i>Enterococcus faecium</i> DSM 33761, <i>Pediococcus acidilactici</i> DSM 33758, <i>Bifidobacterium animalis</i> DSM 16284, <i>Limosilactobacillus reuteri</i> DSM 33751 and <i>Ligilactobacillus salivarius</i> DSM 16351. <i>Analytical method ⁽¹⁾</i> For the identification of <i>Enterococcus faecium</i> DSM 33761, <i>Pediococcus acidilactici</i> DSM 33758, <i>Bifidobacterium animalis</i> DSM 16284, <i>Limosilactobacillus reuteri</i> DSM 33751 and <i>Ligilactobacillus salivarius</i> DSM 16351: — DNA sequencing methods or Pulsed-Field Gel Electrophoresis (PFGE)-CEN/TS 17697 For the enumeration of <i>Enterococcus faecium</i> DSM 33761 in the feed additive, premixtures, compound feed and water for drinking: — Spread plate (or pour plate) method on bile esculin azide agar or on Slanetz and Bartley agar (EN 15788)					procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identification number of the feed additive	Name of the holder of authorisation	Name of the 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/l of water for drinking			
			For the enumeration of <i>Pediococcus acidilactici</i> DSM 33758 in the feed additive, premixtures, compound feed and water for drinking: — Spread plate (or pour plate) method on MRS agar (EN 15786) For the enumeration of <i>Bifidobacterium animalis</i> DSM 16284 in the feed additive, premixtures, compound feed and water for drinking: — Spread plate (or pour plate) method on MRS agar (EN 15785) For the enumeration of <i>Limosilactobacillus reuteri</i> DSM 33751 and <i>Ligilactobacillus salivarius</i> DSM 16351 in the feed additive, premixtures, compound feed and water for drinking: — Spread plate (or pour plate) method on MRS agar (EN 15787)						

(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.