



Brussels, **XXX**
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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the authorisation of a preparation 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)

COMMISSION IMPLEMENTING REGULATION (EU) .../...

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concerning the authorisation of a preparation 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 nutrition¹, 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 *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 preparation 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 2023² that, under the proposed conditions of use, the preparation of *Enterococcus faecium* DSM 33761, *Pediococcus acidilactici* DSM 33758, *Bifidobacterium animalis* DSM 16284, *Limosilactobacillus reuteri* DSM 33751 and *Ligilactobacillus salivarius* DSM 16351 is 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*

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>

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 2025³ 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.

- (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 378/2005⁴, an evaluation report of the Reference Laboratory was therefore not required.
- (6) In view of the above, the Commission considers 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 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation 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 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*.

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

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>).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN