



2025/1465

23.7.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/1465

of 22 July 2025

concerning the authorisation of a preparation of *Enterococcus faecium* ATCC 53519 and a preparation of *Enterococcus faecium* ATCC 55593 as feed additives 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 ⁽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. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾. Article 10(7) of Regulation (EC) No 1831/2003 sets out specific provisions for the placing on the market and use of products used in the Union as silage additives.
- (2) In accordance with Article 10(1), point (b), of Regulation (EC) No 1831/2003, the preparations of *Enterococcus faecium* ATCC 53519 and *Enterococcus faecium* ATCC 55593 were entered in the Register of Feed Additives under the names *Enterococcus faecium* SF202-DSM 4788-ATCC 53519 and *Enterococcus faecium* SF301-DSM 4789-ATCC 55593 respectively, as existing products belonging to the functional group of silage additives, for all animal species.
- (3) In accordance with Article 10(7) of Regulation (EC) No 1831/2003, in conjunction with Article 7 and Article 10(2) thereof, applications were submitted for the authorisation of the preparations of *Enterococcus faecium* ATCC 53519 and *Enterococcus faecium* ATCC 55593 as feed additives for all animal species, requesting those additives to be classified in the category 'technological additives' and in the functional group 'silage additives'. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 1 October 2013 ⁽³⁾, that the use of *Enterococcus faecium* ATCC 53519 and *Enterococcus faecium* ATCC 55593 is safe for all animal species, consumers and the environment. It also concluded that in the absence of evidence, these additives should be regarded as skin and eye irritants and potential skin sensitisers. Given the proteinaceous nature of the active agents, the Authority considers it prudent to treat these additives as respiratory sensitisers. Also, due to the high dusting potential of most of the preparations tested the Authority concluded that there is a need to take measures to minimise inhalation exposure of workers. The Authority could not conclude on the efficacy of these additives. In the subsequent opinions of 27 September 2022 ⁽⁴⁾, 4 July 2023 ⁽⁵⁾ and 15 October 2024 ⁽⁶⁾ the Authority reached the conclusion that the use of *Enterococcus faecium* ATCC 53519 and *Enterococcus faecium* ATCC 55593 in all types of fresh plant materials has the potential to be efficacious in improving the nutrient preservation of silage at the proposed conditions of use.

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

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1, ELI: <http://data.europa.eu/eli/dir/1970/524/oj>).

⁽³⁾ EFSA Journal 2013; 11 (10):3363; <https://doi.org/10.2903/j.efsa.2013.3363>.

⁽⁴⁾ EFSA Journal 2022; 20(10):7603; <https://doi.org/10.2903/j.efsa.2022.7603>.

⁽⁵⁾ EFSA Journal 2023; 21(7):8166; <https://doi.org/10.2903/j.efsa.2023.8166>.

⁽⁶⁾ EFSA Journal, 22(11), e9071. <https://doi.org/10.2903/j.efsa.2024.9071>.

- (5) In view of the above, the Commission considers that the preparations of *Enterococcus faecium* ATCC 53519 and *Enterococcus faecium* ATCC 55593 satisfy the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of those preparations 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,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The preparations specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'silage additives', are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional measures

The feed additives *Enterococcus faecium* SF202-DSM 4788-ATCC 53519 and *Enterococcus faecium* SF301-DSM 4789-ATCC 55593 and feed containing them, which are produced and labelled before 12 August 2026 in accordance with the rules applicable before 12 August 2025 may continue to be placed on the market and used until the stocks concerned are exhausted.

Article 3

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

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								
1k20603	<i>Enterococcus faecium</i> ATCC 53519	<i>Additive composition</i> Preparation of <i>Enterococcus faecium</i> ATCC 53519 containing a minimum of 1 × 10 ¹⁰ CFU/g additive Solid form _____ <i>Characterisation of the active substance</i> Viable cells of <i>Enterococcus faecium</i> ATCC 53519 _____ <i>Analytical method ⁽¹⁾</i> Identification of <i>Enterococcus faecium</i> ATCC 53519: — Pulsed-Field Gel Electrophoresis (PFGE) – CEN/TS 17697 or DNA sequencing methods Enumeration of <i>Enterococcus faecium</i> ATCC 53519: — Spread plate (or pour plate) method on bile esculin azide agar or on Slanetz and Bartley agar (EN 15788)	All animal species	-	-	-	<ol style="list-style-type: none">1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated.2. Minimum dose of the additive when it is not used in combination with other micro-organisms as silage additives: 1 × 10⁷ CFU/kg fresh plant material.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 skin, eye and breathing protective equipment.	12 August 2035

⁽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.

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								
1k20604	<i>Enterococcus faecium</i> ATCC 55593	<p>Additive composition</p> <p>Preparation of <i>Enterococcus faecium</i> ATCC 55593 containing a minimum of 1×10^{10} CFU/g additive</p> <p>Solid form</p> <hr/> <p>Characterisation of the active substance</p> <p>Viable cells of <i>Enterococcus faecium</i> ATCC 55593</p> <hr/> <p>Analytical method ⁽¹⁾</p> <p>Identification of <i>Enterococcus faecium</i> ATCC 55593:</p> <p>— DNA sequencing methods or Pulsed Field Gel Electrophoresis (PFGE) (CEN/TS 17697)</p> <p>Enumeration of <i>Enterococcus faecium</i> ATCC 55593:</p> <p>— Spread plate (or pour plate) method on bile esculin azide agar or on Slanetz and Bartley agar (EN 15788)</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. Minimum dose of the additive when it is not used in combination with other micro-organisms as silage additives: 5×10^6 CFU/kg fresh plant material.</p> <p>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 skin, eye and breathing protective equipment.</p>	12 August 2035

⁽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.