



EUROPEAN
COMMISSION

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

of **XXX**

**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)

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

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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 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. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC². 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 2013³, 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

¹ OJ L 268, 18.10.2003, p. 29.

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>.

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 2022⁴, 4 July 2023⁵ and 15 October 2024⁶ 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.

- (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 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication**] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] 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.

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>.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN