SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 27 September 2022

doi: 10.2903/j.efsa.2022.7603

Assessment of the efficacy of two feed additives consisting of *Enterococcus faecium* ATCC 53519 and *E. faecium* ATCC 55593 for all animal species (FEFANA asbl)

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the efficacy of two technological additives to improve ensiling of forages consisting of *Enterococcus faecium* strains ATCC 53519 and ATCC 55593, respectively, for all animal species. The additives are intended for use with all forages and for all animal species at a proposed minimum concentration of 1×10^7 colony forming units (CFU) of *E. faecium* ATCC 53519/kg forage or 5×10^6 CFU of *E. faecium* ATCC 55593/kg forage, respectively. In a previous opinion, the FEEDAP Panel could not conclude on their efficacy owing to the lack of sufficient evidence for an improvement on the nutrient preservation during the ensiling process. The new data submitted by the applicant as supplementary information provided not enough weight of evidence on the effects of the additives on the ensiling of easy, moderately difficult and difficult to ensile material, and therefore, the FEEDAP Panel is not in the position to conclude on the efficacy of the additive under the proposed conditions of use.

Keywords: technological additives, silage additives, enterococci, *Enterococcus faecium* ATCC 53519, *Enterococcus faecium* ATCC 55593, efficacy

Requestor: European Commission

Question number: EFSA-Q-2021-00634

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Declarations of interest: If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

Acknowledgements: The Panel wishes to thank the contribution following to this scientific output of Yolanda García-Cazorla.

Suggested citation: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis V, Azimonti G, Bastos ML, Christensen H, Dusemund B, Fašmon Durjava M, Kouba M, López-Alonso M, López Puente S, Marcon F, Mayo B, Pechová A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Dierick N, Anguita M, Brozzi R, Galobart J, Ortuño J and Revez J, 2022. Scientific Opinion on the assessment of the efficacy of two feed additives consisting of *Enterococcus faecium* ATCC 53519 and *E. faecium* ATCC 55593 for all animal species (FEFANA asbl). EFSA Journal 2022;20(10):7603, 6 pp. https://doi.org/10.2903/j.efsa.2022.7603

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition and, in particular, Article 9 defines the terms of the authorisation by the Commission.

The applicant FEFANA asbl[2] is seeking a Community authorisation of *Enterococcus faecium* (ATCC 53519, ATCC 55593) as feed additives to be used as silage additives for all animal species (Table 1).

Table 1: Description of the additive

Category of additive	**Technological additives**
Functional group of additives	Silage additives
Description	*Enterococcus faecium* (ATCC 53519, ATCC 55593)
Target animal category	All animal species
Applicant	FEFANA asbl
Type of request	New opinion

On 10 September 2013, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) of the European Food Safety Authority (EFSA), in its opinion on the safety and efficacy of the product, could not conclude on the efficacy of *Enterococcus faecium* (ATCC 53519, ATCC 55593) in all animal species.

The Commission gave the possibility to the applicant to submit supplementary information and data in order to complete the assessment and to allow a revision of the EFSA's opinion. The new data have been received on 20 July 2021 and the applicant has been requested to transmit them to EFSA as well.

In view of the above, the Commission asks the Authority to deliver a new opinion on *Enterococcus faecium* (ATCC 53519, ATCC 55593) as feed additives for all animal species based on the additional data submitted by the applicant, in accordance with Article 29(1)(a) of Regulation (EC) No 178/2002.

1.2. Additional information

EFSA issued one opinion on the safety and efficacy of the additives *E. faecium* ATCC 53519 and *E. faecium* ATCC 55593 when used in feed for all animal species (EFSA FEEDAP Panel, 2013). This opinion regarded the re-evaluation of the additives under category 1 functional group k.

2. Data and Methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of supplementary information[3] to previous application on the same products.[4]

In accordance with Article 38 of the Regulation (EC) No 178/2002[5] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[6] a non-confidential version of the supplementary information has been published on Open.EFSA.[7]

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the council of 22 September 2003 on the additives for use in animal nutrition. OJ L 268, 18.10.2003, pp. 29.
[2] FEFANA Asbl – SILAC "Silage Additives Authorisation Consortium", Rue de Trèves 45, 1,040 Brussels, Belgium.
[3] Dossier reference: EFSA-Q-2021-00634.
[4] Dossier reference: FAD-2010-0135.
[5] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, pp.1–48.
[6] Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements
[7] Available at: https://open.efsa.europa.eu/questions/EFSA-Q-2021-00634

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the efficacy of *E. faecium* ATCC 53519 and ATCC 55593 is in line with the principles laid down in Regulation (EC) No 429/2008[8] and the relevant guidance document: Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018).

3. Assessment

The two additives under assessment contain viable cells of either *E. faecium* strains ATCC 53519 or ATCC 55593 and are intended to be added to forages to promote ensiling (technological additives, functional group: silage additives). The additives composed by *E. faecium* ATCC 53519 and *E. faecium* ATCC 55593 are intended to be used at 1×10^7 colony forming units (CFUs) and 5×10^6 CFU/kg forage, respectively.

In the previous opinion (EFSA FEEDAP Panel, 2013), the FEEDAP Panel could not conclude on the efficacy of the two additives owing to the lack of sufficient evidence for an improvement on the nutrient preservation during the ensiling process. The applicant has now provided new data to support the efficacy of the two products on the production of silage.

Three laboratory experiments were conducted with different forage samples representing the materials easy to ensile (study 1), moderately difficult to ensile (study 2) and difficult to ensile (study 3), as specified by Regulation (EC) No 429/2008 (Table 1). All the studies included a control (without inoculant), a group inoculated with *E. faecium* ATCC 53519 (1×10^7 CFU/kg forage) and a group inoculated with *E. faecium* ATCC 55593 (5×10^6 CFU/kg forage). The additives [redacted] at the intended concentration (confirmed by analysis of the applied suspension). Forage for the control silos were [redacted] without any additive.[9] Samples of the forages, four replicates per treatment, were ensiled for 90 days in 2.75 L mini-silos which had the potential to vent gas. Experiments were conducted at room temperature.[10]

Table 2: Characteristics of the forages used in the three ensiling experiments

Study	Test Material	Dry matter content (%)	Water-soluble carbohydrates content (% fresh matter)
1	Maize	38.6	5.2
2	Alfalfa	38.8	2.4
3	High moisture maize	67.2	1.0

After 90 days, the mini-silos were opened and the contents were analysed for dry matter (DM), pH, volatile fatty acids (VFAs) and lactic acid, ethanol and ammonia concentration. The DM contents were not corrected for volatiles to calculate DM loss.[11]

Statistical analyses were performed using a non-parametric (Kruskal–Wallis)[12] test and significance declared at $p < 0.05$. Results are shown in Table 2.

Table 3: Effects of *Enterococcus faecium* strains ATCC 53519 and ATCC 55593 on the characteristics of ensiled material recovered at the end of the ensiling period (90 days)

Study	Treatment applied	Dry matter (DM) loss** (%)	pH	Lactic acid (%, DM)	Acetic acid (%, DM)	Ammonia-N (%, crude protein)
1	Control	8.31	4.33	4.47	1.08	5.96
	ATCC 53519	1.50*	3.70	3.82*	0.87*	5.64
	ATCC 55593	2.57*	3.73	3.96*	0.87*	5.74

[8] 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, pp. 1.
[9] Certficate of Analysis – EF.
[10] Annex 1 Efficacy Report 2_EF ATCC 53519 & 55593.
[11] 2022-06-21_SILAC E. faecium_SIn reply.
[12] Annex 3 Statistical Summary 2_EF ATCC 53519 & 55,593 and Annex 4 Statistical Results_EF.

Study	Treatment applied	Dry matter (DM) loss** (%)	pH	Lactic acid (%, DM)	Acetic acid (%, DM)	Ammonia-N (%, crude protein)
2	Control	5.18	4.98	8.27	2.49	7.42
	ATCC 53519	2.93*	4.38	8.70	2.37	7.28
	ATCC 55593	3.16*	4.33	8.43	2.41	7.33
3	Control	7.72	5.05	0.44	0.04	2.26
	ATCC 53519	7.01*	4.45	0.50	0.04	1.94
	ATCC 55593	6.98*	4.45	0.47	0.03	2.16

*: Means in a column within a given trial are significantly different to the control $p < 0.05$.
**: With no correction of DM contents for volatiles.

At the end of the ensiling process, the DM loss was significantly reduced in all the forages treated with *Enterococcus faecium* ATCC 53519 or ATCC 55593 compared to controls, which would point to a positive effect on the preservation of nutrients. However, considering that the DM contents were not corrected for volatiles, which may lead to an unreliable estimation of the DM loss, and the lack of positive effects on any of the other parameters, the FEEDAP Panel cannot conclude on the efficacy of the additives (Table 3).

4. Conclusions

The FEEDAP Panel is not in the position to conclude on the efficacy of *E. faecium* strains ATCC 53519 or ATCC 55593 when used as silage additives.

5. Documentation provided to EFSA/Chronology

Date	Event
07/12/2020	Dossier received by EFSA. *E. faecium* – strains ATCC 53519 and ATCC 55593 for all animal species. Submitted by FEFANA asbl
25/10/2021	Reception mandate from the European Commission
29/10/2021	Acceptance mandate from the European Commission by EFSA – Start of the scientific assessment
17/12/2021	Request of supplementary information to the applicant in line with Article 7(3) of Regulation (EC) No 1304/2003 – Scientific assessment suspended. *Issues: efficacy*
28/01/2022	Reception of supplementary information from the applicant - Scientific assessment re-started
30/03/2022	Request of supplementary information to the applicant in line with Article 7(3) of Regulation (EC) No 1304/2003 – Scientific assessment suspended. *Issues: efficacy*
30/05/2022	Reception of supplementary information from the applicant - Scientific assessment re-started
27/09/2022	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

References

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2013. Scientific Opinion on the safety and efficacy of *Enterococcus faecium* (NCIMB 10415, DSM 22502, ATCC 53519 and ATCC 55593) as silage additives for all animal species. EFSA Journal 2013;11(10):3363, 22 pp. https://doi.org/10.2903/j.efsa.2013.3363

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López-Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Anguita M, Galobart J, Innocenti ML and Martino L, 2018. Guidance on the assessment of the efficacy of feed additives. EFSA Journal 2018;16(5):5274, 25 pp. https://doi.org/10.2903/j.efsa.2018.5274

Abbreviations

CFU	colony forming unit
DM	dry matter
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed