SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 26 January 2022

doi: 10.2903/j.efsa.2022.7148

Assessment of the feed additive consisting of *Lentilactobacillus buchneri* (formerly *Lactobacillus buchneri*) DSM 12856 for all animal species for the renewal of its authorisation (Lactosan GmbH & Co KG)

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Fašmon Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa, Ruud Woutersen, Jaume Galobart, Maria Vittoria Vettori and Rosella Brozzi

Abstract

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the assessment of the application for renewal of authorisation of *Lentilactobacillus buchneri* (formerly *Lactobacillus buchneri*) DSM 12856 as a technological additive for use in forage for all animal species. The additive aims at improving the production of silage and is authorised for all animal species. The applicant has provided evidence that the additive currently on the market complies with the existing conditions of authorisation. There is no evidence to lead the FEEDAP Panel to reconsider its previous conclusions. Thus, the Panel concludes that the additive remains safe for all animal species, consumers and the environment under the authorised conditions of use. Regarding user safety *L. buchneri* DSM 12856 is not irritant to skin and eyes but is considered a skin and respiratory sensitiser. There was no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

Keywords: technological additive, silage additive, *Lentilactobacillus buchneri* DSM 12856, safety, efficacy, QPS, renewal

Requestor: European Commission

Question number: EFSA-Q-2020-00769

Correspondence: feedap@efsa.europa.eu

Panel members: Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Maryline Kouba, Mojca Fašmon Durjava, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa and Ruud Woutersen.

Declarations of interest: The declarations of interest of all scientific experts active in EFSA's work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch.

Acknowledgments: The Panel wishes to acknowledge the contribution to this opinion of: Daniel Pagés Plaza and Joana Revez.

Legal notice: Relevant information or parts of this scientific output have been blackened in accordance with the confidentiality requests formulated by the applicant pending a decision thereon by the European Commission. The full output has been shared with the European Commission, EU Member States and the applicant. The blackening will be subject to review once the decision on the confidentiality requests is adopted by the European Commission.

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, Galobart J, Vettori MV and Brozzi R, 2022. Scientific Opinion on the assessment of the feed additive consisting of *Lentilactobacillus buchneri* (formerly *Lactobacillus buchneri*) DSM 12856 for all animal species for the renewal of its authorisation (Lactosan GmbH & Co KG). EFSA Journal 2022;20(2):7148, 7 pp. https://doi.org/10.2903/j.efsa.2022.7148

ISSN: 1831-4732

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

Table of contents

1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 14(1) of that Regulation lays down that an application for renewal shall be sent to the Commission at the latest one year before the expiry date of the authorisation.

The European Commission received a request from Lactosan GmbH & Co.KG[2] for authorisation of the product *Lentilactobacillus buchneri* (formerly *Lactobacillus buchneri*) DSM 12856, when used as a feed additive for all animal species (category: technological additives; functional group: silage additives).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 14(1) (renewal of the authorisation). The particulars and documents in support of the application were considered valid by EFSA as of 15 January 2021.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user, and the environment and on the efficacy of the product *Lentilactobacillus buchneri* (formerly *Lactobacillus buchneri*) DSM 12856, when used under the proposed conditions of use (see Section 3.1.3).

1.2. Additional information

The additive consists of viable cells of *L. buchneri* (formerly *Lactobacillus buchneri*) DSM 12856. It is currently authorised as a feed additive in the European Union (1k2075).[3]

EFSA has adopted one opinion on the safety and efficacy of this product for all animal species (EFSA FEEDAP Panel, 2011).

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier[4] in support of the authorisation request for the use of *L. buchneri* DSM 12856 as a feed additive.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.[5]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of *Lentilactobacillus buchneri* DSM 12856 is in line with the principles laid down in Regulation (EC) No 429/2008[6] and the relevant guidance documents: Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018) and Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2013).

[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, p. 29.
[2] Lactosan GmbH & Co.KG, Industriestraβe West 5, A-8605 Kapfenberg, Austria.
[3] Commission Implementing Regulation (EU) No 1263/2011 of 5 December 2011 concerning the authorisation of *Lactobacillus buchneri* (DSM 16774), *Lactobacillus buchneri* (DSM 12856), *Lactobacillus paracasei* (DSM 16245), *Lactobacillus paracasei* (DSM 16773), *Lactobacillus plantarum* (DSM 12836), *Lactobacillus plantarum* (DSM 12837), *Lactobacillus brevis* (DSM 12835), *Lactobacillus rhamnosus* (NCIMB 30121), *Lactococcus lactis* (DSM 11037), *Lactococcus lactis* (NCIMB 30160), *Pediococcus acidilactici* (DSM 16243) and *Pediococcus pentosaceus* (DSM 12834) as feed additives for all animal species. OJ L 322, 6.12.2011, p. 3.
[4] FEED dossier reference: FAD-2020-0066.
[5] The full report is available on the EURL website: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports
[6] 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, p. 1.

3. Assessment

The product consisting of viable cells of *L. buchneri* DSM 12856 is currently authorised for use as a technological additive (functional group: silage additives) in forages for all animal species. This assessment regards the renewal of the authorisation of *L. buchneri* DSM 12856 for the above-mentioned animal species.

3.1. Characterisation

3.1.1. Characterisation of the additive

The product currently authorised consists of approximately 35–50% of the active agent and 50–65% of carriers ( ) and cryoprotectants ( ). The minimum concentration of active agent (*L. buchneri* DSM 12856) is 5×10^{11} colony forming units (CFU) per gram of additive.

The information submitted regarding the manufacturing process lists some modifications applied to the fermentation process and composition of the additive which have been developed since the first authorisation was granted. The modifications regard the composition of the fermentation medium (e.g.). Regarding the composition of the additive, are also used as cryoprotectants, and is used in replacement of

Analysis of three batches showed a mean value of 6.4×10^{11} CFU/g (range 6.0–6.8 $\times$ 10^{11} CFU/g).[7]

Specifications are set for Enterobacteriaceae ($< 10^2$ CFU/g), yeasts and filamentous fungi ($< 10^2$ CFU/g) and *Salmonella* spp. (no detection in 25 g). Analysis of three recent batches of the additive showed compliance with these limits.[8] Three other recent batches were tested for aflatoxins (B1, B2, G1, and G2), deoxynivalenol, zearalenone[9] and three others for lead, mercury, cadmium and arsenic,[10] showing levels below the respective limits of quantification.[11]

No new data have been provided regarding the physico-chemical properties of the additive. Since the changes introduced in the additive and its manufacturing process are not expected to have a significant effect on these characteristics, the data described in the previous opinion still apply.

3.1.2. Characterisation of the active agent

The active agent was isolated from silage. It is deposited in the Deutsche Sammlung von Mikroorganismen und Zellkulturen (DSMZ) with the accession number DSM 12856.[12] It has not been genetically modified.

as *L. buchneri* DSM 12856

The bacterial strain was tested for antibiotic susceptibility [14] The battery of antibiotics used included those recommended by EFSA (EFSA FEEDAP Panel, 2018).). Exceeding the cut-off value by one dilution is considered to be within the normal range of variation and thus, not a matter of concern. Therefore, the strain is considered to be susceptible to all the relevant antibiotics.

The WGS data of the strain, including the were searched for acquired antibiotic resistance genes by using the

[7] Technical dossier/Section II/Annex II.1_2.
[8] Technical dossier/Section II/Annex II_1_3.
[9] Technical dossier/Section II/Annex II_1_4.
[10] Technical dossier/Section II/Annex II_1_5.
[11] Limits of quantification: aflatoxins B1, B2, G1 and G2: 0.03 μg/kg, deoxynivalenol: 10 μg/kg, zearalenone: 5 μg/kg, Pb: 0.1 mg/kg, Hg: 0.1 mg/kg, Cd: 0.03 mg/kg and As: 0.1 mg/kg.
[12] Technical dossier/Section II/Annex II_2_2.
[13] Technical dossier/Section II/Annex II_2_4.
[14] Technical dossier/Section II/Annex II_2_5.

[redacted] as thresholds.[15] No hits were identified.

3.1.3. Conditions of use

The additive is currently authorised for use in forages for all target species.
Under other provisions of the authorisation, it is specified that:

- In the directions for use of the additive and premixture, indicate the storage temperature and storage life.
- Minimum dose of the additive when used without combination with other micro-organisms as silage additives: 1×10^8 CFU/kg fresh material.
- For safety: it is recommended to use breathing protection and gloves during handling.

The applicant has requested to maintain the same conditions of use.

3.2. Safety

3.2.1. Safety for the target species, consumers, users and the environment

In the previous opinion, the Panel concluded that following the qualified presumption of safety (QPS) approach, the use of *L. buchneri* DSM 12856 in the production of silage was considered safe for target species, consumers and the environment (EFSA FEEDAP Panel, 2011). In the context of this application, the identity of the strain as *L. buchneri DSM* 12856 was confirmed and evidence that the strain does not show acquired antimicrobial resistances for antibiotics of human and veterinary importance was provided. Consequently, the conclusions already reached are still valid and *L. buchneri* DSM 12856 is safe for the target species, consumers and the environment.

In the previous assessment (EFSA FEEDAP Panel, 2011), the Panel concluded regarding user safety: 'Evidence of a lack of irritancy was provided for one formulation of the additive. It is unlikely that considering the nature of the alternative food grade excipients, different results would be obtained for other formulations containing *L. buchneri* DSM 12856. Given the lack of specific information and its proteinaceous nature, the active agent should be considered to have the potential to be a skin/respiratory sensitiser'.

The applicant declares that no adverse effects on the health of workers have been observed in the production plant or during usage of the additive.[16]

The applicant performed a literature search in order to provide evidence that in the light of the current knowledge the additive remains safe under the approved conditions for target species, consumers, users and the environment. The literature search was conducted in September 2020 without time restrictions. The search term used was '*Lactobacillus buchneri* DSM 12856', no further restrictions were made. The applicant searched in a total of seven relevant databases Agricola, Agris, Google scholar, Ingenta, PubMed, Science Direct and World Cat Library. Fourteen papers were retrieved after removing duplicates. However, none was considered because they referred either to the previous EFSA opinion (1), to the authorisation of the additive (1) or to its efficacy (12).[17]

Therefore, the FEEDAP Panel concludes that there is no new evidence to lead it to reconsider the previous conclusions that *L. buchneri* DSM 12856 is safe for the target species, consumers and the environment under the authorised conditions of use. Regarding user safety *L. buchneri* DSM 12856 is not irritant to skin and eyes but is considered a skin and respiratory sensitiser.

3.3. Efficacy

The present application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive. Therefore, there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

[15] Technical dossier/Section II/Annex II_2_6.
[16] Technical dossier/Section III.
[17] Technical dossier/Section III/Annex_III_3_Literature.

4. Conclusions

The applicant has provided evidence that the additive currently on the market complies with the existing conditions of authorisation.

The Panel concludes that *L. buchneri* DSM 12856 remains safe for all animal species, consumers and the environment under the authorised conditions of use. Regarding user safety, the additive is not irritant to skin and eyes but is considered a skin and respiratory sensitiser.

There is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

5. Documentation as provided to EFSA/Chronology

Date	Event
09/11/2020	Dossier received by EFSA. *Lactobacillus buchneri* DSM 12385. Submitted by Lactosan GmbH & Co. KG
09/11/2020	Reception mandate from the European Commission
15/01/2021	Application validated by EFSA – Start of the scientific assessment
16/04/2021	Comments received from Member States
26/01/2022	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), 2011. Scientific Opinion on the safety and efficacy of *Lactobacillus buchneri* (DSM 12856) as a silage additive for all species. EFSA Journal 2011;9(9):2368 11 pp. https://doi.org/10.2903/j.efsa.2011.2368

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2013. Guidance on the renewal of the authorisation of feed additives. EFSA Journal 2013;11(10):3431, 8 pp. https://doi.org/10.2903/j.efsa.2013.3431

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, Glandorf B, Herman L, Kärenlampi S, Aguilera J, Anguita M, Brozzi R and Galobart J, 2018. Guidance on the characterisation of microorganisms used as feed additives or as production organisms. EFSA Journal 2018;16(3):5206, 24 pp. https://doi.org/10.2903/j.efsa.2018.5206

Abbreviations

CFU	colony forming unit
dDDH	digital DNA–DNA hybridisation
DSMZ	German Collection of Microorganisms and Cell Cultures
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
MIC	minimum inhibitory concentration
QPS	qualified presumption of safety
TYGS	DSMZ type strain genome server