

ADOPTED: 26 September 2023

doi: 10.2903/j.efsa.2023.8350

Assessment of the feed additive consisting of *Enterococcus lactis* DSM 7134 and *Lacticaseibacillus rhamnosus* DSM 7133 (Provita LE) for calves for rearing for the renewal of its authorisation (Lactosan GmbH & Co.KG)

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the assessment of the application for renewal of the authorisation of the additive Provita LE for calves for rearing, consisting of *Enterococcus lactis* DSM 7134 (formerly identified as *Enterococcus faecium*) and *Lacticaseibacillus rhamnosus* DSM 7133 (formerly identified as *Lactobacillus rhamnosus*) as a zootechnical feed additive. The applicant has provided evidence that the additive currently on the market complies with the existing terms of the authorisation. The FEEDAP Panel concluded that the use of the feed additive in animal nutrition remains safe for calves for rearing, consumers and the environment under the authorised conditions of use. The additive is not irritant to skin or eyes but should be considered a respiratory sensitiser. It was not possible to draw conclusions on the skin sensitisation potential of the additive under assessment. There was no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

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Keywords: zootechnical additives, digestibility enhancers, Provita LE, *Enterococcus lactis* DSM 7134, *Lacticaseibacillus rhamnosus* DSM 7133, calves, safety

Requestor: European Commission

Question number: EFSA-Q-2022-00820

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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 following for the support provided to this scientific output (in alphabetical order of the last name): Nicole Bozzi Cionci and the members of the Microbiology working group.

Suggested citation: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis, V., Azimonti, G., Bastos, M. L., Christensen, H., Durjava, M., Dusemund, B., Kouba, M., López-Alonso, M., López Puente, S., Marcon, F., Mayo, B., Pechová, A., Petkova, M., Ramos, F., Villa, R. E., Woutersen, R., Alija Novo, N., Anguita, M., ... Tarrés-Call, J. (2023). Assessment of the feed additive consisting of *Enterococcus lactis* DSM 7134 and *Lactocaseibacillus rhamnosus* DSM 7133 (Provita LE) for calves for rearing for the renewal of its authorisation (Lactosan GmbH & Co.KG). *EFSA Journal*, 21(10), 1–9. <https://doi.org/10.2903/j.efsa.2023.8350>

ISSN: 1831-4732

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1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003¹ 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.KG² for the renewal of the authorisation of the additive Provita LE consisting of *Enterococcus lactis*³ DSM 7134 and *Lactobacillus rhamnosus* DSM 7133, when used as a feed additive for calves for rearing (category: zootechnical additive; functional group: gut flora stabilisers).

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 dossier was received on 22 November 2022 and the general information and supporting documentation is available at <https://open.efsa.europa.eu/questions/EFSA-Q-2022-00820>. The particulars and documents in support of the application were considered valid by EFSA as of 27 February 2023.

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 feed additive consisting of *E. faecium* DSM 7134 and *L. rhamnosus* DSM 7133 (Provita LE), when used under the proposed conditions of use (see **Section 3.1.3**).

1.2. Additional information

The additive consists of viable cells of *E. lactis* DSM 7134 and *L. rhamnosus* DSM 7133. EFSA issued one opinion on the safety and efficacy of this product when used in feed for calves for rearing (EFSA FEEDAP Panel, 2013).

The additive is currently authorised for use in feed for calves for rearing up to 4 months of age (4b1706).⁴

The strain *E. lactis* DSM 7134 alone is authorised (as Bonvital®) for weaned piglets, pigs for fattening, sows, chickens for fattening, laying hens, chickens reared for laying and minor poultry species (other than those used for laying).

L. rhamnosus DSM 7133 is authorised as *L. rhamnosus* NCIMB 30121 as a silage additive (1 k20711).

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier⁵ in support of the authorisation request for the use of *E. lactis* DSM 7134 and *L. rhamnosus* DSM 7133 (Provita LE) as a feed additive.

In accordance with Article 38 of the Regulation (EC) No 178/2002⁶ 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

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, Industriestrasse West 5, 8605 Kapfenberg, Austria.

³ Formerly identified as *Enterococcus faecium*.

⁴ Commission Implementing Regulation (EU) No 1101/2013 of 6 November 2013 concerning the authorisation of a preparation of *Enterococcus faecium* DSM 7134 and *Lactobacillus rhamnosus* DSM 7133 as a feed additive for calves for rearing and amending Regulation (EC) No 1288/2004 (holder of authorisation Lactosan GmbH & CoKG), OJ of 7.11.2013, L 296, p. 1–3.

⁵ Dossier reference: FEED-2022-6936.

⁶ 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, p. 1–48.

concerning transparency and confidentiality,⁷ a non-confidential version of the dossier has been published on Open.EFSA.

According to Article 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations, EFSA carried out a public consultation on the non-confidential version of the technical dossier from 18 August to 8 September 2023, for which no comments were received.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 27 February 2023 to 27 May 2023 for which the received comments were considered for the assessment.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA and experts' knowledge, to deliver the present output.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment regarding the methods used for the control of the *E. lactis* DSM 7134 and *L. rhamnosus* DSM 7133 (Provita LE) in animal feed are valid and applicable for the current application.⁸

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of *E. lactis* DSM 7134 and *L. rhamnosus* DSM 7133 (Provita LE) is in line with the principles laid down in Regulation (EC) No 429/2008⁹ and the relevant guidance documents: Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2021).

3. Assessment

The product (here and below referred to with its commercial name Provita LE) consisting of viable cells of *E. lactis* DSM 7134 and *L. rhamnosus* DSM 7133 is currently authorised as a zootechnical additive (functional group: gut flora stabiliser) for use in milk replacer and complete feedingstuffs for calves for rearing. This assessment regards the renewal of the authorisation for the above-mentioned species.

3.1. Characterisation

3.1.1. Characterisation of the active agents

3.1.1.1. *Enterococcus lactis* DSM 7134

The *E. lactis* strain was isolated from plant material (grass) and is deposited in the Deutsche Sammlung von Mikroorganismen und Zellkulturen under the accession number DSM 7134.¹⁰ It has not been genetically modified.

The active agent was originally assigned to the *E. faecium* species [REDACTED]. The description of the species *E. lactis* demonstrated that it is a closely related species to *E. faecium* (Morandi et al., 2012). Recently the strains of *E. faecium* clade B have been reassigned to *E. lactis* species based on genomic studies that showed genetic and evolutionary differences between clade A and the intertwined clade B and *E. lactis* (Belloso Daza et al., 2021).

In the context of the current application, the DSM 7134 strain was identified as *E. lactis* [REDACTED]

[REDACTED]

⁷ Decision available online: <https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements>

⁸ Evaluation report available on the EU Science Hub https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

⁹ 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.

¹⁰ Annex II_8_Deposit_7134.

¹¹ Annex II_10_WGS_7134.

The susceptibility of the *E. lactis* DSM 7134 to antibiotics was tested using [REDACTED] and including the data set of antibiotics recommended by EFSA (EFSA FEEDAP Panel, 2018).¹² The minimum inhibitory concentrations (MICs) of the strain were compared with the defined EFSA cut-off values for the closest related species *E. faecium*. The MIC values for all the antibiotics tested were equal or below the EFSA cut-off values and therefore the strain is considered susceptible to all relevant antibiotics.

The WGS of the strain, including [REDACTED], was interrogated for the presence of antimicrobial resistance genes (AMR) against the ResFinder at [REDACTED] level and the NCBI Bacterial Antimicrobial Resistance Reference Gene Database at [REDACTED] level. In both searches, thresholds were set at [REDACTED] identity and [REDACTED] length coverage.¹³ The search identified [REDACTED]. These genes are considered intrinsic to *E. lactis* and *E. faecium* clade B, and therefore, no genes of concern were identified.

According to the applicable guidance (EFSA FEEDAP Panel, 2018), the safety of *E. faecium* should be assessed by demonstrating the absence of the genetic markers typical of the clinical isolates *E. faecium* clade A (IS16, *esp*, *hyl* Efm) and the susceptibility to ampicillin. In view of the allocation of clade B strains to *E. lactis* species (Belloso Daza et al., 2021), the FEEDAP Panel considers these criteria to be applicable also to *E. lactis* strains. *E. lactis* DSM 7134 is susceptible to ampicillin (MIC < 2 mg/L) and the WGS data were subjected to [REDACTED] for the three genetic elements, and none were detected.¹⁴

3.1.1.2. *Lacticaseibacillus rhamnosus* DSM 7133

The *L. rhamnosus* strain was isolated from corn silage and is deposited the Deutsche Sammlung von Mikroorganismen und Zellkulturen (DSMZ) under the accession number DSM 7133.¹⁵ It has not been genetically modified.

The taxonomic identification of the *L. rhamnosus* strain (formerly identified as *L. rhamnosus*) was confirmed by a bioinformatic analysis using the WGS data. The taxonomic assignment was performed using [REDACTED], obtaining a similarity of [REDACTED] when comparing with the type strain *L. rhamnosus* [REDACTED].¹⁶

The susceptibility of the *L. rhamnosus* to antibiotics was tested using a [REDACTED] and including the battery of antibiotics recommended by EFSA (EFSA FEEDAP Panel, 2018).¹⁷ The MIC values for all the antibiotics tested were equal or below the EFSA cut-off values, [REDACTED] and therefore the strain is considered to be susceptible to all the relevant antibiotics.

The WGS of the strain was interrogated for the presence of antimicrobial resistance genes (AMR) against two databases, ResFinder at [REDACTED] level and the NCBI Bacterial Antimicrobial Resistance Reference Gene Database at a [REDACTED] level. The thresholds of [REDACTED] identity and [REDACTED] length coverage were applied in both cases. No hits were found.¹⁸

3.1.2. Characterisation of the additive

The additive is currently authorised with minimum guaranteed concentration of *E. lactis* DSM 7134 of 7×10^9 colony forming units (CFU)/g and of 3×10^9 CFU/g of *L. rhamnosus* DSM 7133 (ratio 7:3).

The applicant stated that there had been no changes in the composition of the additive, and only minor changes in the manufacturing process since the last authorisation. As regards the manufacturing process, the changes consisted of the use of [REDACTED].¹⁹ The FEEDAP Panel considers that the impact of these changes on the final product is negligible.

Since the formulation and manufacturing process have not been significantly changed since the first authorisation (EFSA FEEDAP Panel, 2013), data on physical-chemical properties, stability and homogeneity previously submitted are considered still valid.

¹² Annex_II_14_Antibio_7134.

¹³ Annex_II_16_AMR_7134.

¹⁴ Annex_II_18_Virulence_7134.

¹⁵ Annex_II_9_Deposit_7133.

¹⁶ Annex_II_12_WGS_7133.

¹⁷ Annex_II_15_Antibio_7133.

¹⁸ Annex_II_17_AMR_7133.

¹⁹ Manufacturing RFI 20230425.

Analytical data to confirm the specifications were provided for five recent batches of the additive, showing the following values: average counts for *E. lactis* were 1.1×10^{10} CFU/g additive (range 9.2×10^9 – 1.2×10^{10} CFU/g additive); average counts for *L. rhamnosus* were 5.2×10^9 CFU/g additive (range 4.5 – 6.1×10^9 CFU/g additive).²⁰

Three batches of the additive were analysed for impurities. Cadmium, lead, mercury and arsenic and mycotoxin levels (aflatoxins B1, B2, G1, G2, deoxynivalenol and zearalenone) were below the limit of quantification (LOQ) of the method in all cases.^{21,22} Microbiological contamination was analysed by determination of Enterobacteriaceae, yeasts and filamentous fungi, which were $< 10^3$ CFU/g each in all three batches; *Salmonella* spp. was not detected in 25-g samples.²³

3.1.3. Conditions of use

The additive is currently authorised for use in milk replacer and complete feed for calves for rearing at a minimum use level of 1×10^9 CFU/kg.

Under other provisions of the authorisation, it is specified that:

- In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting.
- For safety: it is recommended to use breathing protection and gloves during handling.

The applicant requests to maintain the same conditions of use.

3.2. Safety

In the previous opinion (EFSA FEEDAP Panel, 2013) the Panel concluded that the additive was considered safe for the target species, the consumer and the environment. Regarding user safety, the Panel concluded that Provita LE is not irritant to skin or eyes, but given the proteinaceous nature of the active agents, the additive should be considered to have the potential to be a skin/respiratory sensitiser.

The applicant declared that no adverse effects of the additive have been reported for target species (calves for rearing), consumers, user/workers and the environment since its first authorisation.²⁴

In line with the requirements established in EFSA Guidance on the renewal of authorisation of feed additives (EFSA FEEDAP Panel, 2021), the applicant conducted a literature search to provide information to support the safety of the additive under the authorised conditions of use. Nine databases were searched (Agricola, Agris, Basenet, Google scholar, Ingenta, Europe PMC, PubMed, Science direct and World Cat Library) with the only restriction of the publication period (2010–2023).²⁵ The names of the strains of the additive, the name of the additive, the target species and a series of terms related to safety were combined in different search strings with Boolean operator 'and.' A total of 421 references were retrieved. Two reviewers were involved in the screening process (first title and abstract, and subsequently the full text). Exclusion criteria were reported. A total of eight publications were selected. All of them corresponded to opinions of the FEEDAP Panel.

In the context of the current application, the identity of the DSM 7134 strain was reassigned to *E. lactis*, and no evidence that the strain harbours acquired AMR genes or is virulent was provided. The FEEDAP Panel considers the criteria to assess the safety of *E. faecium* applicable also to *E. lactis* strains. In addition, the composition of the additive, its manufacturing process, and the conditions of use for the target species have not been modified. In the current application the new data showed that *L. rhamnosus* was properly identified and no AMR genes could be detected, hence it meets the qualifications of the QPS safety assessment (EFSA, 2007; EFSA BIOHAZ Panel, 2023). Therefore, the Panel considers that the additive Provita LE remains safe for calves for rearing, for consumers and for the environment under the authorised conditions of use.

No new information was provided on user safety. In the previous opinion the additive was considered as having the potential to be a skin sensitiser. However, the FEEDAP Panel notes that the OECD test guidelines available at present are designed to assess the skin sensitisation potential of

²⁰ Annex II.2 Comp and ADR export file for EFSA-Q-2022-00820.

²¹ Annex II.4 Mycotox. LOQ in $\mu\text{g/kg}$ was 0.03 for each aflatoxin type, 5 for zearalenone and 10 for deoxynivalenol.

²² Annex II.5 HeavyMet and ADR export file for EFSA-Q-2022-00820. LOQ in mg/kg was 0.10 for arsenic, lead and mercury; and 0.03 for cadmium.

²³ Annex II.3 Impurity.

²⁴ Annex III 1 Statement.

²⁵ Annex III 2 Literature Report.

chemical substances only, and that currently no validated assays for assessing the sensitisation potential of microorganisms are available.²⁶ Therefore, no conclusion can be drawn on the skin sensitisation potential of the additive.

3.2.1. Conclusions on safety

Based on the above and the fact that the manufacturing process of the additive, its composition and the conditions of use for the target species have not been modified, the FEEDAP Panel considers that there is no new evidence that would lead it to reconsider the previous conclusions. Therefore, the Panel concludes that Provita LE is safe for the target species, consumers and the environment under the authorised conditions of use. The additive is not irritant to skin or eyes but should be considered a potential respiratory sensitiser. No conclusion can be drawn on the potential of the additive to be a skin 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.

3.4. Post-market monitoring

The FEEDAP Panel considers that there is no need for specific requirements for a post-market monitoring plan other than those established in the Feed Hygiene Regulation²⁷ and Good Manufacturing Practice.

4. Conclusions

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

The FEEDAP Panel concludes that the use of Provita LE under the authorised conditions of use remains safe for calves for rearing, consumers and the environment.

Provita LE is not irritant to skin or eyes but should be considered a respiratory sensitiser. It is not possible to draw conclusions on the skin sensitisation potential of the additive under assessment.

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

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²⁶ https://www.efsa.europa.eu/sites/default/files/2022-07/feedap20220629-30_m.pdf

²⁷ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.

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Abbreviations

ANI	average nucleotide identity
CFU	colony forming unit
dDDH	digital DNA–DNA hybridisation
DM	dry matter
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
LOD	limit of detection
LOQ	limit of quantification
MIC	minimum inhibitory concentration
OECD	Organisation for Economic Co-operation and Development
WGS	whole genome sequence