SCIENTIFIC OPINION



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Assessment of eight feed additives consisting of Lactiplantibacillus plantarum CNCM I-3235, L. plantarum CNCM I-3736/DSM 11672, Pediococcus acidilactici CNCM I-3237, P. acidilactici CNCM I-4622/DSM 11673, Pediococcus pentosaceus NCIMB 12455, Acidipropionibacterium acidipropionici CNCM I-4661, Lentilactobacillus buchneri NCIMB 40788/CNCM I-4323 and L. buchneri NCIMB 40788/CNCM I-4323 plus Lentilactobacillus hilgardii CNCM I-4785 for all animal species for the renewal of their authorisation (Danstar Ferment AG)

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Mojca Durjava, Birgit Dusemund, 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, Montserrat Anguita, Rosella Brozzi, Yolanda García-Cazorla, Jaume Galobart, Jordi Tárres-Call and Joana Revez

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 eight technological additives, including two Lactiplantibacillus plantarum (formerly Lactobacillus plantarum) [CNCM I-3235 and CNCM I-3736/ DSM 11672], two Pediococcus acidilactici [CNCM I-3237 and CNCM I-4622/DSM 11673], one Pediococcus pentosaceus [NCIMB 12455], one Acidipropionibacterium acidipropionici (formerly Propionibacterium acidipropionici) [CNCM I-4661], one Lentilactobacillus buchneri (formerly Lactobacillus buchneri) [NCIMB 40788/ CNCM I-4323], and the additive composed by the two active agents L. buchneri NCIMB 40788/ CNCM I-4323 and Lentilactobacillus hilgardii (formerly Lactobacillus hilgardii) CNCM I-4785, as silage additives for use in forage for all animal species. The applicant has provided evidence that the additives currently on the market comply with the existing conditions of authorisation. There is no new evidence that would lead the FEEDAP Panel to reconsider its previous conclusions. Thus, the Panel concluded that the additives remain safe for all animal species, consumers and the environment under the authorised conditions of use. Regarding user safety, the additives should be considered as respiratory sensitisers. In the absence of data, no conclusions could be drawn on the skin sensitisation, and skin and eye irritancy potential of the additives, with the exception for Pediococcus acidilactici CNCM I-4622/DSM 11673 (for which the Panel concluded that is non-irritant to skin and eyes). There is no need for assessing the efficacy of the additives in the context of the renewal of the authorisation.

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Keywords: technological additives, silage additives, QPS, safety, renewal

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Table of contents

Abstract	t	1
1.	Introduction	4
1.1.	Background and Terms of Reference	4
1.2.	Additional information	4
2.	Data and methodologies	5
2.1.	Data	5
2.2.	Methodologies	5
3.	Assessment	6
3.1.	Characterisation	6
3.1.1.	Characterisation of the active agents	6
3.1.2.	Characterisation of the additives	7
3.1.3.	Physical properties of the additives	8
3.1.4.	Conditions of use	9
3.2.	Safety	10
3.2.1.	Safety for the target species, consumer and environment	10
3.2.2.	Safety for the user	10
3.2.3.	Conclusions on safety	11
3.3.	Efficacy	11
4.	Conclusions	11
References 1		11
Abbreviations 13		

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 13(3) of that Regulation lays down that if the holder of an authorisation proposes changing the terms of the authorisation by submitting an application to the Commission, accompanied by the relevant data supporting the request for the change, the Authority shall transmit its opinion on the proposal to the Commission and the Member States and Article 14(1) of that Regulation lays down that an application for renewal shall be sent to the Commission at the latest 1 year before the expiry date of the authorisation.

The European Commission received a request from Danstar Ferment AG represented by Lallemand SAS² for the renewal of the authorisations of the additives consisting of Lactiplantibacillus plantarum CNCM I-3235, L. plantarum CNCM I-3736/ DSM 11672, Pediococcus acidilactici CNCM I-3237, CNCM I-4622/DSM Pediococcus pentosaceus Р. acidilactici 11673, NCIMB 12455, Acidipropionibacterium acidipropionici CNCM I-4661, Lentilactobacillus buchneri NCIMB 40788/ CNCM I-4323, and Lentilactobacillus buchneri NCIMB 40788/ CNCM I-4323 plus Lentilactobacillus hilgardii CNCM I-4785,³ when used as feed additives 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 13(3) (modification of the authorisation of a feed additive) and under Article 14(1) (renewal of the authorisation). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 17 November 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 feed additives consisting of *L. plantarum* CNCM I-3235, *L. plantarum* CNCM I-3736/ DSM 11672, *P. acidilactici* CNCM I-3237, *P. acidilactici* CNCM I-4622/ DSM 11673, *P. pentosaceus* NCIMB 12455, *A. acidipropionici* CNCM I-4661, *L. buchneri* NCIMB 40788/ CNCM I-4323, and *L. buchneri* NCIMB 40788/ CNCM I-4323 plus *L. hilgardii* CNCM I-4785, when used under the proposed conditions of use (see **Section 3.1.4**).

1.2. Additional information

All the products under assessment are currently authorised as silage additives. EFSA issued several opinions on the safety and/or efficacy of the currently authorised products when used in feed for all animal species that are listed below (along with the respective authorisation numbers).

- One opinion (EFSA FEEDAP Panel, 2012a) on Lactiplantibacillus plantarum (formerly Lactobacillus plantarum) CNCM I-3235/ ATCC 8014 (1k20717);⁴
- One opinion (EFSA FEEDAP Panel, 2012a) on *L. plantarum* DSM 11672/CNCM MA 18/5U/ CNCM I-3736 (1k20722);⁴
- One opinion on the safety and efficacy (EFSA FEEDAP Panel, 2012b) and one on the efficacy (EFSA FEEDAP Panel, 2013a) of *Pediococcus acidilactici* CNCM I-3237 (1k21009);⁵
- One opinion on *Pediococcus acidilactici* CNCM I-4622/ DSM 11673 as a silage additive (EFSA FEEDAP Panel, 2012b) (1k2104),⁶ nine opinions as a zootechnical additive (EFSA, 2009a,b, EFSA FEEDAP Panel, 2010a,b, 2012c,d, 2016, 2019a,b) and one as acidity regulator and hygiene condition enhancer (EFSA FEEDAP Panel, 2022);

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 Danstar Ferment AG (Switzerland) represented in the EU by Lallemand SAS, 19 Rue des Briquetiers, BP59, 31,702 Blagnac, France.

³ In the herein opinion the current taxonomic unit nomenclature is used for *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*), *Acidipropionibacterium acidipropionici* (formerly *Propionibacterium acidipropionici*), *Lentilactobacillus buchneri* (formerly *Lactobacillus buchneri*) and *Lentilactobacillus hilgardii* (formerly *Lactobacillus hilgardii*).

⁴ Commission Implementing Regulation (EU) No 1065/2012 of 13 November 2012, OJ L 314, 14.11.2012, p.15.

⁵ Commission Implementing Regulation (EU) No 304/2014 of 25 March 2014; OJ L 90, 26.03.2014, p. 8.

⁶ Commission Implementing Regulation (EU) No 1119/2012 of 29 November 2012; OJ L 330, 30.11.2012, p. 14.

- One opinion (EFSA FEEDAP Panel, 2012b) on *Pediococcus pentosaceus* NCIMB 12455 (1k2106);⁶
- One opinion (EFSA FEEDAP Panel, 2012e) on *A. acidipropionici* CNCM I-4661 (1k2111);⁷
- One opinion on *L. hilgardii* CNCM I-4785 (EFSA FEEDAP Panel, 2017), one opinion on *L. buchneri* CNCM I-4323/ NCIMB 40788 (EFSA FEEDAP Panel 2013b) (1k20739)⁸ and one opinion with both active agents (EFSA FEEDAP Panel, 2018a) for the additive composed by these two strains (1k20757).⁹

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier¹⁰ in support of the authorisation request for the use of *L. plantarum* CNCM I-3235, *L. plantarum* CNCM I-3736/ DSM 11672, *P. acidilactici* CNCM I-3237, *P. acidilactici* CNCM I-4622/ DSM 11673, *Pediococcus pentosaceus* NCIMB 12455, *A. acidipropionici* CNCM I-4661, *L. buchneri* NCIMB 40788/ CNCM I-4323, and *L. buchneri* NCIMB 40788/ CNCM I-4323 plus *L. hilgardii* CNCM I-4785 as feed additives. The dossier was received on 25/03/2021 and the general information and supporting documentation is available at https://open.efsa.europa.eu/questions/EFSA-Q-2021-00426.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 19/11/2021 to 09/03/2022 for which received comments that 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 or other expert bodies, peer-reviewed scientific papers, to deliver the present output.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessments regarding the methods used for the control of the active agents in animal feed are valid and applicable for the current application, in particular for:

- L. buchneri NCIMB 40788/CNCM I-4323, L. plantarum CNCM I-3235/ ATCC 8014, L. plantarum DSM 11672/CNCM MA 18/5U/ CNCM I-3736.¹¹
- Pediococcus acidilactici CNCM I-3237, P. acidilactici CNCM MA 18/5M/ DSM 11673/ CNCM I-4622 and Pediococcus pentosaceus NCIMB 12455.¹²
- Acidipropionibacterium acidipropionici (formerly Propionibacterium acidipropionici) CNCM MA 26/4 U/ CNCM I-4661.¹³
- L. hilgardii CNCM I-4785 and L. buchneri CNCM I-4323/NCIMB 40788.¹⁴

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of the additives is in line with the principles laid down in Regulation (EC) No 429/2008¹⁵ and the relevant guidance documents: Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012f), Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018b) and Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2013c).

⁷ Commission Implementing Regulation (EU) No 990/2012 of 25 October 2012; OJ L 297, 26.10.2012, p. 15.

⁸ Commission Implementing Regulation (EU) No 1113/2013 of 7 November 2013, OJ L 298, 09.11.2013, p.29.

⁹ Commission Implementing Regulation (EU) 2019/764 of 14 May 2019; OJ L 126, 15.05.2019, p. 1.

¹⁰ FEED dossier reference: FAD-2021-0078.

¹¹ The full report is available on the EU Science Hub: https://joint-research-centre.ec.europa.eu/publications/20-fad-dossiers_en

¹² The full report is available on the EU Science Hub: https://joint-research-centre.ec.europa.eu/publications/fad-2010-0127025202590280_en

¹³ The full report is available on the EU Science Hub: https://joint-research-centre.ec.europa.eu/publications/fad-2010-0255_en

 ¹⁴ The full report is available on the EU Science Hub: https://joint-research-centre.ec.europa.eu/publications/fad-2018-0015_en
 ¹⁵ 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 additives based on preparations of viable cells of *L. plantarum* CNCM I-3235, *L. plantarum* CNCM I-3736/ DSM 11672, *P. acidilactici* CNCM I-3237, *P. acidilactici* CNCM I-4622/ DSM 11673, *P. pentosaceus* NCIMB 12455, *A. acidipropionici* CNCM I-4661, *L. buchneri* NCIMB 40788/ CNCM I-4323, and *L. buchneri* NCIMB 40788/ CNCM I-4323 plus *L. hilgardii* CNCM I-4785 are currently authorised as technological additives (functional group: silage additives) for use in forages for all animal species. This assessment regards the renewal of the authorisations of the above-mentioned additives.

3.1. Characterisation

3.1.1. Characterisation of the active agents

The active agents from the eight silage additives under assessment are listed in Table 1 together with their accession numbers in internationally recognised culture collections. Accession numbers for which a copy of the certificate of deposition is provided are shown in bold.¹⁶



The bacterial strains were recently tested to a new antimicrobial susceptibility testing assay using a broth microdilution method and including the set of antimicrobials recommended by the guidance (EFSA FEEDAP Panel, 2018b).



No hits of concern were identified. The genomic data further support the conclusion of the phenotypic analyses.

- ¹⁸ Technical dossier/Section II/Annex_II_4e.
- ¹⁹ Technical dossier/Section II/Annex_II_4f and Supplementary Information November 2022/Annex_5c_Annex_II_4f_AMENDED_ report_wgs_strain PA2_conf.
- ²⁰ Technical dossier/Section II/Annex_II_4h and Supplementary Information November 2022/Annex_5b_Annex_II_4h_AMENDED report_wgs_strain PrA for *A. acidipropionici* CNCM I-4661.
- ²¹ Technical dossier/Section II/Annex_II_4b.
- ²² Technical dossier/Section II/Annex_II_4c.
- ²³ Technical dossier/Section II/Annex_II_4d.

- ²⁵ Technical dossier/Supplementary Information November 2022/Annex_II_4a-4 h.
- ²⁶ Technical dossier/Section II/Annex_II_4a-4 h.
- ²⁷ Technical dossier/Supplementary Information November 2022/Annex_5a_Annex_II_4g_AMENDED_report_wgs_strain PP for for *P. pentosaceus* NCIMB 12455.
- ²⁸ Technical dossier/Supplementary Information November 2022/Annex_5b_Annex_II_4h_AMENDED report_wgs_strain PrA for A. acidipropionici CNCM I-4661.
- ²⁹ Technical dossier/Supplementary Information November 2022/Annex_5c_Annex_II_4f_AMENDED_report_wgs_strain PA2_conf.

¹⁶ Technical dossier/Section II/Annex_II_3b.

¹⁷ Technical dossier/Section II/Annex_II_4a.

²⁴ Technical dossier/Section II/Annex_II_4g and Supplementary Information November 2022/Annex_5a_Annex_II_4g_AMENDED_ report_wgs_strain PP for for *P. pentosaceus* NCIMB 12455.

3.1.2. Characterisation of the additives

The applicant declared that no changes to the manufacturing process were implemented since the first assessment of the products.³⁰

The applicant also declared that no antibiotics are used

during the manufacturing process of the additives.³⁰ Analytical data to confirm the specifications regarding the batch-to-batch variation^{31,32} were

provided for five batches of the additives and are shown in Table 1. **Table 1:** Data of the eight silage additives under assessment regarding accession numbers,

composition, batch-to-batch variation and dusting potential

Active agents of the additives* (authorisation identification	Composition of the additive	Average of Batch-to-batch (range)	Average of dusting potential by Stauber– Heubach ³³ (range)
number)		CFU/g	g/m ^s
L. plantarum CNCM I-3235/ ATCC 8014 (1k20717)	- Preparation of <i>Lactiplantibacillus plantarum</i> (CNCM I-3235) containing a minimum of 5×10^{10} CFU/g additive - Active agent (97%), Sodium Silicoaluminate E554 (3%)	$\begin{array}{l} \text{4.48} \times 10^{11} \\ \text{(4.3-5.3} \times 10^{11}) \end{array}$	40.9 (30.4–47.2)
L. plantarum DSM 11672/ CNCM MA 18/5U/ CNCM I-3736 (1k20722)	- Preparation of Lactiplantibacillus plantarum (CNCM MA 18/5 U) containing a minimum of 2×10^{10} CFU/g additive - Active agent (100%)	$\begin{array}{c} 3.3 \times 10^{11} \\ (2.3 - 4.1 \times 10^{11}) \end{array}$	33.3 (15.9–50.3)
<i>P. acidilactici</i> CNCM I-3237 (1k21009)	 Preparation of <i>Pediococcus acidilactici</i> CNCM I-3237 containing a minimum of 1 × 10¹⁰ CFU/g additive. Active agent (97%), Sodium Silicoaluminate E554 (3%) 	$\begin{array}{c} \textbf{7.67} \times 10^{11} \\ \textbf{(6.90-} \\ \textbf{8.24} \times 10^{11} \textbf{)} \end{array}$	32.7 (29.7–34.8)
<i>P. acidilactici</i> DSM 11673 / CNCM MA 18/5 M/ CNCM I-4622 (1k2104)	- Preparation of <i>Pediococcus acidilactici</i> CNCM MA 18/5 M DSM 11673 containing a minimum of 3×10^9 CFU/g additive - Active agent (97%), Sodium Silicoaluminate E554 (3%)	$\begin{array}{c} \textbf{7.57} \times 10^{11} \\ \textbf{(6.77-} \\ \textbf{8.92} \times 10^{11} \textbf{)} \end{array}$	42.7 (38.5–46.1)
<i>P. pentosaceus</i> NCIMB 12455 ³⁴ (1k2106)	- Preparation of Pediococcus pentosaceus NCIMB 12455 containing a minimum of 3 \times 10 ⁹ CFU/g additive - Active agent (100%)	$\begin{array}{c} 5.06 \times 10^{11} \\ (3.10- \\ 6.60 \times 10^{11}) \end{array}$	18.9 (14.9–23.8)
A. acidipropionici CNCM MA 26/4 U/ CNCM I-4661 (1k2111)	- Preparation of Acidipropionibacterium acidipropionici (CNCM MA 26/4 U) containing a minimum of 1×10^8 CFU/g additive - Active agent (97%), Sodium Silicoaluminate E554 (3%)	$\begin{array}{c} 9.8 \times 10^{11} \\ (8.95 \\ 10.3 \times 10^{11}) \end{array}$	48.3 (39.6–56.3)
L. buchneri NCIMB 40788/CNCM I-4323 (1k20739)	 Preparation of <i>Lentilactobacillus buchneri</i> NCIMB 40788/CNCM I-4323 containing a minimum of 3 × 10⁹ CFU/g additive. Active agent (96%), Sodium Silicoaluminate E554 (3%), xanthan gum E415 (1%) 	$\begin{array}{c} 8.55\times10^{11}\\ (6.53-\\ 10.6\times10^{11}) \end{array}$	41.1 (29.1–56.3)

³⁰ Technical dossier/Supplementary Information November 2022/20221124_FAD-2021-0078_SIn_ADR reply letter.

³¹ Technical dossier/Section II/Annex_II_2a and Supplementary Information November 2022/Annex_1 (for additive 1 k20757).

³² Technical dossier/Supplementary Information January 2023//2023-01-19_efsa_reply_sin_letter.

³³ Technical dossier/Section II/Annex_II_2c and Annex_II_2d.

³⁴ Technical dossier/Supplementary Information November 2022/Annex_3.

Active agents of the additives* (authorisation identification number)	Composition of the additive	Average of Batch-to-batch (range) CFU/g	Average of dusting potential by Stauber- Heubach ³³ (range) g/m ³
L. hilgardii CNCM I-4785 and L. buchneri CNCM I-4323/ NCIMB 40788 (1k20757)	- Preparation of <i>Lentilactobacillus hilgardii</i> CNCM I-4785 and <i>Lentilactobacillus buchneri</i> CNCM I- 4323/NCIMB 40788 containing a minimum of 1.5×10^{11} CFU/g additive (ratio of 1:1). - Active agents (96.5%), Sodium Silicoaluminate E554 (3%), xanthan gum (0.5%)	$\begin{array}{c} 5.40 \times 10^{11} \\ (4.76- \\ 6.01 \times 10^{11}) \end{array}$	2.5 (2–3.1)

ATCC: American Type Culture Collection; CNCM: Collection Nationale de Culture de Microorganismes; NCIMB: National Collection of Industrial and Marine Bacteria.

*: Accession numbers for which a copy of a valid certificate of deposition is provided are shown in **bold**; DSM, Deutsche Sammlung von Mikroorganismen und Zellkulturen.

Three recent batches of each additive were analysed for arsenic, cadmium, mercury and lead contents, as well as for mycotoxins (aflatoxin B1, zearalenone, ochratoxin A).³⁵ Results showed all batches with values below the respective limits of quantification (LOQs),³⁶ with the following exceptions:

- Two batches of *L. buchneri* NCIMB 40788/CNCM I-4323 had concentrations of mercury equal to the limit of quantification (0.02 mg/kg).
- Zearalenone was quantified in one batch of each *L. plantarum* CNCM I-3235 and *Pediococcus* acidilactici CNCM I-3237 (6.5 μg/kg and 6.1 μg/kg, respectively).
- Ochratoxin A was quantified in one batch each of *L. plantarum* CNCM I-3736/ DSM 11672, *A. acidipropionici* CNCM I-4661 and *P. acidilactici* CNCM I-3237 (1.39 μg/kg, 1.77 μg/kg and 1.00 μg/kg, respectively).

The detected amounts of the above-described impurities do not raise safety concerns.

All additives have specifications for coliforms (< 1,000 CFU/g), *Escherichia coli* (< 10 CFU/g), yeasts and filamentous fungi (< 1,000 CFU/g), *Staphylococcus aureus* (< 10 CFU/g) and *Salmonella* spp. (no detection in 25 g). The batches provided for the batch-to-batch variation, showed compliance with these specifications.³⁷ In addition, three recent batches from each additive were tested for the presence of *Enterobacteriaceae* and all were below the limit of detection (< 10 CFU/g).³⁵ All additives complied with the specifications set by the applicant.

3.1.3. Physical properties of the additives

The manufacturing processes have not been modified, therefore the data described in the previous opinions still apply. The applicant has provided new data on the dusting potential of the additives (Table 1).³⁸

In addition, new data on the shelf-life and stability in premixtures was also provided for all additives and stability in water was tested with five additives (*Pediococcus pentosaceus* NCIMB 12455, *Lactiplantibacillus plantarum* CNCM I-3736/ DSM 11672, *Lactiplantibacillus plantarum* CNCM I-3235, *Acidipropionibacterium acidipropionici* CNCM I-4661 and *Pediococcus acidilactici* CNCM I-3237).³⁹

Three batches of each additive were stored in sealed aluminium foil sachets for 18 months (*Lactiplantibacillus plantarum* CNCM I-3235, *Lactiplantibacillus plantarum* CNCM I-3736/ DSM 11672, *Acidipropionibacterium acidipropionici* CNCM I-4661 or *Lactobacillus hilgardii* CNCM I-4785 and *Lactobacillus buchneri* CNCM I-4323/ NCIMB 40788) or 24 months (*Pediococcus acidilactici* CNCM I-3237, *Pediococcus acidilactici* CNCM I-4622/ DSM 11673, *Pediococcus pentosaceus* NCIMB 12455 or *Lactobacillus buchneri* CNCM I-4323/ NCIMB 40788), at 25 °C and 60% relative humidity. All the analysed samples showed losses of < 0.5 log units of the initial value of the active agents.

Four different premixtures of silage additives (containing one or more of the additives under assessment) were stored in aluminium foil sachets, at 25°C and 60% relative humidity, for 6 months

³⁵ Technical dossier/Supplementary Information November 2022/Annex_2.

³⁶ LOQ: aflatoxins B1: 0.3 μg/kg or 0.6 μg/kg; deoxynivalenol 0.05 μg/kg; zearalenone: 5 μg/kg; ochratoxin A: 0.5 μg/kg or 1.00 μg/kg; mercury: 0.01 mg/kg; arsenic: 0.5 mg/kg; cadmium: 0.2 mg/kg; lead: 0.5 mg/kg; mercury: 0.02 mg/kg.

³⁷ Technical dossier/Section II/Annex_II_2a and Annex II_2b.

³⁸ Technical dossier/Section II/Annex_II_2d.

³⁹ Technical dossier/Section II/Annex_II_6a

(one premixture) and 24 months (three premixtures). All the analysed samples showed losses of < 0.5 log units of the initial value of the active agents.

The stability in water was studied in the above-mentioned five additives by suspending the concentrate stock cultures to target 1.5×10^{10} CFU/g (three batches) in 1 L of water and then storing for 48 h at 25°C. Negligible losses were observed with < 0.5 log of the initial value.

3.1.4. Conditions of use

The additives are currently authorised for use in forages and under other provisions of the authorisations the respective specifications are presented in Table 2.

Table 2: Other provisions of the authorisations of the eight silage additives for all animal species

Additive (identification number of the additive)	Other provisions:
L. plantarum CNCM I-3235/ ATCC 8014 (1k20717)	 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 microorganisms as silage additives: 2 × 10⁷ CFU/kg fresh material. For safety: it is recommended to use breathing protection and gloves during handling
Lactobacillus plantarum DSM 11672/ CNCM MA 18/5U/CNCM I-373 (1k20722)	 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 microorganisms as silage additives: 1 × 10⁸ CFU/kg fresh material. For safety: it is recommended to use breathing protection and gloves during handling.
Pediococcus acidilactici CNCM I-3237 (1k21009)	 In the directions for use of the additive and premixture, indicate the storage conditions. Minimum content of the additive when used without combination with other microorganisms as silage additives: 5 × 10⁷ CFU/Kg fresh material. For safety: it is recommended to use breathing protection, eye protection and gloves during handling.
Pediococcus acidilactici DSM 11673/CNCM MA 18/5 M / CNCM I-4622 (1k2104)	 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: 3 × 10⁷ CFU/Kg fresh material. For safety: it is recommended to use breathing protection and gloves during handling.
Pediococcus pentosaceus NCIMB 12455 (1k2106)	 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: 3 × 10⁷ CFU/Kg fresh material. For safety: it is recommended to use breathing protection and gloves during handling.
<i>A. acidipropionici</i> CNCM MA 26/4U/CNCM I-4661 (1k2111)	 In the directions for use of the additive and premixture, indicate the storage temperature and storage life. Minimum dose of the additive when it is not used in combination with other microorganisms as silage additive: 1 × 10⁸ CFU/kg of fresh material. For safety: it is recommended to use breathing protection and gloves during handling.



Additive (identification number of the additive)	Other provisions:
<i>L. buchneri</i> NCIMB 40788/ CNCM I-4323 (1k20739)	 In the directions for use of the additive and premixture, indicate the storage temperature and storage life. Minimum content of the additive when used without combination with other micro-organisms as silage additives: 1 × 10⁸ CFU/kg fresh material. For safety: it is recommended to use breathing protection and gloves during handling.
Lactobacillus hilgardii CNCM I-4785 and Lactobacillus buchneri CNCM I-4323/ NCIMB 40788 (1k20757)	 In the directions for use of the additive and premixtures, the storage conditions shall be indicated. Minimum content of the additive when used without combination with other micro-organisms as silage additives: 3 × 10⁸ CFU/kg (<i>L. hilgardii</i> CNCM I-4785 and <i>L. buchneri</i> CNCM I-4323/NCIMB 40788 in ratio of 1:1) of easy and moderately difficult to ensile fresh material. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.

3.2. Safety

The applicant declares that no adverse effects including accidents for target animals, consumers, users and/or the environment have been reported since the approval of the additives.^{40,41}

3.2.1. Safety for the target species, consumer and environment

In the previous opinions the Panel concluded that, following the qualified presumption of safety (QPS) approach to safety assessment, the use of the strains in the production of silage was considered safe for target species, consumers and the environment (EFSA FEEDAP Panel, 2012a,b,e, 2013b, 2018a). In the context of the current application, the identity of each strain confirmed they all belong to species qualifying for the QPS, and evidence was provided that the strains do not show acquired antimicrobial determinants for antibiotics of human and veterinary importance (EFSA 2007; EFSA BIOHAZ Panel, 2020). Consequently, the conclusions already reached are still valid and the strains are considered safe for the target species, consumers and the environment.

3.2.2. Safety for the user

No specific data to assess user safety were submitted on the effects of the additives under assessment (except for *P. acidilactici* CNCM I-4622/ DSM 11673 in the eyes and skin).

The data provided^{42,43} for *P. acidilactici* CNCM I-4622/ DSM 11673 was previously assessed by the FEEDAP Panel (EFSA, 2009a), where it was concluded that the product tested is non-irritant to skin and eyes but should be considered a respiratory sensitiser. The Panel reiterates its previous conclusions on the skin and eyes irritancy testing. Moreover, the data on the skin sensitisation test⁴⁴ was previously submitted and assessed (EFSA FEEDAP Panel, 2016), however, the Panel notes that the OECD test guidelines available at present are designed to assess the skin sensitisation potential of chemical substances only and that currently no validated assays for assessing the sensitisation potential of the additive.

⁴⁰ Technical dossier/Section III/Sect_III_Safety.

⁴¹ Technical dossier/ Supplementary Information January 2023/2023-01-19_efsa_reply_sin_letter.

⁴² Technical dossier/Section III/ Annex_III_1_dermal_irrit_404.

⁴³ Technical dossier/Section III/ annex_III_3_eyes_sens_405.

⁴⁴ Technical dossier/Section III/ Annex_III_2_skin_sens_429.

⁴⁵ https://www.efsa.europa.eu/sites/default/files/2022-07/feedap20220629-30_m.pdf

The Panel notes that for *P. acidilactici* CNCM I-4622 the conclusions apply to the product tested. For this specific additive, the excipients used in the preparation of the final formulation are not expected to introduce additional risks. Once an active agent has been authorised, different formulations can be placed on the market with reference to that authorisation. The Panel cannot conclude on other formulations that might be placed on the market.

The FEEDAP Panel cannot conclude on the eye and skin irritancy potential of the additives (except *P. acidilactici* CNCM I-4622)/ DSM 11673. The additives are considered respiratory sensitisers and no conclusions can be made regarding the dermal sensitisation potential of the additives.

3.2.3. Conclusions on safety

Based on the QPS approach to safety assessment, the FEEDAP Panel concludes that there is no new evidence that would lead it to reconsider the previous conclusions that *Lactiplantibacillus plantarum* CNCM I-3235, *L. plantarum* CNCM I-3736/ DSM 11672, *Pediococcus acidilactici* CNCM I-3237, *P. acidilactici* CNCM I-4622/ DSM 11673, *Pediococcus pentosaceus* NCIMB 12455, *Acidipropionibacterium acidipropionici* CNCM I-4661, *Lentilactobacillus buchneri* NCIMB 40788/ CNCM I-4323 and *Lentilactobacillus hilgardii* CNCM I-4785 are safe for the target species, consumers and the environment under the authorised conditions of use. All additives are considered respiratory sensitisers and no conclusions can be drawn regarding skin sensitisation potential. Except for the *P. acidilactici* CNCM I-4622 (which is non-irritant to skin and eyes), no conclusions for the additives can be made on the potential to be irritant to eyes and/or skin.

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.

4. Conclusions

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

The Panel concludes that *Lactiplantibacillus plantarum* CNCM I-3235, *L. plantarum* CNCM I-3736/ DSM 11672, *Pediococcus acidilactici* CNCM I-3237, *P. acidilactici* CNCM I-4622/ DSM 11673, *Pediococcus pentosaceus* NCIMB 12455, *Acidipropionibacterium acidipropionici* CNCM I-4661, *Lentilactobacillus buchneri* NCIMB 40788/CNCM I-4323 and *Lentilactobacillus buchneri* NCIMB 40788/ CNCM I-4323 plus *Lentilactobacillus hilgardii* CNCM I-4785 remain safe for the target species, consumers and the environment under the authorised conditions of use.

The additives should be considered respiratory sensitisers. No conclusions can be drawn on the skin sensitisation, and eye and skin irritancy potential of the additives, except for *Pediococcus acidilactici* CNCM I-4622/ DSM 11673 which is non-irritant to skin and eyes.

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

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Abbreviations

ATCC	American Type Culture Collection
CFU	colony forming unit
CNCM	Collection Nationale de Culture de Microorganismes
CV	coefficient of variation
DM	dry matter
DSM	Deutsche Sammlung von Mikroorganismen und Zellkulturen
EURL	European Union Reference Laboratory
FAO	Food Agricultural Organization
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
NCIMB	National Collection of Industrial and Marine Bacteria
OECD	Organisation for Economic Co-operation and Development