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Assessment of the feed additive consisting of *Pediococcus pentosaceus* DSM 12834 for all animal species for the renewal of its authorisation (Lactosan GmbH & Co KG)

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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 the authorisation of *Pediococcus pentosaceus* DSM 12834 as a technological additive 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 that would lead the FEEDAP Panel to reconsider its previous conclusions. Thus, the Panel concludes that the additive remains safe for all animal species, consumer and the environment under the authorised conditions of use. Regarding user safety *Pediococcus pentosaceus* DSM 12834 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.

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Keywords: technological additive, silage additive, *Pediococcus pentosaceus* DSM 12834, safety, efficacy, QPS, renewal

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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 consisting of *Pediococcus pentosaceus* DSM 12834, when used as a feed additive for all animal species and categories (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). 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 09 March 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 *Pediococcus pentosaceus* DSM 12834, when used under the proposed conditions of use (see **Section 3.1.3**).

1.2. Additional information

The additive is a preparation containing viable cells of *P. pentosaceus* DSM 12834. It is currently authorised as a feed additive in the European Union (1k2103).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 dossier⁴ in support of the authorisation request for the use of *Pediococcus pentosaceus* DSM 12834 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 *Pediococcus pentosaceus* DSM 12834 is in line with the principles laid down in Regulation (EC) No 429/2008⁶ and the relevant guidance documents: Guidance on the characterisation of microorganisms used as feed

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 Commission Implementing Regulation (EU) No 1263/2011 of 5 December 2011 concerning the authorisation *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. 3–8.

⁴ FEED dossier reference: FAD-2020-0100.

⁵ The full report is available on the EURL website: <https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-uorg-silage-group1.pdf>

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.

additives or as production organisms (EFSA FEEDAP Panel, 2018) and Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2013).

3. Assessment

The product consisting of viable cells of *P. pentosaceus* DSM 12834 is authorised for use as a technological additive (functional group: silage additives) for use in forages for all animal species. This assessment regards the renewal of the authorisation of *P. pentosaceus* DSM 12834 for the above-mentioned species.

3.1. Characterisation

3.1.1. Characterisation of the additive

The product currently authorised consists of approximately 35–50% biomass and 50–65% carriers ([REDACTED]) and cryoprotectants ([REDACTED]). The minimum concentration of the active agent (*P. pentosaceus* DSM 12834) is 4×10^{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. [REDACTED]). Regarding the composition of the additive [REDACTED] are also used as cryoprotectants.

Analysis of three batches showed compliance with the authorisation with a mean value of 5.16×10^{11} CFU/g (range $4.88\text{--}5.43 \times 10^{11}$ CFU/g).⁷

Specifications are set for Enterobacteriaceae (< 1,000 CFU/g), yeasts and filamentous fungi (1,000 CFU/g) and *Salmonella* spp. (no detection in 25 g). Analysis of the above referred batches of the additive showed compliance with these limits.⁸ Three batches of the additive were tested for aflatoxins (B1, B2, G1, and G2), deoxynivalenol, zearalenone, lead, mercury, and arsenic; results showed levels below the respective limits of detection/quantification except for cadmium (average 0.13, range: 0.12–0.13 mg/kg)^{9,10,11}

No new data have been provided regarding the physico-chemical properties or stability 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 (EFSA FEEDAP Panel, 2011).

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 12834.¹² It has not been genetically modified.

Taxonomic identification of the active agent was confirmed with [REDACTED] the whole genome sequence (WGS).¹³ The results [REDACTED] showed a value of [REDACTED]

The bacterial strain was tested for antibiotic susceptibility using a broth microdilution method.¹⁴ The battery of antibiotics used included those recommended by EFSA for *Pediococcus* spp. (EFSA FEEDAP Panel, 2018). All the minimum inhibitory concentration values were equal or fell below the cut-off values, except for tetracycline, which exceeded by one dilution (16 mg/L vs 8 mg/L).

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 Limit of detection: 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_WGS.pdf.

¹⁴ Technical dossier/Section II/Annex_II_2_5_Antibio.

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 of the strain, [REDACTED], was searched for antibiotic resistance genes [REDACTED].¹⁵ No hits were identified.

3.1.3. Conditions of use

The additive is currently authorised without an inclusion level for use in forages for all animal species. It is to be applied as an aqueous suspension.

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 microorganisms 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

In the previous opinion the FEEDAP Panel concluded that following the qualified presumption of safety (QPS) approach, the use of this strain in the production of silage was considered safe for target species, consumers and the environment (EFSA FEEDAP Panel, 2011). In the context of the current application, the identity of the strain as *P. pentosaceus* was confirmed and evidence was provided that the strain does not harbour antimicrobial resistance determinants to antibiotics of human and veterinary importance. Consequently, the conclusions already reached are still valid and *Pediococcus pentosaceus* DSM 12834 is considered 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 *P. pentosaceus* DSM 12834. Given the lack of information and its proteinaceous nature, the active agent has the potential to be a skin/respiratory sensitiser'. No additional data were provided in the current application.

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 the additive remains safe under the approved conditions for target species, consumers, users and the environment. The literature search was conducted in August 2020 without time restrictions.¹⁷ The search term used was '*Pediococcus pentosaceus* DSM 12834' and the strategy followed was reported. The applicant searched in a total of seven relevant databases (Agricola, Agris, Google scholar, Ingenta, PubMed, Science Direct and World Cat Library). The literature search retrieved 34 publications. However, after removal of nine duplicates, none were considered relevant because they referred either to another product (two publications), or to the previous EFSA FEEDAP opinion (four hits), or to analytical methods (one publication), or to the authorisation of the additive (two publications) or to its efficacy (as a silage additive in 13 publications or as a zootechnical additive in three publications).

Therefore, considering all the above, the FEEDAP Panel concludes that there is no evidence that would lead to reconsider the previous conclusions that *Pediococcus pentosaceus* DSM 12834 is safe for the target species, consumers and the environment under the authorised conditions of use. Regarding user safety, *Pediococcus pentosaceus* DSM 12834 is not irritant to skin and eyes but is considered a skin and respiratory sensitiser.

¹⁵ Technical dossier/Section II/Annex_II_2_6_AMR.

¹⁶ Technical dossier/Section III.

¹⁷ Technical dossier/Section III/Annex 3 Literature.

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 additive currently on the market complies with the existing conditions of authorisation.

There is no evidence that would lead the FEEDAP Panel to reconsider its previous conclusions. Thus, the Panel concludes that *Pediococcus pentosaceus* DSM 12834 remains safe for all animal species, consumer 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 provided to EFSA/Chronology

Date	Event
01/12/2020	Dossier received by EFSA. <i>P. pentosaceus</i> DSM 12834. Submitted by Lactosan GmbH & Co.KG
18/12/2020	Reception mandate from the European Commission
09/03/2021	Application validated by EFSA – Start of the scientific assessment
10/06/2021	Comments received from Member States
23/06/2021	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 *Pediococcus pentosaceus* (DSM 12834) as a silage additive for all species. EFSA Journal 2011;9(9):2369, 11 pp. <https://doi.org/10.2903/j.efsa.2011.2369>
- 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, Lopez-Alonso M, Lopez Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Glandorf B, Herman L, Karenlampi 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, 20 pp. <https://doi.org/10.2903/j.efsa.2018.5206>

Abbreviations

CFU	colony forming unit
dDDH	digital DNA–DNA hybridisation
DSMZ	Deutsche Sammlung von Mikroorganismen und Zellkulturen
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
QPS	qualified presumption of safety
WGS	whole genome sequence