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Assessment of the application for renewal of the authorisation of *Pediococcus pentosaceus* DSM 16244 as a feed additive for all animal species

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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 authorisation of *Pediococcus pentosaceus* DSM 16244 as a technological additive for all animal species. The applicant has provided evidence that the additive currently in the market complies with the existing conditions of authorisation. There was no new evidence that would lead the FEEDAP Panel to reconsider its previous conclusions. Thus, the Panel concluded that the additive remains safe for all animal species, consumer and the environment under the authorised conditions of use. The additive was not irritant to skin and eyes but considered a skin and respiratory sensitiser. The present application for renewal of the authorisation did 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 was no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

Keywords: technological additive, silage additive, *Pediococcus pentosaceus* DSM 16244, all animal species, safety

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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 renewal of the authorisation of the product *Pediococcus pentosaceus* DSM 16244, 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 (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 12 July 2019.

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 16244, when used under the proposed conditions of use (see Section 3.1.3).

1.2. Additional information

The additive is a preparation of *Pediococcus pentosaceus* DSM 16244.

EFSA has issued an opinion on the safety and efficacy of *Pediococcus pentosaceus* DSM 16244 as a feed additive for all animal species (EFSA FEEDAP Panel, 2010).

The additive is authorised in the European Union (EU) as a technological additive (functional group: silage additives) for use in feed for all animal species.[3]

The applicant has requested the renewal of the authorisation of the additive for all animal species.

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 *Pediococcus pentosaceus* DSM 16244 as a feed additive.

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

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 of *Pediococcus pentosaceus* DSM 16244 is in line with the principles laid down in Regulation (EC) No 429/2008[6] and the relevant guidance documents: Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
[2] Lactosan GmbH & Co.KG, Industriestraβe west 5, 8605 Kapfenberg, Austria.
[3] Commission Regulation (EU) No 514/2010 of 15 June 2010 concerning the authorization of Pediococcus pentosaceus (DSM 16244) as a feed additive for all animal species. OJ L 150, 16.6.2010, p. 30.
[4] FEED dossier reference: FAD-2019-0039.
[5] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2009-0024.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.

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

3. Assessment

The additive under assessment is a preparation of *P. pentosaceus* DSM 16244 and is authorised for use as a technological additive (functional group: silage additives) in feed for all animal species. The current assessment is performed in the context of the renewal of the authorisation of the feed additive.

3.1. Characterisation

3.1.1. Characterisation of the additive

The additive is a preparation of *P. pentosaceus* DSM 16244. The information submitted regarding the manufacturing process lists a series of modifications applied to the fermentation process during the last few years. The modifications regard the composition of the fermentation medium: some suppliers were changed and soy peptone and manganese sulphate are added. Regarding the composition of the additive, the options for the cryoprotectant include now sodium ascorbate (instead of ascorbic acid) and dextrose monohydrate (as new cryoprotectant). The FEEDAP Panel considers that these modifications will not significantly modify the final product and none of them is considered of to cause safety concerns. The applicant declares that no antibiotics are used during the manufacturing process.

The additive contains the active agent *P. pentosaceus* DSM 16244 (35–50% of the additive), cryoprotectants (whey powder, mannite, lactose, dextrose monohydrate, sodium ascorbate, sodium citrate or casein peptone) and carrier (whey powder, dextrose anhydrous or maltodextrine) (50–65%). Whey powder was used in all the batches of the products referred to in this application.

The current authorisation is for *P. pentosaceus* DSM 16244 at the minimum total concentration of 4×10^{11} colony forming units (CFU)/g additive. The analysis of three recent batches of the additive (mean count 4.6×10^{11} CFU/g additive, range $4.4–4.7 \times 10^{11}$ CFU/g additive) showed compliance with the specifications of the additive in the authorising Regulation.[7]

Three recent batches of the product were analysed for chemical and microbiological contamination.[8,9]

The analysis of chemical contamination included arsenic (0.17–0.22 mg/kg), and heavy metals (cadmium, lead and mercury were below the corresponding limit of quantification (LOQ)).[10] Mycotoxins (aflatoxin B1, B2, G1 and G2, deoxynivalenol, and zearalenone) were below the corresponding LOQs.[11]

Specifications for microbiological contamination include enterobacteria ($< 10^3$ CFU/g), yeast and moulds ($< 10^3$ CFU/g) and *Salmonella* spp. (absent in 25 g). Analysis in three batches of the additive confirmed compliance with these limits.

3.1.2. Characterisation of the active agent

The *P. pentosaceus* strain was isolated from natural silage. It is deposited in the German collection of microorganisms and cell cultures with the accession number DSM 16244.[12,13] The strain has not been genetically modified.

A bioinformatic analysis of the whole genome sequence (WGS) of the active agent confirmed its identity as *P. pentosaceus*.[14] [redacted]

[7] Technical dossier/Section II/Annex II.1-2.
[8] Technical dossier/Section II/Annex II.1-3 and Annex II.1-5.
[9] Technical dossier/Supplementary information March 2020/Annex_V.
[10] Technical dossier/Section II/Annex II.1-5. LOQ in mg/kg were 0.156 for arsenic, 0.141 for lead, 0.064 for cadmium and 0.001 for mercury.
[11] Technical dossier/Supplementary information March 2020/Annex_V. LOD in μg/kg were 0.03 for aflatoxin B1, B2, G1 and G2; 10 for deoxynivalenol, and 5 for zearalenone.
[12] Technical dossier/Section II/Annex II.2-2.
[13] Technical dossier/Supplementary information March 2020/Annex_I.
[14] Technical dossier/Supplementary information March 2020/Annex_II and Annex_IIa.

[redacted][14]

The susceptibility of the strain to the antibiotics recommended by the FEEDAP Panel (EFSA FEEDAP Panel, 2018) was tested [redacted] FEEDAP Guidance (EFSA FEEDAP Panel, 2018) [redacted] The WGS of the active agent, [redacted] was interrogated for the presence of antimicrobial resistance (AMR) genes [redacted]

3.1.3. Conditions of use

The additive is currently authorised for use with all forages for all animal species without a minimum or maximum content. The authorisation states that 'the minimum dose of the additive used singly is: 1×10^8 CFU/kg of organic material'.

The authorisation also includes under 'Other provisions' 'For Safety: It is recommended to use breathing protection and gloves during handling'.

The applicant does not propose to modify the conditions of use as authorised.

3.2. Safety

Pediococcus pentosaceus is considered by EFSA to be suitable for the qualified presumption of safety (QPS) approach to safety assessment (EFSA, 2007; EFSA BIOHAZ Panel, 2020). Since the identity of the active agent was established, the absence of any determinants of resistance to antibiotics of human and veterinary importance was demonstrated and the additive essentially consists of only the active agent, safety for the target species, consumers of products from animals fed the additive and the environment were presumed (EFSA FEEDAP Panel, 2010). In the present application, the applicant has provided up to date confirmation of the taxonomical identification of the strain as *P. pentosaceus* and evidence that the strain does not show acquired antimicrobial determinants for antibiotics of human and veterinary importance. Consequently, the additive can be presumed as safe for the target species, the consumer and the environment.

The safety for the user was evaluated by the FEEDAP Panel in a previous assessment (EFSA FEEDAP Panel, 2010). The Panel concluded that the additive is not irritant to skin and eyes but considered a skin and respiratory sensitiser. No additional data were provided in the current application.

In line with the requirements established in the EFSA guidance on the renewal (EFSA FEEDAP Panel, 2013), 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 February 2019 and without restrictions.[17] The search term used was '*Pediococcus pentosaceus* DSM 16244' and the strategy followed was reported. The applicant searched in a total of 7 relevant databases Agricola, Agris, Google scholar, Ingenta, PubMed, Science Direct and World Cat Library. The literature search retrieved 12 publications. Most of the publications were excluded from the assessment because they referred to the previous EFSA FEEDAP opinion (EFSA FEEDAP Panel, 2010) or to the authorisation of the additive (8 publications), or the product was not the one under assessment (3 publications). The other publication found (Emerstorfer et al., 2009) did not provide any information on the safety of the product and therefore, was considered not relevant.

Therefore, the FEEDAP Panel concludes that there is no new evidence that would lead it to reconsider previous conclusions that *P. pentosaceus* DSM 16244 is safe for the target species, consumers and the environment under the authorised conditions of use. Regarding user safety *P. pentosaceus* DSM 16244 is not irritant to skin and eyes but considered a skin and respiratory sensitiser.

[15] Technical dossier/Supplementary information March 2020/Annex_III.
[16] Technical dossier/Supplementary information March 2020/Annex_IV.
[17] Technical dossier/Section III/Annex III_3.

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 new 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, *P. pentosaceus* DSM 16244 is not irritant to skin and eyes but 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
17/05/2019	Dossier received by EFSA. *Pediococcus pentosaceus* DSM 16244 for all species. Submitted by Lactosan GmbH & Co. KG.
06/05/2019	Reception mandate from the European Commission
12/07/2019	Application validated by EFSA – Start of the scientific assessment
25/09/2019	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterisation of the strain, purity*
12/10/2019	Comments received from Member States
17/03/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
25/05/2020	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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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

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Emerstorfer F, Kneifel W and Hein W, 2009. The role of plant-based antimicrobials in food and feed production with special regard to silage fermentation. Die Bodenkultur, 60, 55–65.

Abbreviations

AMR	antimicrobial resistance
BIOHAZ	EFSA Panel on Biological Hazards
CFU	colony forming unit
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
LOD	limit of detection
LOQ	limit of quantification
QPS	qualified presumption of safety
WGS	whole genome sequence