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Assessment of the feed additive consisting of *Lactococcus lactis* NCIMB 30160 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 authorisation of *Lactococcus lactis* NCIMB 30160 as a technological additive for all animal species. The additive aims to improve the production of silage and is authorised for all animal species. The applicant provided evidence that the additive currently on the market complies with the existing conditions of authorisation. There was no new evidence to lead the FEEDAP Panel to reconsider its previous conclusions. Thus, the Panel concluded that the additive remains safe for all animal species, consumers and the environment under the authorised conditions of use. Regarding user safety, *Lactococcus lactis* NCIMB 30160 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, *Lactococcus lactis* NCIMB 30160, safety, efficacy, QPS, renewal

Requestor: European Commission

Question number: EFSA-Q-2021-00082

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

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 the renewal of the authorisation of the additive consisting of the product *Lactococcus lactis* NCIMB 30160, 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). 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 02 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 *Lactococcus lactis* NCIMB 30160, when used under the proposed conditions of use (see Section 3.1.3).

1.2. Additional information

The additive consisting of viable cells of *L. lactis* NCIMB 30160 is currently authorised as a technological additive (functional group: silage additive) for use in feed for all animal species in the European Union (1k2082).[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 *Lactococcus lactis* NCIMB 30160 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 or other expert bodies, peer-reviewed scientific papers, other scientific reports 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 agent in animal feed are valid and applicable for the current application.[5]

[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 plus amendments.
[4] FEED dossier reference: FAD-2021-0006.
[5] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/default/files/FinRep-uorg-silage-group1.pdf

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of *L. lactis* NCIMB 30160 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).

3. Assessment

The product consisting of viable cells of *L. lactis* NCIMB 30160 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. lactis* NCIMB 30160 for all animal species.

3.1. Characterisation

3.1.1. Characterisation of the additive

The product currently authorised consists of approximately 35–50% bacterial cells and 50–65% carriers ( ) and cryoprotectants ( ). The minimum concentration of the active agent (*L. lactis* NCIMB 30160) is 4×10^{11} colony forming units (CFU) per gram of additive.

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

Analysis of three recent batches showed a mean value of 4.8×10^{11} CFU/g additive (range $4.7–5.0 \times 10^{11}$ CFU/g additive).[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).[8] Analysis of the above-referred batches of the additive showed compliance with these limits. These recent batches were also tested for aflatoxins (B1, B2, G1 and G2), deoxynivalenol, zearalenone,[9] lead, mercury, cadmium and arsenic concentrations.[10] Results showed 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 are still applicable (EFSA FEEDAP Panel, 2011).

3.1.2. Characterisation of the active agent

The active agent was isolated from silage. It is deposited in the National Collection of industrial, food and marine bacteria (NCIMB) with the following deposit number 30160.[12] It has not been genetically modified.

The taxonomic identification of the strain as *L. lactis* was confirmed

[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.
[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 quantification: aflatoxins (B1, B2, G1, and G2): 0.03 μg/kg, deoxynivalenol 10 μg/kg, zearalenone 5 μg/kg, Pb 0.10 mg/kg, Hg 0.10 mg/kg, Cd 0.03 mg/kg and As 0.10 mg/kg.
[12] Technical dossier/Supplementary information August 2021/Annex _30160.
[13] Technical dossier/Section II/Annex II_2_4.

[redacted]

The bacterial strain was tested for antibiotic susceptibility using [redacted]. The battery of antibiotics used included those recommended by EFSA (EFSA FEEDAP Panel, 2018).[15] [redacted] Therefore, the strain is considered to be susceptible to all the relevant antibiotics.

The WGS of the strain, including the [redacted] as thresholds.[14] No hits were identified.

3.1.3. Conditions of use

The additive is currently authorised for use in forages for all animal species.

According to other provisions of the authorisation, the following is specified:

- '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 requested that the same conditions of use be maintained.

3.2. Safety

In the previous opinion, the 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 this application, the identity of the strain as *L. lactis* was confirmed and evidenced that the strain does not show acquired antimicrobial determinants for antibiotics of human and veterinary importance was provided. Consequently, the conclusions already reached are still valid and *L. lactis* NCIMB 30160 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 *L. lactis* NCIMB 30160. Given the lack of specific information and its proteinaceous nature, the active agent should be considered to have the potential to be a skin and respiratory sensitiser'.

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

The applicant performed a literature search to provide evidence that the additive remains safe under the approved conditions for target species, consumers, users and the environment.[16] The literature search was conducted in November 2020 without time restrictions. The search term used was '*Lactococcus lactis* NCIMB 30160', 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. Seventeen hits were scored after the duplications were removed. However, none was considered relevant because they either referred to the previous EFSA opinion (three), to the authorisation of the additive (one), or to the efficacy of the additive when used alone or in combination with other products (13).

Therefore, the FEEDAP Panel concludes that there is no new evidence to lead it to reconsider the previous conclusions that *L. lactis* NCIMB 30160 is safe for the target species, consumers and the environment under the authorised conditions of use. Regarding user safety, *L. lactis* NCIMB 30160 is not irritating to the skin and eyes but is considered a skin and respiratory sensitiser.

[14] Technical dossier/Section II/Annex_II_2_6.
[15] Technical dossier/Section II/Annex_II_2_5.
[16] Technical dossier/Section III/Annexes III_5-13.

3.3. Efficacy

The present application for renewal of the authorisation does not include a proposal to amend or supplement the conditions of the original authorisation, which 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.

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, *Lactococcus lactis* NCIMB 30160 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
12/02/2021	Dossier received by EFSA. Renewal *Lactococcus lactis* NCIMB 30160 (1k2082). Submitted by Lactosan GmbH & Co.KG
06/05/2021	Reception mandate from the European Commission
02/03/2021	Application validated by EFSA – Start of the scientific assessment
18/08/2021	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*
25/08/2021	Reception of supplementary information from the applicant - Scientific assessment re-started
28/09/2021	Comments received from Member States
10/11/2021	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), 2011. Scientific Opinion on the safety and efficacy of *Lactococcus lactis* (NCIMB 30160) as a silage additive for all species. EFSA Journal 2011;9(9):2366, 43 pp. https://doi.org/10.2903/j.efsa.2011.2366

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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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
NCIMB	National Collection of industrial, food and marine bacteria
QPS	Qualified presumption of safety
TYGS	type strain genome server
WGS	Whole genome sequence