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# Safety and efficacy of a feed additive consisting of *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) DSM 26571 for all animal species (Chr. Hansen A/S)

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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 safety and efficacy of *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) DSM 26571 when used as a technological additive intended to improve ensiling of forage. The additive is intended for use with all forages and for all animal species at a proposed application rate of $1 \times 10^8$ colony forming units (CFU)/kg fresh material. The bacterial species *L. plantarum* is considered by EFSA to be suitable for the qualified presumption of safety approach to safety assessment. As the identity of the strain has been clearly established and no acquired antimicrobial resistance determinants of concern were detected, the use of the strain as a silage additive is considered safe for livestock species, for consumers and for the environment. The additive is not irritant to skin or eyes and is not a skin sensitiser but should be considered a potential respiratory sensitiser. The FEEDAP Panel concluded that the addition of *Lactiplantibacillus plantarum* DSM 26571 at a minimum concentration of $1 \times 10^8$ CFU/kg may improve the production of silage from easy, moderately difficult and difficult to ensile forage material.



**Keywords:** technological additive, silage additive, *Lactiplantibacillus plantarum* DSM26571, safety, efficacy, QPS

**Requestor:** European Commission

**Question number:** EFSA-Q-2020-00279

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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 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from Chr. Hansen A/S[2] for authorisation of the product *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) DSM 26571, 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 4(1) (authorisation of a feed additive or new use of a feed additive). 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 22 July 2020.

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 *L. plantarum* DSM 26571, when used under the proposed conditions of use (see Section 3.1.4).

## 1.2. Additional information

The additive is a preparation containing viable cells of *Lactiplantibacillus plantarum* DSM 26571. It has not been previously authorised as a feed additive in the European Union.

# 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[3] in support of the authorisation request for the use of *Lactiplantibacillus plantarum* DSM 26571 as a feed additive.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the active agent in animal feed. The Executive Summary of the EURL report can be found in Annex A.[4]

## 2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of *L. plantarum* DSM 26571 is in line with the principles laid down in Regulation (EC) No 429/2008[5] and the relevant guidance documents: Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017a), Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018a), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017c), Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012), Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019) and Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018b).

[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] Chr. Hansen A/S, 10-12 Boerge Allé, DK-2970, Hoersholm, Denmark.
[3] FEED dossier reference: FAD-2019-0091.
[4] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/finrep-fad-2019-0091-lactobacillus-plantarum.pdf
[5] 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 additive is based on a preparation of viable cells of *Lactiplantibacillus plantarum* DSM 26571 and is intended to be added to forages to promote ensiling (technological additive, functional group: silage additives) for use in all animal species.

## 3.1. Characterisation

### 3.1.1. Characterisation of the active agent

The active agent *L. plantarum* [redacted] is deposited in the Deustche Sammlung von Mikroorganismen und Zellkuturen GmbH (DSMZ) with the accession number DSM 26571.[7] It has not been genetically modified.

Taxonomical identification was confirmed [redacted]

The bacterial strain was tested for antimicrobial susceptibility using the broth microdilution method and including the list of antimicrobials recommended by the FEEDAP Panel (EFSA FEEDAP Panel, 2018a).[9] All the minimum inhibitory concentration (MIC) values were equal or fell below the corresponding cut-off values defined by the FEEDAP Panel for *L. plantarum/pentosus*, except for kanamycin (MIC: 128 mg/L vs. cut-off value: 64 mg/L) and tetracycline (MIC: 64 mg/L *vs.* cut-off value: 32 mg/L). 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.

[redacted]

### 3.1.2. Characterisation of the additive and manufacturing process

The active agent (*Lactiplantibacillus plantarum* DSM 26571) [redacted] reach a minimum concentration of active agent of $1 \times 10^{11}$ CFU per g of additive.[11]

Analysis of five batches of the additive showed a mean value of $1.8 \times 10^{11}$ CFU/g (range $1.6–1.9 \times 10^{11}$ CFU/g).

The specifications for microbial contaminants include coliforms ($< 10^3$ CFU/g), *Escherichia coli* ($< 10$ CFU/g), *Salmonella* spp. (no detection in 25 g), and yeasts and filamentous fungi ($< 10^3$ CFU/g). Data from five batches confirmed compliance with the established specifications.[12].

The applicant set limits for the following undesirable substances: mycotoxins (aflatoxin B1, < 0.01 mg/kg), heavy metals [cadmium (≤ 0.5 mg/kg), mercury (≤ 0.1 mg/kg) and lead (≤ 5.0 mg/kg)] and arsenic (≤ 2.0 mg/kg). Three batches were tested for mycotoxins, heavy metals and concentration of arsenic,[13] and the results were compliant with the specifications of the additive. The following mean values were obtained: cadmium 0.014 mg/kg (range 0.011–0.019 mg/kg), mercury 0.003 mg/kg (range 0.002–0.003 mg/kg), and arsenic 0.029 mg/kg (range 0.026–0.030 mg/kg). The results of the

[6] Technical dossier/Section II/Annex II.2.1.2a.
[7] Technical dossier/SIn June 2021/Annex Q1.
[8] Technical dossier/Section II/Annex II.2.1.2c.
[9] Technical dossier/Section II/Annex II.2.2.2b.
[10] Technical dossier/Section II/Annex II.2.2.2a and Technical dossier/Sin Oct20/Annex Q1.
[11] Technical dossier/Section II/Annex II.3.1b.
[12] Technical dossier/Section II/Annex II.1.3b.
[13] Technical dossier/Section II/Annex II.1.4.1.

remaining tested substances (namely aflatoxin B1, sum of aflatoxins B1, B2, G1, G2 and lead), were below the corresponding limit of detection.[14]

The additive has an average bulk density of 461 kg/m$^3$ (range: 447–471 kg/m$^3$).[15] The dusting potential of the additive was measured in three batches by the Stauber–Heubach method and showed a mean value of 21.7 mg/m$^3$ (range 15–35 mg/m$^3$).[16] The same batches were tested for particle size distribution by laser diffraction.[17] Results showed that 29% of particles have a diameter between 10 and 50 μm, 8% below 10 μm; and no particles smaller than 1 μm were detected.

#### 3.1.3. Stability

Three batches of the additive (initial counts had an average of $3.8\times10^{11}$ CFU/g and range $3.1–4.8 \times 10^{11}$ CFU/g) were stored in sealed aluminium foil bags at –20°C, 4°C and 25°C for at least 9 months. Negligible losses (< 0.5 log of the initial value) were observed for all conditions tested.[18]

Three batches of the additive (initial counts had an average of $5.0 \times 10^{10}$ CFU/mL and range $4.7–5.3 \times 10^{10}$ CFU/mL) were tested for the stability in water at 5°C and 20°C after 24 and 48 h. Negligible losses (< 0.5 log of the initial value) were observed for both periods and temperatures tested.[19]

#### 3.1.4. Conditions of use

The additive is intended for use in all forages for all animal species at a proposed minimum inclusion rate of $1 \times 10^8$ CFU/kg fresh material.

### 3.2. Safety

#### 3.2.1. Safety for the target species, consumers and environment

The species *L. plantarum* is considered by EFSA to be suitable for the Qualified Presumption of Safety (QPS) approach to safety assessment (EFSA, 2007; EFSA BIOHAZ Panel, 2020a,b). This approach requires the identity of the strain to be conclusively established and evidence that the strain does not harbour acquired resistance to antimicrobials of human and veterinary importance. In the view of the FEEDAP Panel, the identity of the strain has been established as *L. plantarum* and the antimicrobial resistance qualification met. Consequently, *Lactiplantibacillus plantarum* DSM 26571 is considered safe for the target species, consumers and the environment.

#### 3.2.2. Safety for user

##### 3.2.2.1. Effect on respiratory system

No specific tests were submitted; however, based on the proteinaceous nature of the active substance of the additive, it is considered to be a respiratory sensitiser (EFSA FEEDAP Panel, 2012). The Panel also notes that the additive has a low dusting potential (21.7 mg/m$^3$), which makes exposure of users by inhalation unlikely.

##### 3.2.2.2. Effect on eyes and skin

The test item (*Lactiplantibacillus plantarum* DSM 26571) was assessed for eye irritancy in an *in vitro* eye irritation test according to GLP and OECD Test Guideline 492.[20] Under the conditions of the study, the test item is considered as non-irritant to eye.

The test item (*Lactiplantibacillus plantarum* DSM 26571) was assessed for skin irritancy in an *in vitro* skin irritation test according to GLP and OECD Test Guideline 439.[21] From the results of this study the test item is considered to be non-irritant to the skin.

[14] Limit of detection (LOD) for aflatoxin B1 < 0.46 μg/kg, sum of aflatoxins B1, B2, G1, G2 < 0.89 μg/kg, lead < 0.010 mg/kg.
[15] Technical dossier/Section II/Annex II.1.5c.
[16] Technical dossier/Section II/Annex II.1.5b.
[17] Technical dossier/Section II/Annex II.1.5a.
[18] Technical dossier/Section II/Annex II.4.1a.
[19] Technical dossier/Section II/Annex II.4.1b.
[20] Technical dossier/SIn June 2020/Annex Q2_1.
[21] Technical dossier/SIn June 2020/Annex Q2_2.

The test item (*Lactiplantibacillus plantarum* DSM 26571) was assessed for skin sensitisation potential in a local lymph node assay in mice according to GLP and OECD Test Guideline 429.[22] Under the conditions of the assay, the additive demonstrated no skin sensitising potential.

Once an active agent has been authorised as a silage additive, different formulations can be placed on the market with reference to that authorisation. For this specific product, the excipients used in the preparation of the final formulation are not expected to introduce additional risks.

#### 3.2.2.3. Conclusions on safety for the user

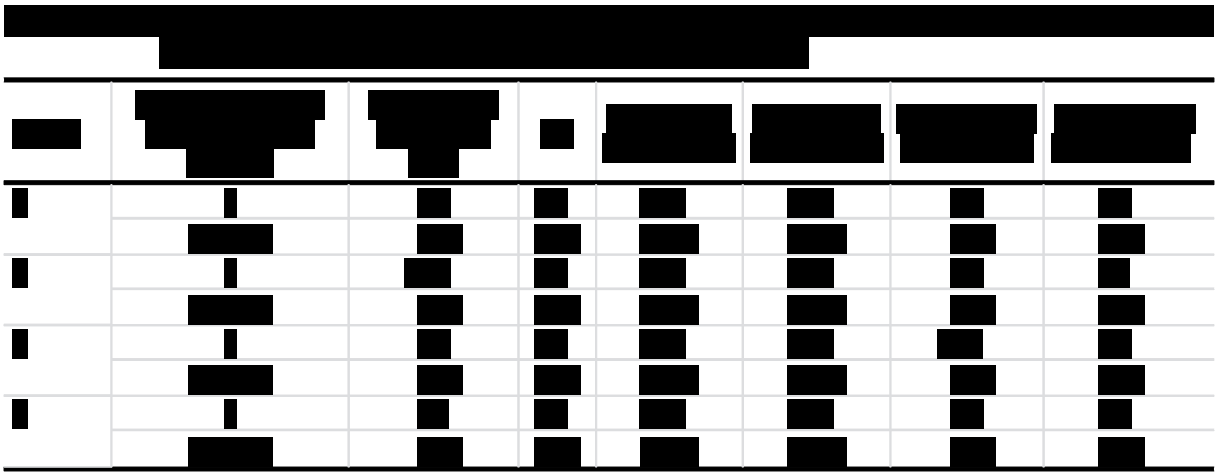
On the basis of the studies submitted, the additive is considered to be non-irritant to eyes or skin and not a dermal sensitiser. The additive is considered a respiratory sensitiser due to its proteinaceous nature, although exposure by inhalation is unlikely.

## 3.3. Efficacy

Four laboratory experiments were conducted with different forage samples representing the materials easy to ensile (study 1), moderately difficult to ensile (studies 2 and 3) and difficult to ensile (study 4), as specified by Regulation (EC) No 429/2008 (Table 1).[23]

[redacted]

[22] Technical dossier/SIn June 2020/Annex Q2_3.
[23] Technical dossier/Section IV/Annex IV.1.1–1.4



CFU: colony-forming unit.
*: Means in a column within a given trial are significantly different to the control $p < 0.05$.

### 3.3.1. Conclusions on efficacy

The use of *Lactiplantibacillus plantarum* DSM 26571 at the proposed inclusion rate has the potential to improve the production of silage with easy, moderately difficult, and difficult to ensile materials by enhancing the preservation of nutrients.

## 4. Conclusions

The identity of the active agent has been established as *Lactiplantibacillus plantarum* and the strain DSM 26571 does not show acquired antimicrobial resistance determinants for antibiotics of human and veterinary interest. Following the QPS approach to safety assessment, the use of the strain as a silage additive is considered safe for the target species, consumers of products from animals fed treated silage and the environment.

The additive is considered to be non-irritant to eyes and skin, not a dermal sensitiser, but is a respiratory sensitiser due to its proteinaceous nature, although exposure by inhalation is unlikely.

*Lactiplantibacillus plantarum* DSM 26571 at a concentration of $1 \times 10^8$ CFU/kg fresh forage showed a potential to improve the preservation of nutrients in silage prepared with easy, moderately difficult, and difficult to ensile materials.

## 5. Documentation as provided to EFSA/Chronology

| Date | Event |
|---|---|
| 20/12/2019 | Dossier received by EFSA. *Lactobacillus plantarum* DSM 26571 for all species. Submitted by Chr. Hansen A/S |
| 07/04/2020 | Reception mandate from the European Commission |
| 22/07/2020 | Application validated by EFSA – Start of the scientific assessment |
| 10/09/2020 | 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 additive* |
| 15/10/2020 | Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives |
| 21/10/2020 | Reception of supplementary information from the applicant - Scientific assessment re-started |
| 23/10/2020 | Comments received from Member States |
| 02/12/2020 | 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 additive, user safety* |

| Date | Event |
|---|---|
| 14/06/2021 | Reception of supplementary information from the applicant - Scientific assessment re-started |
| 29/09/2021 | Opinion adopted by the FEEDAP Panel. End of the Scientific assessment |

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## Abbreviations

| | |
|---|---|
| ANI | Average Nucleotide Identity |
| BLAST | Basic Local Alignment Search Tool |
| CFU | colony forming unit |
| CV | coefficient of variation |
| DM | dry matter |
| DSMZ | Deustche Sammlung von Mikroorganismen und Zellkuturen GmbH |
| EURL | European Union Reference Laboratory |
| FEEDAP | EFSA Panel on Additives and products or substances used in animal feed |
| GLP | Good laboratory practice |
| LAB | lactic acid bacteria |
| LOD | limit of detection |
| MIC | minimum inhibitory concentration |
| OECD | Organisation for Economic Cooperation and Development |
| QPS | Qualified Presumption of Safety |
| VFA | volatile fatty acids |
| WGS | whole genome sequence |

# Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for *Lactobacillus plantarum* DSM 26571

In the current application an authorisation is sought under Article 4(1) for *Lactobacillus plantarum* DSM26571 under the category/functional group 1(k) 'technological additives'/'silage additives', according to Annex I of Regulation (EC) No 1831/2003. The authorisation is sought for the use of the feed additive for all animal species.

According to the Applicant, the feed additive contains as active substance viable cells of the non-genetically modified strain *Lactobacillus plantarum* DSM26571. The feed additive is to be marketed as a preparation containing a minimum content of active substance of $1 \times 10^{11}$ Colony Forming Unit (CFU)/g and to be added to silage as such or mixed with other additives, at a minimum dose of $1 \times 10^{5}$ CFU/g fresh silage.

For the identification of *Lactobacillus plantarum* DSM26571 the EURL recommends for official control Pulsed-Field Gel Electrophoresis (PFGE), a generally recognised methodology for the genetic identification of bacterial strains.

For the enumeration of *Lactobacillus plantarum* DSM26571 in the feed additive the EURL recommends for official control the ring-trial validated spread plate method EN 15787.

Since the enumeration of *Lactobacillus plantarum* DSM26571 initially added to silage is not achievable by analysis, the EURL cannot recommend the method EN 15787 or any other method for official control to enumerate *Lactobacillus plantarum* DSM26571 in silage.

Further testing or validation of the methods to be performed through the consortium of National Reference Laboratories as specified by Article 10 (Commission Regulation (EC) No 378/2005), as last amended by Regulation (EU) 2015/1761) is not considered necessary.