Adopted: 14 November 2023

DOI: 10.2903/j.efsa.2023.8466

efsa JOURNAL

SCIENTIFIC OPINION

Assessment of a feed additive containing *Enterococcus lactis* NCIMB 11181 (Lactiferm®) for weaned piglets, calves for fattening and calves for rearing for the renewal of its authorisation (Chr. Hansen A/S)

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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 the authorisation of *Enterococcus lactis* NCIMB 11181 (Lactiferm®) as a zootechnical additive for weaned piglets, calves for fattening and calves for rearing. The product under assessment is based on a strain originally identified as *Enterococcus faecium*. During the current assessment, the active agent has been reclassified as *Enterococcus lactis*. The additive currently authorised is marketed in two formulations: Lactiferm Basic 50 (a solid formulation to be used in feed), and Lactiferm WS200 (a solid 'water-soluble' formulation to be used in water for drinking). The applicant has provided evidence that the additive currently on the market complies with the existing conditions of authorisation. The Panel concludes that the use of Lactiferm® under the authorised conditions of use remains safe for the target species (calves up to 6 months and weaned piglets up to 35 kg), consumers and the environment. The Lactiferm WS200 formulation of the additive is not irritant to skin or eyes. Owing to the proteinaceous nature of the active agent, both formulations of the additive are considered respiratory sensitisers. It is not possible to conclude on the irritating potential for skin and eyes of the Lactiferm Basic 50 formulation or on the potential of both forms of the additive to cause skin sensitisation. There is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

KEYWORDS

calves, Enterococcus lactis NCIMB 11181, gut flora stabiliser, piglets, safety, zootechnical additives

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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 Chr Hansen A/S[2] for the renewal of the authorisation of the additive consisting of *Enterococcus lactis*[3] NCIMB 11181 (Lactiferm®), when used as a feed additive for piglets (weaned), calves for fattening and calves for rearing (category: zootechnical additive; functional group: gut flora stabilisers).

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 8 February 2023.

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 additive consisting of *E. lactis* NCIMB 11181 (Lactiferm®), when used under the proposed conditions of use (see Section 3.1.4).

1.2 | Additional information

The additive is a preparation containing *Enterococcus lactis* NCIMB 11181.

EFSA issued two scientific opinions on the safety and efficacy of this additive when used in feed for chickens for fattening (EFSA, 2005) and weaned piglets and calves (EFSA FEEDAP Panel, 2012).

The additive is currently authorised for use in feed for calves for rearing and for fattening up to 6 months and for weaned piglets (4b1708).[4]

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[5] in support of the authorisation request for the use of *E. lactis* NCIMB 11181 (Lactiferm®) as a feed additive. The dossier was received on 12 September 2022 and the general information and supporting documentation is available at https://open.efsa.europa.eu/questions/EFSA-Q-2022-00553.

In accordance with Article 38 of the Regulation (EC) No 178/2002[6] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[7] a non-confidential version of the dossier has been published on Open.EFSA.

According to Article 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations,[8] EFSA carried out a public consultation on the non-confidential version of the technical dossier from 23 May to 13 June 2023 for which no comments were received.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 8 February 2023 to 8 May 2023 for which the received comments 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, peer-reviewed scientific papers, other scientific reports and experts' knowledge, to deliver the present output.

[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]Chr. Hansen A/S, 10–12 Boege Allé, DK-2970, Hoersholm, Denmark.

[3]Originally designated as *Enterococcus faecium* NCIMB 11181.

[4]Commission Implementing Regulation (EU) No 797/2013 of 21 August 2013 concerning the authorisation of a preparation of Enterococcus faecium NCIMB 11181 as a feed additive for calves for rearing and for fattening and weaned piglets (holder of authorisation Chr Hansen A/S) and repealing Regulation (EC) No 1333/2004. OJ L 244/6, 22.8.2013, 3 pp.

[5]Dossier reference: FEED-2022-04231.

[6]Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

[7]Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements

[8]Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements

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 *Enterococcus lactis* NCIMB 11181 in animal feed are valid and applicable for the current application.[9]

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of *E. lactis* NCIMB 11181 (Lactiferm®) is in line with the principles laid down in Regulation (EC) No 429/2008[10] and the relevant guidance documents: Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2021).

3 | ASSESSMENT

The additive (here and below referred to with its commercial name Lactiferm®) consisting of viable cells of *Enterococcus lactis* NCIMB 11181 is currently authorised as a zootechnical additive (functional group: gut flora stabilisers) for use in complete feed for weaned piglets and calves for rearing and for fattening. The assessment regards the renewal of the authorisation of the feed additive for these animal species. The additive currently authorised is marketed in two formulations.

3.1 | Characterisation

3.1.1 | Characterisation of the active agent

The active agent was originally isolated from faeces of an infant and is deposited in the National Collections of Industrial and Marine Bacteria (NCIMB) with the accession number NCIMB 11181.[11] It has not been genetically modified. [redacted].

The active agent, originally assigned to the *Enterococcus faecium* species (EFSA FEEDAP Panel, 2012), was identified as *Enterococcus lactis* based on a bioinformatic analysis of the whole genome sequence (WGS) data.[12] The taxonomic assignment was based on an average nucleotide identity (ANI) value of 98.69% with the type strain *E. lactis* DSM 23655^T, as compared to an ANI value of 93.77% with the *E. faecium* type strain (DSM 20477^T).

The susceptibility of the active agent to antimicrobials was tested using broth microdilution method and including the set of antimicrobials recommended by EFSA (EFSA FEEDAP Panel, 2018).[13] The minimum inhibitory concentration (MIC) values were compared with the defined EFSA cut-off values for the closest related species *E. faecium*. All the MIC values were equal to or fell below the cut-off values, and therefore, the strain is considered to be susceptible to all the relevant antibiotics.

The WGS data of the active agent NCIMB 11181, including [redacted] were interrogated for the presence of antimicrobial resistance (AMR) genes by a search against the NCBI Bacterial Antimicrobial Resistance Reference Gene database [redacted] and ResFinder database [redacted].[14] The search identified three hits: *eat(A)* (encoding an efflux pump (ABC transporter) [redacted], *msrC* (encoding an efflux pump transporter) and *aac(6')*-Ii (encoding an aminoglycoside 6'-N-acetyltransferase). Genes *mrs(C)* and *aac(6')*-Ii have recently been shown to be intrinsic to *E. lactis* (Lu et al., 2023), and *eat(A)* was already considered intrinsic in *E. faecium* before the splitting of the species in two separate species (Costa et al., 1993; Singh et al., 2001). Therefore, the FEEDAP Panel considers these genes to be of no concern.

According to the FEEDAP guidance on characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018), the safety of *E. faecium* should be assessed showing the susceptibility to ampicillin and excluding the presence of genetic markers typical of the clinical isolates *E. faecium* clade A (IS*16*, *esp*, *hyl*Efm). In view of the allocation of clade B strains to the *E. lactis* species, the FEEDAP Panel considers these criteria are also applicable to *E. lactis* strains.[15] The active agent NCIMB 11181 was shown to be susceptible to ampicillin (MIC 1–2 mg/L) and none of the three genetic elements was detected [redacted].

The active agent NCIMB 11181 is not expected to produce antimicrobial substances of relevance for human and animal health. The applicant, however, tested the capacity of the active agent to produce antimicrobials using a

[9]The full report is available on the EU Science Hub https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

[10]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.

[11]Annex II.2.1.2a NCIMB deposit public_v2.

[12]Annex II.2.1.2b ID Certificate NCIMB 11181.

[13]Annex II.2.2.2e MIC statement NCIMB11181 03.2022.

[14]Annex II.2.2.2b.

[15]Annex II.2.2.2c.

membrane-filtered eluate of a suspension of the Lactiferm WS200 formulation.[16] This was done using an agar dilution method against the following reference strains: *Escherichia coli* ATCC 25922, *Pseudomonas aeruginosa* ATCC 27853, *Staphylococcus aureus* ATCC 25923, *Enterococcus faecalis* ATCC 29212 and *Bacillus subtilis* ATCC 6633. No antimicrobial activity was detected.

3.1.2 | Characterisation of the additive

The additive currently authorised is marketed in two formulations:

- A solid formulation (Lactiferm Basic 50) containing *E. lactis* NCIMB 11181 at a minimum concentration of 5×10^{10} colony forming units (CFU)/g additive (representing 12%–16% w/w) and maltodextrin as a carrier (representing 84%–88% w/w).
- A solid water-soluble formulation (Lactiferm WS200, a solid product formulated to facilitate the suspension of the active agent when added to water) containing *E. lactis* NCIMB 11181 at a minimum concentration of 2×10^{11} CFU/g additive (representing 45%–50% w/w) and sorbitol as a carrier (representing 50%–55% w/w).

The applicant declared that no modifications have been made to the composition of the additive or to its manufacturing process since the first authorisation was granted.

Analysis of 5 batches of each form of the additive showed compliance with the specifications, with a mean value of 1.1×10^{11} CFU/g (range $0.92–1.2 \times 10^{11}$ CFU/g) for the Lactiferm Basic 50 form and of 3.7×10^{11} CFU/g (range $3.5–4.5 \times 10^{11}$ CFU/g) for the Lactiferm WS200 form.[17]

Specifications are set for coliforms (< 1000 CFU/g), *Salmonella* spp. (no detection in 25 g), *Escherichia coli* (< 10 CFU/g), yeasts and filamentous fungi (< 1000 CFU/g).[18] Analysis of the above-mentioned batches of the additive showed compliance with these limits.

Similarly, specifications are set for arsenic (≤ 2 mg/kg), cadmium (≤ 0.5 mg/kg), mercury (≤ 0.1 mg/kg), lead (≤ 5 mg/kg) and aflatoxin B1 (< 0.01 mg/kg). Analysis of three batches of the Lactiferm Basic 50 formulation indicated levels of cadmium and lead below the limit of quantification (LOQ) of the analytical method,[19] arsenic ranged from 0.008 to 0.019 mg/kg, mercury ranged from 0.0018 to 0.0021 mg/kg and aflatoxin B1 was below the LOQ in all three batches. Analytical data of three batches of the Lactiferm WS200 formulation showed levels of lead below the LOQ, cadmium was up to 0.005 mg/kg, arsenic ranged from 0.005 to 0.008 mg/kg, mercury ranged from 0.0053 to 0.0062 mg/kg, and Aflatoxin B1 was below the LOQ.[20]

The FEEDAP Panel considers that the microbial contamination and the amounts of the detected impurities do not raise safety concerns.

Both formulations of the additive consist of off-white-coloured particles. The bulk density was measured in one batch of each formulation and resulted in 500 kg/m^3 for the Lactiferm Basic 50 formulation form and 600 kg/m^3 for the Lactiferm WS200 formulation.[21]

The dusting potential of three batches of each formulation of the additive was determined using the Stauber-Heubach method. The Lactiferm Basic 50 formulation showed values ranging 5500–7645 mg/m^3, and those for the Lactiferm WS200 formulation ranged 5290–8845 mg/m^3.[22] The particle size distribution of the additive was analysed by laser diffraction in the same three batches of each form. The results of the Lactiferm Basic 50 product showed that the fraction (v/v) < 10 μm ranged 7%–12%; the fraction < 50 μm ranged 27%–39% and the fraction < 100 μm ranged 49%–60%.[23] The Lactiferm WS200 product showed that the fraction (v/v) < 10 μm ranged 5%–6%; the fraction < 50 μm ranged 28%–29% and the fraction < 100 μm ranged 47%–50%.

3.1.3 | Stability and homogeneity

The applicant submitted new data regarding the stability and homogeneity of the additive.

The shelf-life of the Lactiferm Basic 50 formulation of the additive (3 batches, initial average count of 1.1×10^{11} CFU/g additive) was studied in samples packed in sealed bags protected from light and stored at 25°C for 24 months. Viability losses at the end of the storage period were negligible (< 0.5 log). Samples of the Lactiferm WS200 formulation (3 batches), initial average count of 3.6×10^{11} CFU/g were packed in aluminium pouches and stored at 4°C and at

[16] Annex II.2.2.2d.

[17] Annex II.1.3b CoAs Basic60 + WS200.

[18] Annex II.1.3b CoAs Basic60 + WS200.

[19] Applicant's comments FEED-2022-4231.

[20] Annex II.1.4.1 Undes subst Lactiferm Basic50 WS200. The limit of quantification (in mg/kg) was 0.01 for lead and 0.005 for cadmium. The LOQ (in μg/kg) was 46 for aflatoxin B1.

[21] Annex II.1.5c Density Basic WS 2009.

[22] Annex II.1.5b Dust Pot Basic+WS Conf Mark.

[23] Annex II.1.5a Part size Basic+WS Conf Mark.

25°C for 18 months. Viability losses at the end of the storage period were negligible (< 0.5 log) at both temperatures.[24]

The stability of three batches of the Lactiferm WS200 formulation of Lactiferm® in commercial complete feed (meal form) for turkeys, cows and pigs was studied when supplemented at 1×10^8 CFU/kg feed and stored at ambient temperature (about 20°C) in plastic bags for 4 weeks.[25] Viability losses at the end of the storage period were up to 1.5 log in the feed for turkeys while negligible in the feeds for cows and pigs (< 0.5 log). No experimental data on the stability of the additive during feed processing (e.g. pelleting) were submitted.

The stability of the Lactiferm WS200 formulation of the additive (three batches) in water was tested at a concentration of 5×10^8 CFU/mL at ambient temperature for 24 h.[26] No losses (< 0.5 log) were observed.

The capacity of the Lactiferm WS200 formulation to homogeneously distribute in feed for turkeys (in mash form) was studied in 10 subsamples. The coefficient of variation (CV) was 29%.[27]

Further data were provided when incorporating the additive (formulation not described) in feed for poultry species (in mash form, 12 subsamples)[28] and for piglets (10 subsamples).[29] The CVs were 8.5% and 7.0%, respectively.

3.1.4 | Conditions of use

The additive is currently authorised for use in calves for rearing, calves for fattening (up to 6 months of age) and weaned piglets (up to 35 kg) at a minimum inclusion level of 5×10^8 CFU/kg complete feed.

And under other provisions it is stated:

- In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting and in water.
- May be used in milk replacer for calves for rearing and for fattening
- For weaned piglets up to 35 kg
- Recommended minimum doses:
  - Calves for rearing and for fattening 2×10^{10} CFU/kg complete feed
  - Piglets (weaned) $1–2 \times 10^{10}$ CFU/kg complete feed.
- The water-soluble form of the preparation may be used for weaned piglets in water for drinking with a recommended minimum dose of $1–2 \times 10^{10}$ CFU/L
- For user safety: breathing protection, safety glasses and gloves should be worn during handling.

The applicant does not propose a change of the conditions of use.

The applicant is requesting the setting of a minimum use level in water for drinking for Lactiferm WS200 of 2×10^8 CFU/L.

3.2 | Safety

The applicant declared that no reports on adverse effects from the use of the product since last approval had been received.[30]

3.2.1 | Safety for the target species, consumers and the environment

In the previous opinion (EFSA FEEDAP Panel, 2012), the FEEDAP Panel concluded that 'Lactiferm® is safe for weaned piglets and calves at the recommended concentration range. Since neither the active agent nor the other components of the additive give rise to concerns, the FEEDAP Panel considers the use of the additive safe for consumers. *E. faecium* is a natural component of gut microbiota and its use as Lactiferm® in animal feeding would not be expected to pose any additional risk for the environment.'

In the present application, the identity of the NCIMB 11181 strain was reassigned to *E. lactis*, and evidence was provided that the strain does not harbour acquired AMR genes or is virulent. The FEEDAP Panel considers the criteria to assess the safety of *E. faecium* applicable also to *E. lactis* strains. In addition, the manufacturing process of the additive, its composition and the conditions of use for the target species have not been modified. Consequently, the conclusions already reached

[24] Annex II.4.1a Stabiity Lactiferm Basic50 + WS200_v2.
[25] Annex II.4.1b Stability in feed Lactiferm 3mths 2017 and 2023-04-21 ADR Reply.
[26] Annex II.4.1c Stability in water Lactiferm 2011.
[27] Annex II.4.2a Homogeniety mash feed Lactiferm 2017.
[28] Annex_II_4_2b_Homogeneity_feed_Lactiferm_2022f.
[29] Annex II.4.2c_Homogenieity_in_piglet_feed_2003_v2.
[30] Section III Safety Lactiferm 1. Target 2022 final.

are still deemed valid, and the Panel considers that Lactiferm® remains safe for the target species, consumers and the environment.

In support of the safety of the *E. lactis* NCIMB 11181 strain, the applicant submitted the results of an extensive literature search performed in accordance with the requirements of the Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2021). The search period was from 2010 to May 2022. Keywords included the active agent combined with safety terminology related to the safety for the target species, the consumer, users and the environment. Four databases were searched. A total of 335 references were retrieved after excluding the duplicates. After a first screening, nine references were selected for full text review. This resulted in a final selection of three scientific papers that, after being considered by the FEEDAP Panel, do not bring new information that would justify a change in the previous conclusions.

3.2.2 | Safety for the user

In the previous opinion (EFSA FEEDAP Panel, 2012), the Panel concluded that given the lack of specific information, its proteinaceous nature and the high dusting potential, in particular of the Lactiferm WS200 formulation, Lactiferm® should be considered to have the potential to be an irritant to eye and skin and a skin/respiratory sensitiser.

The additive has a high dusting potential (highest measured values: 7645 mg/m^3 for Lactiferm Basic 50 formulation, 8845 mg/m^3 for Lactiferm WS200 formulation); therefore, exposure of users by inhalation is likely. Owing to the proteinaceous nature of the active agent, the additive is considered a respiratory sensitiser.

In the current application an in vivo skin irritation study, two in vitro eye irritation studies, and an in vivo skin sensitisation study (local lymph node assay) testing the Lactiferm WS200 formulation of the additive were submitted. No studies were submitted for the Lactiferm Basic 50 formulation of the additive. The applicant referred to in vitro skin and eye irritation studies performed with a different additive, containing a different active agent and maltodextrin as carrier to support the safety of the Lactiferm Basic 50 formulation of the additive.[31] However, as the active agent differs, these studies cannot be considered adequate for the additive under assessment.

The acute skin irritation potential of the Lactiferm WS200 formulation of the additive was tested in a study performed in rabbits according to the OECD Guideline 404 (2015).[32] The results indicated that the test item was not irritant to skin.

The eye irritation potential of the Lactiferm WS200 formulation of the additive was tested in an in vitro study (EpiOcular™) performed according to OECD Guideline 492.[33] The results indicated that the test item was irritant to eyes. The eye irritation potential of this form of the additive was further tested in another in vitro study (Isolated Chicken Eye) performed according to OECD Guideline 438.[34] The results of this study indicated that the test item requires no category for eye irritation. The FEEDAP Panel considers that the Isolated Chicken Eye test represents a more complete test system for eye irritancy, compared with the EpiOcular™ model, particularly for products such as microorganisms. On this basis, the Panel concludes that the product is not considered to be irritant to the eye.

The FEEDAP 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 microorganisms are available. Therefore, no conclusion can be drawn on the skin sensitisation potential of the additive.[35]

On the basis of the studies submitted, the Lactiferm WS200 formulation of the additive is considered not irritant to skin or eyes. Owing to the proteinaceous nature of the active agent, both formulations of the additive are considered respiratory sensitisers. It is not possible to conclude on the irritating potential for skin and eyes of the Lactiferm Basic 50 formulation or on the potential of both forms of the additive to cause skin sensitisation.

3.3 | Efficacy

The additive is currently authorised for use in calves for rearing, calves for fattening (up to 6 months of age) and weaned piglets (up to 35 kg) at a minimum use level of 5×10^8 CFU/kg complete feed, which equates to a minimum level of 2×10^8 CFU/L in water for drinking and liquid milk replacer (EFSA FEEDAP Panel, 2017). The applicant is requesting the setting of a minimum inclusion level in water for drinking and liquid milk replacer of 2×10^8 CFU/L. The FEEDAP Panel considers that this use level reflects the currently authorised used in feed, considering that the water intake is two to three times higher than feed intake.

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 its authorisation.

[31] ADR export file for EFSA-Q-2022-00553.

[32] Annex III.3.1c_115–404-7124_SkinIrr_Lactiferm.

[33] Annex III.3.1d_115–492-6704_EyeIrrit_InVitro1.

[34] Annex III.3.1e_115–438-7162_EyeIrrit_InVitro2.

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

3.4 | Post-market monitoring

The FEEDAP Panel considers that there is no need for specific requirements for a post-market monitoring plan other than those established in the Feed Hygiene Regulation[36] and Good Manufacturing Practice.

4 | CONCLUSIONS

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

The FEEDAP Panel concludes that the use of Lactiferm® under the authorised conditions of use remains safe for the target species (calves up to 6 months and weaned piglets up to 35 Kg), consumers and the environment.

The Lactiferm WS200 formulation of the additive is not irritant to skin or eyes. Owing to the proteinaceous nature of the active agent, both formulations of the additive are considered respiratory sensitisers. It is not possible to conclude on the irritating potential for skin and eyes of the Lactiferm Basic 50 formulation or on the potential of both formulations of the additive to cause skin sensitisation.

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

ABBREVIATIONS

CFU	colony forming unit
CV	coefficient of variation
EURL	European Union Reference Laboratory
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
OECD	Organisation for Economic Co-operation and Development

ACKNOWLEDGEMENTS

The Panel wishes to thank the following for the support provided to this scientific output (in alphabetical order of the last name): Natalia Alija, Anna Dioni, experts of the Microbiology working group and experts of the Toxicology working group.

CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

European Commission

QUESTION NUMBER

EFSA-Q-2022-00553

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[36]Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.

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How to cite this article: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis, V., Azimonti, G., Bastos, M. L., Christensen, H., Durjava, M., Dusemund, B., Kouba, M., López-Alonso, M., López Puente, S., Marcon, F., Mayo, B., Pechová, A., Petkova, M., Ramos, F., Sanz, Y., Villa, R. E., Woutersen, R., Brantom, P., … Tarrés-Call, J. (2023). Assessment of a feed additive containing *Enterococcus lactis* NCIMB 11181 (Lactiferm®) for weaned piglets, calves for fattening and calves for rearing for the renewal of its authorisation (Chr. Hansen A/S). *EFSA Journal*, *21*(12), e8466. https://doi.org/10.2903/j.efsa.2023.8466