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## Assessment of the feed additive consisting of *Lactococcus lactis* NCIMB 30117 for all animal species 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 *Lactococcus lactis* NCIMB 30117 as a technological additive for use in forage for all animal species. The additive aims to improve the production of silage and is authorised 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 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, the additive should be considered as a respiratory sensitiser. No conclusions can be drawn on the skin sensitisation, and eye and skin irritancy potential of the additive. There is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

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## 1. Introduction

### 1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003<sup>1</sup> 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<sup>2</sup> for the renewal of the authorisation of the additive consisting of *Lactococcus lactis* NCIMB 30117, 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 26 May 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 feed additive consisting of the product *Lactococcus lactis* NCIMB 30117, when used under the proposed conditions of use (see **Section 3.1.3**).

### 1.2. Additional information

The additive *Lactococcus lactis* NCIMB 30117 is currently authorised for use in feed for all animal species in the European Union (1k2083).<sup>3</sup>

EFSA issued one opinion on the safety and efficacy of this product when used in forages 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<sup>4</sup> in support of the authorisation request for the use of *Lactococcus lactis* NCIMB 30117 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.<sup>5</sup>

### 2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of *Lactococcus lactis* NCIMB 30117 is in line with the principles laid down in Regulation (EC) No 429/2008<sup>6</sup> and the relevant guidance documents: Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012), 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).

<sup>1</sup> 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.

<sup>2</sup> Chr Hansen A/S, 10-12 Boege Allé, 2970 Hoersholm, Denmark.

<sup>3</sup> Commission Implementing Regulation (EU) No 227/2012 of 15 March 2012 concerning the authorisation of *Lactococcus lactis* (NCIMB 30117) as a feed additive for all animal species Text with EEA relevance OJ L 77, 16.3.2012, p. 8–9.

<sup>4</sup> FEED dossier reference: FAD-2021-0027.

<sup>5</sup> The full report is available on the EU Science Hub website: [https://joint-research-centre.ec.europa.eu/publications/20-fad-dossiers\\_en](https://joint-research-centre.ec.europa.eu/publications/20-fad-dossiers_en)

<sup>6</sup> 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 based on a preparation of viable cells of *L. lactis* NCIMB 30117 is currently authorised 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 *L. lactis* NCIMB 30117 for the above-mentioned species.

#### 3.1. Characterisation

##### 3.1.1. Characterisation of the additive

The product currently authorised consists of ~ 30% in bulk (range 17–42%) containing the active agent and a cryoprotectant, 8% silica as anticaking agent and 52–70% maltodextrin as a carrier.<sup>7</sup> The additive is currently authorised with a minimum content of the active agent *Lactococcus lactis* NCIMB 30117 of  $5 \times 10^{10}$  colony forming units (CFU) per gram of additive.

Analysis of five recent batches showed compliance with the specifications (mean:  $6.1 \times 10^{11}$  CFU/g additive, range  $5.5\text{--}7.2 \times 10^{11}$  CFU/g additive).<sup>8</sup>

Specifications are set for coliforms (< 1,000 CFU/g), *Salmonella* spp. (no detection in 25 g), *Escherichia coli* (< 10 CFU/g), yeasts and filamentous fungi (< 1,000 CFU/g).<sup>9</sup> Analysis of the above-mentioned batches of the additive showed compliance with these limits<sup>10</sup> except for *Salmonella* spp. detection for which the Panel notes that despite the specification, only data from analyses of five grams instead of 25 g were provided.<sup>11</sup>

Three recent batches of the additive were tested for aflatoxin B1, mercury (Hg), lead (Pb), cadmium (Cd) and arsenic (As) concentrations. Results showed the following mean values: 0.0166 mg Hg/kg (range: 0.0083–0.0227 mg/kg), 0.028 mg Pb/kg (range: 0.015–0.035 mg/kg), 0.015 mg Cd/kg and 0.031 mg As/kg (range: 0.028–0.033 mg/kg).<sup>12</sup> Aflatoxin B1 in all batches was below the limit of quantification (< 0.46 µg aflatoxin B1/kg).<sup>7,12</sup>

The detected amounts of the above-described impurities do not raise safety concerns.

No new data have been provided regarding the physico-chemical properties or stability of the additive. Since no changes were introduced in the additive manufacturing process, the data described in the previous opinion still apply (EFSA FEEDAP Panel, 2011).

##### 3.1.2. Characterisation of the active agent

The active agent is deposited in the National Collections of Industrial, Food and Marine Bacteria under the collection number NCIMB 30117.<sup>13</sup>

The taxonomical identification was confirmed [REDACTED]

The bacterial strain was subjected to antimicrobial susceptibility testing using the broth microdilution method and including the set of antimicrobials recommended by EFSA (EFSA FEEDAP Panel, 2018).<sup>16</sup> All the minimum inhibitory concentration values were equal or fell below the corresponding EFSA cut-off values for *L. lactis*. Therefore, the strain is considered to be susceptible to all the relevant antimicrobials.

The WGS of the strain was interrogated for the presence of antimicrobial resistance genes [REDACTED]

<sup>7</sup> Technical dossier/Supplementary information December 2021/1.Answers\_EFSA\_Qs\_NCIMB30117\_12.2021.

<sup>8</sup> Technical dossier/Section II/Annex II.1.3a.

<sup>9</sup> Technical dossier/Section II/Sect\_II\_Identity.

<sup>10</sup> Technical dossier/Section II/Annex II.1.3a and Technical dossier/Supplementary information December 2021/Annex\_Q3.

<sup>11</sup> Technical dossier/Supplementary information December 2021/Annex\_Q3 and 1.Answers\_EFSA\_Qs\_NCIMB30117\_12.2021.

<sup>12</sup> Technical dossier/Section II/Annex II.1.4.2.

<sup>13</sup> Technical dossier/Section II/Annex II.2.1.2a.

<sup>14</sup> Technical dossier/Section II/Annex II 2.1.2.b.

<sup>15</sup> Technical dossier/Supplementary information December 2021/Annex\_Q4\_ID.Cert\_NCIMB 30117.

<sup>16</sup> Technical dossier/Section II/Annex II 2.2.2.b.

<sup>17</sup> Technical dossier/Section II/Annex II 2.2.2.a.

No hits of concern were identified.

### 3.1.3. Conditions of use

The additive is currently authorised for use with forages and 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 not in combination with other microorganisms as a silage additive:  $1 \times 10^8$  CFU/kg of 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 its previous opinion, the Panel concluded that following the Qualified Presumption of Safety (QPS) approach to safety assessment, 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 a strain as *L. lactis* was confirmed and evidence was provided that the strain does not show acquired antimicrobial determinants for antibiotics of human and veterinary importance. Consequently, the conclusions already reached are still valid and *Lactococcus lactis* NCIMB 30117 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: '*Given the proteinaceous nature of the active agent and in the absence of evidence to the contrary, the additive should be considered to have the potential to be a skin and respiratory sensitiser*'.

No specific data were submitted on the effects of the additive under assessment in the eyes and skin, and in the absence of data, the FEEDAP Panel cannot conclude on skin sensitisation, and on eye and skin irritancy potential of the additive and reiterates its previous conclusions regarding respiratory sensitisation.

The applicant declares that no adverse effects on the health of manufacturing workers nor users of the additive have been reported since the approval of the additive.<sup>19</sup>

### 3.2.1. Extensive Literature Search

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.<sup>20</sup> The literature search was conducted in PubMed and EBSCO EDS (included the databases Academic Onefile, Food Science Source and AGRIS) and covered the period 2010–2020.<sup>21,22</sup> Search terms included the active agent and aspects related to the safety for animals, humans and the environment. The literature search retrieved a total of 26 results that were full text screened, from which three were further included in the review process but none considered relevant for the herein application because they referred either to other strain (two hits) or to biogenic amine production (one hit).

### 3.2.2. Conclusions on safety

The FEEDAP Panel concludes that there is no new evidence that would lead it to reconsider the previous conclusions that *Lactococcus lactis* NCIMB 30117 is safe for the target species, consumers and the environment under the authorised conditions of use. *Lactococcus lactis* NCIMB 30117 is considered a respiratory sensitiser, but no conclusions can be drawn regarding skin sensitisation and its potential to be irritant to eyes and/or skin.

<sup>18</sup> Technical dossier/Supplementary Information December 2021/Annex\_Q6.

<sup>19</sup> Technical dossier/Section III and Section V\_Post\_Mark.

<sup>20</sup> Technical dossier/Section III/Annex\_III\_1.1.

<sup>21</sup> Technical dossier/Section III/Annex\_III\_1.1/3.Search\_Method\_Description.

<sup>22</sup> Technical dossier/Supplementary Information December 2021/Annex\_Q7.



### 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

Based on the QPS approach to safety assessment, *Lactococcus lactis* NCIMB 30117 is presumed safe for the target species, consumers and the environment.

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.

The additive should be considered a respiratory sensitiser. No conclusions can be drawn on the skin sensitisation, and eye and skin irritancy potential of the additive.

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
17/03/2021	Dossier received by EFSA. <i>Lactococcus lactis</i> NCIMB 30117 for all animal species. Submitted by Chr. Hansen A/S
09/04/2021	Reception mandate from the European Commission
26/05/2021	Application validated by EFSA – Start of the scientific assessment
11/06/2021	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. <i>Issues: characterisation and safety</i>
08/12/2021	Reception of supplementary information from the applicant - Scientific assessment re-started
23/03/2022	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

## References

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- EFSA FEEDAP Panel, (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012. Guidance on studies concerning the safety of use of the additive for users/workers. EFSA Journal 2012;10(1):2539, 5 pp. <https://doi.org/10.2903/j.efsa.2012.2539>
- 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
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