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Assessment of the efficacy of the feed additive consisting of *Saccharomyces cerevisae* CNCM I-1077 (Levucell® SC) for dairy cows, cattle for fattening, minor ruminant species and camelids (Lallemand SAS)

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the re-evaluation of the authorisation of the feed additive containing *Saccharomyces cerevisae* CNCM I-1077 (Levucell® SC) as a zootechnical additive for ruminants. The additive is already authorised for use in dairy sheep and dairy goats, lambs and horses, calves, all minor ruminant species (for rearing) other than lambs and camelids (for rearing) and dairy cows. The additive is intended for use in complete feed for dairy cows, minor ruminant species for milk production and all camelids at the minimum dose of 4×10^8 CFU/kg and for cattle for fattening and minor ruminant species for fattening at the minimum dose of 5×10^8 CFU/kg. In a previous opinion, the FEEDAP Panel concluded that the additive has a potential to improve the performance of cattle raised for fattening, minor ruminant species and camelids raised for meat production but could not conclude on the efficacy of Levucell® SC for dairy cows or extrapolate to minor dairy ruminant species or dairy camelids. The applicant has provided supplementary information to support efficacy of the additive in dairy cows. Based on the data provided, the FEEDAP Panel is not in the position to conclude on the efficacy of the additive for dairy cows or other dairy ruminants under the proposed conditions of use.

Keywords: zootechnical additives, digestibility enhancers, gut flora stabilisers, Levucell® SC, *Saccharomyces cerevisae* CNCM I-1077, efficacy, dairy cows

Requestor: European Commission

Question number: EFSA-Q-2021-00527

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1. Introduction

1.1. Background and Terms of Reference as provided by the European Commission

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition and, in particular, Article 9 thereof defines the terms of the authorisation by the Commission.

The applicant, LALLEMAND SAS,[2] is seeking a Community authorisation *of Saccharomyces cerevisiae* CNCM I-1077 as a feed additive to be used as a digestibility enhancer and gut flora stabiliser for all ruminants, buffaloes, camels, cattle for fattening and dairy cows for milk production (Table 1).

Table 1: Description of the additive

Category of additive	**Zootechnical additives**
Functional group of additive	Digestibility enhancers and gut flora stabilisers
Description	*Saccharomyces cerevisiae* CNCM I-1077
Target animal category	All ruminants, buffaloes, camels, cattle for fattening and dairy cows for milk production
Applicant	Lallemand SAS
Type of request	New opinion

On 4 July 2017, the Panel on Additives and Products or Substances used in Animal Feed of the European Food Safety Authority (EFSA), in its opinion on the safety and efficacy of the product, could not conclude on the efficacy of *Saccharomyces cerevisiae* CNCM I-1077 for dairy cows, minor dairy ruminant species or dairy camelids.

During the discussions with the Member States at a meeting of the Standing Committee on Plants, Animals, Food and Feed (Animal Nutrition section), it was suggested to check for the possibility to demonstrate the efficacy of the additive.

The Commission gave the possibility to the applicant to submit supplementary information and data in order to complete the assessment and to allow a revision of the EFSA's opinion. The new data have been received on 22 March 2021 and the applicant has been requested to transmit them to EFSA as well.

In view of the above, the Commission asks the Authority to deliver a new opinion on *Saccharomyces cerevisiae* CNCM I-1077 as a feed additive for all ruminants, buffaloes, camels, cattle for fattening and dairy cows for milk production based on the additional data submitted by the applicant, in accordance with Article 29(1)(a) of Regulation (EC) No 178/2002.

1.2. Additional information

The additive is a preparation of viable cells of *Saccharomyces cerevisiae* CNCM I-1077 and is available in three formulations (non-coated granular form Levucell® SC20, microencapsulated Levucell® SC10 ME and microencapsulated Levucell® SC10 ME Titan). The additive (4b1711) is authorised in the European Union for dairy sheep and dairy goats,[3] lambs and horses,[4] calves, all

[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] Danstar Ferment AG, Switzerland represented in the EU by Lallemand SAS, Rue des Briquetiers, 31,702 Blagnac Cedex, France.

[3] COMMISSION IMPLEMENTING REGULATION (EU) 2019/857 of 27 May 2019 concerning the renewal of the authorisation of *Saccharomyces cerevisiae* CNCM I-1077 as a feed additive for dairy sheep and dairy goats and repealing Regulation (EC) No 226/2007 (holder of authorisation Danstar Ferment AG represented by Lallemand SAS), OJ L 140, 28.5.2019, p. 18.

[4] COMMISSION IMPLEMENTING REGULATION (EU) 2020/149 of 4 February 2020 concerning the renewal of the authorisation of *Saccharomyces cerevisiae* CNCM I-1077 as a feed additive for lambs and horses and repealing Regulations (EC) No 1293/2008 and (EC) No 910/2009 (holder of authorisation Danstar Ferment AG represented in the Union by Lallemand SAS), OJ L33, 5.2.2020, p. 5.

minor ruminant species (for rearing) other than lambs and camelids (for rearing).[5] In addition, the additive is authorised in dairy cows (E 1711).[6]

The EFSA FEEDAP Panel adopted eight opinions on the safety and efficacy of this product when used in feed for dairy goats and dairy ewes (EFSA, 2006a; EFSA FEEDAP Panel, 2018b), horses (EFSA, 2006b, 2009; EFSA FEEDAP Panel, 2019b), lambs (EFSA, 2008; EFSA FEEDAP Panel, 2019b), minor ruminant species and camelids (EFSA FEEDAP Panel, 2017, 2019a), calves (EFSA FEEDAP Panel, 2019a) and dairy cows and cattle for fattening (EFSA FEEDAP Panel, 2017). In the latter, corresponding to the re-evaluation of the additive, the FEEDAP Panel could not conclude on the efficacy of Levucell® SC for dairy cows, minor dairy ruminant species or dairy camelids.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of supplementary information[7] to previous applications on the same product.[8]

In accordance with Article 38 of the Regulation (EC) No 178/2002[9] 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,[10] a non-confidential version of the supplementary information has been published on Open.EFSA.[11]

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

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the efficacy of *Saccharomyces cerevisiae* CNCM I-1077 (Levucell® SC) is in line with the principles laid down in Regulation (EC) No 429/2008[12] and the relevant guidance document: Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018a).

3. Assessment

The additive Levucell® SC is a preparation of viable cells of *Saccharomyces cerevisiae* CNCM I-1077 intended for use as a zootechnical additive (functional groups: gut flora stabilisers and digestibility enhancers) in feed for all ruminants (buffaloes, camelids, cattle for fattening and dairy cows for milk production). The additive will be hereafter referred to as Levucell® SC (its tradename). The additive is intended for use in complete feed for dairy cows, minor ruminant species for milk production and all camelids at the minimum use level of 4×10^8 CFU/kg complete feed and for cattle for fattening and minor ruminant species for fattening at the minimum level of 5×10^8 CFU/kg complete feed.

In a previous opinion (EFSA FEEDAP Panel, 2017), the FEEDAP Panel concluded that the additive has a potential to improve the performance of cattle raised for fattening, minor ruminant species and camelids raised for meat production but could not conclude on the efficacy of Levucell® SC in dairy cows and other minor dairy ruminant species or dairy camelids, since only one study was considered

[5] COMMISSION IMPLEMENTING REGULATION (EU) 2020/1374 of 1 October 2020 concerning the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1077 as a feed additive for calves, all minor ruminant species (for rearing) other than lambs and camelids (for rearing) (holder of authorisation Danstar Ferment AG represented by Lallemand SAS), OJ L 139, 2.10.2020, p. 19.

[6] Commission Regulation (EC) No 1200/2005 of 26 July 2005 concerning the permanent authorisation of certain additives in feedingstuffs and the provisional authorisation of a new use of an additive already authorised in feedingstuffs, OJ L 195 27.7.2005, p. 6.

[7] EFSA question number: EFSA-Q-2021-00527.

[8] FEED dossier references: FAD-2010-0120 and FAD-2013-0054.

[9] 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.

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

[11] Available at: https://open.efsa.europa.eu/questions/EFSA-Q-2021-00527

[12] 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.

to properly support an increase in milk yield. The applicant has provided supplementary information to support efficacy in dairy cows.

3.1. Efficacy

Four trials with dairy cows sharing a common experimental design were submitted. However, three of the studies were not further considered because of the following limitations: in three studies cows were at [redacted] [instead of 4–8 weeks after calving as stated in the Guidance (EFSA FEEDAP Panel, 2018a)],[13] in one study there were biologically relevant differences in the DIM between the control and the treated group ([redacted])[14] and/or milk yield was well below the standards for high-yielding cows of the same breed used under common EU dairy farming practices (two studies).[15]

Although the remaining study included cows which were on average [redacted][16] the Panel considered it in the assessment as the average milk yield was more than 30 kg/day. In this study,[16] 36 Holstein Friesian cows ([redacted] Each cow received daily at the milking parlour [redacted] meal which was either not supplemented (control) or supplemented with Levucell® SC20 to supply 1.0 × 10^{10} CFU/cow per day (equivalent to a calculated dietary concentration of 4 × 10^{8} CFU/kg complete feed).[17] [redacted] BW and BCS score at the start and at the end of the study and their variation between both times were compared between treatment groups. All data were subjected to analysis of variance with significance set at $p < 0.10$. Supplementing feed of cows with Levucell® SC did not have any significant effect on the performance of dairy cows (daily feed intake 24.5 and 25.4 kg DM/cow, milk yield 30.6 and 31.6 kg/day, fat content 3.7 and 3.8% and protein content of 3.5 and 3.5%, in the control and treatment groups, respectively).[18]

Therefore, the Panel is not in the position to conclude on the efficacy of Levucell® SC for dairy cows based on the data provided. In the absence of evidence of efficacy in dairy cows, no conclusions can be drawn on the efficacy of Levucell® SC for other dairy ruminants and camelids.

4. Conclusions

The FEEDAP Panel is not in the position to conclude on the efficacy of Levucell® SC for dairy cows or other dairy ruminants and camelids based on the data provided.

5. Documentation provided to EFSA/Chronology

Date	Event
22/03/2021	Dossier received by EFSA. *Saccharomyces cerevisiae* CNCM I-1077 (Levucell SC). Submitted by Lallemand SAS
26/07/2021	Reception mandate from the European Commission
30/09/2021	Application validated by EFSA – Start of the scientific assessment
17/12/2021	Request of supplementary information to the applicant in line with Article 7(3) of Regulation (EC) No 1304/2003 – Scientific assessment suspended. *Issues: efficacy*

[13] Technical dossier/Annexes study 1, Annexes study 2 and Annexes study 4.
[14] Technical dossier/Annexes study 3/.
[15] Technical dossier/Annexes study 1 and Annexes study 4.
[16] Technical dossier/Annexes study 2/.
[17] Technical dossier/levucell_sc_dairy_cows_11_2021 and Annexes study 2/Annex 2c.
[18] Technical dossier/Supplementary Information March 2022/ 2022-03-07_SIn reply_lsc and Annex 2.

Date	Event
08/03/2022	Reception of supplementary information from the applicant - Scientific assessment re-started
29/06/2022	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

BW	body weight
CFU	colony forming unit
DIM	days in milk
DMI	dry matter intake
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
TMR	total mixed ratio