Assessment of the modification of the authorisation of the feed additive consisting of Saccharomyces cerevisiae CNCM I-1077 for lambs and its extension of use to all ruminants and camelids reared for milk production/suckling/reproduction, all minor (young) ruminant species and camelids for fattening and Equidae other than horses (Lallemand SAS)

Villa, R. E., Azimonti, G., Bonos, E., Christensen, H., Durjava, M., Dusemund, B., Gehring, R., Glandorf, B., Kouba, M., López-Alonso, M., Marcon, F., Nebbia, C., Pechová, A., Prieto-Maradona, M., Röhe, I., Theodoridou, K., Woutersen, R., Anguita, M., Brozzi, R., ... EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) (2024). Assessment of the modification of the authorisation of the feed additive consisting of *Saccharomyces cerevisiae* CNCM I-1077 for lambs and its extension of use to all ruminants and camelids reared for milk production/suckling/reproduction, all minor (young) ruminant species and camelids for fattening and Equidae other than horses (Lallemand SAS). *EFSA Journal*, *22*(11), Article e9075. https://doi.org/10.2903/j.efsa.2024.9075

Published in:
EFSA Journal

Document Version:
Publisher's PDF, also known as Version of record

Adopted: 15 October 2024

DOI: 10.2903/j.efsa.2024.9075

efsa JOURNAL

SCIENTIFIC OPINION

Assessment of the modification of the authorisation of the feed additive consisting of *Saccharomyces cerevisiae* CNCM I-1077 for lambs and its extension of use to all ruminants and camelids reared for milk production/suckling/reproduction, all minor (young) ruminant species and camelids for fattening and Equidae other than horses (Lallemand SAS)

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) | **Roberto Edoardo Villa** | **Giovanna Azimonti** | **Eleftherios Bonos** | **Henrik Christensen** | **Mojca Durjava** | **Birgit Dusemund** | **Ronette Gehring** | **Boet Glandorf** | **Maryline Kouba** | **Marta López-Alonso** | **Francesca Marcon** | **Carlo Nebbia** | **Alena Pechová** | **Miguel Prieto-Maradona** | **Ilen Röhe** | **Katerina Theodoridou** | **Ruud Woutersen** | **Montserrat Anguita** | **Rosella Brozzi** | **Jaume Galobart** | **Matteo L. Innocenti** | **Daniel Pagés**

Correspondence: feedap@efsa.europa.eu

The declarations of interest of all scientific experts active in EFSA's work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch

Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety and efficacy of a preparation of *Saccharomyces cerevisiae* CNCM I-1077 as a zootechnical feed additive for several animal species. The additive, existing in a not-coated and a coated form, is currently authorised for use in feed for calves, cattle for fattening, dairy cows, dairy goats and dairy sheep, lambs, all minor ruminant species for fattening and rearing, horses and camelids for fattening and rearing. This application regards the request for the extension of use in all ruminants and camelids reared for milk production/suckling/reproduction, all minor (young) ruminant species and camelids for fattening and Equidae other than horses, and the modification of the authorisation for lambs to reduce the minimum use level. The identity of the active agent as *S. cerevisiae* was confirmed. Based on the qualified presumption of safety approach and since no concerns are expected from other components, the additive is considered safe for the target species, consumers and the environment. The not-coated form of the additive is not irritant to skin or eyes. The additive in both formulations should be considered a skin and respiratory sensitiser and any exposure through skin and respiratory tract is considered a risk. No conclusion could be drawn on the eye irritation potential of the coated form of the additive due to the lack of data. The additive has the potential to be efficacious when used in feed for all ruminants and camelids reared for milk production/suckling/reproduction at the minimum proposed use level of 5×10^8 CFU (colony forming unit)/kg complete feed, all minor (young) ruminant species and camelids for fattening and lambs at 1×10^9 CFU/kg complete feed, and in all Equidae species other than horses at 3×10^9 CFU/kg complete feed.

KEYWORDS

digestibility enhancer, efficacy, gut flora stabiliser, *Saccharomyces cerevisiae* CNCM I-1077, safety, zootechnical additive

CONTENTS

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 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of feed additive shall submit an application in accordance with Article 7 and Article 13(3) of that Regulation lays down that if the holder of an authorisation proposes changing the terms of the authorisation by submitting an application to the Commission, accompanied by the relevant data supporting the request for the change, the Authority shall transmit its opinion on the proposal to the Commission and the Member States.

The European Commission received a request from Lallemand SAS, on behalf of Danstar Ferment AG[2] for the modification of the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1077 for lambs and the request for authorisation for its use in all ruminants and camelids reared for milk production/suckling/reproduction, all minor (young) ruminant species and camelids for fattening and Equidae other than horses (category: zootechnical additives; functional group: digestibility enhancers and 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 4(1) (authorisation of a feed additive or new use of a feed additive) and under Article 13(3) (modification of the authorisation of a feed additive. The dossier was received on 14th November 2023 and the general information and supporting documentation are available at https://open.efsa.europa.eu/questions/EFSA-Q-2023-00724). The particulars and documents in support of the application were considered valid by EFSA as of 29th 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 *S. cerevisiae* CNCM I-1077, when used under the proposed conditions of use (see Section 3.1.3).

1.2 | Additional information

The additive is a preparation of viable cells of *S. cerevisiae* CNCM I-1077. It is authorised in the European Union for dairy goats and dairy sheep,[3] lambs and horses,[4] calves, all minor ruminant species for rearing other than lambs and camelids for rearing,[5] dairy cows, cattle for fattening, all minor ruminant species for fattening and camelids for fattening (4b1711).[6]

The EFSA FEEDAP Panel adopted eight opinions on the safety and efficacy of this product (EFSA, 2006a, 2006b, 2008, 2009; EFSA FEEDAP Panel, 2017a, 2019a, 2019b).

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[7] in support of the authorisation request for the use of *Saccharomyces cerevisiae* CNCM I-1077 as a feed additive.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 1 March 2024 to 1 June 2024; the comments received were considered for the assessment.

In accordance with Article 38 of the Regulation (EC) No 178/2002[8] 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

[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 - 19, rue des Briquetiers - BP 59–31702 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.

[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 319, 2.10.2020, p. 19–21.

[6]Commission Implementing Regulation (EU) 2023/1170 of 15 June 2023 concerning the authorisation of a preparation of Saccharomyces cerevisiae CNCM I-1077 as a feed additive for dairy cows, cattle for fattening, minor ruminant species for fattening and camelids for fattening (holder of the authorisation: Danstar Ferment AG represented by Lallemand SAS) and repealing Regulation (EC) No 1200/2005 (Text with EEA relevance).

[7]Dossier reference: FEED-2021-1013.

[8]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.

Executive Director laying down practical arrangements concerning transparency and confidentiality,[9] 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, EFSA carried out a public consultation on the non-confidential version of the technical dossier from 13 August to 3 September 2024 for which no comments were received.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA, 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 active agent in animal feed are valid and applicable for the current application.[10]

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of *Saccharomyces cerevisiae* CNCM I-1077 is in line with the principles laid down in Regulation (EC) No 429/2008[11] and the relevant guidance documents: Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018a), Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018b) and Guidance on the assessment of the safety of feed additives for the users (EFSA FEEDAP Panel, 2023).

3 | ASSESSMENT

The additive under assessment is a preparation of viable cells of *S. cerevisiae* CNCM I-1077. It is currently authorised for use in feed for calves, cattle for fattening, dairy cows, dairy goats and dairy sheep, lambs, all minor ruminant species for fattening and rearing, camelids for fattening and rearing and horses. The applicant is requesting the modification of the authorisation for lambs to reduce the minimum use level and the extension of the authorisation as a zootechnical additive for use in feed for all ruminants and camelids reared for milk production/suckling[12]/reproduction, all minor (young) ruminant species and camelids for fattening (functional group: gut flora stabilisers) and Equidae other than horses (functional group: digestibility enhancers).

3.1 | Characterisation

3.1.1 | Characterisation of the active agent

The active agent *S. cerevisiae* was isolated from a fruit, and it is deposited in the Collection Nationale de Cultures de Microorganismes (CNCM) under the accession number CNCM I-1077.[13] It has not been genetically modified.[14]

The taxonomical identification of the strain was confirmed based on the whole genome sequence (WGS) data.[15] Two sets of data were provided. The first concerned a read-mapping approach in which sequence reads were aligned to a set of genomes of various *Saccharomyces* species. The reads showed the highest similarity to those of the reference genome of *S. cerevisiae* S288C. The second dataset consisted of the comparison of the ribosomal internal transcribed spacer (ITS) sequence with those of the type strains of the *Saccharomyces* genus. The results showed *S. cerevisiae* NRRL Y-12632^T as the closest match.

3.1.2 | Characterisation of the additive

The additive under assessment is a preparation of viable cells of *S. cerevisiae* CNCM I-1077 and is presented in two formulations:

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

[10]Evaluation report 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.

[11]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.

[12]2024-10-10_sin_3_reply. 'Ruminants and camelids reared for suckling' refer to female ruminants/Camelids reared to feed their young after birth, until weaning and not maintained primarily for the production of milk.

[13]Annex_II_5.

[14]Annex_II_4.

[15]Annex_II_6_and 2024-09-06_sin_2_reply_q1_conf.

- a not-coated form, with a minimum concentration of viable yeast cells of 2×10^{10} colony forming units (CFU) per gram of additive.
- a coated or microencapsulated form (coated with vegetable oil derivatives) with a minimum concentration of viable yeast cells of 1×10^{10} CFU per gram of additive.

The additive has the same composition and method of manufacture as those considered in previous applications (EFSA FEEDAP Panel, 2017a), [redacted] Therefore, all the information/data pertaining to composition, physico-chemical properties and shelf-life described thereof are also considered valid for this application. New data on batch-to-batch variation, purity and dusting potential were provided and are described below.

Analytical data to confirm the specifications were provided for five batches of each form of the additive, showing the following average values: 2.8×10^{10} CFU/g (range 2.4–3.4×10^{10} CFU/g) for the not-coated preparation and 1.9×10^{10} CFU/g (range 1.7–2.0×10^{10} CFU/g) for the coated one.[17]

Specifications are set by the applicant for *Escherichia coli* (< 10 CFU/g additive), *Salmonella* spp. (no detection in 25 g additive), Enterobacteriaceae and coliforms (< 1000 CFU/g additive). The analysis of three batches of each form of the additive showed compliance with the specifications.[18]

The FEEDAP Panel considers that the results of the microbial contamination analyses do not raise safety concerns.

The not-coated form appears as brown/beige granular particles and the coated form as brown/beige beadlets with glossy appearance.

The dusting potential of three batches of each formulation of the additive was determined using the Stauber-Heubach method and showed values on average of 600 mg/m^3 (400–800 mg/m^3) (mg airborne dust per m^3 of air) for the not-coated formulation, while the coated formulation produced no dust.[19]

3.1.3 | Conditions of use

The additive is currently authorised for use in feed for cattle and minor ruminant species for fattening, dairy cows and goats, lambs, calves, horses, all minor ruminant species for rearing and camelids (for rearing and fattening).

The applicant has requested the extension of use of the authorisation to include:

- Equidae other than horses at a minimum inclusion level of 3×10^9 CFU/kg complete feed.
- All ruminants and camelids for milk production/suckling/reproduction at a minimum inclusion level of 5×10^8 CFU/kg complete feed
- Minor (young) ruminants and camelids for fattening at a minimum inclusion level of 1×10^9 CFU/kg complete feed.

In addition, the applicant has requested to lower the minimum inclusion level in feed for lambs from 3×10^9 to 1×10^9 CFU/kg complete feed.

3.2 | Safety

The safety of the additive for horses, calves, cattle for fattening and camelids has been established in previous assessments based on the Qualified Presumption of Safety (QPS) approach of the active agent and the lack of concerns deriving from other components (EFSA, 2009; EFSA FEEDAP Panel, 2017a, 2019a). The Panel considers that the proposed extension of use to new species/categories would not introduce hazards not already considered in the past opinions.

In the current opinion, the identity of the strain CNCM I-1077 has been established as *S. cerevisiae*, and consequently, it has been confirmed that the strain qualifies for the QPS approach (EFSA BIOHAZ Panel, 2023). Therefore, *S. cerevisiae* CNCM I-1077 is presumed safe for the target species, consumers and the environment. Since no concerns are expected from other components of the product, the additive is also considered to be safe for the target species, consumers and the environment.

3.2.1 | Safety for the user

The highest dusting potential reported for the not-coated form of the additive (800 mg/m^3) suggests that exposure by inhalation is possible. Since the coated form is dust-free, exposure by inhalation is unlikely.

[16] 2024-06-17_sin_reply_q2.
[17] Annex_II_2.
[18] Annex_II_2.
[19] Annex_II_3. Limit of detection: 0.1 mg/m^3.

In a previous opinion (EFSA FEEDAP Panel, 2017a) three experiments (i.e. an eye irritation study performed according to the Organisation for Economic Co-operation and Development (OECD) guideline (GL) 405, a skin irritation study performed according to the OECD GL 404 and a skin sensitisation study performed according to the OECD GL 429) were conducted with the not-coated form of the additive as the test item. Based on the results of these studies, the not-coated form of the additive was considered not to be a skin irritant or a dermal sensitiser, but it was considered to be an eye irritant. In the context of the current assessment, the FEEDAP Panel noted that the results of the eye irritation study, when interpreted according to the most recent version of the OECD 405,[20] indicated that the additive is not irritant to the eye.[21]

No data were provided regarding the eye irritancy potential of the coated form of the additive.[22]

Although the not-coated form of the additive was considered to be a non-sensitiser under the test conditions in the experiment mentioned above, the FEEDAP Panel notes that the OECD GL 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. The additive under assessment consists of a microorganism, and therefore, it should be considered as a potential skin and respiratory sensitiser.

3.2.1.1 | *Conclusions on safety for the user*

The not-coated form of the additive is not irritant to skin or eyes. The additive in both formulations, should be considered a skin and respiratory sensitiser and any exposure through skin and respiratory tract is considered a risk. No conclusion can be drawn on the eye irritation potential of the coated form of the additive due to the lack of data.

3.3 | Efficacy

The applicant is requesting the authorisation for use of the additive in feed for:

- all ruminant species and camelids reared for milk production/suckling/reproduction at a minimum content of 5×10^8 CFU/kg complete feed,
- all minor (young) ruminant species and camelids for fattening at a minimum content of 1×10^9 CFU/kg complete feed and
- Equidae other than horses at a minimum content of 3×10^9 CFU/kg complete feed

Taking into account that the efficacy of the additive has been previously established in calves at 1×10^9 CFU/kg (EFSA FEEDAP Panel, 2019a), cattle for fattening at 6×10^8 CFU/kg complete feed (EFSA FEEDAP Panel, 2017a) and horses at 3×10^9 CFU/kg complete feed (EFSA, 2009), the FEEDAP Panel considers that the conclusions reached in these species can be extrapolated to the respective physiologically similar target species at the corresponding developmental stage. Therefore, the FEEDAP Panel concludes that the additive has the potential to be efficacious when used in feed for:

- all ruminants and camelids reared for milk production/suckling/reproduction at the minimum proposed use level of 5×10^8 CFU/kg complete feed,
- all minor (young) ruminant species and camelids for fattening at 1×10^9 CFU/kg complete feed,
- all Equidae species other than horses at 3×10^9 CFU/kg complete feed.

Additionally, the applicant has requested to lower the minimum inclusion level in feed for lambs from 3×10^9 to 1×10^9 CFU/kg complete feed. Considering that the efficacy has been established in calves and cattle for fattening at 1×10^9 and 6×10^8 CFU/kg complete feed, respectively, the Panel concludes that the additive has the potential to be efficacious in lambs at the new minimum proposed use level of 1×10^9 CFU/kg complete feed.

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[23] and Good Manufacturing Practice.

4 | CONCLUSIONS

The additive consisting of *S. cerevisiae* CNCM I-1077 is considered safe for the target species, consumers and the environment.

[20]Test Guideline No. 405 Acute Eye Irritation/Corrosion. Available online at: https://www.oecd-ilibrary.org/docserver/9789264185333-en.pdf?expires=1730729839&id=id&accname=guest&checksum=C52EA4DDEB48E2DA331A32D808C8C1CA.

[21]2024-09-06_sin_2_reply_q2.

[22]2024-09-06_sin_2_reply_q2.

[23]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.

The not-coated form of the additive is not irritant to skin or eyes. The additive in both formulations, should be considered a skin and respiratory sensitiser and any exposure through skin and respiratory tract is considered a risk. No conclusion can be drawn on the eye irritation potential of the coated form of the additive due to the lack of data.

The additive consisting of *S. cerevisiae* CNCM I-1077 has the potential to be efficacious when used in feed for all ruminants and camelids reared for milk production/suckling/reproduction at a minimum proposed use level of 5×10^8 CFU/kg complete feed, all minor (young) ruminant species and camelids for fattening and lambs at 1×10^9 CFU/kg complete feed, and in all Equidae species other than horses at 3×10^9 CFU/kg complete feed.

ABBREVIATIONS

CFU	colony forming unit
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
OECD	Organisation for Economic Co-operation and Development
QPS	Qualified Presumption of Safety

REQUESTOR

European Commission

QUESTION NUMBER

EFSA-Q-2023-00724

COPYRIGHT FOR NON-EFSA CONTENT

PANEL MEMBERS

Roberto Edoardo Villa, Giovanna Azimonti, Eleftherios Bonos, Henrik Christensen, Mojca Durjava, Birgit Dusemund, Ronette Gehring, Boet Glandorf, Maryline Kouba, Marta López-Alonso, Francesca Marcon, Carlo Nebbia, Alena Pechová, Miguel Prieto-Maradona, Ilen Röhe, and Katerina Theodoridou.

LEGAL NOTICE

Roberto Edoardo Villa, Giovanna Azimonti, Eleftherios Bonos, Henrik Christensen, Mojca Durjava, Birgit Dusemund, Ronette Gehring, Boet Glandorf, Maryline Kouba, Marta López-Alonso, Francesca Marcon, Carlo Nebbia, Alena Pechová, Miguel Prieto-Maradona, Ilen Röhe, and Katerina Theodoridou.

REFERENCES

EFSA (European Food Safety Authority). (2006a). Opinion of the panel on additives and products or substances used in animal feed (FEEDAP) on the safety and efficacy of the product "Levucell SC20/Levucell SC10ME", a preparation of *Saccharomyces cerevisiae*, as a feed additive for dairy goats and dairy ewes in accordance with regulation (EC) No 1831/2003. *EFSA Journal*, 370. https://doi.org/10.2903/j.efsa.2006.370

EFSA (European Food Safety Authority). (2006b). Opinion of the Panel on additives and products or substances used in animal feed (FEEDAP) on the safety and efficacy of the product "Levucell SC20/Levucell SC10ME", a preparation of *Saccharomyces cerevisiae*, as a feed additive for leisure horses. *EFSA Journal*, *4*(9), 385. https://doi.org/10.2903/j.efsa.2006.385

EFSA (European Food Safety Authority). (2008). Scientific Opinion of the panel on additives and products or substances used in animal feed (FEEDAP) on a request from the European Commission on the safety and efficacy of Levucell SC20/Levucell SC10ME, a preparation of *Saccharomyces cerevisiae*, as feed additive for lambs for fattening. *EFSA Journal*, 772. https://doi.org/10.2903/j.efsa.2008.772

EFSA (European Food Safety Authority). (2009). Opinion of the Panel on additives and products or substances used in animal feed (FEEDAP) on the efficacy of the product Levucell SC20/Levucell SC10ME (*Saccharomyces cerevisiae*) as feed additive for leisure horses. *EFSA Journal*, *7*(4), 1040. https://doi.org/10.2903/j.efsa.2009.1040

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Koutsoumanis, K., Allende, A., Álvarez-Ordóñez, A., Bolton, D., Bover-Cid, S., Chemaly, M., De Cesare, A., Hilbert, F., Lindqvist, R., Nauta, M., Peixe, L., Ru, G., Simmons, M., Skandamis, P., Suffredini, E., Cocconcelli, P. S., Fernández Escámez, P. S., Prieto Maradona, M., … Herman, L. (2023). Scientific Opinion on the update of the list of qualified presumption of safety (QPS) recommended microorganisms intentionally added to food or feed as notified to EFSA. *EFSA Journal*, *21*(1), 7747. https://doi.org/10.2903/j.efsa.2023.7747

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen, G., Aquilina, G., Azimonti, G., Bampidis, V., Bastos, M. L., Bories, G., Chesson, A., Cocconcelli, P. S., Flachowsky, G., Gropp, J., Kolar, B., Kouba, M., López Puente, S., López-Alonso, M., Mantovani, A., Mayo, B., Ramos, F., Villa, R. E., … Saarela, M. (2017a). Scientific opinion on the safety and efficacy of Levucell® SC (*Saccharomyces cerevisiae* CNCM I-1077) as a feed additive for dairy cows, cattle for fattening, minor ruminant species and camelids. *EFSA Journal*, *15*(7), 4944. https://doi.org/10.2903/j.efsa.2017.4944

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen, G., Aquilina, G., Azimonti, G., Bampidis, V., Bastos, M. L., Bories, G., Chesson, A., Cocconcelli, P. S., Flachowsky, G., Gropp, J., Kolar, B., Kouba, M., López-Alonso, M., López Puente, S., Mantovani, A., Mayo, B., Ramos, F., Saarela, M., … Innocenti, M. L. (2017b). Guidance on the identity, characterisation and conditions of use of feed additives. *EFSA Journal*, *15*(10), 5023. https://doi.org/10.2903/j.efsa.2017.5023

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen, G., Aquilina, G., Azimonti, G., Bampidis, V., Bastos, M. L., Bories, G., Chesson, A., Cocconcelli, P. S., Flachowsky, G., Gropp, J., Kolar, B., Kouba, M., López-Alonso, M., López Puente, S., Mantovani, A., Mayo, B., Ramos, F., Saarela, M., … Martino, L. (2018a). Guidance on the assessment of the efficacy of feed additives. *EFSA Journal*, *16*(5), 5274. https://doi.org/10.2903/j.efsa.2018.5274

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen, G., Aquilina, G., Azimonti, G., Bampidis, V., Bastos, M. L., Bories, G., Chesson, A., Cocconcelli, P. S., Flachowsky, G., Gropp, J., Kolar, B., Kouba, M., López-Alonso, M., López Puente, S., Mantovani, A., Mayo, B., Ramos, F., Saarela, M., … Galobart, J. (2018b). Guidance on the characterisation of microorganisms used as feed additives or as production organisms. *EFSA Journal*, *16*(3), 5206. https://doi.org/10.2903/j.efsa.2018.5206

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis, V., Azimonti, G., Bastos, M. L., Christensen, H., Dusemund, B., Kouba, M., Kos Durjava, M., López-Alonso, M., López Puente, S., Marcon, F., Mayo, B., Pechová, A., Petkova, M., Ramos, F., Sanz, Y., Villa, R., Woutersen, R., Anguita, M., & Brozzi, R. (2019a). Scientific Opinion on the safety and efficacy of Levucell SC® (*Saccharomyces cerevisiae* CNCM I-1077) as a feed additive for calves and minor ruminant species and camelids at the same developmental stage. *EFSA Journal*, *17*(6), 5723. https://doi.org/10.2903/j.efsa.2019.5723

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis, V., Azimonti, G., Bastos, M. L., Christensen, H., Dusemund, B., Kouba, M., Kos Durjava, M., López-Alonso, M., López Puente, S., Marcon, F., Mayo, B., Pechová, A., Petkova, M., Ramos, F., Sanz, Y., Villa, R. E., Woutersen, R., & Brozzi, R. (2019b). Scientific Opinion on the assessment of the application for renewal of authorisation of Levucell SC (*Saccharomyces cerevisiae* CNCM I-1077) as a feed additive for lambs and horses. *EFSA Journal*, *17*(3), 5639. https://doi.org/10.2903/j.efsa.2019.5639

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., Villa, R. E., Woutersen, R., Brantom, P., Chesson, A., … Galobart, J. (2023). Guidance on the assessment of the safety of feed additives for the users. *EFSA Journal*, *21*(12), e8469. https://doi.org/10.2903/j.efsa.2023.8469

How to cite this article: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Villa, R. E., Azimonti, G., Bonos, E., Christensen, H., Durjava, M., Dusemund, B., Gehring, R., Glandorf, B., Kouba, M., López-Alonso, M., Marcon, F., Nebbia, C., Pechová, A., Prieto-Maradona, M., Röhe, I., Theodoridou, K., Woutersen, R., Anguita, M., … Pagés, D. (2024). Assessment of the modification of the authorisation of the feed additive consisting of *Saccharomyces cerevisiae* CNCM I-1077 for lambs for fattening and its extension of use to all ruminants and camelids reared for milk production/suckling/reproduction, all minor (young) ruminant species and camelids for fattening and Equidae other than horses (Lallemand SAS). *EFSA Journal*, *22*(11), e9075. https://doi.org/10.2903/j.efsa.2024.9075