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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 Panel on Additives and Products or Substances used in Animal Feed (EFSA FEEDAP Panel), Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Maryline Kouba, Mojca Kos Durjava, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa, Ruud Woutersen and Rosella Brozzi

Abstract

Levucell® SC is the trade name for a feed additive based on viable cells of a strain *Saccharomyces cerevisiae.* The product is currently authorised for use in feed for horses, lambs, dairy sheep and dairy goats, dairy cows and cattle for fattening. This opinion concerns the renewal of the authorisation of Levucell® SC as a zootechnical additive for lambs and horses. *S. cerevisiae* is considered by EFSA to be suitable for the qualified presumption of safety (QPS) approach to establishing safety for the target species, consumers and the environment. The identity of the strain present in the additive was established. Accordingly, this strain is presumed safe for the target species, consumers of products from animals fed the additive and the environment. Since no concerns are expected from other components of the additive, Levucell® SC is also considered safe for the target species, consumers of products from animals fed the additive and the environment. The applicant has provided data demonstrating that the additive currently in the market complies with the conditions of authorisation. Furthermore, according to the information provided in the technical dossier, no new evidence has been identified that would make the FEEDAP Panel reconsider the previous conclusions on the safety of the product for target species, consumers, users and the environment under the authorised conditions of use. Levucell® SC is an eye irritant.

Keywords: Levucell SC, *Saccharomyces cerevisiae* CNCM I-1077, safety, efficacy, QPS, lambs, horses

Requestor: European Commission

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Correspondence: feedap@efsa.europa.eu

Panel members: Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Maryline Kouba, Mojca Kos Durjava, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa and Ruud Woutersen.

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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 of that Regulation specifies that for products authorised according to Article 9, an application for renewal shall be submitted in accordance with Article 7, at the latest one year before the expiry date of the authorisation.

The European Commission received a request from Lallemand SAS[2] for renewal of the authorisation of the product Levucell® SC (*Saccharomyces cerevisiae* CNCM I-1077), when used as a feed additive for lambs (category: zootechnical additive; functional group: gut flora stabiliser) and horses (category: zootechnical additive; functional group: digestibility enhancers).

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 an authorised 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 28 May 2018.

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 Levucell® SC (*Saccharomyces cerevisiae* CNCM I-1077), when used under the proposed conditions of use (see Section 3.1.3).

1.2. Interpretation of the Terms of Reference

The 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, efficacy is not assessed. The present opinion will focus only on the safety aspects.

1.3. Additional information

The additive Levucell® SC is a preparation of *Saccharomyces cerevisiae* CNCM I-1077. EFSA issued several opinions on the safety and efficacy of this product for the following species: dairy goats and dairy ewes (EFSA, 2006a; EFSA FEEDAP Panel, 2018), leisure horses (EFSA, 2006b, 2009), lambs for fattening (EFSA, 2008), dairy cows, cattle for fattening, minor ruminant species and camelids (EFSA FEEDAP Panel, 2017).

The product is currently authorised for use in horses,[3] lambs,[4] dairy goats and dairy sheep,[5] dairy cows and cattle for fattening.[6]

[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] Lallemand SAS. 137, 19 Rue des Briquetiers, BP 31702. 59700 Blagnac, France.
[3] Commission Regulation (EC) No 910/2009 of 29 September 2009 concerning the authorisation of a new use of the preparation *of Saccharomyces cerevisiae* CNCM I-1077 as a feed additive for horses (holder of authorisation Lallemand SAS). OJ L 257, 30.9.2009, p. 7.
[4] Commission Regulation (EC) No 1293/2008 of 18 December 2008 concerning the authorisation of a new use of *Saccharomyces cerevisiae* CNCM I-1077 (Levucell SC20 and Levucell SC10 ME) as a feed additive. OJ L 340, 19.12.2008, p. 38 plus.
[5] Commission Regulation (EC) No 226/2007 of 1 March 2007 concerning the authorisation of *Saccharomyces cerevisiae* CNCM I 1077 (Levucell SC20 and Levucell SC10 ME) as a feed additive. OJ L 64, 02.03.2007, p. 26 plus amendments.
[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 plus amendments.

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 request for the renewal of the authorisation for the use of Levucell® SC (*Saccharomyces cerevisiae* CNCM I-1077) as a feed additive.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessments are valid and applicable for the current application.[8]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety of Levucell® SC (*Saccharomyces cerevisiae* CNCM I-1077) is in line with the principles laid down in Regulation (EC) No 429/2008[9] and the relevant guidance documents: Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2013).

3. Assessment

The additive is a preparation consisting of dried cells of *S, cerevisiae* (CNCM I-1077) intended for use as a zootechnical additive in feed for lambs (gut flora stabiliser) and horses (digestibility enhancer).

3.1. Characterisation

3.1.1. Characterisation of the additive

The product is authorised in two forms:

- Levucell® SC20, a fine, granulated free-flowing powder with a minimal concentration of viable yeast cells of 2×10^{10} colony forming units (CFU)/g of additive (granulated form), and
- Levucell® SC10 ME (coated or microencapsulated form), with a minimal concentration of viable yeast cells of 1×10^{10} CFU/g of additive.

The applicant is requesting the authorisation of a third form, Levucell® SC10 ME Titan[10] [redacted][11] For practical purposes, the two forms are considered equivalent.

The applicant states that no changes in the manufacturing process or composition of the additive have been introduced since the authorisation (other than the production of the Titan form, see above). This was confirmed by the analysis of three batches of Levucell® SC20 and SC10 forms produced in 2017, which showed compliance with specifications (2.6×10^{10}–3.1×10^{10} CFU/g and 1.5×10^{10}–1.7×10^{10} CFU/g for SC20 and SC10 ME, respectively).[12]

Data from three 2017 production batches of Levucell® SC20 form and three of Levucell® SC10 ME Titan were provided for microbiological purity.[12] Measurements for the Levucell® SC20 form included aerobic bacteria (30–2.6×10^3 CFU/g), total coliforms ($< 10^3$ CFU/g), *Escherichia coli* (absent), *Staphylococcus* (absent) and *Salmonella* (absent in 25 g). For the Levucell® SC10 ME Titan, values were provided for total bacteria ($< 10^4$ CFU/g), enterobacteria ($< 10^2$ CFU/g), *E. coli* (< 10 CFU/g) and *Salmonella* (absent in 25 g).

[7] FEED dossier reference: FAD-2017-0069.
[8] The reports linked to the previous dossiers are available on the EURL website: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2005-0016?search&form-return and https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2010-0120?search&form-return
[9] 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.
[10] Levucell® SC Titan may be marketed with other tradenames: Lallemand SC20/SC10 ME/SC10 ME Titan.
[11] The applicant claims that the Standing Committee on the Food Chain and Animal Health in its meeting of 18 February 2010 concluded that Levucell® SC Titan falls within the description as provided for in the authorisation Regulation.
[12] Technical dossier/Section II/Annex II 3.

Chemical contamination was measured in two batches of Levucell® SC20 produced in 2016 and one in 2017.[13] Data were provided for heavy metals (cadmium, mercury and lead < 0.05 mg/kg[14]), arsenic (< 0.05, 0.064 and 0.10 mg/kg), aflatoxins (B1, B2, G1 and G2 < 1.0 μg/kg), ochratoxin A (< 0.2 μg/kg), zearalenone (< 5.0 μg/kg); dioxins (polychlorinated dibenzo-*p*-dioxins and dibenzofurans (PCDD/F)) ≤ 0.0971 ng WHO-PCDD/F-TEQ/kg), the sum of dioxins and dioxin-like polychlorinated biphenyls ((DL-PCBs) ≤ 0.0507 ng WHO-PCDD/F-DL-PCB-TEQ/kg) and non-DL-PCBs (≤ 0.0186 μg/kg). Other three batches of Levucell® SC10 ME Titan[15] (one produced in 2016 and two in 2017) were analysed for arsenic (0.040, 0.014 and < 0.2 mg/kg), cadmium (0.0080, 0.014 and < 0.02 mg/kg), lead (0.012, 0.014 and < 0.02 mg/kg), mercury (< 0.0006 and < 0.1 mg/kg), aflatoxin B1 (< 0.10 μg/kg), dioxins (≤ 0.161 ng WHO-PCDD/F-TEQ/kg) and the sum of dioxins and dioxin-like polychlorinated biphenyls (≤ 0.274 ng WHO-PCDD/F- PCB-TEQ/kg). None of these values give rise to concerns.

3.1.2. Characterisation of the active agent

The active agent is a *S. cerevisiae* strain deposited at the National Culture Collection of Microorganisms (CNCM, France) with the accession number CNCM I-1077.[16] The strain is not genetically modified.[17] The strain was identified as *S. cerevisiae* by sequence analysis of the D1/D2 domains of the 26S rRNA gene.[18] Strain level identification is based on delta-polymerase chain reaction (PCR) and microsatellite genotyping of 13 loci.

3.1.3. Conditions of use

Levucell® SC20 and Levucell® SC10 ME are currently authorised at a minimum dose of 3.0×10^9 CFU/kg of complete feed for horses and lambs for fattening, with no maximum dose. For lambs the additive is recommended to be used at 7.3×10^9 CFU/kg of complete feedingstuffs. The applicant proposes to keep these conditions and to request the authorisation of Levucell® SC10 ME Titan at the same conditions.

Under other provisions the authorisation for horses foresees that:

- storage temperature, storage life and stability to pelleting are indicated in the directions for use of the additive and premixtures,
- the coated form is included only through a pelleted feed,
- safety glasses and masks are used for mixing if the mixers are not equipped with exhaust systems and if the product is handled or mixed in a confined atmosphere.

While that for lambs foresees that:

- storage temperature, storage life and stability to pelleting are indicated in the directions for use of the additive and premixtures,
- 50°C are not exceeded with Levucell® SC20 and 80°C with Levucell® SC10 ME in complementary feedingstuffs,
- the coated form is included only through a pelleted feed.

3.2. Safety

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

The species *S. cerevisiae* is considered by EFSA to be suitable for the qualified presumption of safety (QPS) approach to safety assessment (EFSA, 2007; EFSA BIOHAZ Panel, 2017). This approach requires the identity of the strain to be conclusively established. In the view of the FEEDAP Panel, the identity of the strain *S. cerevisiae* (CNCM I-1077) was confirmed. Accordingly, this strain is considered by EFSA to be suitable for the QPS approach to safety and is presumed safe for the target species, consumers of products from animals fed the additive and the environment. Since no concerns are expected from other components of the additive, Levucell® SC is also considered safe for the target species, consumers of products from animals fed the additive and the environment.

[13] Technical dossier/Section II/Annex II 4a.
[14] Limit of quantification.
[15] Technical dossier/Section II/Annex II 4b.
[16] Technical dossier/Section II/Annex II 6b.
[17] Technical dossier/Section II/Annex II 6a.
[18] Technical dossier/Section II/Annex II 6f.

3.2.2. Safety for the user

In a previous opinion, the FEEDAP Panel concluded that Levucell® SC is not a dermal irritant or sensitiser but is an eye irritant. Inhalation exposure is unlikely. Encapsulation is not expected to introduce hazards for users (EFSA FEEDAP Panel, 2017).

3.2.3. Further evidence of safety

The applicant states that no adverse effects or specific interactions or incompatibilities have been reported for the additive.[19]

The applicant conducted a literature search on the safety of Levucell® SC using several databases: CAB Abstracts, Agris, Scopus, Google Scholar, Bielefeld Academic Search Engine (BASE) and the Liège University library.[19] The search included the terms: CNCM I-1077, Levucell SC, *Saccharomyces cerevisiae*, safe*, tox*, tolerance, adverse effects, epidemiology, feed, incompatib* and interact*. The search covered the period 2006–2018. The search identified 74 relevant publications (Appendix A). None was designed to assess the safety per se of the additive, but the use of Levucell® SC in farm animals (ruminants and/or horses). However, the studies were mostly designed to observe the effect of the additive on zootechnical performance and included some health parameters (i.e. blood biochemistry). None of these studies reported safety issues with the additive under assessment.

Therefore, the FEEDAP Panel concludes that there is no new evidence that would lead the Panel to reconsider its previous conclusions on the safety of the product for target species, consumers and the environment under the authorised conditions of use.

3.3. 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[20] and Good Manufacturing Practice.

4. Conclusions

The applicant has provided evidence that the additive currently in the market complies with the existing conditions of authorisation.

The FEEDAP Panel confirms its previous conclusion that Levucell® SC is safe for the target species, consumers of products from animals fed the additive, users and the environment. Levucell® SC is an eye irritant.

Documentation provided to EFSA

1) Levucell SC. *Saccharomyces cerevisiae* CNCM I-1077 for lambs and horses. December 2017. Submitted by Lallemand SAS.
2) Member States comments.

Chronology

Date	Event
20/12/2017	Dossier received by EFSA
01/02/2018	Reception mandate from the European Commission
28/05/2018	Application validated by EFSA – Start of the scientific assessment
28/08/2018	Comments received from Member States
26/02/2019	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

[19] Technical dossier/Section III.

[20] 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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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 2006;4(9):385, 9 pp. https://doi.org/10.2903/j.efsa.2006.385

EFSA (European Food Safety Authority), 2007. Introduction of a Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA – Opinion of the Scientific Committee. EFSA Journal 2007;5(12):587, 16 pp. https://doi.org/10.2903/j.efsa.2007.587

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. The EFSA Journal 2008;6(8):772, 11 pp. 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 2009;7(4):1040, 7 pp. https://doi.org/10.2903/j.efsa.2009.1040

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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. Available online: www.efsa.europa.eu/efsajournal

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, Lóopez Puente S, López-Alonso M, Mantovani A, Mayo B, Ramos F, Villa RE, Wallace RJ, Wester P, Brozzi R and Saarela M, 2017. 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 2017;15(7):4944, 16 pp. https://doi.org/10.2903/j.efsa.2017.4944

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Abbreviations

BASE	Bielefeld Academic Search Engine
BIOHAZ	EFSA Panel on Biological Hazards
CFU	colony forming unit
CNCM	National Culture Collection of Microorganisms
DL-PCB	dioxin-like polychlorinated biphenyl
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on additives and products or substances used in animal feed
PCBs	polychlorinated biphenyls
PCDD/F	polychlorinated dibenzo-*p*-dioxins and dibenzofurans
PCR	polymerase chain reaction
QPS	Qualified Presumption of Safety
SCAN	Scientific Committee on Animal Nutrition
TEQ	toxic equivalent
WHO	World Health Organization

Appendix A – List of references retrieved from the literature search provided by the applicant to support safety of the additive

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