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SCIENTIFIC OPINION

Assessment of the feed additive consisting of *Saccharomyces cerevisiae* CNCM I-4407 (Actisaf® Sc 47) for rabbits for fattening and non-food producing rabbits for the renewal of its authorisation (S. I. Lesaffre)

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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 authorisation of a preparation of dried cells of *Saccharomyces cerevisiae* CNCM I-4407 (Actisaf® Sc 47) as a zootechnical additive for rabbits for fattening and non-food producing rabbits. The applicant provided evidence that the additive currently in the market complies with the existing terms of the authorisation. The Panel concluded that the additive remains safe for the target species, consumers and the environment. Regarding the safety for the user, the additive is not a skin or eye irritant. However, it should be considered as a potential skin and respiratory sensitiser, and any exposure through skin and respiratory tract is considered a risk. The present application for renewal of the authorisation did 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 was no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

KEYWORDS

Actisaf® Sc47, efficacy, gut flora stabilisers, rabbits for fattening and non-food producing rabbits, *Saccharomyces cerevisiae* CNCM I-4407, 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 14(1) of that Regulation lays down that an application for renewal shall be sent to the Commission at the latest 1 year before the expiry date of the authorisation.

The European Commission received a request from S. I. LESAFFRE[2] for the renewal of the authorisation of the additive consisting of *Saccharomyces cerevisiae* CNCM I-4407[3] (Actisaf® Sc 47),[4] when used as a feed additive for rabbits for fattening and non-food producing rabbits (category: zootechnical; 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). The dossier was received on 29 June 2021 and the general information and supporting documentation are available at https://open.efsa.europa.eu/questions/EFSA-Q-2021-00382. The particulars and documents in support of the application were considered valid by EFSA as of 20 June 2022.

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 *Saccharomyces cerevisiae* CNCM I-4407 (Actisaf® Sc 47), when used under the proposed conditions of use (see **Section 3.1.3**).

1.2 | Additional information

The additive Actisaf® Sc 47 is a preparation of dried cells of *S. cerevisiae* CNCM I-4407. The additive is authorised for use in feed as a zootechnical additive (4b1702) under the functional group digestibility enhancer for horses,[5] and under the functional group gut flora stabilisers for calves for rearing;[6] rabbits for fattening and non-food producing rabbits;[7] lambs for fattening, dairy goats and dairy sheep, pigs for fattening, dairy buffaloes[8] and piglets (weaned), sows and dairy cows.[9] EFSA has issued an opinion on the safety and efficacy of this product for rabbits for fattening and non-food producing rabbits (EFSA FEEDAP Panel, 2012) and for several other species (EFSA, 2006a, 2006b, 2006c, 2007a, 2007b, 2008, 2010; EFSA FEEDAP Panel, 2018a, 2018b, 2019, 2020).

The applicant has requested the renewal of the authorisation of the additive for rabbits for fattening and non-food producing rabbits.

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[10] in support of the authorisation request for the use of *Saccharomyces cerevisiae* CNCM I-4407 (Actisaf® Sc 47) as a feed additive.

In accordance with Article 38 of the Regulation (EC) No 178/2002[11] 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]Société Industrielle LESAFFRE (S. I. LESAFFRE), 137, rue Gabriel Péri, BP 3029–59,703 Marcq-en-Baroeul, France.

[3]Previously deposited in the National Collection of Yeast Cultures (NCYC) with accession number NCYC Sc47.

[4]Former trade name: Biosaf® Sc 47.

[5]Commission Implementing Regulation (EU) No 2019/899 of 29 May 2019 concerning the renewal of the authorisation of *Saccharomyces cerevisiae* CNCM I-4407 as a feed additive for lambs for fattening, dairy goats, dairy sheep, dairy buffaloes, horses and pigs for fattening and repealing Regulations (EC) No 1447/2006, (EC) No 188/2007, (EC) No 232/2009, (EC) No 186/2007 and (EC) No 209/2008 (holder of authorisation S.I. Lesaffre). OJ L 144, 03.06.2019. p. 32.

[6]Commission Implementing Regulation (EU) 2021/367 of 1 March 2021 concerning the renewal of the authorisation of a preparation of *Saccharomyces cerevisiae* CNCM I-4407 as a feed additive for calves for rearing and repealing Regulation (EU) No 883/2010 (holder of authorisation S.I. Lesaffre). OJ L 71, 02.03.2021. p. 1.

[7]Commission Implementing Regulation (EU) No 334/2012 of 19 April 2012 concerning the authorisation of a preparation of Saccharomyces cerevisiae CNCM I-4407 as a feed additive for rabbits for fattening and non food-producing rabbits and amending Regulation (EC) No 600/2005 (holder of the authorisation Société Industrielle Lesaffre). OJ L 108, 20.04.2012. p. 6.

[8]Commission Implementing Regulation (EU) 2019/899 of 29 May 2019 concerning the renewal of the authorisation of Saccharomyces cerevisiae CNCM I-4407 as a feed additive for lambs for fattening, dairy goats, dairy sheep, dairy buffaloes, horses and pigs for fattening and repealing Regulations (EC) No 1447/2006, (EC) No 188/2007, (EC) No 232/2009, (EC) No 186/2007 and (EC) No 209/2008 (holder of authorisation S.I. Lesaffre). OJ L 144, 03.06.2019. p. 32.

[9]Commission Implementing Regulation (EU) 2020/147 of 3 February 2020 concerning the authorisation of the preparation of Saccharomyces cerevisiae CNCM I-4407 as a feed additive for weaned piglets, sows (in order to have a benefit for suckling piglets) and dairy cows and amending Regulations (EC) No 2148/2004, (EC) No 1288/2004 and (EC) No 1811/2005 (holder of authorisation S.I. Lesaffre). OJ L 31, 04.02.2020. p. 7.

[10]Dossier reference: FEED-2021-0501.

[11]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,[12] 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 application from 12 January to 2 February 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 20 June to 20 September 2022; the comments received were considered for the assessment.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment are valid and applicable to the current application.[13]

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety of *Saccharomyces cerevisiae* CNCM I-4407 (Actisaf® Sc 47) is in line with the principles laid down in Regulation (EC) No 429/2008[14] and the relevant guidance documents: Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2021).

3 | ASSESSMENT

The additive consisting of dried cells of *S. cerevisiae* CNCM I-4407 (Actisaf® Sc 47) is currently authorised as a zootechnical additive (functional group: gut flora stabiliser) for rabbits for fattening and non-food producing rabbits. This assessment regards the renewal of the authorisation of the feed additive for those animals.

3.1 | Characterisation

3.1.1 | Characterisation of the additive

The additive is currently authorised with a minimum content of the active agent (*S. cerevisiae* CNCM I-4407) of 5×10^9 colony forming units (CFU)/g of additive. The product contains only dried cells of *S. cerevisiae* CNCM I-4407 and it is marketed in three forms: Actisaf® Sc 47 standard (STD), [redacted] the powder (PWD), [redacted] and the heat resistant (HR+), [redacted][15] The applicant states that no changes in the manufacturing process or composition of the additive have been introduced since the last authorisation.[16]

The analysis of 16 batches in total, [redacted][17] and showed compliance with the specifications of the additive as authorised.[18]

The analysis of [redacted] batches for each form of the additive showed compliance also with the specifications set for total coliforms (< 10 CFU/g), β-glucuronidase-positive *Escherichia coli* (< 10 CFU/g), *Salmonella* spp. (no detection in 25 g), coagulase-positive staphylococci including *Staphylococcus aureus* (no detection in 1 g), *Enterobacteriaceae* (< 10 CFU/g) and filamentous fungi (< 10 CFU/g).[19]

The analysis of nine batches [redacted] showed values below the limit of quantification (LOQ) of the analytical method for cadmium, mercury, lead, arsenic, fluorine and aflatoxins B1, B2, G1 and G2.[20] The exceptions were one batch [redacted] and one batch [redacted], which showed values for fluorine of 40 mg/kg. Additionally, one batch [redacted] was also analysed for selenium 0.1 mg/kg, copper 2.2 mg/kg, zinc 135 mg/kg, nickel < 0.1 mg/kg, antimony < 0.1 mg/kg, aluminium 4.3 mg/kg and iron 8.8 mg/kg. One batch [redacted] was also analysed for the same additional elements, showing values for selenium < 0.5 mg/kg, copper 2.9 mg/kg, zinc 130 mg/kg, nickel 0.1 mg/kg, antimony < 0.1 mg/kg, aluminium 0.6 mg/kg and iron 21 mg/kg, and for the presence of pesticides.[21,22]

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

[13]The full report is available on the EURL website: https://joint-research-centre.ec.europa.eu/system/files/2013-02/FinRep-FAD-2010-0038.pdf.

[14]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.

[15]Section_II_Identity_2.12.2_May2024, Section_II_Identity_2.3_May24 and Annex_II_3_c_Molasses composition.

[16]Annex_II_3_d_Antibiotics free statement 2024.

[17]Obtained from five independent fermentation batches.

[18]Annex_II_1_b_CFU results_May24.

[19]Annex_II_1_c_Microbio results_Feb24.

[20]LOQ for cadmium 0.1 mg/kg, mercury 0.05 mg/kg, lead 1 mg/kg, arsenic 0.4 mg/kg, fluorine 30 mg/kg, aflatoxins B1, B2 and G1 0.1 μg/kg and aflatoxin G2 0.2 μg/kg.

[21]Annex_II_1_d_Heavy Metals_Actisaf and Annex_II_1_e_Aflatoxins results_Actisaf.

[22]Pesticides analysed by multi-residue method.

The FEEDAP Panel considers that the amounts of the detected impurities do not raise safety concerns, with the exception of nickel (see Section 3.2).

Nine batches of the additive (three for each form) were analysed for bulk density, tap density, particle size distribution and dusting potential. The average bulk density and average tap density of the additive were 796 and 871 kg/m^3 for the [redacted] form, 788 and 880 kg/m^3 for the [redacted] form and 774 and 860 kg/m^3 for the [redacted] form.[23] The analysis for dusting potential using Stauber-Heubatch method showed values of 0, 6.25 and 25 mg/m^3 for [redacted]; 0, 40 and 45 mg/m^3 for [redacted]; and 0, 1.25 and 65 mg/m^3 for [redacted].[24] The analysis for particle size distribution by a sieve shaker did not identify particles below 125 µm in any form of the additive.[25]

No additional new data were provided regarding the physico-chemical properties of the additive. Since no changes were introduced in the manufacturing process or composition of the additive, the data described in the previous opinion (EFSA FEEDAP Panel, 2012) still apply.[26]

3.1.2 | Characterisation of the active agent

The *S. cerevisiae* strain of unknown origin is deposited at the [redacted] with the accession number CNCM I-4407. The applicant declared that the strain has not been genetically modified.[27]

A bioinformatic analysis of the whole genome sequence (WGS) data of the strain CNCM I-4407 confirmed its identity as *S. cerevisiae*. [redacted][28]

3.1.3 | Conditions of use

The additive is currently authorised at the minimum level of 5×10^9 CFU/kg complete feed for rabbits for fattening and non-food producing rabbits. Under other provisions of the authorisation, it is specified that "In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting". The applicant did not request any changes in the current conditions of use.[29]

3.2 | Safety

In its previous opinions, the FEEDAP Panel concluded that, following the qualified presumption of safety (QPS) approach to the safety assessment, *S. cerevisiae* CNCM I-4407 is safe for the target species, consumers and the environment (EFSA FEEDAP Panel, 2012, 2020). The safety for the user was evaluated by EFSA FEEDAP Panel in previous assessments (EFSA FEEDAP Panel, 2012, 2018a, 2019, 2020). The FEEDAP Panel concluded that Actisaf® Sc 47 in any form is not a skin or eye irritant and no conclusions could be drawn on the dermal sensitisation potential of the additive. Moreover, the Panel concluded that the additive should be considered a respiratory sensitiser.

The applicant declared that no incidents or safety issues for target animals, consumers, users and/or the environment have been documented or reported regarding the additive since its approval.[30]

In the context of the current application, the identity of the strain as *Saccharomyces cerevisiae* was confirmed, and therefore, the strain qualifies for the QPS approach to safety assessment (EFSA BIOHAZ Panel, 2023). Consequently, the conclusions previously reached are still valid and, since the additive consists of the active agent alone, the Panel considers that Actisaf® Sc 47 remains safe for the target species, consumers and the environment.[31]

In previous assessments for the renewal of the authorisation of the additive, two literature searches on the safety of the product covering the periods 2007–2016 (EFSA FEEDAP Panel, 2018a) and 2016–2019 (EFSA FEEDAP Panel, 2020) were evaluated by the FEEDAP Panel. These searches did not reveal any safety issue related to the additive under assessment. The applicant submitted in the current application an additional literature search covering the period 2019–2021 and using the following nine databases: BIOSIS Toxicology, CAB Abstracts, Current Contents Search, Embase, FSTA, Global Health, Medline, Registry of Toxic Effects of Chemical Substances (RTECS) and ToxFile. The search included *Saccharomyces cerevisiae* and

[23] Annex_II_1_g_Density results_Actisaf.
[24] Annex_II_1_h_Dusting potential_Feb24.
[25] Annex_II_1_f_PSD results_Actisaf.
[26] SECTION II_Identity_Point 2–4.
[27] Annex_II_2_a_CNCM deposition certificate and Annex_II_2_f_Statement_strain origin_May24.
[28] Annex_II_2_b_WGs and Annex_II_2_e_Phylogenomic report.
[29] Sect_II_Identity_2.5_Conditions_of_use.
[30] Annex_III_5_a Complaints_Actisaf_2006–2020, Annex_III_1_a Certificate_2019, Annex_III_1_d_Statement consumer safety, Annex_III_1_e_Statement environment safety and Annex_III_1_f_Statement animal safety.
[31] These safety conclusions can be extended to all categories of rabbits.

other terms relevant for target species safety and for toxicological aspects. The literature search retrieved 21 hits. None of the articles described safety concerns related to the use of *Saccharomyces cerevisiae*-based products.[32]

In previous assessments, the Panel evaluated an acute skin irritation study according to OECD 404 (EFSA FEEDAP Panel, 2012) and an eye irritation study according to OECD 405 (EFSA FEEDAP Panel, 2018a). The conclusions previously reached are still valid and the Panel considers that Actisaf® Sc 47 is not irritant to skin or eyes.[33]

The highest analysed nickel content in the additive was 0.1 mg/kg. Considering the dusting potential of 25 mg/m^3 and assuming a similar proportion of nickel in the dust as in the additive, the nickel content in the dust would be up to 0.0025 µg Ni/m^3. This value would not exceed the transitional limit value of 0.1 mg Ni/m^3 for the inhalable fraction and 8 h time-weighted average (8 h TWA) exposure established in Directive (EU) 2022/431.[34] However, due to the presence of Ni, the additive should be considered a skin and respiratory sensitiser.

The FEEDAP Panel concludes that the additive should be considered as a potential skin and respiratory sensitiser, and any exposure through skin and respiratory tract is considered a risk.

3.2.1 | Conclusions on safety

The FEEDAP Panel concludes that Actisaf® Sc 47 remains safe for the target species, consumers and the environment under the authorised conditions of use. The additive is not a skin or eye irritant; however, it is considered as a potential dermal and respiratory sensitiser. Any exposure through skin and respiratory tract is considered a risk.

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 authorisations 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.

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[35] and good manufacturing practice.

4 | CONCLUSIONS

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

The Panel concludes that Actisaf® Sc 47 remains safe for the target species, consumers and the environment. Regarding the safety for the user, the additive is not a skin or eye irritant, but is considered a dermal and respiratory sensitiser, and any exposure through skin and respiratory tract is considered a risk.

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

ABBREVIATIONS

AMR Antimicrobial resistance
CFU colony forming unit
DSM Deutsche Sammlung von Mikroorganismen und Zellkulturen
EURL European Union Reference Laboratory
FEEDAP EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
LOQ limit of quantification
MIC minimum inhibitory concentration
WGS Whole Genome Sequence

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[32]Annex_III_6_a Literature search_2019–2021.

[33]SECTION III_point 3–3 safety user and Section_III_Safety_Feb24.

[34]Directive (EU) 2022/431 of the European Parliament and of the Council of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. OJ L 88, 16.3.2022, p. 1–14.

[35]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.

CONFLICT OF INTEREST

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