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SCIENTIFIC OPINION

Assessment of the feed additive consisting of *Saccharomyces cerevisiae* NCYC R404 for dairy cows for the renewal of its authorisation (Volac International Ltd)

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

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 the authorisation of *Saccharomyces cerevisiae* NCYC R404 as a zootechnical additive (functional group: gut flora stabilisers) for dairy cows. The applicant has provided evidence that the additive currently on the market complies with the existing conditions of authorisation. There was no new evidence that would lead the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) to reconsider its previous conclusions on the safety of the product for the target species, consumers and the environment, for which the additive is considered to remain safe. Regarding user safety, the Panel reiterates its previous conclusions that the additive is not irritant to eyes and skin but should be considered a potential skin 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 renewal of the authorisation.

KEYWORDS

gut flora stabilisers, *Saccharomyces cerevisiae* NCYC R404, safety, zootechnical additives

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 Volac International Ltd, represented in the EU by Volac Feeds Ltd.[2] for the renewal of the authorisation of the additive consisting of *Saccharomyces cerevisiae* NCYC R404, when used as a feed additive for dairy cows (category: zootechnical additives; 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 18 April 2024 and the general information and supporting documentation are available at https://open.efsa.europa.eu/questions/EFSA-Q-2024-00260. The particulars and documents in support of the application were considered valid by EFSA as of 25 July 2024.

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* NCYC R404, when used under the proposed conditions of use (see **Section 3.1.3**).

1.2 | Additional information

The additive is a preparation containing *S. cerevisiae* NCYC R404 and is currently authorised for use in feed for dairy cows (4b1871).[3] EFSA issued two opinions on the safety and efficacy of this product when used in feed for dairy cows (EFSA FEEDAP Panel, 2009, 2014).

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[4] in support of the authorisation request for the use of *S. cerevisiae* NCYC R404 as a feed additive.

In accordance with Article 38 of the Regulation (EC) No 178/2002[5] 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,[6] 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 29 November 2024 to 20 December 2024 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 7 August 2024 to 7 November 2024; 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 regarding the methods used for the control of the *S. cerevisiae* NCYC R404 in animal feed are valid and applicable for the current application.[7]

[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]Volac House, 50 Fishers Lane, Orwell, Royston, Herts – the United Kingdom (represented in the EU by Volac Feeds Ltd., Feagh, Mullagh, Kells- Ireland).

[3]Commission Implementing Regulation (EU) 2015/502 of 24 March 2015 concerning the authorisation of the preparation of *Saccharomyces cerevisiae* NCYC R404 as a feed additive for dairy cows (holder of the authorisation Micro Bio-System Ltd). OJ L 79, 25.3.2015, p. 57.

[4]Dossier reference: FEED-2024-22093.

[5]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, pp. 1–48.

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

[7]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.

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of *S. cerevisiae* NCYC R404 is in line with the principles laid down in Regulation (EC) No 429/2008[8] and the relevant guidance documents: Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2021).

3 | ASSESSMENT

The additive *S. cerevisiae* NCYC R404 is currently authorised as a zootechnical additive (functional group: gut flora stabilisers) for use in feed for dairy cows. The assessment regards the renewal of the authorisation.

3.1 | Characterisation

3.1.1 | Characterisation of the additive

The additive currently authorised is a solid preparation containing *S. cerevisiae* NCYC R404 at a minimum concentration of 1×10^{10} colony forming units (CFU)/g additive.

The applicant declared that the manufacturing process has not been modified since the previous application and no antimicrobials are used at any stage of the production process.[9]

The active agent is grown by fermentation and concentrated by centrifugation. Excipients are added and the resulting mixture is dried and milled. The final product contains about 1% dextrose, 1% sorbitan monostearate, used as stabiliser and 98% yeast cells.[10] Sorbitan monostearate is authorised in the EU as food additive. Its safety is assessed in the Appendix A.

Analytical data to confirm the specifications regarding the minimum concentration of the active agent were provided for five batches of the additive, showing an average value of 1.32×10^{10} CFU/g ($1.20–1.40 \times 10^{10}$ CFU/g additive).[11]

Three batches of the additive were analysed for cadmium, lead, mercury, arsenic and fluoride levels. All the values were below limit of quantification (LOQ) of the analytical methods, except for cadmium (0.04–0.05 mg/kg).[12]

Polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and dioxin-like polychlorinated biphenyls (DL-PCBs) were analysed in three batches. The calculated upper bound (UB) concentrations for the sum of PCDD/Fs ranged between 0.0649 and 0.0654 ng WHO(2005)-PCDD/F-TEQ/kg, and between 0.101 and 0.102 ng WHO(2005)-PCDD/F + PCB-TEQ/kg for the sum of PCDD/Fs and DL-PCBs. The calculated UB concentration for the sum of non DL-PCBs was 0.354 µg/kg in all three batches (all values are expressed based on 88% dry matter).[13]

The analysis of mycotoxins, including aflatoxins (B1, G1, B2, G2), ochratoxin A, deoxynivalenol, T-2 and HT-2 toxins, diacetoxyscirpenol, fumonisins (B1 and B2), zearalenone, citrinin, cyclopiazonic acid, mycophenolic acid, penicillic acid, patulin and roquefortine C showed values below the limit of detection (LOD) of the analytical methods.[14]

The analysis of pesticides performed on one batch of the additive showed results below the LOQ of the analytical methods.[15]

Specifications were set by the applicant for coliforms (< 10 CFU/g), *Enterobacteriaceae* (< 10 CFU/g), *Staphylococcus aureus* (< 10 CFU/g) and moulds (< 1000 CFU/g). The analysis of three batches showed compliance with these specifications. *Salmonella* spp. and *Escherichia coli* were not detected in 25 g and 10 g of samples, respectively.[16]

The FEEDAP Panel considers that the microbial contamination and the amounts of the detected impurities do not raise safety concerns.

The average bulk density measured for five batches was 769 kg/m^3.[17] The dusting potential of three batches of the additive was determined using the Stauber-Heubach method and showed values ranging from 0 to 6.25 mg/m^3. The particle size distribution of the additive was analysed by laser-diffraction method; the results showed that 0.02% of the particles were below 100 µm, 0.01% below 50 µm and 0.01% below 10 µm.[18]

Considering that no changes have been introduced in the manufacturing process and composition, the data on stability and homogeneity described in the previous opinion (EFSA FEEDAP Panel, 2014) are still valid.

[8]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.

[9]2.3 Section_Manufacturing.

[10]Scientific Summary *S. cerevisiae* NCYC R404.

[11]Annex 2-1-5 Batch to Batch Variation S. *cerevisiae* NCYC R404.

[12]Annex 2-1-9 Relevant impurities_Heavy metals. LOQ: 0.01 mg/kg for arsenic, 0.05 mg/kg for lead, 0.005 mg/kg for mercury, 6 mg/kg for fluoride.

[13]Annex 2-1-11 Purity analysis_Dioxins_PCBS. Upper bound concentrations are calculated on the assumption that all values of the different congeners below the limit of quantification are equal to the limit of quantification. TEQ = toxic equivalency factors for PCDD/Fs and DL-PCBs established by WHO in 2005 (van den Berg et al., 2006).

[14]Annex 2-1-10 Purity analysis_Mycotoxins. LOD: 2 µg/L for aflatoxins (B1, B2, G1, G2); 20 µg/L for ochratoxin A, deoxynivalenol, T2 and HT2 toxins, diacetoxyscirpenol, fumonisins (B1 and B2), zearalenone; 8 µg/L for citrinin, mycophenolic acid, penicillic acid and roquefortine C; 40 µg/L for cyclopiazonic acid and patulin.

[15]Annex 2-1-12 Purity analysis_Pesticides and list. LOQ: 0.05–0.50 mg/kg for the listed parameters.

[16]Annex 2-1-8 Purity Microbial contamination_*Salmonella_E.coli* and Annex 2-1-7 Purity analysis_microbial internal.

[17]Annex 2-1-13 Bulk Density Report.

[18]Annex 2-1-14 IFF Report No. 4.035_Particle size and dusting potential.

The applicant provided new data on the shelf life of the additive (three batches) when stored at −18, 4, 10 and 20°C in sealed foil sachets for 4 months. Negligible losses (< 0.5 log) were observed at the end of the storage period for each condition.[19]

3.1.2 | Characterisation of the active agent

The active agent was isolated from silage, and it is deposited in the National Collection of Yeast Cultures (NCYC) with the accession number R404.[20] According to the applicant it has not been genetically modified.

The taxonomical identification was confirmed by a bioinformatic analysis of the whole genome sequence (WGS) data.[21] This was based on a phylogenomic analysis (using 98 single-copy orthogroups) on publicly available genomes of *S. cerevisiae* strains, including the reference strain *S. cerevisiae* S288C and the nomenclature type *S. cerevisiae* NRRL Y-12632, and representatives of 10 other *Saccharomyces* species and of the *Kazachstania*, *Naumovozyma* and *Torulaspora* genera. The analysis showed that *S. cerevisiae* NCYC R404 clustered with *S. cerevisiae* strains, including the reference strain *S. cerevisiae* S288C and the nomenclature type *S. cerevisiae* NRRL Y-12632.

The active agent was tested for antifungal susceptibility using a broth microdilution method.[22] The minimum inhibitory concentration (MIC) values obtained for anidulafungin (0.12 mg/L), amphotericin B (0.5 mg/L), micafungin (0.12 mg/L), caspofungin (0.5 mg/L), 5-flucytosine (< 0.06 mg/L), posaconazole (1 mg/L), voriconazole (0.12 mg/L), itraconazole (0.25 mg/L) and fluconazole (4 mg/L) were considered low.

3.1.3 | Conditions of use

The additive is currently authorised for use in feed for dairy cows at a minimum inclusion level of 4.4×10^8 CFU/kg complete feedingstuff. Under other provisions of the authorisation, it is specified that:

1. In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting.
2. Recommended dose of the additive: 1×10^{10} CFU/head/day.
3. For safety: breathing and skin protection shall be used during handling.

The applicant did not request any change in the current conditions of the authorisation.[23]

3.2 | Safety

In the previous opinion, the Panel concluded that following the qualified presumption of safety (QPS) approach to safety assessment, *S. cerevisiae* NCYC R404 is considered safe for target species, consumers and the environment (EFSA FEEDAP Panel, 2014). Regarding user safety, the Panel concluded that the additive was not irritant to the skin or eyes and was a skin sensitiser. Considering that the product had no dusting potential, exposure via the respiratory route was of no concern.

The applicant declared that no incidents or safety issues for the target species, consumers, user and the environment have been documented or reported regarding the additive since its first authorisation.[24]

In the context of the current application, the active agent was confirmed to belong to *S. cerevisiae*, a species suitable to the QPS approach (EFSA BIOHAZ Panel, 2023). Consequently, the conclusions already reached are still valid and the FEEDAP Panel considers that the strain *S. cerevisiae* NCYC R404 remains safe for target species, consumers and the environment.

Furthermore, in the current dossier the applicant performed a literature search in order to provide evidence that in the light of the current knowledge the additive remains safe under the approved conditions for target species, consumers, users and the environment.[25] The search was conducted in Medline (OVID), Scopus, Web of Science, SciFinder, ProQuest and EBSCOhost Academic Search Premier covering the period from 2014 to 2024. None of the hits retrieved were further considered relevant for the safety assessment related to the additive.

The additive contains sorbitan monostearate used as stabiliser. Its safety at the proposed concentration of the additive was assessed and is reported in detail in Appendix A. The Panel concludes that sorbitan monostearate does not raise concerns for the safety for the target species, consumer and environment.

The Panel considers that the additive *S. cerevisiae* NCYC R404 remains safe for target species, consumer and environment.

[19] Annex 2-4-1 S. cerevisiae NCYC R404 Stability.

[20] Annex 2-2-3 Certificate of Deposition_R404 and Source of isolation Declaration.

[21] Annex 2-2-2 WGS_*S. cerevisiae* R404.

[22] Annex 2-2-5 MIC Report *S. cerevisiae* NCYC R404 and Annex 2-2-7 MICs EUCAST.

[23] 2.5 Section_Conditions of Use.

[24] EFSA Declaration – Safety for the consumer, EFSA Declaration – Safety for the environment, EFSA Declaration – Safety for the target species and 3. Section_Safety.

[25] Annex 3-1-2 Literature Search Summary.

Regarding the safety for the users, no new data have been provided. Based on the highest dusting potential measured value (6.25 mg/m^3), the FEEDAP Panel considered that the exposure of users through inhalation is possible. The Panel reiterates its previous conclusions that the additive is not irritant to eye and skin. The additive consists of a microorganism, and therefore should be considered a potential skin and respiratory sensitiser, and any inhalation and dermal exposure 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 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.

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[26] and Good Manufacturing Practice.

4 | CONCLUSIONS

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

The Panel concludes that the additive *S. cerevisiae* NCYC R404 remains safe for dairy cows, consumers and the environment under the current approved conditions of the authorisation.

Regarding user safety, the additive is not irritant to skin or eyes, and it should be considered a potential skin 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

ADI	acceptable daily intake
ANS	EFSA Scientific Panel on Additives and Nutrient Sources added to Food
BW	body weight
CFU	colony forming unit
DL-PCBs	dioxin-like polychlorinated biphenyls
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
NCYC	National Collection of Yeast Cultures
NOAEL	no observed adverse effect level
PCDDs	Polychlorinated dibenzo-p-dioxins
PCDFs	polychlorinated dibenzofurans
QPS	qualified presumption of safety
UB	upper bound
WGS	whole genome sequence

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REQUESTOR

European Commission

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[26]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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APPENDIX A

Safety of sorbitan monostearate as stabiliser

The additive contains approximately 1% sorbitan monostearate, which is used as stabiliser. Sorbitan monostearate is authorised in the EU as a food additive but it is not a feed material and is not authorised as a feed additive. The applicant provided data to support the safety of the above-mentioned stabiliser for the target species and the environment. The safety for the consumers is also evaluated in this appendix.

A.1 | Safety for the target species

Based on a long-term toxicity study in mice, the ANS Panel identified a no observed adverse effect level (NOAEL) for sorbitan monostearate of 2600 mg/kg BW per day for male rats, from which an acceptable daily intake (ADI) of 6 mg/kg bw per day was proposed (EFSA ANS Panel, 2017).[27]

To estimate the amount of sorbitan monostearate to which the target species could be exposed, the following data/assumptions were considered: (i) *S. cerevisiae* NCYC R404 is present in the additive at the concentrations analysed in the batch to batch analysis (see section 3.1.1), resulting in an average of 1.32×10^{10} CFU/g additive (range 1.20–1.40×10^{10} CFU/g); (ii) the additive is added to the feed at the proposed minimum concentration of 4.4×10^{8} CFU/kg complete feeding stuff; (iii) sorbitan monostearate is added to the feed additive at about 1%. Therefore, the concentration of sorbitan monostearate in compete feed would correspond to approximately 0.31 mg sorbitan monostearate/kg complete feed.

Based on the NOAEL of 2600 mg/kg BW and applying an uncertainty factor of 100, the maximum safe concentration of sorbitan monostearate in feed was calculated following the methodology described in the Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017), and thus the maximum safe feed concentration was calculated for dairy cows. The maximum safe concentration was 743.60 mg sorbitan monostearate/kg complete feed and is higher than the estimated maximum concentration in complete feed (0.31 mg/kg).

Therefore, the Panel concludes that the use of sorbitan monostearate as stabiliser in the additive under assessment at the proposed inclusion levels is of no concern for the safety for the target species.

A.2 | Safety for the consumers

Sorbitan monostearate is authorised as a food additive, to be used in several food commodities, at concentrations varying from 500 to 10,000 mg/kg. Even if no data on the potential deposition of residues of sorbitan monostearate in animal food products were available, the Panel considers that the use of this compound as a stabiliser in the additive will not significantly contribute to the exposure of consumers to sorbitan monostearate. Therefore, its use at the proposed inclusion levels is of no concern for the consumers.

A.3 | Safety for the environment

The applicant provided information on the safety for the environment of the stabiliser sorbitan monostearate, considering the proposed conditions of use.[28]

The concentration of sorbitan monostearate in the additive ranges 0.8 to 1.4%. Using the FERA calculation tool (EFSA FEEDAP Panel, 2019), it gives a PECsoil below the trigger value of 10 µg/kg soil dry weight. Sorbitan monostearate is not soluble in water and will remain adsorbed in the soil rather than in the aquatic compartment.

Considering its negligible water solubility and the characteristics of the substance, a concern for groundwater is not expected.

The use of sorbitan monostearate as stabiliser of the additive is considered of no concern for the environment.

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[27]Sorbitan Monostearate_EFSA RFI_Target Animal Safety and RFI Target Animal Safety_Annex S-2_Toxicity Study Summaries.

[28]Sorbitan_Monostearate_EFSA RFI_Environmental Safety, RFI Environmental Safety_Annex S-1_Literature Search and RFI Environmental Safety_Annex S-2_FERA Tool.

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