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SCIENTIFIC OPINION

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Assessment of the feed additive consisting of *Saccharomyces cerevisiae* MUCL 39885 (Biosprint®) for cattle for fattening for the renewal of its authorisation (Prosol SPA)

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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 the authorisation of *Saccharomyces cerevisiae* MUCL 39885 (Biosprint®) as a feed additive for cattle for fattening (category: zootechnical; functional group: gut flora stabiliser). The applicant provided evidence that the additive currently in the market complies with the conditions of authorisation. The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) confirmed that the use of Biosprint® under the current authorised conditions of use remains safe for the target species, the consumers and the environment. Taking into account the nature of the additive, 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. The additive is not a skin/eye irritant. There is no need to assess the efficacy of Biosprint® in the context of the renewal of the authorisation.

KEYWORDS

Biosprint®, gut flora stabiliser, QPS, renewal, *Saccharomyces cerevisiae* MUCL 39885, 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 Prosol Spa[2] for the renewal of the authorisation of the additive consisting of *Saccharomyces cerevisiae* MUCL 39885 (Biosprint®), when used as a feed additive for cattle for fattening (category: zootechnical; functional group: gut flora stabiliser).

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 11 August 2022 and the general information and supporting documentation are available at https://open.efsa.europa.eu/questions/EFSA-Q-2022-00513. The particulars and documents in support of the application were considered valid by EFSA as of 08 May 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* MUCL 39885 (Biosprint®), when used under the proposed conditions of use (see **Section 3.1.3**).

1.2 | Additional information

The additive is a preparation containing viable cells of *S. cerevisiae* MUCL 39885. It is currently authorised in dairy cows, cattle for fattening,[3] minor ruminants for fattening and minor ruminants for dairy, horses,[4] all *Suidae* and dogs[5,6,7] (4b1710).

EFSA has issued several opinions on the safety and efficacy of this product when used in feed for the above-mentioned target species (EFSA, 2004, 2009; EFSA FEEDAP Panel, 2010a, 2010b, 2010c, 2011, 2013, 2015, 2019a, 2019b, 2020, 2021a, 2021b, 2023).

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[8] in support of the authorisation request for the use of *S. cerevisiae* MUCL 39885 (Biosprint®) as a feed additive.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 8 May 2023 to 8 August 2023 for which the received comments were considered for the assessment.

In accordance with Article 38 of the Regulation (EC) No 178/2002[9] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[10] a non-confidential version of the 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 16 November 2023 to 07 December 2023 for which no comments were received.

[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]Prosol Spa, Via Carso, 99, 24,040, Madone, Italy.

[3]Commission Implementing Regulation (EU) No 1059/2013 of 29 October 2013 concerning the authorisation of a preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for cattle for fattening and amending Regulation (EC) No 492/2006 (holder of the authorisation Prosol SpA).

[4]Commission Implementing Regulation (EU) 2020/1096 of 24 July 2020 concerning the renewal of the authorisation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for dairy cows and horses and repealing Regulation (EU) No 1119/2010 (holder of authorisation Prosol S.p.A.).

[5]Commission Implementing Regulation (EU) 2020/1094 of 24 July 2020 concerning the renewal of the authorisation of the preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for sows and repealing Regulation (EC) No 896/2009 (holder of authorisation Prosol S.p.A.).

[6]Commission Implementing Regulation (EU) 2021/508 of 23 March 2021 concerning the renewal of the authorisation of a preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for weaned piglets and repealing Regulation (EU) No 170/2011 (holder of authorisation: Prosol S.p.A.).

[7]Commission Implementing Regulation (EU) 2022/272 of 23 February 2022 concerning the authorisation of a preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for all suidae other than weaned piglets and sows, and dogs (holder of authorisation: Prosol S.p.A.).

[8]Dossier reference: FEED-2022-8330.

[9]Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

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

The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA or other expert bodies, peer-reviewed scientific papers, other scientific reports and experts' knowledge, 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 substance in animal feed are valid and applicable for the current application.[11]

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of *S. cerevisiae* MUCL 39885 (Biosprint®) is in line with the principles laid down in Regulation (EC) No 429/2008[12] and the relevant guidance documents: Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018), Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2021a, 2021b, 2021c).

3 | ASSESSMENT

The additive Biosprint® contains viable cells of *S. cerevisiae* MUCL 39885, currently authorised as a zootechnical additive (functional group: gut flora stabilisers) for use in several animal species. This assessment regards the renewal of the authorisation for the use in cattle for fattening.

3.1 | Characterisation

3.1.1 | Characterisation of the additive

The additive is authorised as a preparation of viable cells of *S. cerevisiae* MUCL 39885 with a minimum content of 1×10^9 colony forming units (CFU)/g. It is manufactured in two forms differing only in the drying process: spherical (Biosprint® S) and granulated (Biosprint® G) with no carriers or excipients present in the final product.

The applicant stated that no modifications have been introduced to the manufacturing process or the composition of the additive since the last authorisation.

Analytical data to confirm the specifications were provided for a total of 54 batches of the additive (33 batches of Biosprint® G and 21 batches of Biosprint® S) showing the following average values of viable spores content: 1.75×10^{10} CFU/g of additive (range $1.6–1.98 \times 10^{10}$) for Biosprint® G and 1.74×10^{10} CFU/g of additive (range $1.61–1.88 \times 10^{10}$) for Biosprint® S.[13]

Three batches of Biosprint® G were analysed for chemical impurities. The panel considers that given the identical formulation, only differing in the drying process, the values obtained in Biosprint® G apply to both formulations.

In two batches, arsenic, cadmium and lead were below the corresponding limit of detection (0.20 mg As/kg additive, 0.04 Cd/kg additive, 0.20 mg Pb/kg additive and 0.02 mg Hg/kg additive, respectively) and chromium was below the limit of quantification (LOQ) (0.5 mg Cr/kg additive). Mercury and copper were quantified in one of the batches at 27.1 mg Hg/kg and 3.5 mg Cu/kg of additive, respectively. In another batch analysed in a different laboratory, mercury and chromium were below the LOQ (0.01 mg Hg/kg additive and 0.05 mg Cr/kg additive, respectively), whereas the other elements were quantified as follows: 0.05 mg As/kg additive, 0.014 mg Cd/kg additive, 0.013 mg Pb/kg and 6.75 mg Cu/kg additive. Iron was quantified in all three batches and showed the following range values: 3.6–43 mg Fe/kg additive.[14]

Polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and dioxin-like polychlorinated biphenyls (DL-PCBs) were analysed in three batches.[15] All values were below the corresponding LOQ. The calculated upper bound (UB) concentration was 0.08–0.1 ng WHO-TEQ/kg for the sum of PCDD/Fs, and 0.119–0.182 ng WHO-TEQ/kg the sum of PCDD/Fs and DL-PCBs. The UB for the sum of non DL-PCBs was 0.078–1.2 mg/kg (all values are expressed based on 88% dry matter).

The analysis of mycotoxin concentration in three batches, including aflatoxins (B1, G1, B2, G2), deoxynivalenol, fumonisins (B1 and B2), ochratoxin A, zearalenone, HT-2 toxin and T-2 toxin, as well as a pesticide multiresidue analysis, showed

[11]Evaluation report received on 02/02/2010 and 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

[12]Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.

[13]Annex_II_2_Variability of vitality Biosprint.

[14]Annex_II_5 Heavy metals contaminants.

[15]Annex_II_7 PCB_Dioxins.

values below the LOQ[16] of the analytical methods except for low amounts of the pesticides difenoconazole (range 0.015–0.016 mg/kg) and epoxiconazole (ranging 0.05 and 0.073 mg/kg).[17]

Regarding the microbial contamination, the 54 batches used for the batch-to-batch variation study were analysed. Results showed an average of total bacteria counts of 570 CFU/g (range 200–800 CFU/g) for Biosprint® G and 18,330 CFU/g (range 1000–100,000 CFU/g) for Biosprint® S. Filamentous fungi, xerophilic moulds and *Escherichia coli* were < 10 CFU/g in all batches, and *Salmonella* spp. and *Listeria* spp. were not detected in 25 g of any batch.[18]

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

As no changes have been introduced in the composition and manufacturing process, the data pertaining to physico-chemical properties, stability and homogeneity described in the previous opinion (EFSA FEEDAP Panel, 2021a) apply to the current assessment. The applicant provided new data on particle size and stability in premixtures which are described below.

The particle size distribution measured by sieving of three batches of the product for both formulations was provided. Regarding the S form, most of the particles had a diameter > 711 μm, with no particles below 90 μm. The G form of the additive had most of the particles with a diameter > 355 μm, with no particles below 125 μm.[19] A further determination of particle size distribution using centrifugal liquid sedimentation of three samples of the G form of the additive showed that 100% of the particles were larger than 0.25 μm.[20]

The stability of the additive in a premixture for cattle for fattening was studied in 20 batches when supplemented at 3.5×10^{10} CFU/kg and stored in sealed bags at room temperature up to 18 months. Yeast counts showed no losses (< 0.5 Log) up to the nineth month, while losses up to 3 Log were observed at the end of the storage period.[21]

3.1.2 | Characterisation of the active agent

The active agent was isolated from a food matrix, and it is deposited in the Belgian Coordinated Collection of Microorganism (BCCM) – Mycothèque de l'Université Catholique de Louvain (MUCL) under the accession number 39885.[22] It has not been genetically modified.

A bioinformatic analysis of the whole genome sequencing (WGS) of the active agent confirmed its identity as *S. cerevisiae*.[23] This was based on a phylogenomic analysis (using 1201 core genes) that included strains of related *Saccharomyces* species with publicly available genomes, which showed that the active agent MUCL 39885 clustered with the reference strain *S. cerevisiae* S288C, and on an average nucleotide identity (ANI) analysis against *S. cerevisiae* S288C, which showed an OrthoANI value of 99.36%.

The active agent *S. cerevisiae* MUCL 39885 was tested for antifungal susceptibility using the broth microdilution method according to EUCAST (The European Committee on Antimicrobial Susceptibility Testing, 2022). The minimum inhibitory concentration (MIC) values of the strain were equal to or fell below the epidemiology cut-off (ECOFF) values set by EUCAST for *S. cerevisiae* for amphotericin B and itraconazole. Therefore, the active agent can be considered susceptible to those antifungal compounds.[24]

3.1.3 | Conditions of use

The additive is currently authorised for the use in feed for cattle for fattening at a minimum inclusion level of 4×10^9 CFU/kg complete feedingstuff.

Under other provisions of the authorisation, it is stated:

1. In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting.
2. Minimum recommended content of additive for head per day: 3.6×10^{10} CFU.
3. For safety: glasses and gloves shall be used during handling.

The applicant has not asked to modify these conditions of use.

[16] LOQ (ug/kg): aflatoxins (B1, G1, B2, G2): 0.3; vomitoxin: 10, Fumonisin (B1 and B2): 3; Ochratoxin A: 0.2, Zearalenone: 10, HT-2 Toxin: 5 and T-2 Toxin: 3.
[17] Annex_II_4 Micotoxins residual and Annex_II_6 Pesticides residual.
[18] Annex_II_3 Microbiological contaminants.
[19] Annex_II_10 Particle size distribution.
[20] Annex_II_8 Particle size distr. w. centrif. liquid sedimentation.
[21] Annex_II_30_Biosprint_Stability_in_feedstuff for beef 2021.
[22] Annex_II_12_Safe deposit.
[23] Annex_II_34 WGS BCCM 2023-1543_Report.
[24] Annex_II_9 Antibiotic resistance.

3.2 | Safety

In the previous opinion, the Panel concluded that following the qualified presumption of safety (QPS) approach to safety assessment, *S. cerevisiae* MUCL 39885 is considered safe for target species, consumers and the environment (EFSA FEEDAP Panel, 2010a, 2010b). Regarding user safety, the Panel concluded that: 'In the absence of data on skin and eye irritancy or skin sensitisation, Biosprint® is considered as a potential irritant and sensitiser and should be treated accordingly. Biosprint® S and Biosprint® G are unlikely to form respirable dust. Consequently, it was concluded that the inhalation exposure associated with the use of this product would be minimal'.

In the present application, the applicant has provided up to date confirmation of the taxonomical identification of the active agent as *S. cerevisiae* and evidence that the strain is susceptible to the antifungal compounds amphotericin B and itraconazole. Therefore, the active agent MUCL 39885 meets the qualifications of the QPS approach for safety assessment (EFSA, 2007; EFSA BIOHAZ Panel, 2024).

The applicant declared that no incidents or safety issues have been documented or reported for target animal species, consumers users and environment since the market authorisation of Biosprint®.[25]

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.

The literature search was conducted in CAB Abstract, Scopus and PubMed covering the period from 2012 to 2022. For each of the different aspects of the safety (i.e. target species, consumers, users and the environment), a search was conducted using the relevant keywords and Booleans. The number of hits identified for each of the searches was of 43, 45, 18 and 86, respectively. Titles and abstracts were screened and none of them were further considered relevant for the assessment because either they were EFSA opinions or did not refer to the additive under assessment.

Consequently, the conclusions already reached are still valid, and the Panel considers that the additive remains safe for the target species, the consumer and the environment.

Regarding the safety for the user, the applicant submitted skin/eye irritancy tests conducted with Biosprint® G, the results from this form can be extrapolated to the other form because the composition is the same.

Biosprint® was investigated for skin irritation potential in an in vitro skin irritation study according to OECD TG 439 (Reconstructed Human Epidermis test methods).[26] The results of the study indicated that the test item is non-irritant to the skin.

The eye irritation potential was investigated in an in vitro eye irritation test performed according to OECD TG 429b (Reconstructed Human Corneal epithelium).[27] The results of these study showed that the test item is not an eye irritant.

Taking into account the nature of the additive, 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 the additive Biosprint® (*S. cerevisiae* MUCL 39885) remains safe for the target species, consumers and the environment. The additive is not a skin or eye irritant but should be considered a skin and respiratory sensitiser, and therefore, any exposure through skin and the 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 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[28] and Good Manufacturing Practice.

[25]Section_III_1, Section_III_2, Section_III_3 and Section_III_4.

[26]Annex_III_3 29 skin irritation test.

[27]Annex_III_3 30 cornea-like epithelium hazard OECD492b.

[28]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.

4 | CONCLUSIONS

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

Biosprint® remains safe for the target species, the consumers and the environment.

The additive is not irritant to skin and eyes, but it should be considered a skin and respiratory sensitiser, and therefore, any exposure through skin and the respiratory tract is considered a risk.

There is no need to assess the efficacy of Biosprint® in the context of the renewal of the authorisation.

ABBREVIATIONS

BCCM	Belgian Coordinated Collection of Microorganism
CFU	colony forming unit
ECOFF	Epidemiology cut-off
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
LOQ	limit of quantification
MUCL	Mycothèque de l'Université Catholique de Louvain
PCB	polychlorinated biphenyls
PCDD	Polychlorinated dibenzodioxins
PCDF	polychlorinated dibenzofurans
UB	Upper bound

CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

European Commission

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