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Assessment of the application for renewal of authorisation of Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) as a feed additive for weaned piglets

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Abstract

Following a request from the European Commission, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the assessment of the application for renewal of the authorisation of the product Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) as a feed additive for weaned piglets. Biosprint® is composed of only viable cells of *Saccharomyces cerevisiae* MUCL 39885. *S. cerevisiae* is considered by EFSA to have qualified presumption of safety status. The applicant has provided data demonstrating that the additive currently in the market complies with the conditions of the authorisation. The FEEDAP Panel confirms that the use of Biosprint® under the current authorised conditions of use is safe for weaned piglets, the consumers and the environment. The additive is considered as a potential skin and eye irritant and a skin and respiratory sensitiser. There is no need to assess the efficacy of Biosprint® in the context of the renewal of the authorisation.

Keywords: zootechnical additive, Biosprint, *Saccharomyces cerevisiae*, renewal, QPS, weaned piglets

Requestor: European Commission

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

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 one year before the expiry date of the authorisation.

The European Commission received a request from Prosol S.p.A.[2] for renewal of the authorisation of the product Biosprint® (*Saccharomyces cerevisiae* MUCL 39885), when used as a feed additive for weaned piglets (category: zootechnical additives; 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 particulars and documents in support of the application were considered valid by EFSA as of 3 June 2020.

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 Biosprint® (*Saccharomyces cerevisiae* MUCL 39885), when used under the proposed conditions of use (see Section 3.1.1).

1.2. Additional information

Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) is currently authorised in sows,[3] dairy cows, horses,[4] piglets (weaned),[5] cattle for fattening,[6] minor ruminants for fattening and minor ruminants for dairy products (4b1710).[7]

The EFSA FEEDAP Panel issued several opinions on the safety and efficacy of Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) in different target species (EFSA FEEDAP Panel, 2004, 2009, 2010a,b,c, 2013a, 2015, 2019a,b).

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 Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) as a feed additive.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.[9]

[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] Prosol S.p.A. via Carso 99, Madone (Italy).
[3] Commission Regulation (EC) No 896/2009 of 25 September 2009 concerning the authorisation of a new use of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for sows (holder of the authorisation Prosol SpA). OJ L 256, 29.9.2009, p. 6.
[4] Commission Regulation (EU) No 1119/2010 of 2 December 2010 concerning the authorisation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for dairy cows and horses and amending Regulation (EC) No 1520/2007 (holder of the authorisation Prosol SpA). OJ L 317, 3.12.2010, p. 9.
[5] Commission Regulation (EU) No 170/2011 of 23 February 2011 concerning the authorisation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for piglets (weaned) and amending Regulation (EC) No 1200/2005 (holder of authorisation Prosol SpA), OJ L 49, 24.2.2011, p. 8.
[6] 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) OJ L 289, 31.10.2013, p. 30.
[7] Commission implementing Regulation (EU) 2016/104 of 27 January 2016 concerning the authorisation of a preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for minor ruminant species for fattening and dairy production (holder of the authorisation Prosol SpA), OJ L 21, 28.1.2016, p. 71.
[8] FEED dossier reference: FAD-2020-0025.
[9] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2009-0028.pdf

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) is in line with the principles laid down in Regulation (EC) No 429/2008, the Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2013b) and the Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018).

3. Assessment

The additive Biosprint® is a preparation of *S. cerevisiae* MUCL 39885. The current application is for the renewal of the authorisation for use as a zootechnical additive (functional group: gut flora stabiliser) in feed for weaned piglets.

3.1. Characterisation

The additive contains viable cells of the strain *S. cerevisiae* MUCL 39885 (no carriers or excipients are present in the final product) and it is authorised with a minimum declared content of 1×10^9 colony forming unit (CFU)/g.

The applicant declared that the manufacturing process has not been modified since the previous authorisation and provided data from recent batches on the composition of the additive to support this statement.

The additive is marketed in two forms, 'spherical' (Biosprint® S) and 'granulated' (Biosprint® G). Compliance with the specifications set in the authorisation was confirmed by analysis of three batches of the G form (range 1.69–1.79 $\times$ 10^{10}, mean 1.73 $\times$ 10^{10} CFU/g) and three batches of the S form (range 1.69–1.77 $\times$ 10^{10}, mean 1.73 $\times$ 10^{10} CFU/g).

Three batches of each formulation were analysed for microbial contamination. The results confirm compliance with limit levels set (*Escherichia coli* < 10 CFU/g, *Salmonella* spp. absent in 25 g, moulds < 10 CFU/g, *Listeria monocytogenes* absent in 1 g, coliforms < 100 CFU/g, *Staphylococcus aureus* < 10 CFU/g).[10,11]

Possible presence of chemical contaminants was measured on at least three recent batches of the product.[12] Measurable concentrations of cadmium (0.014 mg/kg), lead (0.015 mg/kg) and arsenic (0.03 mg/kg) were detected in one batch. In the same batch, mercury was below the limit of quantification (LOQ 0.01 mg/kg).[13] In the other two batches, heavy metals and arsenic were below the corresponding LOQ (cadmium 0.001 mg/kg, mercury 0.001 mg/kg, lead 0.001 mg/kg, arsenic 0.005 mg/kg).[14] In the same batches, aflatoxins B1, B2, G1 and G2 were < 0.5 mg/kg, deoxynivalenol < 20 μg/kg, ochratoxin A < 1 μg/kg, zearalenone < 10 μg/kg. Pesticides screened in a multiresidue analysis were < 0.01 mg/kg, with the exception of 2,4,6,-trichlorophenol (0.04 mg/kg), epoxiconazole (0.076 mg/kg), tetraconazole (0.018 mg/kg) and difenoconazole (0.025 mg/kg) in one batch. Based on the results, no concern is identified.

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 > 355 μm (98.7–99.8% w/v), with no particles below 120 μm. The G form of the additive had most of the particles with a diameter > 250 μm (98.4–99.0% w/v), with no particles below 90 μm. These results are in line with those provided for the previous assessment (EFSA FEEDAP Panel, 2019a,b).

The same batches of the G form of the additive were tested in triplicate for dusting potential[15] according to Stauber–Heubach method. The average value of dust was 260 mg/m^3 (range: 217–290 mg/m^3).

The non-genetically modified strain of *S. cerevisiae* composing the additive is deposited in the Belgian Coordinated Collection of Microorganism BCCM™/MUCL Culture Collection – Mycothéque de l'Université Catholique de Louvain with the accession number 39885.[16]

[10] Technical Dossier/Section II/Annex_35.
[11] Technical Dossier/Section II/Annex_36.
[12] Technical Dossier/Section II/Annex_2, 3 and 4 and Supplementary information/Annex_II_2-4.
[13] Technical dossier/Supplementary information/Annex 4.
[14] Technical dossier/Supplementary information/Annex 2-3.
[15] Technical Dossier/Section II/Supplementary information/Annex_II_7-9.
[16] Technical Dossier/Section II/Supplementary information/Annex_II_29 Sequencing DNA v1.

A phylogenetic analysis based on whole genome sequence data confirmed the taxonomic identification of the strain as *S. cerevisiae*. The analysis of the whole genome single nucleotide polymorphism against a well-known strain of *S. cerevisiae* was also submitted and supports the identification of the strain.

3.1.1. Conditions of use

The additive is currently authorised for use in feed for weaned piglets at a minimum level of 3×10^9 CFU/kg of complete feed.

Under other provisions the following are indicated:

1) In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.
2) For safety: glasses and gloves shall be used during handling.
3) For piglets (weaned) up to 35 kg.

The applicant does not propose to modify the conditions of use as authorised.

3.2. Safety

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, 2020). This approach requires the identity of the strain under assessment to be conclusively established. In the context of the current application, the identity of the active agent strain was confirmed as *S. cerevisiae*. Accordingly, this strain is presumed safe for the target species, consumers of products from animals fed the additive and the environment.

The safety for the user has been evaluated in a previous opinion (EFSA FEEDAP Panel, 2010a–c). In 2010, the Panel concluded that the additive should be considered as a potential skin and eye irritant and a skin sensitiser and that the inhalation exposure would be minimal. No additional data were provided in the current application that would lead to a revision of the previous conclusions. Considering the proteinaceous nature of the additive, it should be considered a respiratory sensitiser.

Two literature searches on the safety of the product covering the period 2008-2018 and 2018-2019 were evaluated by EFSA FEEDAP Panel in previous assessments (EFSA FEEDAP Panel, 2019a,b). These searches did not reveal any safety issue related to the additive under assessment. The applicant performed a new literature search, covering the period 2019–2020 and using the following databases: CAB Abstracts, PubMed and Scopus. It included '*Saccharomyces cerevisiae*' and other terms relevant for target species safety and for toxicological aspects. This new search retrieved 30 publications. However, no relevant papers were identified that would highlight a safety concern for the target species, the consumer or the environment. Moreover, no relevant papers were identified that would add any additional concerns to those already identified for the safety for the user.

3.2.1. Conclusions of safety

Based on the above and the fact that the manufacturing process of the additive, its composition and the conditions of use for the target species have not been modified, the Panel considers that there is no evidence to reconsider the conclusions reached in previous assessments. Therefore, the Panel concludes that Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) is considered safe for the target species, for the consumer, and the environment under the current authorised conditions of use. The additive should be considered as a potential skin and eye irritant and a skin and respiratory sensitiser.

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[17] and Good Manufacturing Practice.

4. Conclusions

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

The FEEDAP Panel confirms that the use of Biosprint® under the current authorised conditions of use is safe for weaned piglets, the consumers and the environment.

The additive is considered as a potential skin and eye irritant and a skin and respiratory sensitiser.

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

5. Documentation as provided to EFSA/Chronology

Date	Event
31/03/2020	Dossier received by EFSA. Biosprint® for piglets (weaned). Submitted by Prosol S.p.A
06/04/2020	Reception mandate from the European Commission
03/06/2020	Application validated by EFSA – Start of the scientific assessment
07/09/2020	Comments received from Member States
22/06/2020	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. Issues: characterisation
14/07/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
30/09/2020	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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[17] 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.

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2013a. Scientific Opinion on the efficacy of Biosprint® (*Saccharomyces cerevisiae*) as a feed additive for cattle for fattening. EFSA Journal 2013;11(4):3174, 6 pp. https://doi.org/10.2903/j.efsa.2013.3174

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Abbreviations

CFU	colony forming unit
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
LOQ	limit of quantification
QPS	Qualified Presumption of Safety
WGS	whole genome sequence