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Assessment of the application for renewal of authorisation of Biosprint[®] (*Saccharomyces cerevisiae* MUCL 39885) for sows

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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 the product Biosprint[®] (*Saccharomyces cerevisiae* MUCL 39885) as a feed additive for sows. *S. cerevisiae* is considered by EFSA to have qualified presumption of safety (QPS) status. The applicant has provided data demonstrating that the additive currently in the market complies with the conditions of authorisation. The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) Panel confirms that the use of Biosprint[®] under the current authorised conditions of use is safe for sows, the consumers and the environment. The additive is considered as a potential skin and eye irritant and skin/respiratory sensitiser. There is no need to assess the efficacy of Biosprint[®] in the context of the renewal of the authorisation.

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Keywords: zootechnical additive, Biosprint, *Saccharomyces cerevisiae*, renewal, QPS, sows

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1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003¹ 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 S.p.A.² for renewal of the authorisation of the product Biosprint® (*Saccharomyces cerevisiae* MUCL 39885), when used as a feed additive for sows (category: zootechnical additive; 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 22 August 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 Biosprint® (*Saccharomyces cerevisiae* MUCL 39885), when used under the proposed conditions of use (see Section 3.1.3).

1.2. Additional information

Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) is currently authorised in sows³, dairy cows, horses,⁴ piglets (weaned),⁵ cattle for fattening,⁶ minor ruminants for fattening and minor ruminants for dairy products.⁷

The EFSA FEEDAP Panel issued several opinions on the safety and efficacy of Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) in different target species (EFSA, 2004; EFSA FEEDAP Panel, 2009, 2010, 2011, 2013, 2015).

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier⁸ in support of the authorisation request for the use of Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) as a feed additive.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA and experts' knowledge, to deliver the present output.

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-2018-0032.

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

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 and the Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2013).

3. Assessment

The additive Biosprint® is a preparation of *Saccharomyces cerevisiae* MUCL 39885. The current application is for the renewal of the authorisation of use as a zootechnical additive (functional group: gut flora stabiliser) in feed for sows. The additive is authorised with a minimum declared content of 1×10^9 CFU/g.

3.1. Characterisation

3.1.1. Characterisation of the additive

The additive is authorised in powder and granular forms, both with a minimum content of *Saccharomyces cerevisiae* MUCL 39885 of 1×10^9 CFU/g. In the first application, three forms were described, powder, oval granulated and spherical. The applicant states that the powder form is not produced anymore, and that the product is present on the market in two forms: Biosprint® oval granulated (G) and Biosprint® spherical (S). The strain is the additive itself and no carriers or excipients are present in the final product.

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

The applicant states that the specifications are 1×10^9 with an average 1.5×10^{10} CFU/g. Compliance with specifications was confirmed by analysis of five batches of the G form (range $1.7\text{--}2.0 \times 10^{10}$, mean 2.0×10^{10} CFU/g) and for five batches of the S form (range $1.8\text{--}2.3 \times 10^{10}$, mean 2.0×10^{10} CFU/g).¹⁰

The same batches were analysed for microbial contamination. The results showed confirm compliance with limit levels (*Escherichia coli* < 10 CFU/g, *Salmonella* absence in 25 g, moulds < 10 CFU/g, *Listeria* absent).¹⁰

The possible presence of contaminants was measured on three batches of the product. Aflatoxins B1, B2, G1 and G2 < 0.5 mg/kg, deoxynivalenol < 20 µg/kg, ochratoxin A < 1 µg/kg, zearalenone < 10 µg/kg. Arsenic ≤ 0.005 mg/kg, cadmium 0.001 mg/kg, mercury < 0.005 mg/kg, lead ≤ 0.001 mg/kg, nitrites, dioxins, dioxin-like polychlorinated biphenyls (PCBs), polychlorinated dibenzo-*p*-dioxin/polychlorinated dibenzofuran (PCDD/PCDF), non-dioxin-like PCBs, melamine, cyanuric acid, pesticides.^{11,12,13} Based on the results, no concern is identified.

The applicant provided results on particle size measured by sieving on three samples of the product for each formulation. The analysis confirmed the previous data provided by the applicant. The average particle size of the spherical form was 710 µm, with no particles below 355 µm. The average particle size of the granular form was between 250 and 355 µm, with no particles below 90 µm.¹⁴

3.1.2. Characterisation of the active agent

The active ingredient of the additive Biosprint® is the yeast *S. cerevisiae* MUCL 39885. The strain of *S. cerevisiae* is deposited in Belgian Coordinated Collection of Microorganism BCCM™/MUCL Culture

⁹ The full report is available on the EURL website: <https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2009-0028.pdf>

¹⁰ Technical Dossier/Section II/Annex_31.

¹¹ Technical Dossier/Section II/Annex_2.

¹² Technical Dossier/Section II/Annex_3.

¹³ Technical Dossier/Section II/Annex_4.

¹⁴ Technical Dossier/Section II/Annex_29.

Collection – Mycothèque de l'Université Catholique de Louvain with Deposit number 39885.¹⁵ The strain of *S. cerevisiae* used in the additive is not genetically modified.

The applicant provided evidences in support of the taxonomical identification of the strain as *S. cerevisiae*. In particular, the applicant provided results from a whole genome sequence (WGS) analysis,¹⁶ a phylogenetic analysis¹⁷ and a whole genome single nucleotide polymorphism (SNP) analysis.¹⁸ Based on the data, the strain was confirmed as *Saccharomyces cerevisiae*.

3.1.3. Conditions of use

The additive is currently authorised to be used in sows at a minimum concentration of 6.4×10^9 CFU/kg of complete feedstuffs. 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, 2017). This approach requires the identity of the strain to be conclusively established. In the context of the current application, the identity of the 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 users has been evaluated in a previous opinion (EFSA FEEDAP Panel, 2010). The Panel concluded in 2010 that the additive should be considered as a potential skin and eye irritant and skin sensitiser and that the inhalation exposure would be minimal. No additional data were provided in the current application. Considering the proteinaceous nature of the additive, it should be considered a potential respiratory sensitiser.

The applicant submitted the results of a literature search, which covered the period from 2008 to 2018, to provide information on the safety for the target species, the consumers, the users and the environment. The databases used were CAB Abstracts, PubMed and Scopus. The strings used for the search, the exclusion criteria and the search strategy were provided.¹⁹

The literature search for the target species produced 22 results, 6 of them were discarded by the applicant based on the exclusion criteria.²⁰ Out of the 16 remaining papers, 9 were EFSA scientific opinions regarding the use of *S. cerevisiae* in swine as a feed additive. None of the left seven references highlighted a possible safety concern (see Appendix A).

The literature search for the consumers produced 30 results, 27 of them were discarded by the applicant based on the exclusion criteria. Out of the three remaining papers, two were EFSA scientific opinions regarding the use of *S. cerevisiae* as a feed additive. The left one is not relevant for the assessment of the safety for the consumers.²¹ (see Appendix A).

The safety for the users has been evaluated in a previous opinion. No data on skin and eye irritancy or skin sensitisation have been provided; therefore, Biosprint® should be considered as a potential irritant and sensitiser and treated accordingly. Based on the particle size distribution, Biosprint® S and Biosprint® G are unlikely to form respirable dusts. It has been concluded that the inhalation exposure associated with the use of this product would be minimal (EFSA FEEDAP Panel, 2010).

The literature search for the user safety produced 26 results, 24 of them were discarded by the applicant based on the exclusion criteria, and 1 was an EFSA scientific opinion regarding the use of *S. cerevisiae* as a feed additive. The left one is not relevant for the assessment of the safety for the user.²² (see Appendix A).

¹⁵ Technical Dossier/Section II/Annex_5.

¹⁶ Technical Dossier/Section II/Additional information/Annex_1.

¹⁷ Technical Dossier/Section II/Additional information/Annex_3.

¹⁸ Technical Dossier/Section II/Additional information/Annex_4.

¹⁹ Technical Dossier/Section III/Annex_0.

²⁰ Technical Dossier/Section III/Annex_3.

²¹ Technical Dossier/Section III/Annex_4.

²² Technical Dossier/Section III/Annex_5.

The literature search for the safety of the environment produced 143 results, 95 of them were discarded by the applicant based on the exclusion criteria. All the left papers retrieved did not highlight a safety concern for the environment²³ (see Appendix A).

3.2.1. Conclusion on safety

The Panel concluded that Biosprint® is considered safe for the target species, for the consumer, and the environment. The additive should be considered as a potential skin and eye irritant and skin sensitiser and the inhalation exposure would be minimal. No additional data were provided in the current application.

3.3. Efficacy for sows

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 Regulation²⁴ 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 sows, the consumers and the environment.

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

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

Documentation provided to EFSA

- 1) Biosprint® for sows. June 2018. Submitted by Prosol S.p.A.
- 2) Biosprint® for sows. Supplementary information. April 2019. Submitted by Prosol S.p.A.
- 3) Comments from Member States.

Chronology

Date	Event
23/05/2018	Dossier received by EFSA. Biosprint® for sows. Submitted by Prosol S.p.A.
04/06/2018	Reception mandate from the European Commission
22/08/2016	Application validated by EFSA – Start of the scientific assessment
15/04/2018	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. <i>Issues: characterisation, safety for target species, safety for the consumer, safety for the user, safety for the environment</i>
22/11/2018	Comments received from Member States
14/05/2019	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

²³ Technical Dossier/Section III/Annex_6.

²⁴ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.

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- 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 BIOHAZ Panel (EFSA Panel on Biological Hazards), Ricci A, Allende A, Bolton D, Chemaly M, Davies R, Girones R, Herman L, Koutsoumanis K, Lindqvist R, Nørrung B, Robertson L, Ru G, Sanaa M, Simmons M, Skandamis P, Snary E, Speybroeck N, Ter Kuile B, Threlfall J, Wahlström H, Cocconcelli PS, Klein G (deceased), Prieto Maradona M, Querol A, Peixe L, Suarez JE, Sundh I, Vlcek JM, Aguilera-Gomez M, Barizzone F, Brozzi R, Correia S, Heng L, Istace F, Lythgo C and Fernández Escámez PS, 2017. Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA. EFSA Journal 2017;15(3):4664, 177 pp. <https://doi.org/10.2903/j.efsa.2017.4664>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2009. Safety and efficacy of Biosprint® (*Saccharomyces cerevisiae*) as a feed additive for sows. EFSA Journal 2009;7(2):970, 9 pp. <https://doi.org/10.2903/j.efsa.2009.970>
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- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2011. Scientific Opinion on the safety and efficacy of Biosprint® (*Saccharomyces cerevisiae*) for cattle for fattening. EFSA Journal 2011;9(11):2439, 8 pp. <https://doi.org/10.2903/j.efsa.2011.2439>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2015. Scientific Opinion on the safety and efficacy of Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) for minor ruminant species for meat and milk production. EFSA Journal 2015;13(7):4199, 8 pp. <https://doi.org/10.2903/j.efsa.2015.4199>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2013. Guidance on the renewal of the authorization of feed additives. EFSA Journal 2013;11(10):3431, 8 pp. <https://doi.org/10.2903/j.efsa.2013.3431>

Abbreviations

BCCM	Belgian Coordinated Collection of Microorganism
CFU	colony forming unit
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
MUCL	Mycothèque de l'Université Catholique de Louvain
PCB	polychlorinated biphenyl
PCDD	polychlorinated dibenzo- <i>p</i> -dioxin
PCDF	polychlorinated dibenzofuran
QPS	qualified presumption of safety
SNP	single nucleotide polymorphism
WGS	whole genome sequence

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

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