SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 12 November 2019

doi: 10.2903/j.efsa.2019.5915

Assessment of the application for renewal of authorisation of Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) for dairy cows and horses

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Maryline Kouba, Mojca Kos Durjava, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa, Ruud Woutersen, Montserrat Anguita, Jaume Galobart, Orsolya Holczknecht, Paola Manini, Jordi Tarrés-Call, Elisa Pettenati and Fabiola Pizzo

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 dairy cows and horses. *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 the target species, 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.

Keywords: zootechnical additive, Biosprint, *Saccharomyces cerevisiae*, renewal, QPS, horses, dairy cows

Requestor: European Commission

Question Number: EFSA-Q-2019-00219

Correspondence: feedap@efsa.europa.eu

Panel members: Giovanna Azimonti, Vasileios Bampidis Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Maryline Kouba, Mojca Kos Durjava, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa and Ruud Woutersen.

Acknowledgements: The Panel wishes to acknowledge the contribution of Lucilla Gregoretti and Konstantinos Sofianidis to this opinion.

Suggested citation: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis V, Azimonti G, Bastos ML, Christensen H, Dusemund B, Kouba M, Kos Durjava M, López-Alonso M, López Puente S, Marcon F, Mayo B, Pechová A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Anguita M, Galobart J, Holczknecht O, Manini P, Tarrés-Call J, Pettenati E and Pizzo F, 2019. Scientific Opinion on the assessment of the application for renewal of authorisation of Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) for dairy cows and horses. EFSA Journal 2019;17(11):5915, 7 pp. https://doi.org/10.2903/j.efsa.2019.5915

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

Table of contents

1. Introduction

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

Regulation (EC) No 1831/2003 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. for renewal of the authorisation of the product Biosprint® (*Saccharomyces cerevisiae* MUCL 39885), when used as a feed additive for horses and dairy cows (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 (renewal of the authorisation). The particulars and documents in support of the application were considered valid by EFSA as of 21 June 2019.

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

Saccharomyces cerevisiae MUCL 39885 is currently authorised in sows,[1] dairy cows, horses,[2] piglets (weaned),[3] cattle for fattening,[4] minor ruminants for fattening and minor ruminants for dairy products.[5]

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, 2009, 2010a,b,c, 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 dossier[6] 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.

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.[7]

[1] 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.

[2] 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.

[3] 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.

[4] 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.

[5] 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.

[6] FEED dossier reference: FAD-2019-0004.

[7] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2008-0058.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 and the Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2013) 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 *Saccharomyces 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 horses and dairy cows.

3.1. Characterisation

3.1.1. Characterisation of the additive

The additive is authorised as a preparation of viable cells *Saccharomyces cerevisiae* MUCL 39885 with a minimum content of 1×10^9 CFU/g. 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 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 98 batches of the G form (range 1.7–2.09 $\times$ 10^{10}, mean 1.89 $\times$ 10^{10} CFU/g) and for 46 batches of the S form (range 1.75–2.13 $\times$ 10^{10}, mean 1.92 $\times$ 10^{10} CFU/g).[8,9]

The same batches were analysed for microbial contamination. The results confirm compliance with limit levels set (*Escherichia coli* < 10 CFU/g, *Salmonella* absent in 25 g, moulds < 10 CFU/g, *Listeria monocytogenes* absent in 1 g).

Possible presence of chemical 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 < 10 mg/kg, polychlorinated dibenzo-*p*-dioxin (PCDD) < 25 pg/kg, melamine < 1 mg/kg, cyanuric acid < 10 mg/kg, pesticides < 0.01 mg/kg.[10,11,12] 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 100 μm. The average particle size of the granular form was between 250 and 355 μm, with no particles below 90 μm.[13]

3.1.2. Characterisation of the active agent

The active ingredient of the additive Biosprint® is the yeast *Saccharomyces cerevisiae* MUCL 39885. The strain of *S. cerevisiae* is deposited in Belgian Coordinated Collection of Microorganism BCCM™/MUCL Culture Collection – Mycothéque de l'Université Catholique de Louvain with Deposit number 39885.[14] The strain of *S. cerevisiae* used in the additive is not genetically modified.

The applicant provided results from a whole genome sequence (WGS) analysis, a phylogenetic analysis and a whole genome single-nucleotide polymorphism (SNP) analysis. Based on the data, the strain was confirmed to belong to the species *S. cerevisiae*.

[8] Technical Dossier/Section II/Annex_31.
[9] Technical Dossier/Section II/Annex_32.
[10] Technical Dossier/Section II/Annex_2.
[11] Technical Dossier/Section II/Annex_3.
[12] Technical Dossier/Section II/Annex_4.
[13] Technical Dossier/Section II.
[14] Technical Dossier/Section II/Annex_5.

3.1.3. Conditions of use

The additive is currently authorised to be used in horses at a minimum concentration of 3×10^9 CFU/kg of complete feedingstuffs and in dairy cows at a minimum concentration of 2×10^9 CFU/kg of complete feedingstuffs. Under other provisions, it is indicated that for safety: glasses and gloves shall be used during handling. The applicant proposes the same 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 present application, the applicant has provided up to date confirmation of the taxonomical identification of the strain as *S. cerevisiae*. Consequently, the additive can be presumed as safe for the target species, the consumer and the environment.

The safety for the users has been evaluated in a previous opinion (EFSA FEEDAP Panel, 2010a). 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.

In support of the safety of Biosprint® for target species, consumers, users and environment, the applicant provided results of a literature search. The FEEDAP Panel noted that the literature search for the target species covered only 1 year. However, no relevant papers were identified that would highlight a safety concern for the target species, the consumer, the user and the environment.

3.2.1. Conclusions on safety

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

3.3. Efficacy for dairy cows and horses

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[15] 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 dairy cows and horses, 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.

[15] 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.

Documentation as provided to EFSA/Chronology

Date	Event
04/02/2019	Dossier received by EFSA. Biosprint® for dairy cows and horses. Submitted by Prosol S.p.A.
02/04/2019	Reception mandate from the European Commission
21/06/2019	Application validated by EFSA – Start of the scientific assessment
13/09/2019	Spontaneous submission
25/09/2019	Comments received from Member States
12/11/2019	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

References

EFSA (European Food Safety Authority), 2007. Opinion of the Scientific Committee on a request from EFSA on the introduction of a Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA. 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, Vlak JM, Aguillera-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 of Feed 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

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2010a. Scientific Opinion on the safety and efficacy of Biosprint® (*Saccharomyces cerevisiae*) as a feed additive for dairy cows. EFSA Journal 2010;8(7):1662, 8 pp. https://doi.org/10.2903/j.efsa.2010.1662

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2010b. Scientific Opinion on the safety and efficacy of Biosprint® (*Saccharomyces cerevisiae*) as a feed additive for horses. EFSA Journal 2010;8(7):1659, 10 pp. https://doi.org/10.2903/j.efsa.2010.1659

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2010c. Scientific Opinion on the safety and efficacy of Biosprint® (Saccharomyces cerevisiae) for piglets. EFSA Journal 2010;8(10):1864, 9 pp. https://doi.org/10.2903/j.efsa.2010.1864

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

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 of Feed Additives and Products or Substances used in Animal Feed), 2018. Guidance on the characterisation of microorganisms used as feed additives or as production organisms. EFSA Journal 2018;16(3):5206, 24 pp. https://doi.org/10.2903/j.efsa.2018.5206

Abbreviations

CFU ccolony forming unit
EURL European Union Reference Laboratory
GC–MS gas chromatography–mass spectrometry
PCDD polychlorinated dibenzo-*p*-dioxin
SNP single-nucleotide polymorphism
WGS whole genome sequence