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SCIENTIFIC OPINION

# Efficacy of a feed additive consisting of *Saccharomyces cerevisiae* DBVPG 48 SF (BioCell®) for ruminants (Mazzoleni S.p.A.)

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**Abstract**

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety and efficacy of *Saccharomyces cerevisiae* DBVPG 48 SF (BioCell®) as a zootechnical feed additive for horses, pigs and ruminants. In a previous opinion, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) concluded that the additive has the potential to be efficacious at the proposed conditions of use for horses, dairy ruminants and all pigs. However, the Panel was not in the position to conclude on the efficacy of BioCell® for calves, and, consequently, for other ruminants for fattening or rearing. The applicant provided three additional efficacy trials in veal calves to support the efficacy of BioCell® for ruminants for fattening or rearing. The three studies showed positive effects of the supplementation with the additive at $1.7 \times 10^9$ colony forming unit (CFU)/kg complete feed on the performance of veal calves. Considering the previously submitted studies in dairy cows and the new submitted trials, the FEEDAP Panel concluded that the additive has the potential to be efficacious for all ruminants at the proposed condition of use: $4.0 \times 10^8$ CFU/kg complete feed for dairy ruminants and $4.0 \times 10^9$ CFU/kg complete feed for ruminants for fattening and rearing.

**KEYWORDS**

BioCell®, digestibility enhancers, efficacy, *Saccharomyces cerevisiae* DBVPG 48 SF, zootechnical additives

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# 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 and, in particular, Article 9 defines the terms of the authorisation by the Commission.

The applicant, Mazzoleni S.p.A.,[1] is seeking a Community authorisation of *Saccharomyces cerevisiae* DBVPG 48 SF (BioCell®) as a zootechnical feed additive for horses, pigs and ruminants (Table 1).

**TABLE 1** Description of the additive.

| | |
|---|---|
| **Category of additive** | Zootechnical additives |
| **Functional group of additive** | Digestibility enhancers |
| **Description** | *Saccharomyces cerevisiae* DBVPG 48 SF (BioCell®) |
| **Target animal category** | For horses, pigs and ruminants |
| **Applicant** | Mazzoleni S.p.A. |
| **Type of request** | New opinion |

On 23.3.2023, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) of the European Food Safety Authority (EFSA), in its opinion on the safety and efficacy of a feed additive consisting of *Saccharomyces cerevisiae* DBVPG 48 SF (BioCell®) for horses, pigs and ruminants, could not conclude on the efficacy of the additive for veal calves, and, consequently, for other ruminants for fattening or rearing.

The Commission gave the possibility to the applicant to submit supplementary information and data to complete the assessment and to allow a revision of the EFSA's opinion. The new data have been transmitted by the applicant using the e-submission food chain platform (application number FEED-2023-18711).

In view of the above, the Commission asks EFSA to deliver a new opinion on *Saccharomyces cerevisiae* DBVPG 48 SF (BioCell®) as a zootechnical feed additive for ruminants other than for milk production based on the supplementary information and data submitted by the applicant, in accordance with Article 29(1)(a) of Regulation (EC) No 178/2002.

## 1.2 | Additional information

The additive consists of viable cells of *Saccharomyces cerevisiae* DBVPG 48 SF. EFSA issued an opinion on the safety and efficacy of this product when used in feed for horses, pigs and ruminants (EFSA FEEDAP Panel, 2023). The additive is currently authorised for the use in feed for horses, dairy ruminants an pigs (4d24).[2]

# 2 | DATA AND METHODOLOGIES

## 2.1 | Data

The present assessment is based on data submitted by the applicant in the form of supplementary information[3] to a previous application on the same product.[4] The dossier was received on 23 October 2023 and the general information and supporting documentation are available on Open.EFSA at https://open.efsa.europa.eu/questions/EFSA-Q-2023-00694.

In accordance with Article 38 of the Regulation (EC) No 178/2002[5] and taking into account the protection of confidential information and personal data in accordance with Articles 39 to 39e of the same Regulation, and the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[6] a non-confidential version of the supplementary information has been published on Open.EFSA.

[1]Via Stezzano, 87. Bergamo (BG) c/o Kilometro Rosso (Italy).

[2]Commission Implementing Regulation (EU) 2023/2734 of 7 December 2023. OJ L, 8.12.2023, p. 1-4.

[3]Dossier reference: FEED-2023-18711.

[4]Dossier reference: FAD-2021-0040.

[5]Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the generalprinciples and requirements of food law, establishing the European Food Safety Authority and laying down procedures inmatters 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.

## 2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the efficacy of *Saccharomyces cerevisiae* DBVPG 48 SF (BioCell®) is in line with the principles laid down in Regulation (EC) No 429/2008[7] and the relevant guidance documents: Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018).

# 3 | ASSESSMENT

The additive under assessment, with the trade name BioCell®, consists of viable cells of *Saccharomyces cerevisiae* DBVPG 48 SF and is intended to be used as a zootechnical additive in feed for ruminants (other zootechnical additives: performance enhancer).

The additive is intended to be used at the following proposed minimum use levels for:

- Dairy cows and minor dairy species: $4.0 \times 10^8$ colony forming unit (CFU)/kg complete feed
- Calves, cattle for fattening and minor growing and fattening ruminants: $4.0 \times 10^9$ CFU/kg complete feed

The additive was fully characterised in the previous opinion of the FEEDAP Panel (EFSA FEEDAP Panel, 2023). The FEEDAP Panel concluded that the additive is considered safe for the target species, the consumers and the environment. The additive, in any of its formulations, is not an irritant to the eyes and skin but should be considered a respiratory sensitiser. No conclusions could be drawn on the skin sensitisation potential of the additive. The FEEDAP Panel also concluded that the additive has the potential to be efficacious at the proposed conditions of use for horses, dairy ruminants and all pigs.

In that opinion, three long-term trials were submitted aiming to demonstrate the efficacy of BioCell® on the zootechnical performance of veal calves. However, none could be further considered as evidence of the efficacy due to the high number of veterinary medical treatments administered (ranging 20%–45% of total animals) and the high mortality rates (6%–7% in the control groups).

The applicant provided three additional in vivo efficacy trials with a similar experimental design to support the efficacy of BioCell® in veal calves.

## 3.1 | Efficacy

Three long-term trials sharing a common design were submitted aiming at assessing the effect of the additive on the zootechnical performance of veal calves. The details on the study design are provided in Table 2 and the main results in Table 3.

**TABLE 2** Trial design and use level of the efficacy trials performed in veal calves.

| Trial | Total no of animals (animals × replicate) replicates × treatment | Breed Sex (duration) | Feeding regime (composition) | Groups (CFU/kg solid feed) | | |
|---|---|---|---|---|---|---|
| | | | | Intended | Analysed[1] | Calculated[2] |
| 1[8] | | | | 0<br>$4.0 \times 10^9$ | | |
| 2[9] | | | | 0<br>$4.0 \times 10^9$ | | |
| 3[10] | | | | 0<br>$4.0 \times 10^9$ | | |

[1]Analysed in solid feed.

[2]Calculated based on the total dry matter intake.

*Limit of quantification (LOQ):

[7]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.

[8]Annex_IV_3_13_Calves_4.

[9]Annex_IV_3_14_Calves_5.

[10]Annex_IV_3_15_Calves_6.

[redacted]

**TABLE 3** Effects of BioCell® on the performance of veal calves ([redacted]).

| Trial | Groups (CFU/kg solid feed) | Total dry matter intake (kg) | Initial body weight (kg) | Final body weight (kg) | Average daily weight gain (kg) | Feed-to-gain ratio | Mortality and culling (%) |
|---|---|---|---|---|---|---|---|
| 1[11] | 0<br>$4.0\times10^9$ | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 2[12] | 0<br>$4.0\times10^9$ | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| 3[13] | 0<br>$4.0\times10^9$ | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |

[a,b]Mean values within a trial and within a column with a different superscript are significantly different $p < 0.1$.

[redacted]

Overall, the three studies showed positive effects of the supplementation with BioCell® at the proposed conditions of use on the performance of veal calves.

### 3.1.1 | Conclusions on the efficacy

In its previous opinion, the FEEDAP Panel concluded that the additive has the potential to be efficacious for dairy ruminants at the use level of $4.0\times10^8$ CFU/kg complete feed. Considering the results of the new studies in calves, the FEEDAP Panel concludes that the additive has the potential to be efficacious as a zootechnical additive for all ruminants at the proposed condition of use: $4.0\times10^8$ CFU/kg complete feed for dairy ruminants and $4.0\times10^9$ CFU/kg complete feed for ruminants for fattening and rearing.

## 4 | CONCLUSIONS

The additive has the potential to be efficacious in feedingstuffs for all ruminants at the proposed condition of use of $4.0\times10^8$ CFU/kg complete feed for dairy ruminants and $4.0\times10^9$ CFU/kg complete feed for ruminants for fattening and rearing.

### ABBREVIATIONS

| | |
|---|---|
| CFU | colony forming unit |
| FEEDAP | Panel on Additives and Products or Substances used in Animal Feed |
| LOQ | limit of quantification |

### ACKNOWLEDGEMENTS

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[11]Annex_IV_3_13_Calves_4.

[12]Annex_IV_3_14_Calves_5.

[13]Annex_IV_3_15_Calves_6.

## 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

## QUESTION NUMBER

EFSA-Q-2023-00694

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