SCIENTIFIC OPINION

Scientific Opinion on the efficacy of Biosprint® (*Saccharomyces cerevisiae*) as a feed additive for cattle for fattening[1]

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

In a previous opinion on Biosprint, the FEEDAP Panel could not conclude on the efficacy of this additive when used in feed for cattle for fattening because of insufficient evidence. The European Commission has requested the European Food Safety Authority to re-evaluate the efficacy of the additive Biosprint® when used as a zootechnical additive (functional group: gut flora stabilisers) in diets for cattle for fattening at a minimum dose of 4.0×10^9 and a maximum dose of 9.0×10^9 CFU/kg complete feedingstuffs. In the present application, the results of two new efficacy studies performed in cattle for fattening were presented. Both showed significant improvements in final body weight, average daily gain and feed to gain ratio in Biosprint®-treated animals. Taking into account the positive result from the initial application, the FEEDAP Panel concludes that Biosprint® has the potential to be efficacious in cattle for fattening at the dose of 3.6×10^{10} CFU/head per day approximately equating to 4×10^9 CFU/kg feedingstuffs.

KEY WORDS

Zootechnical additive, gut flora stabiliser, Biosprint®, *Saccharomyces cerevisiae*, cattle for fattening, efficacy

[1] On request from the European Commission, Question No EFSA-Q-2012-00925, adopted on 13 March 2013.

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SUMMARY

In 2011 the European Food Safety Authority delivered an opinion on Biosprint® when used as a zootechnical additive (functional group: gut flora stabilisers) in diets for cattle for fattening at a minimum dose of 4.0×10^9 and a maximum dose of 9.0×10^9 CFU/kg complete feedingstuffs. The dossier submitted at that time included six efficacy studies, four of which could not be further considered owing to significant weaknesses in the experimental designs. Of the remaining two, only one showed evidence of a significant benefit in weight gain. As a consequence, the FEEDAP Panel was unable to conclude on the efficacy of Biosprint® when used in feed for cattle for fattening.

In the present application the results from two new efficacy studies performed with cattle for fattening were presented. Both showed significant improvements in final body weight, average daily gain and feed to gain ratio in Biosprint®-treated animals. Taking into account the positive result from the initial application, the FEEDAP Panel concludes that Biosprint® has the potential to be efficacious in cattle for fattening at the dose of 3.6×10^{10} CFU/head/day, equating to approximately 4×10^9 CFU/kg feedingstuffs.

TABLE OF CONTENTS

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 1831/2003[4] establishes rules governing the Community authorisation of additives for animal nutrition and in particular, Article 9 defines the terms of the authorisation by the Commission.

The company Prosol is seeking a Community authorisation of its *Saccharomyces cerevisiae* MUCL 39885 for use in cattle for fattening (Table 1).

Table 1: Description of the substance

Category of additive	Zootechnical additives
Functional group of additive	Gut flora stabilisers
Trade name	-
Description	*Saccharomyces cerevisiae* MUCL 39885
Target animal category	Cattle for fattening
Applicant	Prosol
Type of request	Update opinion

On 15 November 2011, the Authority, in its opinion on "Safety and efficacy of *Saccharomyces cerevisiae* MUCL 39885 for use in cattle for fattening", was not able to give a conclusive opinion on the efficacy of the product because of lack of data provided by the company.

Therefore, the Commission gave the possibility to the company to submit complementary information to complete the assessment on efficacy for cattle for fattening to allow a revision of that opinion.

The Commission has now received an additional dossier from the applicant, Prosol, on its *Saccharomyces cerevisiae* MUCL 39885 for use in cattle for fattening, with supplementary information, concerning the efficacy.

The Commission, in order to give the appropriate follow-up to the application, asks the European Food Safety Authority to issue an updated opinion on the efficacy of this product under the terms of reference specified in the Annex. The data generated by the company and compiled in the above-mentioned supplementary report have been sent directly to Authority by the applicant.[5]

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

In view of the above, the Commission asks to the European Food Safety Authority to deliver an opinion on the efficacy of this *Saccharomyces cerevisiae* MUCL 39885 for use in cattle for fattening, produced by Prosol as zootechnical additive taking into account the new information submitted.

[4] 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.
[5] Dossier reference: FAD-2012-0030.

ASSESSMENT

1. Introduction

Biosprint® is a dried preparation of a strain of *Saccharomyces cerevisiae* MUCL 39885. The additive is manufactured in two forms, described by the applicant as 'spherical' (Biosprint® S) and 'granulated' (Biosprint® G), with a minimum guaranteed content of viable yeast cells of 1.0×10^9 CFU/g. It is already authorised for use in cattle for fattening,[6] piglets,[7] sows,[8] dairy cows and horses.[9]

In 2011, EFSA was requested by the European Commission to re-evaluate the product when used as a zootechnical additive (functional group: gut flora stabilisers) in diets for cattle for fattening at a minimum dose of 4.0×10^9 and a maximum dose of 9.0×10^9 CFU/kg complete feedingstuffs. The dossier submitted at that time included six efficacy studies, four of which could not be further considered owing to significant weaknesses in the experimental design. Of the remaining two, only one showed evidence of a significant benefit in weight gain. Therefore, the FEEDAP Panel in its opinion was unable to conclude on the efficacy of Biosprint® when used in feed for cattle for fattening (EFSA, 2011).

With the aim of demonstrating the efficacy of Biosprint® when used in diets for cattle for fattening, the applicant has provided two more trials which are the subject of the current opinion.

2. Efficacy

Two trials with the same experimental design were performed over the same period in two different farms allowing measurements of individual feed intake. The duration of the studies was 150 and 154 days. In each study 54 female Charolais cattle (10 months of age) were homogeneously divided in two experimental groups based on initial body weight. Control animals received a basal diet whilst treated animals received the same diet supplemented with the additive at the dose of 2 g/head per day (i.e. 3.6×10^{10} CFU/head per day), confirmed by analyses. This corresponds to 4×10^9 CFU/kg feed (analysed value 3.9×10^9 CFU/kg). Biosprint® was provided by the applicant to the experimental farm already mixed with wheat bran. In trial 1, the diet was based on maize silage, corn meal, mixed hay and wheat bran and straw. In trial 2, the main ingredients of the diet were maize silage, corn meal, dried beet pulp, wheat straw and sunflower meal. Body weights were determined individually at the beginning and at the end of the study (Table 2). Individual dry matter intake and feed to gain ratio were determined. Statistical analysis was performed by a multivariate analysis of variance (ANOVA) for repeated measurements (mixed and a general linear model (GLM)) considering the individual animal as the experimental unit.

In both trials, the final body weight, the average daily gain and the feed to gain ratio were significantly improved in Biosprint®-treated animals compared with the control animals (Table 2). Similarly, in the study assessed in the previous opinion, cattle receiving Biosprint® showed a significantly higher weight gain compared with control animals.

[6] Commission Regulation (EC) No 492/2006 of 27 March 2006 concerning the provisional and permanent authorisation of certain additives in feedingstuffs. OJ L 89, 28.3.2006, p. 6.

[7] 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.

[8] 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 .

[9] 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. 31.

Table 2: Summary of data on the effects of Biosprint® on the performance of cattle for fattening

Trial no (duration, days)	No of animals per treatment	Dose (CFU/kg feed)	Initial weight (kg)	Final weight (kg)	Average weight gain (kg/day)	Total feed intake/head (kg DM)	Feed to gain ratio (kg/kg)
1[10]	27	0	364	514[b]	1.00[b]	1367[b]	9.11[a]
(150)	27	4×10^9	364	524[a]	1.07[a]	1372[a]	8.54[b]
2[11]	27	0	366	520[b]	1.03[b]	1369[b]	8.85[a]
(154)	27	4×10^9	366	533[a]	1.11[a]	1374[a]	8.23[b]
Old trial							
3[12]	60	0	346	482	0.89[a]	1133	8.36
(154)	60	4×10^9	347	499	0.99[b]	1173	7.79

[a,b] Treatment means with a different superscript letter differ at at least $P \leq 0.1$.

CONCLUSIONS

The FEEDAP Panel concludes that Biosprint® has the potential to be efficacious in cattle for fattening at the dose of 3.6×10^{10} CFU/head/day, equivalent to 4×10^9 CFU/kg feedingstuffs.

DOCUMENTATION PROVIDED TO EFSA

Dossier on Biosprint® for cattle for fattening. September 2012. Submitted by Prosol S.A.

REFERENCES

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), 2011. Scientific Opinion on the safety and efficacy of Biosprint® (*Saccharomyces cerevisiae*) for cattle for fattening. EFSA Journal, 9(11):2439. 8 pp.

[10] Technical dossier/Annexes 1 and 2.
[11] Technical dossier/Annexes 3 and 4.
[12] Technical dossier FAD-2009-0031/Supplementary information July 2011/Annexes 5 and 6.