European Food Safety Authority

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## SCIENTIFIC OPINION

# Scientific Opinion on the safety and efficacy of Biosprint® (*Saccharomyces cerevisiae* MUCL 39885) for minor ruminant species for meat and milk production[1]

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

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## ABSTRACT

Biosprint® is a zootechnical feed additive consisting of a dried preparation of a strain of *Saccharomyces cerevisiae*. It is already authorised for use in feed for piglets, cattle for fattening, dairy cows, horses and sows. The applicant has now requested that the product be authorised for use as a zootechnical additive (functional group: gut flora stabilisers) in diets for dairy buffaloes, dairy sheep and dairy goats, and for buffaloes and goats for fattening. *Saccharomyces cerevisiae* is considered by the European Food Safety Authority (EFSA) to be suitable for the qualified presumption of safety approach to safety assessment. As the identity of the production strain has been previously established and as the additive essentially consists of only the active agent, safety for the new target species, for consumers of milk and/or meat derived from minor ruminants and for the environment is presumed. The efficacy of the additive has been demonstrated for dairy cows and cattle for fattening (considered the relevant major species). As the mechanism of action of the additive can be reasonably assumed to be the same, efficacy for minor ruminant species used for milk and/or for fattening when used at minimum doses established for the major species can be presumed without the need for specific studies. This would be $2 \times 10^9$ colony-forming units (CFU)/kg feed for minor dairy ruminants and $4 \times 10^9$ CFU/kg feed for minor ruminants used for fattening.



## KEY WORDS

zootechnical additive, Biosprint, *Saccharomyces cerevisiae*, safety, QPS, efficacy, minor species

[1] On request from the European Commission, Question No EFSA-Q-2014-00792, adopted on 9 July 2015.

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## SUMMARY

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety and efficacy of Biosprint®. Biosprint® is a zootechnical feed additive consisting of a dried preparation of a strain of *Saccharomyces cerevisiae*. It is already authorised for use in feed for piglets, cattle for fattening, dairy cows, horses and sows. The applicant has now requested that the product be authorised for use as a zootechnical additive (functional group: gut flora stabilisers) in diets for dairy buffaloes, dairy sheep and dairy goats, and for buffaloes and goats for fattening.

The additive that is the subject of the present application has the same formulation and method of manufacture as that considered in previous applications. Thus, the data pertaining to impurities, physical properties and shelf life still apply. The data on stability in premixtures, mash feed and pelleted feed for dairy cows and cattle for fattening are considered applicable to minor species, given the likely similarity in feed formulation.

*Saccharomyces cerevisiae* is considered by EFSA to be suitable for the qualified presumption of safety approach to safety assessment. As the identity of the production strain has been previously established and as the additive essentially consists of only the active agent, safety for the new target species, for consumers of milk and/or meat derived from minor ruminants and for the environment is presumed.

The efficacy of the additive has been demonstrated for dairy cows and cattle for fattening, which are considered the relevant major species. As the mechanism of action of the additive can be reasonably assumed to be the same, efficacy for minor ruminant species used for milk and/or for fattening when used at minimum doses established for the major species can be presumed without the need for specific studies. This would be $2 \times 10^9$ colony-forming units (CFU)/kg feed for minor dairy ruminants and $4 \times 10^9$ CFU/kg feed for minor ruminants for fattening.

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## BACKGROUND

Regulation (EC) No 1831/2003[4] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from Prosol[5] for authorisation of the product Biosprint®, *Saccharomyces cerevisiae* (MUCL 39885), when used as a feed additive for dairy buffaloes, sheep and goats, growing buffaloes and growing goats (category: zootechnical additive; functional group: gut flora stabilisers) under the conditions mentioned in Table 1.

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 4(1) (authorisation of a feed additive or new use of a feed additive). EFSA received directly from the applicant the technical dossier in support of this application.[6] According to Article 8 of that Regulation, 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. The particulars and documents in support of the application were considered valid by EFSA as of 11 February 2015.

The additive Biosprint® is a preparation of *Saccharomyces cerevisiae* (MUCL 39885). This product is currently authorised for use in sows,[7] piglets,[8] cattle for fattening,[9] horses and dairy cows.[10]

The Scientific Committee on Animal Nutrition (SCAN) issued an opinion on the safety of this product for cattle for fattening, piglets and pigs for fattening, including the safety for the user, the consumer and the environment (EC, 1997, updated in 2003). EFSA issued one opinion on the safety of Biosprint® for dairy cows (EFSA, 2004), one on the safety and efficacy for sows (EFSA, 2009), one on the safety and efficacy for horses (EFSA FEEDAP Panel, 2010a), one on the safety and efficacy for dairy cows (EFSA FEEDAP Panel, 2010b), one on the safety and efficacy for piglets (EFSA FEEDAP Panel, 2010c) and two on the safety and efficacy for cattle for fattening (EFSA FEEDAP Panel, 2011 and 2013).

## TERMS OF REFERENCE

According to Article 8 of Regulation (EC) No 1831/2003, EFSA shall 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 the efficacy of the Biosprint® (*Saccharomyces cerevisiae* MUCL 39885), when used under the conditions described in Table 1.

[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] Prosol S.p.A., Via Carsol 99, 24040, Italy.
[6] EFSA Dossier reference: FAD-2014-0039.
[7] 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.
[8] 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.
[9] 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.
[10] 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 31, 3.12.2010, p. 9.

**Table 1:** Description and conditions of use of the additive as proposed by the applicant

| | |
|---|---|
| **Additive** | *Saccharomyces cerevisiae* MUCL 39885 |
| **Registration number/EC No/No** | 4b1710 |
| **Category of additive** | Zootechnical additives |
| **Functional group(s) of additive** | Gut flora stabilizer |

| **Description** | | | |
|---|---|---|---|
| Composition, description | Chemical formula | Purity criteria | Method of analysis |
| *Saccharomyces cerevisiae* | | 100% | EN15789 |

| | |
|---|---|
| **Trade name** | Biosprint® |
| **Name of the holder of authorisation** | Prosol S.P.A. |

| **Conditions of use** | | | | |
|---|---|---|---|---|
| Species or category of animal | Maximum Age | Minimum content | Maximum content | Withdrawal period |
| | | CFU/kg of complete feedingstuffs | | |
| Dairy goat | | $2 \times 10^9$ | | |
| Dairy sheep | | $2 \times 10^9$ | | |
| Dairy buffalo | | $2 \times 10^9$ | | |
| Growing goat | | $4 \times 10^9$ | | |
| Growing buffalo | | $4 \times 10^9$ | | |

| **Other provisions and additional requirements for the labelling** | |
|---|---|
| Specific conditions or restrictions for use | |
| Specific conditions or restrictions for handling | |
| Post-market monitoring | |
| Specific conditions for use in complementary feedingstuffs | |

| **Maximum Residue Limit (MRL)** | | | |
|---|---|---|---|
| Marker residue | Species or category of animal | Target tissue(s) or food products | Maximum content in tissues |
| | | | |

## ASSESSMENT

### 1. Introduction

Biosprint® is a dried preparation 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 $1.0 \times 10^9$ colony-forming units (CFU)/g.

The additive is already authorised for use in piglets, cattle for fattening, dairy cows, horses and sows (see 'Background' section). The applicant has now requested that the product be authorised for use as a zootechnical additive (functional group: gut flora stabilisers) in diets for dairy buffaloes, dairy sheep and dairy goats, and for buffaloes and goats for fattening.

The safety of Biosprint® was assessed by the European Food Safety Authority (EFSA) Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) in 2010 (EFSA FEEDAP Panel, 2010a, b). *Saccharomyces cerevisiae* is considered by EFSA to be suitable for the qualified presumption of safety (QPS) approach to safety assessment (EFSA, 2007; EFSA BIOHAZ Panel, 2013). As the identity of the strain has been established, Biosprint® is assumed to be safe for the target species, the consumer and the environment without the need for further studies (EFSA FEEDAP Panel, 2010a, b). The safety of Biosprint® for the user and its efficacy when used in feed for cattle for fattening and dairy cows was also established in previous opinions (EFSA FEEDAP Panel 2010a, b, 2011, 2013). The FEEDAP Panel is unaware of any new data that would lead it to revise these conclusions. Therefore, the focus of the present opinion is on the consequences of the new use in feed for dairy buffaloes, dairy sheep, dairy goats, and buffaloes and goats for fattening.

### 2. Characterisation

The additive that is the subject of the present application has the same formulation and method of manufacture as that considered in previous applications (EFSA FEEDAP Panel, 2010a, b). Thus, the data pertaining to impurities, physical properties and shelf life still apply. The data on stability in premixtures, mash feed and pelleted feed for dairy cows and cattle for fattening are considered applicable to minor species, given the likely similarity in feed formulation.

#### 2.1. Conditions of use

The additive is intended for use with dairy buffaloes, dairy sheep and dairy goats at a minimum dose of $2.0 \times 10^9$ CFU/kg complete feedingstuffs, and with buffaloes and goats for fattening at a minimum dose of $4.0 \times 10^9$ CFU/kg complete feedingstuffs. It is intended for use with dry feeds only.

#### 2.2. Evaluation of the analytical methods by the European Union Reference Laboratory (EURL)

The EURL considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.[11]

### 3. Safety

*Saccharomyces cerevisiae* is considered by EFSA to be suitable for the QPS approach to safety assessments (EFSA, 2007; EFSA BIOHAZ Panel, 2013). As the identity of the strain has been established, no assessment of safety for the target species, the consumer or the environment is required. Therefore, Biosprint® is presumed to be safe for the new target species, for consumers of milk and meat from the minor species and for the environment.

[11] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/default/files/FinRep-FAD-2009-0028.pdf

## 4. Efficacy

### 4.1. Efficacy for minor species for milk production

In a previous opinion, the FEEDAP Panel concluded that Biosprint®, when added to diets at $2.3 \times 10^9$ CFU/kg feedingstuffs, has the potential to increase milk production in dairy cows (EFSA FEEDAP Panel, 2010b). The applicant proposes the use of essentially the same dose in minor ruminant dairy species. As efficacy has been demonstrated for the major species (dairy cows) and as the mechanism of action of the additive can be reasonably assumed to be the same, efficacy for minor species used for milk production at this dose can be presumed without the need for specific studies.

### 4.2. Efficacy for minor species reared for fattening

In a previous opinion, the FEEDAP Panel concluded that Biosprint® has the potential to be efficacious in cattle for fattening at a dose of $3.6 \times 10^{10}$ CFU/head per day, equating approximately to $4 \times 10^9$ CFU/kg feedingstuffs (EFSA FEEDAP Panel, 2013). The applicant proposes that the same dose be used in minor ruminant species for fattening, as proposed for beef cattle. As efficacy has been demonstrated for the major species (cattle for fattening) and as the mechanism of action of the additive can be reasonably assumed to be the same, efficacy for minor ruminant species for fattening can be presumed at a minimum dose of $4 \times 10^9$ CFU/kg feedingstuffs, without the need for specific studies.

## 5. 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 by the Feed Hygiene Regulation[12] and Good Manufacturing Practice.

## CONCLUSIONS

*Saccharomyces cerevisiae* is considered by EFSA to be suitable for the QPS approach to safety assessment. As the identity of the production strain has been established and as the additive essentially consists of only the active agent, safety for the target species, the consumer and the environment is presumed.

The efficacy of the additive has been demonstrated for dairy cows and cattle for fattening, which are considered the relevant major species. As the mechanism of action of the additive can be reasonably assumed to be the same, efficacy for minor ruminant species used for milk and/or for fattening when used at minimum doses established for the major species can be presumed without the need for specific studies. This would be $2 \times 10^9$ CFU/kg feed for minor dairy ruminants and $4 \times 10^9$ CFU/kg feed for minor ruminants for fattening.

## DOCUMENTATION PROVIDED TO EFSA

1. Biosprint® (*Saccharomyces cerevisiae*) for minor ruminant species for meat and milk production. November 2014. Submitted by Prosol S.p.A.

2. Comments from Member States received through the ScienceNet.

## REFERENCES

EC (European Commission), 1997, updated 2003. Opinion on the use of certain micro-organisms as additives in feedingstuffs. Available online: http://ec.europa.eu/food/fs/sc/scan/out93_en.pdf

EFSA (European Food safety Authority), 2004. Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed on a request from the Commission on the safety of "Biosprint BCCM™/MUCL39885" for dairy cows. The EFSA Journal 2004, 26, 1–6.

[12] 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 (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. The EFSA Journal 2007, 587, 1–16.

EFSA (European Food Safety Authority), 2009. Scientific Opinion of the Panel on additives and products or substances used in animal feed (FEEDAP) on the safety and efficacy of Biosprint® (*Saccharomyces cerevisiae*) as a feed additive for sows. The EFSA Journal 2009, 970, 1–9.

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), 2013. Scientific Opinion on the maintenance of the list of QPS biological agents intentionally added to food and feed (2013 update). EFSA Journal 2013;11(11):3449, 105 pp. doi:10.2903/j.efsa.2013.3449

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 horses. EFSA Journal 2010;8(7):1659, 10 pp. doi:10.2903/j.efsa.2010.1659

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 dairy cows. EFSA Journal 2010;8(7):1662, 8 pp. doi:10.2903/j.efsa.2010.1662

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*) as a feed additive for piglets. EFSA Journal 2010;8(10):1864, 9 pp. doi:10.2903/j.efsa.2010.1864

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. doi:10.2903/j.efsa.2011.2439

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2013. Scientific Opinion on the efficacy of Biosprint® (*Saccharomyces cerevisiae*) as a feed additive for cattle for fattening. EFSA Journal 2013;11(4):3174, 8 pp. doi:10.2903/j.efsa.2013.3174