Assessment of the application for renewal of authorisation of Actisaf® Sc47 (Saccharomyces cerevisiae CNCM I-4407) for lambs for fattening, minor dairy ruminants, horses and pigs for fattening

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Abstract

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 renewal of the authorisation of Actisaf Sc47 as a zootechnical additive for lambs for fattening, minor dairy ruminants, horses and pigs for fattening. In 2006, 2007 and 2008, the FEEDAP Panel adopted opinions on the safety and efficacy of Actisaf Sc47 when used in lambs for fattening, minor dairy ruminants, horses and pigs for fattening. Actisaf Sc47 is the trade name for a feed additive based on viable cells of Saccharomyces cerevisiae CNCM I-4407 with no carrier. It is currently authorised for use in sows, piglets, pigs for fattening, cattle for fattening, calves for rearing, dairy cows, dairy buffaloes, lambs for fattening, dairy sheep, dairy goats, horses, rabbits for fattening and non-food producing rabbits. Actisaf Sc47 is marketed in three forms: standard, powder and HR. All of them are authorised with a declared minimal concentration of viable yeast cells in the additive of $5 \times 10^9$ CFU/g. The applicant has provided data demonstrating that the additive currently in the market complies with the conditions of authorisation. In previous opinions, Actisaf Sc47 was presumed safe for the target species, consumers of products from animals fed the additive and the environment. Additionally, it was not found to be a skin or eye irritant. No new evidence has been identified that would make the FEEDAP Panel reconsider the previous conclusions on the safety of Actisaf Sc47. Therefore, the Panel considers that the additive Actisaf SC47 remains safe under the approved conditions for lambs for fattening, minor dairy ruminants, horses and pigs for fattening, the consumer, user and the environment.

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Keywords: zootechnical additive, Actisaf Sc47, Saccharomyces cerevisiae CNCM I-4407, safety, lambs for fattening, dairy small ruminants, horses and pigs for fattening

Requestor: European Commission

Question numbers: EFSA-Q-2016-00090, EFSA-Q-2016-00297, EFSA-Q-2016-00292 and EFSA-Q-2017-00286

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1. Introduction

1.1. Background and Terms of Reference

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 four requests from Lesaffre Feed Additives for renewal of the authorisations of the product Actisaf® Sc47 (Saccharomyces cerevisiae CNCM I-4407), when used as a feed additive for lambs for fattening, dairy goats, dairy sheep, dairy buffaloes, pigs for fattening (category: zootechnical additive; functional group: gut flora stabiliser) and horses (category: zootechnical additive; functional group: digestibility enhancer).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the applications to the European Food Safety Authority (EFSA) under Article 14(1) (renewal of an authorised feed additive). EFSA received directly from the applicant four technical dossiers in support of these applications. The particulars and documents in support of the applications were considered valid by EFSA as of 11 April 2016 (lambs for fattening), 1 June 2016 (minor dairy ruminants and horses) and 1 June 2017 (pigs for fattening).

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 Actisaf® Sc47 (Saccharomyces cerevisiae CNCM I-4407), when used under the proposed conditions of use (see Section 3.1.4).

1.2. Interpretation of the Terms of Reference

The applications for renewal of the authorisations do not include a proposal for amending or supplementing the conditions of the original authorisations that would have an impact on the efficacy of the additive; therefore efficacy is not assessed. The present opinion will focus only on the safety aspects.

1.3. Additional information

The additive Actisaf® Sc47 is a preparation of Saccharomyces cerevisiae CNCM I-4407. The Scientific Committee on Animal Nutrition (SCAN) issued an opinion on the safety of this product for piglets, sows, beef and dairy cattle, including the safety for the user, the consumer and the environment (European Commission, 1997/2003), and another on the efficacy for cattle for fattening (European Commission, 2002). EFSA issued several opinions on the safety and efficacy of this product for the following species: lambs for fattening (EFSA, 2006a), dairy small ruminants (EFSA, 2006b), horses (EFSA, 2006c), calves for rearing (EFSA, 2007a), pigs for fattening (EFSA, 2007b), dairy buffaloes (EFSA, 2008), calves for rearing (EFSA, 2010) and rabbits for fattening and non food-producing rabbits (EFSA FEEDAP Panel, 2012a).

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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 Phileo – Division of S.I. Lesaffre. 137, rue Gabriel Péri, BP 3029. 59700 Marcq en Baroeul, France.
3 The applicant used to market this product with the trade name Biosaf® Sc 47.
4 In former notifications and applications, the strain had the deposition identification numberNCYC SC 47.
The product is already authorised for use in cattle for fattening, sows, piglets, dairy cows, lambs for fattening, dairy goats, dairy sheep, horses, pigs for fattening, dairy buffaloes, calves for rearing, rabbits for fattening and non-food producing rabbits.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of four technical dossiers in support of the request for the renewal of the authorisation for the use of Actisaf® Sc47 (Saccharomyces cerevisiae CNCM I-4407) as a feed additive. The technical dossiers were prepared following the provisions of Article 14 of Regulation (EC) No 1831/2003 and the applicable EFSA guidance documents.

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

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessments are valid and applicable for the current applications.

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Actisaf® Sc47 (Saccharomyces cerevisiae CNCM I-4407) is in line with the principles laid down in Regulation (EC) No 1829/2003 and the relevant guidance documents: Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2013), Guidance on zootechnical additives (EFSA FEEDAP Panel, 2012b) and Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012c).

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5 Commission Regulation (EC) No 316/2003 of 19 February 2003 concerning the permanent authorisation of an additive in feedingstuffs and the provisional authorisation of a new use of an additive already authorised in feedingstuffs. OJ L 46, 20.2.2003, p. 15.
6 Commission Regulation (EC) No 1288/2004 of 14 July 2004 concerning the permanent authorisation of certain additives and the provisional authorisation of a new use of an additive already authorised in feedingstuffs. OJ L 243, 15.7.2004, p. 10.
7 Commission Regulation (EC) No 2148/2004 of 16 December 2004 concerning the permanent and provisional authorisations of certain additives and the authorisation of new uses of an additive already authorised in feedingstuffs. OJ L 370, 17.12.2004, p. 24.
8 Regulation (EC) No 1811/2005 of 4 November 2005 concerning the provisional and permanent authorisations of certain additives in feedingstuffs and the provisional authorisation of a new use of an additive already authorised in feedingstuffs. OJ L 291, 5.11.2005, p. 12.
9 Commission Regulation (EC) No 1447/2006 of 29 September 2006 concerning the authorisation of a new use of Saccharomyces cerevisiae (Biosaf SC 47) as a feed additive. OJ L 57, 30.9.2006, p. 28.
10 Commission Regulation (EC) No 188/2007 of 23 February 2007 concerning the authorisation of a new use of Saccharomyces cerevisiae (Biosaf SC 47) as a feed additive. OJ L 57, 24.2.2007, p. 3.
11 Commission Regulation (EC) No 186/2007 of 21 February 2007 concerning the authorisation of a new use of Saccharomyces cerevisiae (Biosaf SC 47) as a feed additive. OJ L 63, 1.3.2007, p. 6.
12 Commission Regulation (EC) No 209/2008 of 6 March 2008 concerning the authorisation of a new use of Saccharomyces cerevisiae (Biosaf SC 47) as a feed additive. OJ L 63, 7.3.2008, p. 3.
13 Commission Regulation (EC) No 232/2009 of 19 March 2009 concerning the authorisation of a new use of Saccharomyces cerevisiae NCYC Sc47 as a feed additive for dairy buffaloes (holder of the authorisation Société Industrielle Lesaffre). OJ L 74, 20.3.2009, p. 14.
14 Commission Regulation (EU) No 883/2010 of 7 October 2010 concerning the authorisation of a new use of Saccharomyces cerevisiae NCYC Sc 47 as a feed additive for calves for rearing (holder of the authorisation Société Industrielle Lesaffre). OJ L 265, 8.10.2010, p. 1.
15 Commission Implementing Regulation (EU) No 334/2012 of 19 April 2012 concerning the authorisation of a preparation of Saccharomyces cerevisiae CNCM I-4407 as a feed additive for rabbits for fattening and non food-producing rabbits and amending Regulation (EC) No 600/2005 (holder of the authorisation Société Industrielle Lesaffre). OJ L 108, 20.4.2012, p. 6–8.
16 FEED dossier reference: FAD-2015-0027 (fattening lambs), FAD-2016-0022 (minor dairy ruminants), FAD-2016-0023 (horses) and FAD-2017-0016 (fattening pigs).
17 The full reports are available on the EURL website: https://ec.europa.eu/jrc/sites/default/files/FinRep-FAD-2005-0013.pdf; https://ec.europa.eu/jrc/sites/default/files/FinRep-FAD-2005-0026.pdf; https://ec.europa.eu/jrc/sites/default/files/FinRep-FAD-2007-0049.pdf; https://ec.europa.eu/jrc/sites/default/files/FinRep-FAD-2007-0004.pdf; https://ec.europa.eu/jrc/sites/default/files/FinRep-FAD-2005-0001.pdf; https://ec.europa.eu/jrc/sites/default/files/FinRep-FAD-2007-0013.pdf
3. Assesment

The additive Actisaf® Sc47 is a preparation consisting of dried cells of *S. cerevisiae* (CNCM I-4407) with no carriers, intended for use as a zootechnical additive in feed for lambs for fattening, dairy goats, dairy sheep, dairy buffaloes, pigs for fattening (gut flora stabiliser), and horses (digestibility enhancer). It is authorised at a minimum content of $1.4 \times 10^8$ CFU/Kg of complete feed for lambs for fattening, $7 \times 10^8$ CFU/Kg of complete feed for dairy goats and dairy sheep, $5 \times 10^8$ CFU/Kg of complete feed for dairy buffaloes, $8 \times 10^8$ CFU/kg of complete feed for horses and $1.25 \times 10^9$ CFU/Kg of complete feed for pigs for fattening. The additive is authorised with no maximum content.

3.1. Characterisation

3.1.1. Characterisation of the active agent

The *S. cerevisiae* strain of unknown origin is deposited at the Collection Nationale de Cultures de Microorganismes (CNCM, France) with the accession number CNCM I-4407.18 It has not been genetically modified.

Identification at the species level was achieved by sequence analysis of the D1/D2 region of the 26S rRNA gene.19 Strain level identification was based on Delta-polymerase chain reaction (PCR).20 Genetic stability was confirmed by pulse-field gel electrophoresis of three colonies obtained from cultures produced in 1990, 1999 and 2000, and by comparison of the Delta-PCR profiles of culture samples produced in 1999 and 2010.

3.1.2. Characterisation of the additive

The product is marketed in three forms: Actisaf® Sc47 standard, Actisaf® Sc47 powder and Actisaf® Sc47 HR. All of them were authorised with a declared minimum concentration of viable yeast cells in the additive of $5 \times 10^9$ CFU/g.

The applicant declared that additive has not been modified since the last authorisation and provided data from recent batches on the composition and purity. Compliance with specifications was confirmed by analysis of nine batches from 2015 (three of each form) (mean value of $1.0 \times 10^{10}$ CFU/g, range $= 0.8 \times 1.1 \times 10^{10}$ CFU/g, coefficient of variation CV $= 11\%$).21

The same batches were analysed for microbial contaminants. Results confirm compliance with limit levels (mesophilic bacteria $< 10^6$ CFU/g, total coliforms $< 100$ CFU/g, *Escherichia coli* $< 10$ CFU/g, *Staphylococcus aureus* absence in 1 g and *Salmonella* absence in 25 g). Compliance was further confirmed in three batches produced in 2016 (two of the standard form and one of the powder form).22

Five batches (three of the standard form and one of each of the others) produced in 2016 were analysed for chemical contaminants. Results confirm compliance with limit levels for heavy metals (cadmium $< 1$ mg/kg, mercury $< 0.1$ mg/kg, lead $< 5$ mg/kg), arsenic ($< 2$ mg/kg), fluorine ($< 150$ mg/kg) and aflatoxin B1 ($< 1 \mu$g/kg).23

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18 FAD-2015-0027 Technical dossier/Section II/Annex II -2-a; FAD-2016-0022 Technical dossier/Section II/Annex II-2-a; FAD-2016-0023 Technical dossier/Section II/Annex II -2-a; FAD-2017-0016 Technical dossier/Section II/Annex II -2-a.
19 FAD-2015-0027 Technical dossier/Supplementary information July 2017; FAD-2016-0022 Technical dossier/Supplementary information July 2017; FAD-2016-0023 Technical dossier/Supplementary information July 2017.
20 FAD-2016-0022 Technical dossier/Section II/Annex II-6-c; FAD-2016-0023 Technical dossier/Section II/Annex II-6-c; FAD-2017-0016 Technical dossier/Section II/Annex II-6-c.
21 FAD-2015-0027 Technical dossier/Section II/Annex II-1-b; FAD-2016-0022 Technical dossier/Section II/Annex II-1-b; FAD-2016-0023 Technical dossier/Section II/Annex II-1-b.
22 FAD-2017-0016 Technical dossier/Section II/Annex II-1-b.
23 FAD-2015-0027 Technical dossier/Supplementary information October 2016/Appendix II-1-b-bis; FAD-2015-0027 Technical dossier/Section II/Annex II-1-b.
3.1.3. Stability and homogeneity

Shelf life and stability of each form of the additive, and its capacity to be uniformly distributed in premixtures and feed for the target species were addressed in a previous opinion (EFSA FEEDAP Panel 2012a). The applicant provided new data on stability of the product in premixtures and feedingstuffs which supported previous conclusions.

3.1.4. Conditions of use

Actisaf® Sc47 is currently authorised at the minimum dose of:

- $1.4 \times 10^9$ CFU/kg of complete feed for lambs for fattening,
- $7 \times 10^8$ CFU/kg of complete feed for dairy goats and dairy sheep,
- $5 \times 10^8$ CFU/kg of complete feed for dairy buffaloes,
- $8 \times 10^8$ CFU/kg of complete feed for horses and
- $1.25 \times 10^9$ CFU/kg of complete feed for pigs for fattening.

The applicant proposes to maintain the same conditions of use.

3.2. Safety

The species *S. cerevisiae* is considered by EFSA to be suitable for the qualified presumption of safety (QPS) approach to establishing safety for the target species, consumers and the environment (EFSA, 2007c; EFSA BIOHAZ Panel, 2017). This approach requires the identity of the active agent to be established. In the view of the FEEDAP Panel, the identity of the strain *S. cerevisiae* (CNCM I-4407) was confirmed by sequence analysis of the 26S rRNA gene in the present assessment. Accordingly, this strain is considered by EFSA to be suitable for the QPS approach to safety and is presumed safe for the target species, consumers of products from animals fed the additive and the environment.

In a previous opinion (EFSA FEEDAP Panel, 2012a), Actisaf® Sc47 STD was found not to be a skin irritant. The FEEDAP Panel considered that the conclusion could be extrapolated to the other two forms of the additive. In the same opinion, the Panel concluded that given the absence of particles of inhalable size and the virtual absence of dust, exposure and therefore, toxicity and sensitisation via a respiratory route is not to be expected.

A new eye irritation study according to OECD 405 of Actisaf® Sc47 STD has been provided. Results showed slight redness and corneal opacity, reversible after 2 days. Therefore, the test item is considered non-irritant to the eyes. The result on the standard formulation can be extrapolated to the other formulations.

The applicant provided a certificate from the production plant medical doctors stating that no allergic reactions have occurred in workers and a summary record of users complaints from 2006, where no complaint on the safety of the product is observed.

The applicant also performed a literature search on the safety of *S. cerevisiae* using the following databases: BIOSIS Toxicology, CAB Abstracts, Current Contents, Embase, FSTA, Global Health, MEDLINE, RTECS and ToxFile. The search covered the period 2007-2016 and the search terms included *Saccharomyces cerevisiae*, and different sets of keywords relating to toxicity, cytotoxicity, genotoxicity, allergenicity, sensitisation and pathogenicity for humans and animals. The search did not reveal other publications than reports of occasional infections on immune suppressed patients (Annex A), which are well known and unrelated to the additive under assessment.

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24 FAD-2015-0027 Technical dossier/Section II/Annex II-4-d; FAD-2016-0022 Technical dossier/Section II/Annex II-4-d; FAD-2016-0023 Technical dossier/Section II/Annex II-4-d and FAD-2017-0016 Technical dossier/Section II/Annex II-4-d.

25 FAD-2015-0027 Technical dossier/Section II/Annex II-4-e; FAD-2016-0022 Technical dossier/Section II/Annex II-4-e; FAD-2016-0022 Technical dossier/Section II/Annex II-4-e and FAD-2017-0026 Technical dossier/Section II/Annex II-4-e.

26 FAD-2015-0027 Technical dossier/Supplementary information October 2016/Appendix III-1-c.

27 FAD-2015-0027 Technical dossier/Supplementary information October 2016/Appendix III-1-b.

28 FAD-2015-0027 Technical dossier/Supplementary information October 2016/Appendix III-1-d; FAD-2017-0016 Technical dossier/Supplementary information October 2016/Appendix III-1-a.

29 FAD-2015-0027 Technical dossier/Supplementary information October 2016/Appendix III-1-e; FAD-2017-0016 Technical dossier/Supplementary information October 2016/Appendix III-1-b.
Therefore, the FEEDAP Panel concludes that there is no new evidence that would lead it to reconsider previous conclusions that Actisaf® Sc47 is safe for the target species, consumers, users/workers and the environment under the authorised conditions of use.

3.3. 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\(^\text{30}\) and Good Manufacturing Practice.

4. Conclusions

The applicant has provided evidence that the additive currently on the market complies with the existing conditions of authorisation.

In previous opinions, Actisaf® Sc47 was presumed safe for the target species, consumers of products from animals fed the additive and the environment. Additionally, it was found not to be a skin or eye irritant.

No new evidence has been found that would make the panel reconsider the previous conclusions on the safety of the additive. Therefore, the Panel considers that the additive Actisaf® Sc47 remains safe under the approved conditions for lambs for fattening, minor dairy ruminants, horses and pigs for fattening, the consumer, user and the environment.

Documentation provided to EFSA

1) Actisaf Sc47 for lambs for fattening. April 2016. Submitted by Lesaffre Feed Additives.
2) Actisaf Sc47 lambs for fattening. Supplementary information. October 2016. Submitted by Lesaffre Feed Additives.
3) Actisaf Sc47 lambs for fattening. Supplementary information. July 2017. Submitted by Lesaffre Feed Additives.
4) Actisaf Sc47 for minor dairy ruminants. June 2016. Submitted by Lesaffre Feed Additives.
5) Actisaf Sc47 for minor dairy ruminants. Supplementary information. July 2017. Submitted by Lesaffre Feed Additives.
6) Actisaf Sc47 for horses. June 2016. Submitted by Lesaffre Feed Additives.
7) Actisaf Sc47 for horses. Supplementary information. July 2017. Submitted by Lesaffre Feed Additives.
8) Actisaf Sc47 for pigs for fattening. March 2017. Submitted by Lesaffre Feed Additives.
9) Comments from Member States.

Chronology EFSA-Q-2016-00090

| Date   | Event                                                                 |
|--------|-----------------------------------------------------------------------|
| 6/8/2015 | Dossier received by EFSA                                              |
| 25/8/2015 | Reception mandate from the European Commission                          |
| 11/4/2016 | Application validated by EFSA – Start of the scientific assessment       |
| 30/5/2016 | Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. Issues: characterisation, safety for target species, consumer, user and environment |
| 11/7/2016 | Comments received from Member States                                   |
| 11/7/2016 | Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives |
| 31/10/2016 | Reception of supplementary information from the applicant - Scientific assessment re-started |

\(^{30}\) 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.
Chronology EFSA-Q-2016-00297

Date | Event
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17/3/2016 | Dossier received by EFSA
14/6/2016 | Reception mandate from the European Commission
1/6/2016 | Application validated by EFSA – Start of the scientific assessment
18/5/2016 | Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. Issues: characterisation
1/9/2016 | Comments received from Member States
19/7/2017 | Reception of supplementary information from the applicant - Scientific assessment re-started
13/6/2018 | Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

Chronology EFSA-Q-2016-00292

Date | Event
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23/3/2016 | Dossier received by EFSA
14/4/2016 | Reception mandate from the European Commission
1/6/2016 | Application validated by EFSA – Start of the scientific assessment
18/5/2016 | Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. Issues: characterisation
1/9/2016 | Comments received from Member States
19/7/2016 | Reception of supplementary information from the applicant - Scientific assessment re-started
13/6/2018 | Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

Chronology EFSA-Q-2017-00286

Date | Event
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22/3/2017 | Dossier received by EFSA
11/4/2017 | Reception mandate from the European Commission
1/6/2017 | Application validated by EFSA – Start of the scientific assessment
1/9/2017 | Comments received from Member States
13/6/2018 | Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

References

EFSA (European Food Safety Authority), 2006a. Opinion of the Scientific Panel on additives and products or substances used in animal feed (FEEDAP) on the safety and efficacy of the product Biosaf Sc47, a preparation of Saccharomyces cerevisiae (NCYC Sc47), as a feed additive for lambs in accordance with Regulation (EC) No 1831/2003. EFSA Journal 2006;4(2):321, 1–8. https://doi.org/10.2903/j.efsa.2006.321

EFSA (European Food Safety Authority), 2006b. Scientific Opinion of the Panel on additives and products or substances used in animal feed (FEEDAP) on the safety and efficacy of the product Biosaf Sc47, a preparation of Saccharomyces cerevisiae, as a feed additive for dairy small ruminants. EFSA Journal 2006;4(7):379, 1–9. https://doi.org/10.2903/j.efsa.2006.379

EFSA (European Food Safety Authority), 2006c. Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the safety and efficacy of the product “Biosaf Sc 47”, a preparation of Saccharomyces cerevisiae, as a feed additive for horses. EFSA Journal, 2006;4(9):384, 1–9. https://doi.org/10.2903/j.efsa.2006.384
EFSA (European Food Safety Authority), 2007a. Scientific Opinion of the Scientific Panel on additives and products or substances used in animal feed (FEEDAP) on the safety and efficacy of Biosaf® Sc47, a preparation of Saccharomyces cerevisiae, as a feed additive for calves for rearing according to Regulation (EC) No 1831/2003. EFSA Journal 2007;5(6):459, 8 pp. https://doi.org/10.2903/j.efsa.2007.459

EFSA (European Food Safety Authority), 2007b. Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed on the safety and efficacy of Biosaf Sc47 (Saccharomyces cerevisiae) as feed additive for pigs for fattening. EFSA Journal 2007;5(12):585, 1–9. https://doi.org/10.2903/j.efsa.2007.585

EFSA (European Food Safety Authority), 2007c. 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

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Abbreviations

CFU colony forming unit
CNCM Collection Nationale de Cultures de Microorganismes
CV coefficient of variation
EURL European Union Reference Laboratory
FEEDAP EFSA Panel on Additives and Products or Substances used in Animal Feed
PCR polymerase chain reaction
QPS qualified presumption of safety
SCAN Scientific Committee on Animal Nutrition
Annex A – List of references retrieved from the literature search provided by the applicant to support safety of the additive

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