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Safety and efficacy of Actisaf® Sc47 (*Saccharomyces cerevisiae* CNCM I-4407) as a feed additive for cattle for fattening, dairy cows, weaned piglets and sows

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Abstract

Following a request from the European Commission, the EFSA 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 Actisaf® Sc47 for dairy cows, cattle for fattening, weaned piglets and sows when used as a zootechnical additive. Actisaf® Sc47 consists of viable cells of a strain *Saccharomyces cerevisiae* and is marketed in three formulations. The FEEDAP Panel considers that the three available formulations are equivalent when used to deliver the same dose of the microorganism in feed. The active agent fulfils the requirements of the qualified presumption of safety approach to the assessment of safety. Since the additive is composed of the active agent only, Actisaf® Sc47 is also presumed safe for the target animals, consumers of products derived from treated animals and the environment. Actisaf® Sc47 is not a skin irritant. In the absence of data, no conclusions can be drawn on the eye irritancy and dermal sensitisation potential of the additive. Inhalation exposure is unlikely. The additive has the potential to be efficacious in weaned piglets and sows to have benefits in piglets at the recommended dose of 5×10^9 CFU/kg feed. Insufficient evidence was provided to conclude on the efficacy of the additive in dairy cows and cattle for fattening.

Keywords: zootechnical additive, Actisaf® Sc47, *Saccharomyces cerevisiae* CNCM I-4407, dairy cows, cattle for fattening, piglets, sows

Requestor: European Commission

Question number: EFSA-Q-2016-00137

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1. Introduction

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

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 10(2) of that Regulation also specifies that for existing products within the meaning of Article 10(1), an application shall be submitted in accordance with Article 7, at the latest one year before the expiry date of the authorisation given pursuant to Directive 70/524/EEC for additives with a limited authorisation period, and within a maximum of seven years after the entry into force of this Regulation for additives authorised without a time limit or pursuant to Directive 82/471/EEC.

The European Commission received a request from Lesaffre Feed Additive[2] for re-evaluation of the product Actisaf® Sc47[3] (*Saccharomyces cerevisiae* CNCM I-4407),[4] when used as a feed additive for cattle for fattening, dairy cows, piglets (weaned) and sows (category: zootechnical additive; functional groups: 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 10(2) (re-evaluation of an authorised feed additive). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 11 April 2016.

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 3.1.3).

1.2. 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), 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).

[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] Lesaffre Feed Additive, a division of Société Industrielle Lesaffre, 137 Rue Gabriel Péri, 59700, Marcq en Baroeul, France.
[3] Previously marketed as Biosaf® Sc47.
[4] Previously identified as *Saccharomyces cerevisiae* NCYC Sc47.

The product is already authorised for use in cattle for fattening,[5] sows,[6] piglets,[7] dairy cows,[8] lambs for fattening,[9] dairy goats, dairy sheep,[10] horses,[11] pigs for fattening,[12] dairy buffaloes,[13] calves for rearing[14] and rabbits for fattening and non-food producing rabbits.[15]

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[16] in support of the authorisation request for the use of Actisaf Sc47 (*Saccharomyces cerevisiae* CNCM I-4407) as a feed additive.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the active agent in animal feed. The Executive Summary of the EURL report can be found in Annex A.[17]

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 429/2008[18] and the relevant guidance documents: Guidance on zootechnical additives (EFSA FEEDAP Panel, 2012b), Technical guidance: Tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011) and Guidance on studies concerning the safety of use of the additive for users/ workers (EFSA FEEDAP Panel, 2012c).

3. Assessment

The additive is a preparation consisting of dried cells of *Saccharomyces cerevisiae* CNCM I-4407 intended for use as a zootechnical additive (gut flora stabiliser) in feed for cattle for fattening, dairy cows, piglets (weaned) and sows.

[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] Commission 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 271, 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-2010-0264.

[17] The full report is available on the EURL website: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2010-0264?search&form-return

[18] 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.

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 (Paris, France) with the accession number CNCM I-4407.[19]

Identification at species level was achieved by sequence analysis of the D1/D2 region of the 26S rRNA gene.[20] Strain level identification was based on delta-polymerase chain reaction (PCR). 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.[20]

3.1.2. Manufacturing process and properties of the additive

[redacted] The final product consists of dry yeast cream without spent medium or carriers, and is marketed in three forms: Actisaf® Sc47 standard (STD), powder and heat resistant (HR+), all with a declared minimum concentration of viable yeast cells in the additive of 5×10^9 colony forming unit (CFU)/g. [redacted]

The analysis of 19 batches of an unspecified form of the additive produced between 2004 and 2009[22] and of more recent batches (from 2017 and 2018) of the powder and HR+ forms (five each)[23] showed that the minimum specifications were exceeded in all cases [redacted].

Each production batch is tested for microbiological purity. Specifications are set for total coliforms (< 100 CFU/g), *Escherichia coli* (< 10 CFU/g), *Staphylococcus aureus* (absence in 1 g) and *Salmonella* (absence in 25 g). Analyses of six batches of the STD form confirm compliance with these limits.[24]

Contamination with heavy metals is monitored once a year. Action limits are set for cadmium (< 1 mg/kg), mercury (< 0.1 mg/kg), lead (< 5 mg/kg) and arsenic (< 2 mg/kg). Compliance with these limits was confirmed by the analysis of seven batches of a non-identified form produced from 2003 to 2009 (for heavy metals and arsenic) and of three batches of the STD and HR+ forms each.[24]

The particle size distribution of one batch of the STD form tested by mechanical sieving showed a mean particle size of 988 μm and no particles with a diameter smaller than 80 μm.[25] The same test of four batches of the HR+ form showed a mean particle size of 900 μm and less than 0.1% of particles with diameter smaller than 125 μm. One batch of the powder form showed a mean particle size of 305 μm with 9.1% of the particles with diameter smaller than 125 μm and 0.3% smaller than 80 μm.

The dusting potential of one batch of each form, tested using the Stauber–Heubach dustometer, gave values of [redacted]

3.1.3. Stability and homogeneity

The viability of *S. cerevisiae* CNCM I-4407 was measured in three batches of the STD form in its commercial packaging (vacuum-sealed bags) at 26 °C for up to 2 years.[27] Counts remained within the specifications after this period ($7.0–8.5 \times 10^9$ CFU/g), although initial counts exceeded specifications ($9–11 \times 10^9$ CFU/g) but were in line with those seen in the batch to batch analyses (see Section 3.1.2). A second study was made to investigate the effect of the exposure to air on the stability of the standard form. One batch of the additive was stored in commercial bags (under

[19] Technical dossier/Supplementary information June 2018/Annexes II-2-a.
[20] Technical dossier/Supplementary information June 2018/Annexes II-2-b.
[redacted]
[22] Technical dossier/Supplementary information June 2018/Annexes II-4-l.
[23] Technical dossier/Supplementary information June 2018/Annexes II-4-m.
[24] Technical dossier/Section II/Annex II-1-b.
[25] Technical dossier/Section II/Annex II_1-c.
[redacted]
[27] Technical dossier/Section II/Annex II-4-a.

vacuum) or in flasks (with air), at 4, 20 and 30°C for up to 1 year. Although initial counts were not reported, results showed negligible losses (< 0.5 Log) in all cases. Samples with and without air behaved similarly.

The stability of HR+ (two batches) was measured when stored in its commercial packaging at 25°C for 1 year and at room temperature (ca 20°C) for 14 months.[28] Counts remained within specifications (losses < 0.5 log) in all cases.

The stability of the powder form was studied in three batches stored in commercial bags, at 25°C and at 30°C for up to 18 months. Negligible losses (< 0.5 log) were observed after this period.

The stability of the three forms of the additive (two batches each) mixed with a mineral/vitamin premixture for sows[29] (incorporated at 20%) and for dairy cows[30] (two batches, additive incorporated at 1%) was investigated when stored at room temperature (approx. 28°C) for nine months. No viability losses were observed after this period.

Resistance to pelleting was studied in two batches of STD in feeds for dairy cows, pigs and chickens (intended concentration 8×10^9 CFU/kg feed).[31] Counts made after the pelleting process up to 83 °C showed no losses of viability (< 0.5 log CFU/g) in all cases. In a second study, resistance to pelleting of STD (four batches) and HR+ (five batches) were investigated in feeds for several target animals, including pigs and dairy and growing ruminants (intended concentration 1×10^{10} CFU/kg feed).[31] Enumeration of the yeasts cells made after pelleting process up to 92 °C confirmed the results described above for STD and showed negligible losses (< 0.5 log CFU/g) for HR+.

In a first study, the stability of three batches of the additive (unspecified form) was measured when mixed with two feeds for pigs (one based on wheat and corn, the other on extruded cereals and bakery by-product, concentration 9–13 $\times 10^9$ CFU/kg feed) and stored at ± 20°C for 3 months.[32] In a second study, three batches of each form of the additive were mixed at the proposed inclusion level with feed for piglets (based on wheat and barley, concentration 3–15 $\times 10^9$ CFU/kg feed) and stored under the same conditions for three months. No viability losses (< 0.5 log) were observed at the end of this period in any of the cases.

The stability of an unspecified form of the additive was studied in dairy cattle protein concentrate (mash and pelleted, declared inclusion level 2×10^{10} CFU/kg), stored in plastic sachets at room temperature for 3 months.[33] No viability losses were observed (< 0.5 log) in any case. In another study, the three forms of the additive were mixed with a ruminant feed (inclusion level 1–4 $\times 10^{10}$ CFU/kg) and stored for 3 months at room temperature. No viability losses (< 0.5 log) were observed after this period.

The ability of the powder form of the additive (two batches) to homogeneously disperse in mash feed for piglets (inclusion 0.1%) was tested in a study.[34] Analyses of cell counts of 10 subsamples showed coefficient of variation (CV) of 14%. A second study investigated the capacity of HR+ (three batches) to homogeneously mix with a protein concentrate for dairy animals in mash and pelleted form (inclusion level 2×10^{10} CFU/kg), and with a feed for the same target animals consisting of wheat, soybean meal and rapeseed meal (inclusion level not specified). Analysis of 10 subsamples in each case showed a CV of 23% for the mash feed, of 45% for the pelleted feed and of 29% in the third feed.[35,36] The Panel notes that the HR+ form showed low capacity to homogeneously mix with feedingstuffs.

3.1.4. Conditions of use

Actisaf® Sc47 is intended for use in feed for cattle for fattening at 4×10^9 CFU/kg feed, for dairy cows at 4×10^8 CFU/kg of complete feed, and for sows and weaned piglets at 5×10^9 CFU/kg feed.

[28] Technical dossier/Section II/Annex II-4-b.
[29] Technical dossier/Section II/Annex II-4-d.
[30] Technical dossier/Section II/Annex II-4-e.
[31] Technical dossier/Section II/Annex II-4-c.
[32] Technical dossier/Section II/Annex II-4-f.
[33] Technical dossier/Section II/Annex II-4-g.
[34] Technical dossier/Section II/Annex II-4-i.
[35] Technical dossier/Section II/Annex II-4-j.
[36] Technical dossier/Supplementary information June 2018.

3.2. Safety

3.2.1. Safety for the target species, consumers and the environment

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, accordingly, this strain is presumed safe for the target species, consumers of products from animals fed the additive and the environment. Since the additive is composed of only the active agent, also Actisaf® Sc47 is presumed safe for the target species, consumers of products from animals fed the additive and the environment.

3.2.2. Safety for the user

No specific studies on inhalation toxicity were submitted. Although the active agent, owing to its proteinaceous nature, is considered to be a potential respiratory sensitiser, since the dusting potential of the three forms measured is low, the exposure of users is considered unlikely.

An acute skin irritation study was performed with three New Zealand rabbits according to OECD Guideline 404.[37] Under the experimental conditions Actisaf® Sc47 STD was found to be non-irritant. Since the three forms of the additive have the same composition, the conclusion can be considered valid also for the other two forms of the additive (powder and HR+).

In the absence of data, no conclusions can be drawn on the eye irritancy and dermal sensitisation potential of the additive.

3.2.2.1. Conclusions on safety for the user

Actisaf® Sc47 is not a skin irritant. In the absence of data, no conclusions can be drawn on the eye irritancy and dermal sensitisation potential of the additive. Inhalation exposure is unlikely.

3.3. Efficacy

All the studies provided have been conducted with Actisaf® Sc47 STD. The Panel considers that the results obtained from studies made with this formulation of the additive can be extrapolated to the other forms.

3.3.1. Efficacy for cattle for fattening

Three studies were performed in two European countries aiming to demonstrate the efficacy of Actisaf® Sc47 on cattle performance. However, none could be further considered due to flaws in the experimental design. [redacted]

3.3.1.1. Conclusions on efficacy for cattle for fattening

There is no evidence to conclude on the efficacy of Actisaf® Sc47 in cattle for fattening.

3.3.2. Efficacy for dairy cows

Four trials were performed in two different Member States aiming to demonstrate the efficacy of Actisaf® Sc47 on dairy cows. However, one[41] was not considered due to lack of replication and due to a bias introduced in the study [redacted]

[37] Technical dossier/Supplementary information June 2018/Annex III-3-a.

[redacted]

[41] Technical dossier/Section IV/Annex IV2.2.

[redacted]. A second study[42] could not be further considered due to lack of replication. [redacted]

The milk yield of the treated group was significantly greater than that of the control group (43.5 kg vs 41.9 kg, $p < 0.05$). Feed intake and milk composition (fat (3.2% vs 3.5%) or protein (3% in both cases) content) were not influenced by treatment.

[redacted]

The milk yield of the treated group was significantly greater than that of the control group (35.8 kg vs 34.3 kg, $p < 0.10$). Feed intake and milk composition (fat (4.1% in both cases) or protein (3.3% in both cases) content) were not influenced by treatment.

3.3.2.1. Conclusions on efficacy dairy cows

As Actisaf® Sc47 only showed positive effects on the performance of dairy cows in two studies, the Panel cannot conclude on the efficacy of Actisaf® Sc47 for this target species.

3.3.3. Efficacy for piglets

Four trials were performed in two different Member States aiming to demonstrate the efficacy of Actisaf® Sc47 on weaned piglets' performance. However, one[46] could not be considered because of extensive veterinary interventions throughout the trial denoting poor health of animals. [redacted]

[42] Technical dossier/Section IV/Annex IV-2-1, Supplementary information June 2018/Annex_IV-2-1-C.

[redacted]

[46] Technical dossier/Section IV/Annex IV_3_1.

[redacted]

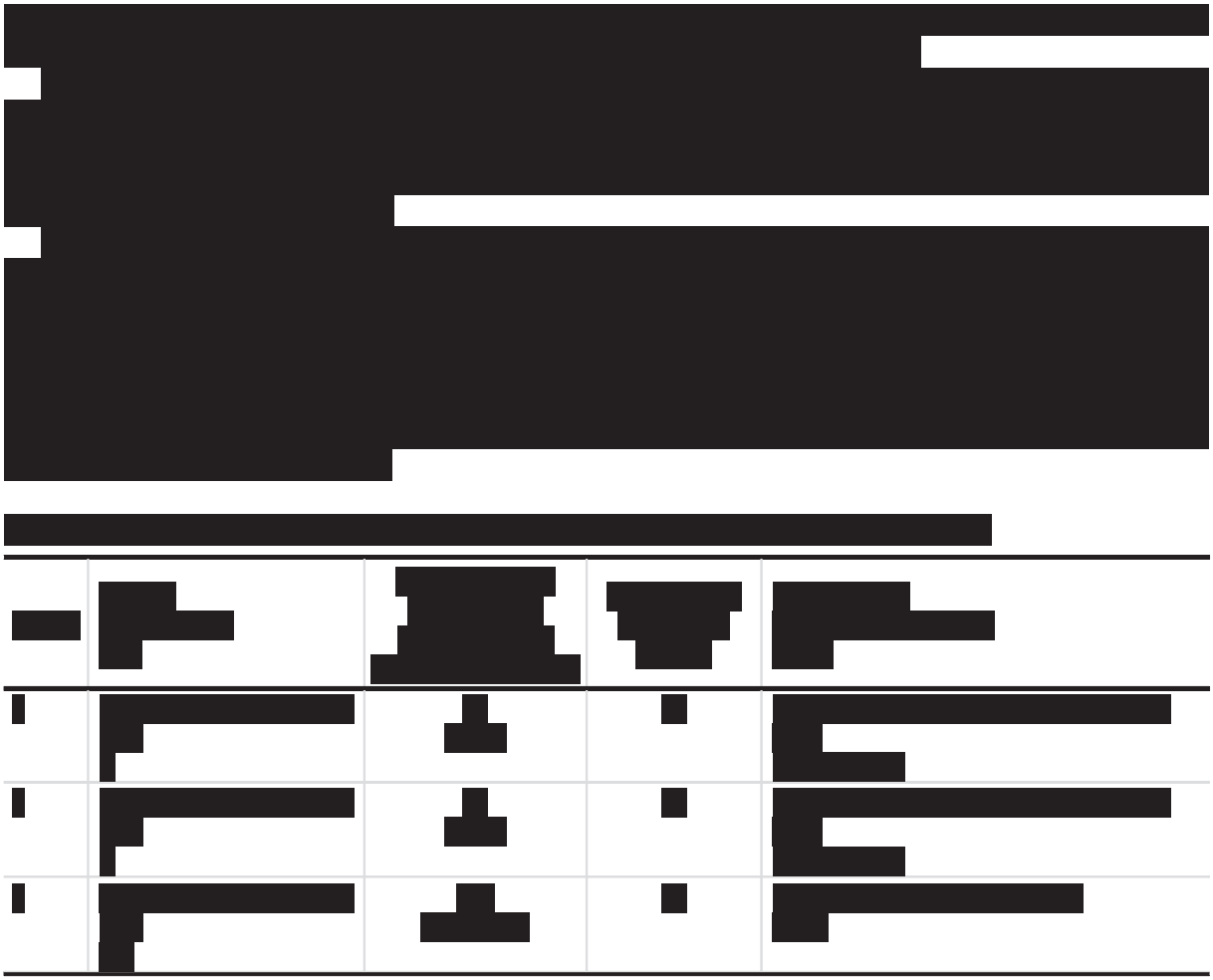

Table 2: Effect of Actisaf Sc47® on the performance of weaned piglets

Study	Actisaf® Sc47 (CFU/kg feed)	Initial weight (kg)(1)	Final body weight (kg)	Weight gain (kg)(2)	Feed intake (kg)(3)	Feed to gain ratio	Mortality (n)
1	0	11.3	32.0	20.7[a]	38.4	1.91[b]	0
	5×10^9	11.9	35.1	23.2[b]	38.9	1.71[a]	0
2	0	11.2	27.5	16.2[a]	34.8	2.16[b]	0
	5×10^9	11.3	30.0	18.6[b]	35.0	1.89[a]	0
3	0	7.2	23.3	0.385	504.8	1.73[b]	3
	5×10^9	7.2	24.6	0.414	515.5	1.66[a]	1

CFU: colony forming unit.
a,b: Values within a column for a given study with different superscript are significantly different ($p < 0.05$).
(1): The Panel notes that weight of piglets at the start of the trials 1 and 2 is higher than expected for piglets of that age.
(2): Total weight gain in studies 1 and 2 and daily weight gain in study 3.
(3): Per pen in study 3.

Supplementation of the additive led to a significantly greater weight gain in two trials (1 and 2) and a significantly improved feed to gain ratio in the three studies considered.

3.3.3.1. Conclusions on efficacy for weaned piglets

Actisaf® Sc47 at the recommended level of 5×10^9 CFU/kg complete feed has the potential to improve the performance of weaned piglets.

3.3.4. Efficacy for sows

Four studies were performed in three different Member States aiming to demonstrate the efficacy of Actisaf Sc47 supplemented to sows to have effects on the offspring and/or the reproductive performance of sows. However, one[51] was not considered due to a very high mortality in piglets (at least 29% in the control and 19% in the Actisaf® SC 47 group) and low growth, denoting poor health.

[redacted]

[51] Technical dossier/Section IV/Annex IV_4_4.

[redacted]

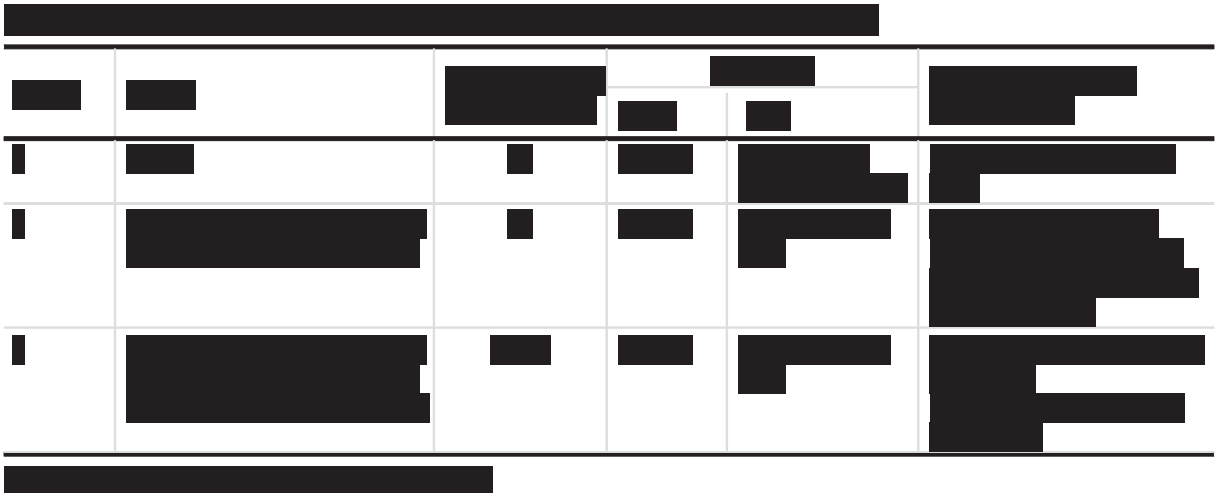

Table 4: Effects of Actisaf® Sc47 on the feed intake of sows during lactation and on the performance of suckling piglets

Study no	Actisaf (CFU/kg feed)	Sow's feed intake in lactation (kg/day)	Litter size (n)			Initial litter weight (kg)	Average litter daily weight gain (kg/day)	Litter weight at weaning (kg)	Piglets weight at weaning (kg)
			Born alive	Alive after 48 h	Final				
1(1)	0	n.r.	12.0	11.3	10.5	20.6	2.0[a]	68.0	6.5[a]
	5×10^9		11.6	11.2	11.1	22.7	2.3[b]	77.7	7.0[b]
2	0	6.8	13.4	11.7	10.2	16.0	2.3	66.0	6.4[a]
	5×10^9	7.1	12.7	12.3	10.8	18.5	2.6	75.4	6.9[b]
3	0	5.8	10.7	10.6	10.1	15.8	2.4[a]	76.8[a]	7.5[a]
	5×10^9	6.2	12.5	11.8	10.9	17.5	2.7[b]	89.4[b]	8.2[b]

CFU: colony forming unit; n.r.: not reported.
a,b: Values within a column for a given study with different superscript are significantly different ($p < 0.05$).
(1): Mean values of two consecutive cycles.

Mortality of piglets was not treatment-related. Supplementation of the additive to the sow led to a significantly greater weight of piglets at weaning in the three studies considered.

3.3.4.1. Conclusions on efficacy for sows

Actisaf® Sc47 at the recommended dose has the potential to improve the performance of the suckling piglets from sows receiving the additive over at least one reproductive cycle.

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[55] and Good Manufacturing Practice.

5. Conclusions

The identity of the strain present in the additive was established as *S. cerevisiae*. Accordingly, this strain is considered 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. Since the additive is composed of the active agent only, Actisaf® Sc47 is also considered safe for target animals, consumers of products from treated animals and the environment.

Actisaf® Sc47 is not a skin irritant. In the absence of data, no conclusions can be drawn on the eye irritancy and dermal sensitisation potential of the additive. Inhalation exposure is unlikely.

[55] 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.

The additive has the potential to be efficacious in weaned piglets and sows to have benefits in piglets at the recommended level of 5×10^9 CFU/kg feed. Insufficient evidence was provided to conclude on the efficacy of the additive in dairy cows and cattle for fattening. The different forms of the additive are considered to be equivalent when used to deliver the same dose.

Documentation provided to EFSA

1) Actisaf Sc47 cattle for fattening, dairy cows, weaned piglets and sows. November 2011. Submitted by Lesaffre Feed Additives.
2) Actisaf Sc47 for cattle for fattening, dairy cows, weaned piglets and sows. Supplementary information. June 2018. Submitted by Lesaffre Feed Additives.
3) Actisaf Sc47 for cattle for fattening, dairy cows, weaned piglets and sows. Supplementary information. September 2018. Submitted by Lesaffre Feed Additives.
4) Evaluation report of the European Union Reference Laboratory for Feed Additives on the Methods(s) of Analysis for Actisaf Sc47.
5) Comments from Member States.

Chronology

Date	Event
3/11/2010	Dossier received by EFSA
10/9/2015	Reception mandate from the European Commission
11/4/2016	Application validated by EFSA – Start of the scientific assessment
23/5/2016	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 the user and efficacy*
3/7/2018	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended *Issues: Efficacy*
8/7/2016	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives
11/7/2016	Comments received from Member States
25/9/2018	Reception of supplementary information from the applicant - Scientific assessment re-started
22/10/2018	Reception of clarifications on supplementary information submitted on 25/09/2018 from applicant. Received by email
22/1/2019	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

bw	body weight
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
RH	relative humidity
SCAN	Scientific Committee on Animal Nutrition

Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method of Actisaf® Sc47

In the current application, authorisation is sought under Article 10 (2) for *Actisaf® Sc47* under the category/functional group 4(b) 'zootechnical additives'/'gut flora stabilisers', according to Annex I of Regulation (EC) No 1831/2003. Authorisation is sought for the use of the *feed additive* for weaned piglets, sows, dairy cows and cattle for fattening.

According to the Applicant, the *feed additive* contains as active substance viable cells of the non-genetically modified strain *Saccharomyces cerevisiae* NCYC Sc47. The *feed additive* is marketed in powder form containing a minimum *Saccharomyces cerevisiae* NCYC Sc47 concentration of 5×10^9 Colony Forming Unit (CFU)/g. The *feed additive* is to be used directly in *feedingstuffs* or through *premixtures* at minimum doses ranging from 4×10^8 to 5×10^9 CFU/kg complete feedingstuffs, depending on the animal species of concern.

For the identification of *Saccharomyces cerevisiae* NCYC Sc47, the EURL recommends for official control Polymerase Chain Reaction (PCR), a generally recognised standard methodology for genetic identification of yeasts.

For the enumeration of *Saccharomyces cerevisiae* NCYC Sc47 in *feed additive, premixtures* and *feedingstuffs*, the Applicant submitted the ring-trial validated pour plate method EN 15789. Based on the performance characteristics available, the EURL recommends this method for official control.

Further testing or validation of the methods to be performed through the consortium of National Reference Laboratories as specified by Article 10 (Commission Regulation (EC) No 378/2005) is not considered necessary.