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Assessment of the application for renewal of the authorisation of Actisaf® Sc 47 (*Saccharomyces cerevisiae* CNCM I-4407) as a feed additive for calves for rearing

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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 assessment of the application for renewal of authorisation of Actisaf® Sc 47 (*Saccharomyces cerevisiae* CNCM I-4407) as a zootechnical additive for calves for rearing. The applicant has provided evidence that the additive currently in the market complies with the existing conditions of authorisation. There is no new evidence that would lead the FEEDAP Panel to reconsider its previous conclusions. Thus, the Panel concludes that the additive remains safe for calves for rearing, consumers and the environment under the authorised conditions of use. The additive is not a skin or eye irritant. In the absence of data, no conclusions can be drawn on the dermal sensitisation potential of the additive. Inhalation exposure is unlikely. The present application for renewal of the authorisation did not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive. Therefore, there was no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

Keywords: zootechnical additive, Actisaf® Sc47, *Saccharomyces cerevisiae* CNCM I-4407, calves for rearing, safety

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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 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 a request from Phileo-Division of S.I. Lesaffre[2] for renewal of the authorisation of the product Actisaf® Sc 47[3] (*Saccharomyces cerevisiae* CNCM I-4407),[4] when used as a feed additive for calves for rearing (category: zootechnical additives; functional group: gut flora stabilisers).

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 14(1) (renewal of the authorisation). The particulars and documents in support of the application were considered valid by EFSA as of 6 January 2020.

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® Sc 47 (*S. cerevisiae* CNCM I-4407) when used under the proposed conditions of use (see Section 3.1.3).

1.2. Additional information

The additive Actisaf® Sc 47 is a preparation of yeast cells of *S. cerevisiae* CNCM I-4407.

EFSA has issued several opinions on the safety and efficacy of this additive for the following species: lambs for fattening (EFSA, 2006a; EFSA FEEDAP Panel, 2018a, 2019), dairy small ruminants (EFSA, 2006b; EFSA FEEDAP Panel, 2018a, 2019), horses (EFSA, 2006c; EFSA FEEDAP Panel, 2018a, 2019), calves for rearing (EFSA, 2007a; EFSA, 2010), pigs for fattening (EFSA, 2007b; EFSA FEEDAP Panel, 2018a, 2019), dairy buffaloes (EFSA, 2008; EFSA FEEDAP Panel, 2018b), rabbits for fattening and non-food producing rabbits (EFSA FEEDAP Panel, 2012), and cattle for fattening, dairy cows, piglets (weaned) and sows (EFSA FEEDAP Panel, 2019).

The product is authorised to be used in feed for cattle for fattening,[5] sows, piglets and dairy cows,[6] calves for rearing,[7] rabbits for fattening, non-food producing rabbits,[8] lambs for fattening, dairy goats, dairy sheep, dairy buffaloes, horses and pigs for fattening.[9]

The applicant has requested the renewal of the authorisation of the additive for calves for rearing.

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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, Rue Gabriel Péri-137-BP 3029, 59700, Mareq en Baroeul, France.

[3] Former trade name: Biosaf® Sc 47.

[4] Previously identified as *Saccharomyces cerevisiae* NCYC Sc47.

[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 Implementing Regulation (EU) 2020/147 of 3 February 2020 concerning the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-4407 as a feed additive for weaned piglets, sows (in order to have a benefit for suckling piglets) and dairy cows and amending Regulation (EC) No 2148/2004, (EC) No 1288/2004 and (EC) No 1811/2005 (holder of authorization S.I. Lesaffre). OJ L 31, 4.2.2020, p. 7.

[7] 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 L265, 8.10.2010, p. 1.

[8] 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.

[9] Commission Implementing Regulation (EC) No 2019/899 of 29 May 2019 concerning the renewal of the authorisation of *Saccharomyces cerevisiae* CNCM I-4407 as a feed additive for lambs for fattening, dairy goats, dairy sheep, dairy buffaloes, horses and pigs for fattening and repealing Regulations (EC) No 1447/2006, (EC) No 188/2007, (EC) No 232/2009, (EC) No 186/2007 and (EC) No 209/2008 (holder of authorization S.I. Lesaffre). OJ L 144, 3.6.2019, p. 32.

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[10] in support of the authorisation request for the use of Actisaf® Sc 47 as a feed additive.

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 assessment regarding the methods used for the control of the active agent in animal feed are valid and applicable for the current application.[11]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety of Actisaf® Sc 47 is in line with the principles laid down in Regulation (EC) No 429/2008[12] and the relevant guidance documents: Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2013) and Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018b).

3. Assessment

The additive Actisaf® Sc 47 (*S. cerevisiae* CNCM I-4407) is currently authorised as a zootechnical additive (functional group: gut flora stabiliser) for calves for rearing at a minimum level of 1.5×10^9 colony forming units (CFU)/kg complete feedingstuff. The applicant is requesting the renewal of the authorisation of the feed additive for calves for rearing.

3.1. Characterisation

3.1.1. Characterisation of the additive

The additive is a preparation consisting of dried cells of *S. cerevisiae* CNCM I-4407 with no carriers and is marketed in three forms: Actisaf® Sc 47 standard (STD), powder (PWD) and heat resistant (HR+). The applicant stated that no changes in the manufacturing process or composition of the additive have been introduced since the last authorisation. The analysis of 12 recent batches in total (four batches for each formulation) (STD form with mean count 1.4×10^{10} CFU/g (range $1.3–1.5 \times 10^{10}$ CFU/g), PWD form with mean count 1.1×10^{10} CFU/g (range $1.0–1.4 \times 10^{10}$ CFU/g) and HR+ form with mean count 1.0×10^{10} CFU/g (range $1.0–1.1 \times 10^{10}$ CFU/g)) showed compliance with the specifications of the additive in the authorising Regulation(s) (minimum concentration of viable yeast cells in the additive of 5×10^9 CFU/g).[13,14]

Action limits are set for 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 μg/kg). Seven batches (two batches of the STD and PWD forms and three batches of the HR+ form) were analysed for chemical and microbiological contamination.[15] The results showed that lead, mercury and arsenic were below their corresponding limits of quantification (LOQs) in all batches tested (except for one batch of the HR+ form, arsenic was 0.1 mg/kg), and cadmium ranged from 0.02 to 0.08 mg/kg. Fluorine was also below the LOQ.[16] Aflatoxins B1, B2, G1 and G2 were below their LOQs.[17]

[10] FEED dossier reference: FAD-2019-0065.
[11] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2010-0038.pdf
[12] 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.
[13] Technical dossier/Section II/Annexes_Sect. II/Annex_II_1_b.
[14] Technical dossier/Supplementary information March 2020/FAD-2019-0065_SIn_060220/Answer EFSA-Q-2019-00740_FAD-2019-0065.
[15] Technical dossier/Section II/Annexes_Sect. II/Annex_II_1_c, Annex_II_1_d and Annex_II_1_e.
[16] Technical dossier/Section II/Annexes_Sect. II/Annex II_1_d. Limit of quantification in mg/kg were 0.05 for lead, 0.005 for mercury, 0.1 for arsenic and 20 for fluorine.
[17] Technical dossier/Section II/Annexes_Sect. II/Annex II_1_e. LOQ in μg/kg were 0.1 for aflatoxins B1, B2 and G1; and 0.2 for aflatoxin G2.

Specifications are set for total coliforms (< 10^2 CFU/g), *Escherichia coli* (< 10 CFU/g), *Staphylococcus* coagulase positive (absence in 1 g) and *Salmonella* (absence in 25 g). Analysis of the above-mentioned seven batches confirmed compliance with these limit levels.

The average bulk density and average tap density of the additive measured in three recent batches of each form were respectively: 790 and 870 kg/m^3 for the STD form, 799 and 891 kg/m^3 for the PWD form and 782 and 876 kg/m^3 for the HR+ form.[18]

Nine recent batches of the additive (three for each form) were analysed for particle size distribution by a sieve shaker.[19] No particles below 125 μm were identified. In six recent batches (one batch of the STD form, three batches of the PWD form, and two batches of the HR+ form) the dusting potential measured according to Stauber–Heubach gave values of 0.025 g/m^3 (STD); 0.000–0.045 g/m^3 (PWD); 0.000 and 0.065 g/m^3 (HR+).[20]

3.1.2. Characterisation of the active agent

The *S. cerevisiae* strain of unknown origin is deposited at the Collection Nationale de Cultures de Micro-organismes (CNCM) with the accession number CNCM I-4407.[21]

A bioinformatic analysis of the whole genome sequence (WGS) of the production strain, CNCM I-4407, confirmed its identity as *S. cerevisiae*.[22] [redacted][23]

3.1.3. Conditions of use

Actisaf® Sc 47 is currently authorised at the minimum level of 1.5 × 10^9 CFU/kg of complete feedingstuff for calves for rearing. The applicant proposes to maintain the same conditions of use.

3.2. Safety

Saccharomyces cerevisiae is considered by EFSA to be suitable for the qualified presumption of safety (QPS) approach to safety assessment (EFSA, 2007c; EFSA BIOHAZ Panel, 2020). Since the identity of the active agent was established and the additive essentially consists of only the active agent, safety for the target species, consumers of products from animals fed the additive and the environment was presumed in a previous assessment (EFSA, 2007b). In the present application, the applicant has provided up to date confirmation of the taxonomic identification of the strain as *S. cerevisiae*. Consequently, the additive can be presumed as safe for the target species, the consumers and the environment.

The safety for the user was evaluated by EFSA FEEDAP Panel in previous assessments (EFSA FEEDAP Panel, 2012, 2018a, 2019). The FEEDAP Panel concluded that Actisaf® Sc 47 in any form was not a skin or eye irritant and, in the absence of data, no conclusions could be drawn on the dermal sensitisation potential of the additive. Moreover, the Panel concluded that given the proteinaceous nature of the active agent it is considered a respiratory sensitiser. However, given the low dusting potential the exposure of users by inhalation is unlikely.

The applicant provided a certificate from the production plant medical doctors stating that no skin sensitisation has occurred in workers[24] and a summary record of users' complaints from 2006, where no complaint on the safety of the product is observed.[25]

A literature search on the safety of the product covering the period 2007-2016 was evaluated by EFSA FEEDAP Panel in a previous assessment (EFSA FEEDAP Panel, 2018a). It did not reveal any safety issue related to the additive under assessment. The applicant performed a new literature search, covering the period 2016–2019 and using the following databases: BIOSIS Toxicology, CAB Abstracts, Current Contents Search, Embase, FSTA, Global Health, Medline, Registry of Toxic Effects of

[18] Technical dossier/Section II/Annexes_Sect. II/Annex_II_1_g.
[19] Technical dossier/Section II/Annexes_Sect. II/Annex_II_1_f.
[20] Technical dossier/Section II/Annexes_Sect. II/Annex_II_1_h.
[21] Technical dossier/Section II/Annexes_Sect. II/Annex_II_2_a.
[22] Technical dossier/Section II/Annexes_Sect. II/Annex_II_2_b.
[23] Technical dossier/Supplementary information March 2020/FAD-2019-0065_SIn_060220/Appendices_CONFIDENTIAL/Appendix_I_1 and Appendix_I_2.
[24] Technical dossier/Section III/Annexes_Sect. III/Annex_III_1_a.
[25] Technical dossier/Section III/Annexes_Sect. III/Annex_III_5_a.

Chemical Substances (RTECS) and ToxFile.[26] It included *S. cerevisiae* and other terms relevant for target species safety and for toxicological aspects. This new search retrieved eight publications and seven of them were excluded from the assessment because referred to previous EFSA FEEDAP opinions regarding other *S. cerevisiae* based products. One publication referred to reported cases of human infections by *S. cerevisiae* mainly on immune suppressed patients, which are well known and unrelated to the additive under assessment (Costa et al., 2018).

Therefore, the FEEDAP Panel concludes that there is no new evidence that would lead it to reconsider previous conclusions that Actisaf® Sc 47 is safe for the target species, consumers and the environment under the authorised conditions of use. Regarding user safety Actisaf® Sc47 in any form is not a skin or eye irritant and, in the absence of data, no conclusions can be drawn on the dermal sensitisation potential of the additive. Inhalation exposure is unlikely.

3.3. Efficacy

The present application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive. Therefore, there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

3.4. 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[27] and Good Manufacturing Practice.

4. Conclusions

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

There is no new evidence that would lead the FEEDAP Panel to reconsider its previous conclusions. Thus, the Panel concludes that the additive remains safe for calves for rearing, consumer and the environment under the authorised conditions of use. Regarding user safety Actisaf® Sc47 in any form is not a skin or eye irritant and, in the absence of data, no conclusions can be drawn on the dermal sensitisation potential of the additive. Inhalation exposure is unlikely.

There is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

5. Documentation as provided to EFSA/Chronology

Date	Event
17/10/2019	Dossier received by EFSA. Actisaf® Sc 47 (*Saccharomyces cerevisiae* CNCM I-4407) for calves for rearing. Submitted by Phileo - Division of S. I. LESAFFRE.
13/11/2019	Reception mandate from the European Commission
06/01/2020	Application validated by EFSA – Start of the scientific assessment
06/02/2020	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*
06/03/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
06/04/2020	Comments received from Member States
25/05/2020	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

References

Costa RL, Moreira J, Lorenzo A and Lamas CC, 2018. Infectious complications following probiotic ingestion: a potentially underestimated problem? A systemic review of reports and case series. BMC Complementary Alternative Medicine, 18.

[26] Technical dossier/Section III/Annexes_Sect. III/Annex_III_6_a.

[27] 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), 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 Sc 47), as a feed additive for lambs in accordance with Regulation (EC) No1831/2003. EFSA Journal 2006;4(2):321, 8 pp. 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, 9 pp. 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 Sc47", a preparation of *Saccharomyces cerevisiae*, as a feed additive for horses. EFSA Journal 2006;4(9):384, 9 pp. 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, 9 pp. https://doi.org/10.2903/j.efsa.2007.585

EFSA (European Food Safety Authority), 2007c. 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. EFSA Journal 2007;5(12):587, 16 pp. https://doi.org/10.2903/j.efsa.2007.587

EFSA (European Food Safety Authority), 2008. 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* NCYC Sc 47) as a feed additive for dairy buffaloes. EFSA Journal 2008;6(10):837, 10 pp. https://doi.org/10.2903/j.efsa.2008.837

EFSA (European Food Safety Authority), 2010. EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP). Scientific Opinion on the efficacy of Biosaf Sc47 (Saccharomyces cerevisiae) for calves for rearing. EFSA Journal 2010;8(4):1576, 5 pp. https://doi.org/10.2903/j.efsa.2010.1576

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Koutsoumanis K, Allende A, Alvarez-Ordóñez A, Bolton D, Bover-Cid S, Chemaly M, Davies R, De Cesare A, Hilbert F, Lindqvist R, Nauta M, Peixe L, Ru G, Simmons M, Skandamis P, Suffredini E, Cocconcelli PS, Fernández Escámez PS, Maradona MP, Querol A, Suarez JE, Sundh I, Vlak J, Barizzone F, Correia S and Herman L, 2020. Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA (2017–2019). EFSA Journal 2020;18(2):5966, 56 pp. https://doi.org/10.2903/j.efsa.2020.5966

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012. Scientific Opinion on the safety and efficacy of Actisaf Sc47 (*Saccharomyces cerevisiae*) as a feed additive for rabbits for fattening and non food-producing rabbits. EFSA Journal 2012;10(1):2531, 12 pp. https://doi.org/10.2903/j.efsa.2012.2531

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2013. Guidance on the renewal of the authorisation of feed additives. EFSA Journal 2013;11(10):3431, 8 pp. https://doi.org/10.2903/j.efsa.2013.3431

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López-Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Villa RE, Wallace RJ, Wester P, Aguilera J, Brozzi R and Saarela M, 2018a. Scientific Opinion on the 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. EFSA Journal 2018;16(7):5339, 11 pp. https://doi.org/10.2903/j.efsa.2018.5339

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López-Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Glandorf B, Herman L, Kärenlampi S, Aguilera J, Anguita M, Brozzi R and Galobart J, 2018b. Guidance on the characterisation of microorganisms used as feed additives or as production organisms. EFSA Journal 2018;16(3):5206, 24 pp. https://doi.org/10.2903/j.efsa.2018.5206

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis V, Azimonti G, Bastos ML, Christensen H, Dusemund B, Kouba M, Kos Durjava M, López-Alonso M, López Puente S, Marcon F, Mayo B, Pechová A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Chesson A, Cocconcelli PS, Rychen G, Wallace RJ, Brozzi R and Saarela M, 2019. Scientific Opinion on the safety and efficacy of Actisaf® Sc 47 (*Saccharomyces cerevisiae* CNCM I-4407) as a feed additive for cattle for fattening, dairy cows, weaned piglets and sows. EFSA Journal 2019;17(3):5600, 15 pp. https://doi.org/10.2903/j.efsa.2019.5600

Abbreviations

BIOHAZ	EFSA Panel on Biological Hazards
CFU	colony forming unit
CNCM	Collection Nationale de Cultures de Micro-organismes
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
HR+	heat resistant
LOQ	limit of quantification
PWD	powder
QPS	qualified presumption of safety
RTECS	Registry of Toxic Effects of Chemical Substances
STD	standard
WGS	whole genome sequence