SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 20 October 2016

doi: 10.2903/j.efsa.2016.4624

Safety and efficacy of selenium-enriched yeast (*Saccharomyces cerevisiae* NCYC R397) for all animal species

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety and efficacy of selenium-enriched yeast (*Saccharomyces cerevisiae* NCYC R397) for all animal species, based on a dossier submitted for the modification of the terms of authorisation of the additive. The additive is currently authorised as selenomethionine produced by *S. cerevisiae* NCYC R397 as a nutritional additive (compound of trace elements) with a minimum selenium content of 2,000 mg/kg. The applicant proposed the inclusion of an additional formulation with a minimum content of selenium in the additive of 3,000 mg/kg. Considering that there are no changes in (i) the manufacturing of the product compared to the former application, and (ii) the conditions of use already authorised, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) stated that the modification requested would not affect safety and efficacy of the product, with the exception of safety for the target animals and safety for the users. The applicant provided data of 15 batches which supported a specification for a minimum selenium content of 3,000 mg/kg, with at least 63% and 17% of the organic selenium content from selenomethionine and selenocysteine, respectively. The FEEDAP Panel concluded that there are no concerns for the safety of the target animals based on its previous assessment and an additional study on homogeneity of the additive. Selenium is hazardous upon inhalation; owing to the high dusting potential, persons handling the additive are at risk by inhalation. The additive is an irritant for the eyes, skin and mucosae, should be considered as a dermal sensitiser, and likely as a respiratory sensitiser.

Keywords: nutritional additive, compounds of trace elements, selenium, selenium-enriched yeast, Alkosel®, safety

Requestor: European Commission

Question number: EFSA-Q-2016-00088

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Suggested citation: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, de Lourdes Bastos M, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López Puente S, López-Alonso M, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, López-Gálvez G and Mantovani A, 2016. Scientific opinion on the safety and efficacy of selenium-enriched yeast (*Saccharomyces cerevisiae* NCYC R397) for all animal species. EFSA Journal 2016;14(11):4624, 10 pp. doi:10.2903/j.efsa.2016.4624

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

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 selenium-enriched yeast (*Saccharomyces cerevisiae* NCYC R397) for all animal species. The additive is currently authorised as selenomethionine produced by *S. cerevisiae* NCYC R397 as a nutritional additive (compound of trace elements) with a minimum selenium content of 2,000 mg/kg. The applicant proposed to modify the minimum content of selenium in the additive by including also the option of 3,000 mg/kg. The applicant also proposed to include the selenocysteine content in the product characterisation of the authorisation.

Considering (i) that there are no relevant changes in the manufacturing of the product compared to the former application and (ii) that the conditions of use already authorised remain the same, the FEEDAP Panel stated that the modification requested would not affect safety and efficacy of the product, with the exception of safety for the target animals and safety for the users.

The applicant provided data of 15 batches which supported specifications for (i) selenium content of minimum 3,000 mg/kg, (ii) selenomethionine content of minimum 63% of the organic selenium and (iii) selenocysteine content of minimum 17% of the organic selenium.

Based on a study on homogeneity of the additive, and the results of the previous assessment delivered in 2006, the FEEDAP Panel concluded that there are no concerns for the safety of the target animals.

Selenium is hazardous upon inhalation; owing to the high dusting potential, persons handling the additive are at risk by inhalation. The additive is an irritant for the eyes, skin and mucosae, should be considered as a dermal sensitiser, and likely as a respiratory sensitiser.

The FEEDAP Panel gave some recommendations regarding (i) the denomination of the additive under assessment as 'selenium in the form of organic compounds produced by the selenium-enriched yeast *Saccharomyces cerevisiae* NCYC R397', (ii) the consideration of a maximum selenium guaranteed specification and (iii) the inclusion of the selenocysteine content in the characterisation of the product.

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1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 13(3) of that Regulation lays down that if the holder of an authorisation proposes changing the terms of the authorisation by submitting an application to the Commission, accompanied by the relevant data supporting the request for the change, the Authority shall transmit its opinion on the proposal to the Commission and the Member States.

The European Commission received a request from Lallemand S.A.S.[2] for the modification of the terms of the authorisation of the product selenium-enriched yeast (*Saccharomyces cerevisiae* NCYC R397), when used as a feed additive for all animal species (category: nutritional additives; functional group: compounds of trace elements).

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 13(3) (modification of the authorisation of a feed additive). The particulars and documents in support of the application were considered valid by EFSA as of 12 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 selenium-enriched yeast (*Saccharomyces cerevisiae* NCYC R397), when used under the proposed conditions of use (see Section 3.1.4).

1.2. Additional information

The additive is based on a selenium-enriched yeast from *S. cerevisiae* NCYC R397. The FEEDAP adopted in 2006 an opinion on the safety and efficacy of this additive for all species in accordance with Regulation (EC) No 1831/2003 (EFSA FEEDAP Panel, 2007). The respective authorisation of selenomethionine produced by *S. cerevisiae* NCYC R397 was granted in 2007 by Regulation (EC) No 634/2007[3]; the additive was catalogued under the *Category* of 'nutritional additives' and the *Functional group* 'compounds of trace elements'. The authorisation was later modified by Commission Regulation Implementing Regulation (EU) No 427/2013[4] limiting the maximum selenium supplementation rate from organic selenium sources to 0.2 mg/kg complete feed.

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[5] in support of the request of modification of the authorisation for selenium-enriched yeast (*Saccharomyces cerevisiae* NCYC R397) as a feed additive. The technical dossier was prepared following the provisions of Article 13 of Regulation (EC) No 1831/2003, Regulation (EC) No 429/2008[6] 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 or other expert bodies, peer-reviewed scientific papers, other scientific reports and experts' elicitation knowledge, to deliver the present output.

[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] Lallemand S.A.S., 19 Rue Briquetiers BP 59, 31702, Blagnaq, France.
[3] Commission Regulation (EC) No 634/2007 of 7 June 2007 concerning the authorisation of selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397 as a feed additive. OJ L 146, 8.6.2007, p. 1.
[4] Commission Implementing Regulation (EU) No 427/2013 of 8 May 2013 concerning the authorisation of selenomethionine produced by *Saccharomyces cerevisiae* NCYC R646 as a feed additive for all animal species and amending Regulations (EC) No 1750/2006, (EC) No 634/2007 and (EC) No 900/2009 as regards the maximum supplementation with selenised yeast. OJ L 127, 9.5.2013, p. 20.
[5] FEED dossier reference: FAD-2015-0045.
[6] 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.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.[7]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of selenium-enriched yeast (*Saccharomyces cerevisiae* NCYC R397) is in line with the principles laid down in Regulation (EC) No 429/2008 and the relevant guidance documents: Guidance on nutritional additives (EFSA FEEDAP Panel, 2012a), Technical guidance: Tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011), Technical Guidance for assessing the safety of feed additives for the environment (EFSA FEEDAP Panel, 2008), Guidance for the preparation of dossiers for additives already authorised for use in food (EFSA FEEDAP Panel, 2012b), Guidance for establishing the safety of additives for the consumer (EFSA FEEDAP Panel, 2012c) and Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012d).

3. Assessment

The additive selenium-enriched yeast (*Saccharomyces cerevisiae* NCYC R397) is authorised as a nutritional additive, functional group 'Compounds of trace elements', to be used in feedingstuffs for all animal species up to the maximum content in complete feeds authorised in the European Union (EU). The specifications of the currently authorised additive are organic selenium mainly Se-Met (63%) content of 2,000–2,400 mg Se/kg (97–99% of organic selenium).

The application is for the modification of the current authorisation to introduce a new formulation of the additive with a higher selenium concentration (minimum 3,000 mg Se/kg; trade name: Alkosel 3000), with the same conditions of use as for the authorised product. Owing to the availability of analytical methods which allow a more precise quantification of the contents of Se-Met and selenocysteine (Se-Cys) in the additive, the applicant also proposed to include the Se-Cys content in the characterisation of the product.

The FEEDAP Panel has already assessed the safety and efficacy of selenium-enriched yeast (*Saccharomyces cerevisiae* NCYC R397) in a previous opinion (EFSA, 2007). It considered that the proposed modification would not substantially affect the previous assessment as related to the safety of the consumers and the environment and the efficacy of the product. Consequently, the FEEDAP Panel focused this assessment on the characterisation of the product and relevant safety aspects (target animals and users).

3.1. Characterisation

3.1.1. Manufacturing Process[8]

The manufacturing process is fully described in the technical dossier; it is, in essence, identical to that of the previously submitted and authorised product. No new components of concern have been introduced.

3.1.2. Characterisation of the additive

The product consists of inactivated whole cell yeast[9] containing a minimum of 3,000 mg/kg of total selenium and a maximum of 2% of residual inorganic selenium. At least 63% of the total organic selenium is in the form of Se-Met and about 18 % in the form of Se-Cys.

The additive does not have a chemical name according to International Union of Pure and Applied Chemistry (IUPAC) nomenclature or a Chemical Abstracts Service (CAS) number.

Five batches of the additive were analysed for total selenium and for selenium from Se-Met, Se-Cys and unidentified selenium sources. The mean values were: for total selenium 3,068 mg/kg (range 2,971–3,153), for selenium from Se-Met 1,993 mg/kg (range 1,785–2,112), for selenium from Se-Cys 545 mg/kg (range 462–671), for selenium from an unidentified source 171 mg/kg (range 115–209),

[7] The report linked to the previous dossier (related to EFSA-Q-2005-117) is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2005-0012.pdf

[8] This section has been amended following the confidentiality claims made by the applicant.

[9] Technical dossier/Section II.

for selenium from water-soluble selenium sources 351 mg Se/kg (range 274–414) and for selenium from water-insoluble selenium sources 90 mg Se/kg (range 76–101). It is noted that soluble and insoluble selenium fractions are likely to contain some amount of unidentified organic selenium sources.[10] In summary, the mean values would indicate that total selenium of the additive consists of approximately 65% of Se-Met, 17% of Se-Cys, 5% of unidentified selenium source, 11% of water-soluble selenometabolites and 3% of water-insoluble selenometabolites.

The analyses of an additional set of 10 batches for selenium content gave values between 3,120 and 3,492 mg/kg (specification > 3,000 mg/kg). The percentage of moisture ranged between 3.7% and 5.2% (specification < 7%).[11]

Heavy metals, arsenic and dioxins in the additive were analysed in four batches. The average results were: lead 0.035 mg/kg; cadmium 0.018 mg/kg; mercury < 0.005 mg/kg; arsenic 0.082 mg/kg; dioxins 0.063 ng WHO-PCDD/F-TEQ)/kg; sum of dioxins plus dioxin-like PCBs 0.10 ng WHO-PCDD/F-PCB-TEQ/kg.[12] The applicant also provided analytical data on mycotoxins in four batches.[13] The mycotoxins levels were below the limit of quantification (average level, in μg/kg: aflatoxin B1 < 0.1, aflatoxin B2 < 0.1, aflatoxin G1 < 0.1, aflatoxin G2 < 0.2, zearalenone < 20, ochratoxin A < 0.2, fumonisin B1 < 20, fumonisin B2 < 20 and deoxynivalenol < 50). All the reported values are within limits set in the Directive 2002/32/EC on Undesirable Substances in animal feed[14] for feed additives belonging to the functional group compounds of trace elements or, where no specific limit is mentioned, do not represent a safety concern.

The applicant provided analytical data from ten batches on total aerobic plate counts, yeast and moulds, coliforms, *Escherichia coli*, *Staphylococcus aureus* and *Salmonella*.[15] The results showed average contents of (in colony-forming units (CFU)/g): total aerobic plate counts 580, yeast and moulds 7.5, and coliforms < 10. *E. coli*, *S. aureus* showed negative results. *Salmonella* was negative in 25 g product.

3.1.2.1. Physical state of the product

The additive is a light brown tan free-flowing powder with baker's yeast odour.[9] Its bulk density is 619 kg/m^3 (range 602–633).[16]

Particle size distribution was measured by laser diffraction in four batches and calculated to be in the range of 13–120 μm with a mean particle size of 32–37 μm. On average, about 6% of the particles had a size of < 10 μm, 74% a size of < 50 μm and 98% a size of < 100 μm.[17] A comparison of these data with those provided in the previous dossier was not possible due to the different range of particles reported from each dossier and mainly because of the lack of the specific data on the fraction of less than 10 μm in the former dataset.

The dusting potential of four batches of the additive was analysed by the Stauber–Heubach method. The calculated average of dust-forming potential was 3.0 g/m^3 (range 2.18–4.15).[18,19] The selenium content of the dust was 2,902 mg Se/kg (range 2,771–2,964).[20]

3.1.3. Stability and homogeneity

For compounds of trace elements, stability studies are generally not required.

The applicant presented, upon request, a homogeneity study of the product incorporated into a protein concentrate for dairy cow (soy cake 59.5%, rape cake 36.0%, sunflower cake 2.5%, urea 2.0%; calculated background selenium content 0.1 mg/kg).[21] Selenium was supplemented at a rate of 0.2 mg Se (from Alkosel 3,000)/kg and 0.1 mg Se (from sodium selenite)/kg. The expected total selenium content of the protein concentrate was 0.4 mg/kg. Ten subsamples of this mixture were analysed for selenium, the mean value was 0.398 mg/kg and the coefficient of variation (CV) was

[10] Technical dossier/Section II/Annex II_1_4.
[11] Technical dossier/Section II/Annex II_1_7.
[12] Technical dossier/Section II/Annex II_1_5.
[13] Technical dossier/Section II/Annex II_1_8.
[14] Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed. OJ L 140, 30.5.2002, p. 10.
[15] Technical dossier/Section II/Annex II_1_7.
[16] Technical dossier/Section II/Annex II_1_15.
[17] Technical dossier/Section II/Annex II_1_11.
[18] Technical dossier/Section II/Annex II_1_13.
[19] This dusting potential is about one order of magnitude higher than that estimated for the previously assessed product (Alkosel®2000).
[20] Technical dossier/Section II/Annex II_1_14.
[21] Technical dossier/Supplementary Information.

6.3%. Although only half of the total selenium originated from the additive under assessment, the small CV indicates the capacity of the additive to homogeneously distribute in feed.

3.1.4. Conditions of use

The additive is intended to be used as a nutritional feed additive to all animal species. The additive is not intended to be used for dispersion in water for drinking.

The maximum supplementation of feed with the additive should not exceed 0.2 mg Se/kg of complete feed with a moisture content of 12%, and should respect the maximum total content of selenium authorised (0.5 mg Se/kg complete feed).

3.2. Safety

In its previous opinion (EFSA FEEDAP Panel, 2007), the FEEDAP Panel concluded that the additive was safe at the maximum total dose of selenium at the time of the assessment. Safety for consumer and environment of the product would not be affected by the proposed modification to the terms of authorisation, considering (i) that there are no relevant changes in the manufacturing of the product compared to the former application, and (ii) that the application does not interfere with Commission Implementing Regulation (EU) No 427/2013[4] establishing a maximum supplementation of selenium from all organic sources (0.2 mg/kg).

3.2.1. Safety for the target species

The only aspect which would require a reconsideration of the previous assessment of the safety for target species could be derived from the higher selenium concentration of the additive and the subsequent potential of a less homogeneous distribution in feed. However, homogeneity data (see Section 3.1.3) could demonstrate that there is no concern. The active compound/s in the additive is/are the same as in the previously assessed selenised yeast (EFSA FEEDAP Panel, 2007), consequently the additive is considered safe for all animal species.

3.2.2. Safety for the user

3.2.2.1. Effects on the respiratory system

In the previous assessment, the FEEDAP Panel concluded that 'the use of Alkosel® is unlikely to elicit a significant exposure to selenium for the user. However, appropriate measures to minimise skin contact and inhalation exposure to Alkosel® should be taken' (EFSA FEEDAP Panel, 2007). Owing to the higher concentration of selenium in the additive proposed within the current application, safety for the user could be impacted and therefore the FEEDAP Panel considers it necessary to update its former assessment.

The highest dusting potential of the additive is 4.15 g/m^3. The selenium concentration in the dust would correspond to that in the additive, which has been approximately confirmed by analytical data (2,771–2,964 mg Se/kg). It can therefore be expected that about 12 mg Se/m^3 (4.15 g dust/m^3 × 3000 mg Se/kg dust from the additive) could be released by the dust when handling the additive. The selenium content in dust from respirable particles would be less than 12 mg/kg, but no figure on the size of this fraction in dust was reported. A conservative estimate of respirable selenium from dust would be about 1 mg/m^3.[22]

Selenium compounds are recognised as highly toxic by inhalation. Concerning threshold limit values (TLV) for selenium compounds, air concentrations between 0.02 and 0.2 mg Se/m^3 have been set by different organisations (e.g. German Maximale Arbeitsplatz Konzentration (MAK) List, Occupational Safety and Health Administration (OSHA), National European Authorities). Consequently, and considering the above estimate of selenium from the dust of the additive, its handling is a risk to users by inhalation.

3.2.2.2. Effects on the eyes and skin[23]

The FEEDAP Panel concluded in its previous opinion on Alkosel 2000 that 'Exposure to high concentrations of selenium can cause skin rash and irritation of the eyes and the mucosae.

[22] The respirable fraction in the additive was 6%, the fraction < 50 μm was 74%. Assuming that the dust consists only of particles ≤ 50 μ, its respirable fraction could be estimated to be 8% (6 of 74), the selenium concentration in the respirable dust would then be 0.96 mg/m^3 (8 × 12 mg Se/m^3 per 100).

[23] This section has been amended following the confidentiality claims made by the applicant.

Information on possible long-term effects is limited. [...]. In common with all proteinaceous products, the potential for sensitisation via inhalation cannot be excluded' (EFSA FEEDAP Panel, 2007).

In the context of the current application, the applicant submitted a local lymph node assay, performed under the OECD Test Guideline 429, aimed to test the skin sensitisation potential of the additive.[24] The product (*S. cerevisiae* NCYC R397, named Alkosel®R397, containing 2338 mg Se/kg) was tested. The substance was classified as a sensitiser, subcategory 1B.[25] Since the test item was produced under the same conditions and showed a similar composition as Alkosel 3000, it is concluded that the additive under assessment should be considered as a dermal sensitiser.

3.2.2.3. Conclusions on safety for the user

Selenium is hazardous upon inhalation and an irritant for the eyes, skin and mucosae. Owing to the high dusting potential, persons handling the additive are at risk by inhalation. The additive should be considered as a dermal sensitiser and likely as a respiratory sensitiser.

3.3. Efficacy

As already stated in the introductory paragraph under Assessment (Section 3), the efficacy of the product would not be affected by the proposed modification to the terms of 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[26] and Good Manufacturing Practice.

4. Conclusions

The modification of the terms of authorisation of the selenium-enriched yeast, consisting of an introduction of a new formulation with a minimum selenium content of 3,000 mg Se/kg additive does not affect the conclusions of the FEEDAP Panel on safety for the consumer, safety for the environment and efficacy of the product made in a previous assessment of a similar product with a lower selenium concentration.

Based on a newly submitted homogeneity study and the tolerance study provided for the already authorised product, the Panel concludes that the additive is safe for the target animals

Selenium is hazardous upon inhalation; owing to the high dusting potential, persons handling the additive are at risk by inhalation. The additive is an irritant for the eyes, skin and mucosae, should be considered as a dermal sensitiser and likely as a respiratory sensitiser.

5. Recommendations

In accordance with the more recent relevant opinions on selenium from selenised yeasts, the FEEDAP Panel recommends the denomination of the additive under assessment as 'selenium in the form of organic compounds produced by the selenium-enriched yeast *Saccharomyces cerevisiae* NCYC R397'. In the view of the Panel, the denomination of selenised-yeast derived additives as selenomethionine could be misleading.

In order to respect the maximum supplementation dose of selenium currently permitted in the EU with selenised yeast (0.2 mg Se/kg), and in agreement with the previous assessment of this selenised yeast (selenium-enriched yeast (*Saccharomyces cerevisiae* NCYC R397)), the FEEDAP Panel recommends the potential newly guaranteed minimum selenium content of 3,000 mg/kg additive being supplemented by a maximum guaranteed specification (e.g. up to 3,500 mg/kg).

The FEEDAP Panel has no concerns regarding the inclusion of a minimum Se-Cys content of the additive in the official characterisation of the product.

[24] Technical Dossier/Supplementary Information/Appendix_1_skin sensitization_alkosel_conf.pdf

[25] According to the definition provided by Commission Regulation No 286/2011 and by the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), 'Subcategory 1B' is defined as: 'Substances showing a low to moderate frequency of occurrence in humans and/or a low to moderate potency in animals can be presumed to have the potential to produce sensitisation in humans. Severity of reaction may also be considered'.

[26] 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.

6. Remark

The FEEDAP Panel considers that the method for the determination of the Se-Cys content in the additive should be subjected to an official evaluation by the EURL.

Documentation provided to EFSA

1) Dossier *Saccharomyces cerevisiae* NCYC R397. Alkosel® 3000 (Selenium-enriched yeast). April 2015. Submitted by LALLEMAND SAS.
2) Dossier *Saccharomyces cerevisiae* NCYC R397. Alkosel® 3000 (Selenium-enriched yeast). August 2016. Submitted by LALLEMAND SAS.
3) Comments from Member States.

References

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2007. Opinion of the Panel on additives and products or substances used in animal feed (FEEDAP) on the safety and efficacy of the product Selenium enriched yeast (*Saccharomyces cerevisiae* NCYC R397) as a feed additive for all species in accordance with Regulation (EC) No 1831/2003. EFSA Journal 2007;5(1):430, 23 pp. doi:10.2903/j.efsa.2007.430

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2008. Technical Guidance of the Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) for assessing the safety of feed additives for the environment. EFSA Journal 2008;6(10):842, 28 pp. doi:10.2903/j.efsa.2008.842

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2011. Technical guidance: Tolerance and efficacy studies in target animals. EFSA Journal 2011;9(5):2175, 15 pp. doi:10.2903/j.efsa.2011.2175

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012a. Guidance for the preparation of dossiers for nutritional additives. EFSA Journal 2012;10(1):2535, 14 pp. doi:10.2903/j.efsa.2012.2535

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012b. Guidance for the preparation of dossiers for additives already authorised for use in food. EFSA Journal 2012;10(1):2538, 4 pp. doi:10.2903/j.efsa.2012.2538

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012c. Guidance for establishing the safety of additives for the consumer. EFSA Journal 2012;10(1):2537, 12 pp. doi:10.2903/j.efsa.2012.2537

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012d. Guidance on studies concerning the safety of use of the additive for users/workers. EFSA Journal 2012;10(1):2539, 5 pp. doi:10.2903/j.efsa.2012.2539

Abbreviations

CAS	Chemical Abstracts Service
CFU	colony-forming units
CV	coefficient of variation
DMSO	dimethyl sulfoxide
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
IUPAC	International Union of Pure and Applied Chemistry
MAK	German Maximale Arbeitsplatz Konzentration
OECD	Organisation for Economic Cooperation and Development
OSHA	Occupational Safety and Health Administration
PCBs	polychlorinated biphenyls
PCDD	polychlorinated dibenzo-*p*-dioxin
TEQ	toxic equivalent
TLV	threshold limit values
WHO	World Health Organization