

ADOPTED: 10 November 2021

doi: 10.2903/j.efsa.2021.6979

Safety and efficacy of the feed additive consisting of selenium-enriched yeast (*Saccharomyces cerevisiae* CNCM I-3060) for all animal species (Alltech Ireland)

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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 safety and efficacy of selenium-enriched yeast (*Saccharomyces cerevisiae* CNCM I-3060) for all animal species, based on a dossier submitted for the modification of the terms of the authorisation of the additive. The additive is currently authorised as selenomethionine produced by *S. cerevisiae* CNCM I-3060 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 (i) that the main changes in the manufacturing of the product compared to the former application involve the drying phase (spray-drying vs drum drying), which has led to slightly different values of the dusting potential and particle size, and (ii) the conditions of use already authorised, the FEEDAP Panel stated that the modification requested would only affect the safety for the target animals and the users, without impacting the safety for the consumers, safety for the environment or the efficacy of the additive. 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. The additive is hazardous by inhalation, is not irritant for the eyes, skin and is not a dermal sensitiser.

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Keywords: nutritional additive, compounds of trace elements, selenium, selenium-enriched yeast, *Saccharomyces cerevisiae* CNCM I-3060, safety

Requestor: European Commission

Question number: EFSA-Q-2020-00495

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Declarations of interest: The declarations of interest of all scientific experts active in EFSA's work are available at <https://ess.efsa.europa.eu/doi/doiweb/doisearch>.

Acknowledgements: The Panel wishes to acknowledge the contribution of Angelica Amaduzzi to this opinion.

Suggested citation: 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, Fašmon Durjava M, Kouba M, López-Alonso M, López Puente S, Marcon F, Mayo B, Pechová A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Brozzi R, Galobart J, Gregoretto L, Innocenti ML, Vettori MV and López-Gálvez G, 2021. Scientific Opinion on the safety and efficacy of the feed additive consisting of selenium-enriched yeast (*Saccharomyces cerevisiae* CNCM I-3060) for all animal species (Alltech Ireland). EFSA Journal 2021;19(12):6979, 10 pp. <https://doi.org/10.2903/j.efsa.2021.6979>

ISSN: 1831-4732

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



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1. Introduction

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

Regulation (EC) No 1831/2003¹ 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 Alltech Ireland² for the modification of the terms of the authorisation of the product selenium-enriched yeast (*Saccharomyces cerevisiae* CNCM I-3060), 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 15 September 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 selenium-enriched yeast (*S. cerevisiae* CNCM I-3060), when used under the proposed conditions of use (see Section 3.1.6).

1.2. Additional information

The additive consists of organic selenium (mainly selenomethionine, Se-Met) from a selenium-enriched yeast from *S. cerevisiae* CNCM I-3060. The FEEDAP Panel has adopted three opinions on the safety and efficacy of this additive (EFSA, 2006; EFSA FEEDAP Panel, 2011, 2018a). The additive is authorised as 'Selenised yeast *Saccharomyces cerevisiae* CNCM I-3060, inactivated' (3b810).³

The application is for the modification of the current authorisation (content of selenium: 2,000–2,400 mg Se/kg) to introduce a new formulation of the additive with a higher selenium concentration (minimum 3,000 mg Se/kg), with the same conditions of use as for the authorised product.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier⁴ in support of the authorisation request for the use of selenium-enriched yeast (*S. cerevisiae* CNCM I-3060) 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 or other expert bodies, peer-reviewed scientific papers, other scientific reports, to deliver the present output.

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.⁵

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 Alltech Ireland, Sarney, Summerhill Road, A86 X006 Dunboyne, Co. Meath, Ireland.

³ Commission Implementing Regulation (EU) 2019/804 of 17 May 2019 concerning the renewal of the authorisation of organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060 and of selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397 as feed additives for all animal species and repealing Regulations (EC) No 1750/2006 and (EC) No 634/2007. OJ L 132, 20.05.2019, p. 28.

⁴ FEED dossier reference: FAD-2020-0019.

⁵ The report linked to the previous dossier (related to EFSA-Q-2009-00752) is available on the EURL website: <https://ec.europa.eu/jrc/sites/default/files/FinRep-FAD-2009-0029%2B2010-0044.pdf>

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of selenium-enriched yeast (*S. cerevisiae* CNCM I-3060) is in line with the principles laid down in Regulation (EC) No 429/2008⁶ and the relevant guidance documents: Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017a), Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018b), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017c), Technical guidance: Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012), Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019) and Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018c).

3. Assessment

The additive 'Selenised yeast *Saccharomyces cerevisiae* CNCM I-3060, inactivated' is authorised in the European Union (EU) as a nutritional additive, functional group 'compounds of trace elements', to be used in feedingstuffs for all animal species up to the maximum selenium content of 0.50 mg Se/kg total Se/kg complete feed; the maximum supplementation with organic selenium being of 0.20 mg Se/kg of complete feed. The authorisation specifies the following for the additive composition: content of selenium 2,000–2,400 mg Se/kg, organic selenium > 97–99% of total selenium and selenomethionine (Se-Met) > 63% of total selenium. The active substance is characterised as 'Selenomethionine produced by *Saccharomyces cerevisiae* CNCM I-3060'.

The present 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), with the same conditions of use as for the authorised product.

The FEEDAP Panel has already assessed the safety and efficacy of selenium-enriched yeast (*S. cerevisiae* CNCM I-3060) as a nutritional additive in two previous opinions (EFSA, 2006; EFSA FEEDAP Panel, 2018a).

The additive under assessment, Selenised yeast *Saccharomyces cerevisiae* CNCM I-3060 inactivated, will be referred from here onwards as Sel-Plex.

3.1. Characterisation

3.1.1. Manufacturing process

The manufacturing process is fully described in the technical dossier.⁷ Some changes in the manufacturing process have been introduced mainly in the drying phase (spray-drying vs drum drying). These modifications have led to slightly different values of the dusting potential and particle size (see Section 3.1.4), as compared to those reported in previous assessments.

3.1.2. Characterisation of the additive

The new proposed formulation consists of inactivated whole cell yeast containing a minimum of 3,000 mg/kg of total selenium of which the residual inorganic selenium amounts to a maximum of 3%. At least 63% of the total organic selenium is in the form of Se-Met.

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 content. The mean values were: 3,075 mg/kg for total selenium (range: 2,981–3,122 mg/kg) and 2,059 mg/kg for selenium from Se-Met (range: 1,942–2,143 mg/kg) – corresponding to 67% of total selenium (specification ≥ 63%). The same batches were also analysed for inorganic selenium content: Se(IV) (range: 1.0–1.8 mg/kg) and Se(VI) (below the quantification level) contents.⁸ These results are

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.

⁷ Technical dossier/Section II/Annexes/Annex_II_3_1.

⁸ Technical dossier/Section II/Annexes/Annex_II_1_3.

in line with the new formulation proposed by the applicant, with the exception of one batch in which the minimum total selenium was less than 3,000 mg/kg additive.

Heavy metals (lead (Pb), cadmium (Cd), mercury (Hg)) and arsenic (As) concentration in the additive were analysed in three batches. The average results were: 0.077 mg Pb/kg, 0.022 mg Cd/kg, 0.007 mg Hg/kg, 0.388 mg As/kg additive. The content of dioxins, the sum of dioxins and dioxin-like PCBs and the non-dioxin-like PCBs were analysed in the same batches showing 0.073 ng WHO-PCDD/F-TEQ/kg, 0.079 ng WHO-PCDD/F-PCB-TEQ/kg and 0.022 µg/kg additive, respectively. The applicant also provided analytical data on mycotoxins from the same three batches of the additive: zearalenone, aflatoxins (B1, B2, G1 and G2), deoxynivalenol, T2-toxin HT-2 toxin, fumonisins (B1 and B2), fusarenon X and neosolaniol and ochratoxin A.⁹ The mycotoxin levels were in all cases below the respective limits of detection (LODs).¹⁰ All the reported values are within limits set in the Directive 2002/32/EC on undesirable substances in animal feed 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 the same three batches on microbial contaminants⁹ reporting the following results: total aerobes, 193 CFU/g; coliforms, < 10 CFU/g; *Escherichia coli* beta-glucuronidase positive β-glucuronidase-positive *Escherichia coli*, < 10 CFU/g; positive-coagulase staphylococci (*S. aureus* and other species) < 10 CFU/g; *Pseudomonas* spp., < 50 CFU/g; anaerobic sulfite reducers, < 10 CFU/g; *Clostridium perfringens*, < 10 CFU/g; filamentous fungi and yeasts, < 10 CFU/g; *Salmonella* spp. and *Listeria monocytogenes* not detected in 25 g product.

3.1.3. Characterisation of the production strain

The additive 'organic form of selenium (selenised yeast inactivated)' is produced by a strain of *S. cerevisiae*, which is deposited at the French Collection Nationale de Cultures de Microorganismes (CNCM) with accession number CNCM I-3060.¹¹ This strain is not genetically modified. The strain was identified as *S. cerevisiae* based on whole genome sequence (WGS) data by multigene phylogenomic analysis which grouped the strain CNCM I-3060 with *S. cerevisiae* strains, being the reference strain S288c the closest one. The following genes were included in the analysis: (1) the site encoding ribosomal rRNA repeat (18S rRNA, internal transcribed spacers 1 and 2, and 25S rRNA gene); one mitochondrial gene: (2) mitochondrial cytochrome c oxidase subunit 2 (cox2); and two nuclear housekeeping genes: (3) translation elongation factor 1-alpha (EF-1α) and (4) RNA polymerase II (rpb2). The phylogenomic analysis included six *S. cerevisiae* strains (including S288c), and one *S. jurei* and one *S. kudriavzevii*.

The alignment-free genome distance estimation analysis with Mash using MinHash supported *S. cerevisiae* S288c as the closest genome.

Alignment of the production strain was assessed against the *S. cerevisiae* S288c by whole genome alignment (using ProgressiveMauve), showing good alignment except for a contig₁₇ (85,791 bp), which was the CNCM I-3060 mitochondrial genome.

The *de novo* assembly produced a 6,178-bp circular sequence, which was identified as a plasmid typically detected in the *S. cerevisiae* genomes.

3.1.4. Physical state of the product

The additive is described as a light to dark brown, free-flowing powder with typical yeast odour. Its bulk density is 614 kg/m³ (range: 588–639, three batches).¹²

Particle size distribution was measured by laser diffraction in three batches.¹² The particle fractions below 1, 10, 50 and 100 µm were 0.08–0.20%, 3.61–4.52%, 54.60–58.92% and 88.23–93.99% (v/v), respectively.

The direct comparison of these data with that referred in the previous Sel-Plex[®] opinion (EFSA, 2006) misses some issues, namely that the current data covers smaller particles (< 10 µm and < 50 µm) and that the measure units of dusting potential are different (mg/50 g sample vs mg dust/m³). Nevertheless,

⁹ Technical dossier/Section II/Annexes/Annex_II_1_5.

¹⁰ Limits of detection. Zearalenone, 0.01 mg/kg. Aflatoxins (B1, B2, G1 and G2), 0.5 µg/kg. Trichothecenes: deoxynivalenol, 0.02 mg/kg; toxin HT-2: 5 µg/kg; toxin T-2: 2.5 µg/kg. Zearalenone metabolites: alpha-zearalenol, 0.01 mg/kg; beta-zearalenol, 0.01 mg/kg. Fumonisin (B1 and B2), 0.010 mg/kg. Trichothecene metabolites: fusarenon X, 0.01 mg/kg; neosolaniol, 0.02 mg/kg. Ochratoxin A, 0.0005 mg/kg.

¹¹ Technical dossier/Section II/Annexes/Annex_II_2_1.

¹² Technical dossier/Section II/Annexes/Annex_II_1_6.

taking into account that no major changes in the manufacturing process were identified and that particle size distribution are comparable with data previously reported (87% below 0.1 mm) (EFSA, 2006), no impact on the physical state of the product is expected. The dusting potential of three batches of the additive was analysed by the Stauber–Heubach method, showing on average 1.76 g dust/m³ (1.26–2.24 g/m³). The applicant provided data on the total selenium content of the dust measured in three samples; the average selenium content was 3,285 mg Se/kg dust (range 3,244–3,338 mg Se/kg).

3.1.5. Homogeneity

The applicant conducted a study to investigate the capacity of the additive to be homogeneously distributed in mash and pelleted feed.¹⁴ For this purpose, feed for chickens for fattening (selenium background level not considered) was supplemented with the additive via a premixture to reach a level of 0.2 mg Se/kg complete feed. A fraction of the mash feed was subsequently pelleted. Ten samples each of the mash and pelleted feeds were analysed for total selenium content using inductively coupled plasma mass spectrometry (ICP-MS). The mean values of total selenium in mash and pelleted feed were 0.37 mg/kg and 0.39 mg/kg, respectively, with a coefficient of variation (CV) of 0.09% and 0.1%.

3.1.6. Conditions of use

The additive is intended to be used as a nutritional feed additive for all animal species. The maximum supplementation of feed with the additive should not exceed 0.2 mg Se/kg 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

The FEEDAP Panel considers that the proposed modification to the terms of authorisation (higher Se concentration in the additive) would not have an impact on the safety for the consumer and the environment since the conditions of use reflect the current maximum limits of supplementation of selenium from all organic sources (0.2 mg/kg complete feed) established by the Commission Implementing Regulation (EU) No 427/2013. However, the changes introduced might have an impact on the safety for the target animals and the users, which are assessed below.

3.2.1. Safety for the target species

The safety of the additive currently authorised was established in previous opinions (EFSA, 2006; EFSA FEEDAP Panel, 2018a) and the Panel considers that 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 of selenium in feed. The data provided in the homogeneity study (see Section 3.1.5) show that the additive distributes homogeneously in the complete feed. Therefore, the exposure of target animals to organic selenium is not expected to be affected by the use of a product with a higher Se concentration. Therefore, the FEEDAP Panel concludes that the proposed modification in the Se concentration of the additive is safe for all animal species.

3.2.2. Safety for user

3.2.2.1. Effect on the respiratory system

No specific studies were provided by the applicant regarding the toxicity of the additive on the respiratory system.

The highest dusting potential of Sel-Plex was 2.24 g/m³¹³ and the selenium concentration in the dust 3,338 mg Se/kg. It can be calculated that a maximum concentration of 7.48 mg Se/m³ could be released by the dust when handling the additive. A conservative estimate of respirable selenium from dust would be about 0.60 mg/m³ assuming that the dust consists only of particles ≤ 50 µm and its respirable fraction about 8%.

¹³ Technical dossier/FAD-2020-0019_SIn_29072021/Annex II - Alltech Report No. 3.708 Selenium content dust.

¹⁴ Technical dossier/Section II/Annexes/Annex_II_4_3.

Concerning threshold limit values (TLVs) for selenium compounds, maximum tolerable air concentrations between 0.02 and 0.2 mg Se/m³ have been set by different organisations (e.g. Deutsche Forschungsgemeinschaft (DFG) Maximale Arbeitsplatz Konzentration (MAK) List, Occupational Safety and Health Administration (OSHA)-Permissible Exposure Limit (PEL), and National European Authorities). Consequently, and considering the above estimate of selenium from the dust of the additive, its handling represents a risk to users by inhalation.

3.2.2.2. Effect on eyes and skin

The FEEDAP Panel, in its previous opinion, concluded that Sel-Plex proved to have no significant potential for skin and eyes irritation (EFSA, 2006; EFSA FEEDAP Panel, 2018a). The applicant has provided new studies with the additive under assessment.

The potential of skin irritancy of the additive was tested in a GLP *in vitro* study performed according to the OECD Guideline No 439.¹⁵ Under the conditions of this study, Sel-Plex is considered a non-irritant to skin.

The applicant performed a test to assess the potential eyes irritancy of the additive; the test selected was the *in vitro* EpiOcular™ eye irritation test (OECD Guideline No 492) and the study was done under GLP.¹⁶ Under the conditions of this study, Sel-Plex is not considered an eye irritant.

An *in vivo* skin sensitisation study in guinea pigs was performed according to OECD guidelines No 406.¹⁷ The additive did not elicit a sensitisation response in the guinea pig.

3.2.2.3. Conclusions on safety for the user

The FEEDAP Panel concludes that the more concentrated form of the additive poses a risk to users by inhalation. It is considered not irritant to the eyes and skin and not a skin sensitiser.

3.3. Efficacy

As the conditions of use of the additive are the same as the ones already authorised, the Panel considers that 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 Regulation¹⁸ and Good Manufacturing Practice.

4. Conclusions

As the conditions of use of the additive are the same as the ones already authorised, the modification of the terms of authorisation of the selenium-enriched yeast, consisting in the increasing of the minimum concentration of Se in the additive to 3,000 mg/kg does not raise safety concerns for the target species, consumer and the environment.

The FEEDAP Panel concludes that the additive is hazardous by inhalation, is not irritant for the eyes, skin and is not a dermal sensitiser.

The Panel considers that the efficacy of the product would not be affected by the proposed modification to the terms of authorisation.

5. Recommendation

In order to respect the maximum supplementation level 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 (*S. cerevisiae* CNCM I-3060), 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).

¹⁵ Technical dossier/FAD-2020-0019_SIn_29072021/Annex V - Skin Irrit.

¹⁶ Technical dossier/FAD-2020-0019_SIn_29072021/ Annex VI - Eye Irrit.

¹⁷ Technical dossier/FAD-2020-0019_SIn_29072021/Annex IV - Skin Sens.

¹⁸ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.

6. Documentation as provided to EFSA/Chronology

Date	Event
10/03/2020	Dossier received by EFSA. Safety and efficacy of selenium-enriched yeast (<i>Saccharomyces cerevisiae</i> CNCM I-3060) for all animal species. Submitted by Alltech Ireland.
07/07/2020	Reception mandate from the European Commission
15/09/2020	Application validated by EFSA – Start of the scientific assessment
26/10/2020	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. <i>Issues: characterisation, safety for the users</i>
16/12/2020	Comments received from Member States
29/07/2021	Reception of supplementary information from the applicant - Scientific assessment re-started
10/11/2021	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

BIOHAZ	EFSA Scientific Panel on Biological Hazards
CAS	Chemical Abstracts Service
CFU	colony forming unit
CNCM	Collection Nationale de Cultures de Microorganismes
CV	coefficient of variation
DFG	Deutsche Forschungsgemeinschaft
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
ICP-MS	inductively coupled plasma mass spectrometry
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
MAK	Maximale Arbeitsplatz Konzentration
OECD	Organisation for Economic Co-operation and Development
OSHA	Occupational Safety and Health Administration
PCB	polychlorinated biphenyl
PCDD/F	polychlorinated dibenzo-p-dioxins and dibenzofurans
PEL	permissible Exposure Limit
QPS	Qualified Presumption of Safety
SeMet	selenomethionine
TEQ	toxic equivalents
TLV	threshold limit values
WGS	whole genome sequence
WHO	World Health Organization