European Food Safety Authority

The EFSA Journal (2009) 1070, 1-6

SCIENTIFIC OPINION

Inability to assess the safety of silicon-enriched yeast added for nutritional purposes as a source of silicon in food supplements and the bioavailability of silicon from this source, based on the supporting dossier [1]

Scientific Statement of the Panel on Food Additives and Nutrient Sources added to Food (ANS)

(Question No EFSA-Q-2005-202)

Adopted on 29 April 2009

PANEL MEMBERS

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[1] For citation purposes: Scientific Statement of the Panel on Food Additives and Nutrient Sources added to Food on the inability to assess the safety of silicon-enriched yeast added for nutritional purposes as a source of silicon in food supplements and the bioavailability of silicon from this source based on the supporting dossier, following a request from the European Commission. *The EFSA Journal* (2009) 1070, 1-6.

BACKGROUND AS PROVIDED BY THE COMMISSION

The European Community legislation lists nutritional substances that may be used for nutritional purposes in certain categories of foods as sources of certain nutrients.

The Commission has received a request for the evaluation of silicon-enriched yeast added for nutritional purposes to food supplements. The relevant Community legislative measure is:

- Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements[2].

TERMS OF REFERENCE AS PROVIDED BY THE COMMISSION

In accordance with Article 29 (1) (a) of Regulation (EC) No 178/2002, the European Commission asks the European Food Safety Authority to provide a scientific opinion, based on its consideration of the safety and bioavailability of silicon-enriched yeast added to food supplements.

[2] OJ L 183, 12.7.2002, p.51.

STATEMENT

1. Summary of information provided in the supporting dossier on silicon-enriched yeast

Silicon-enriched yeast is derived from cultures of specified strains of *Saccharomyces cerevisiae* grown in the presence of silicon dioxide. Fermentation takes place at a specified temperature and pressure for defined periods of time. This is followed by increasing the temperature to kill the yeast. The cell wall is ruptured enzymatically to release the contents which are then spray dried.

The petitioner has provided some general information on the manufacturing process, but no details on the procedures used to produce silicon-enriched yeast are provided.

According to the petitioner, silicon in silicon-enriched yeast is naturally integrated by the growing yeast into its own structure and occurs therefore, in the way silicon would be present in any food material.

The petitioner states that during fermentation in the presence of silicon dioxide, a specific strain of *Saccharomyces cerevisiae* produces specific forms of silicon, the metabolic fate and the biological distribution of which are similar to those produced in other species.

The petitioner states that the integration will be chemically multi-formatted by the organism and therefore, its chemical name, formula, chemical family and CAS Registry Number is undefined. Further details on the characterisation of the fermentation products to demonstrate that the expected forms of the silicon are present in the enriched yeast were not provided.

A comparative C:H:N analysis and X-ray Photoelectron Spectra (XPS) for both the starter yeast and the silicon-enriched yeast have been provided.

Silicon-enriched yeast is described as a creamy powder with slight yeast odour. A 5% solution in water (20°C) gives a hazy solution.

According to the petitioner, silicon is present at 1% of the source. The majority of the remaining 99% is made up of enzymatically ruptured yeast cells consisting of 37% carbohydrate, 34% protein and 6% lipid. The loss on drying is 6% and the ash content is 15%. The petitioner further indicates that the glutathione content is 0.1 g/kg, beta glucans 5 g/kg and RNA/DNA 20 g/kg.

The petitioner also provided microbiological specifications. Specifications for cadmium, lead and arsenic were not provided.

The petitioner states that silicon-enriched yeast is to be used as a source of silicon in food supplements, and that the quantities added to the food supplements are product-dependent and determined by the individual manufacturers, but in general at levels providing up to 0.75 mg silicon/day.

No data were provided on the bioavailability of silicon from silicon-enriched yeast or on the safety of the source.

2. Assessment

The Panel notes that *Saccharomyces cerevisiae* has a qualified presumption of safety (EFSA, 2008) but considers that this presumption of safety might not be applicable to the specific conditions of culture of the yeast in presence of a high quantity of silicon.

According to the petitioner, fermentation in the presence of silicon within eukaryotic cells will produce organic silicon compounds similar to those produced *in vivo* in other species. Further characterisation of the fermentation product demonstrating that the expected organic silicon compounds would be present was not provided.

According to the petitioner, the difference in the C:H:N ratio between the starter yeast and the silicon-enriched yeast supports the hypothesis that changes within the yeast due to the complexing of the mineral into the internal structure of the yeast may have modified the overall composition of the yeast. However the Panel considers that the C:H:N analysis is not relevant to compare the starter yeast and the silicon-enriched yeast and notes that other organic material added in the manufacturing process, such as soya, nutrient organic media and plant enzymes can also influence the C:H:N ratio in the final product.

According to the petitioner, the X-ray Photoelectron Spectroscopy (XPS) showed binding energies (eV, electron volt) in the bio-transformed nutrients, which are claimed to correspond to two forms of silicon. Using the NIST XPS (National Institute of Standards and Technology) database the petitioner has identified these forms as silicon dioxide ($SiO_{2;}$; binding energy 104eV) and either Mg_2SiO_4 or Fe_2SiO_4 (binding energy 153eV). The petitioner concludes from these data that the silicon moiety with a binding energy of 153eV is the result of the fermentation process. The Panel considers that the XPS spectra provided can give some information on the content of the crystal compounds in enriched yeasts, but do not provide a significant contribution to the chemical characterization of the product.

The description of the manufacturing process used to produce silicon-enriched yeast was insufficient to characterise the product.

According to the petitioner, silicon from silicon-enriched yeast source is safe. Although not explicitly stated in the dossier, the argument for the safety of silicon-enriched yeast appears to be based on silicon being a normal constituent of the diet, and the long history of use of *Saccharomyces cerevisiae* in fermented food and beverages. The assumption is that, provided there is no overload of normal metabolic pathways, fermentation within eukaryotic cells will produce forms of silicon similar to those produced *in vivo* in other species.

The Panel notes that the petitioner has insufficiently characterised the product and therefore has not demonstrated that the organic silicon compounds are similar to those present in the diet, and that there is no overload of normal metabolic pathways leading to unexpected metabolic products.

The Panel notes that it was not possible to assess the bioavailability of silicon from silicon-enriched yeast since neither data nor suitable supporting references were provided.

The Panel notes that neither safety data nor suitable supporting references were provided to support the assumption of safety.

CONCLUSIONS

The Panel concludes that due to the lack of an appropriate dossier supporting the use of silicon-enriched yeast in food supplements, the bioavailability of silicon from silicon-enriched yeast and the safety of silicon-enriched yeast cannot be assessed.

Key words:

Food supplements, silicon, silicon dioxide, biotransformed silicon, yeast-transformed silicon, silicon-enriched yeast.

DOCUMENTATION PROVIDED TO EFSA

1. Dossier on Bio-transformed Silicon Proposed for Addition to Annex II of Directive 2002/46/EC of the European Parliament and of the Council Relating to Food Supplements. Original submission June 2005; Additional information submitted January 2008, November 2008, January 2009 and February 2009. Submitted by Higher Nature Ltd UK.

REFERENCES

EFSA, 2008. Opinion of the Panel on Biological Hazards on the maintenance of the list of QPS microorganisms intentionally added to food or feed. The EFSA Journal 923, 1-48.

ACKNOWLEDGEMENTS

The European Food Safety Authority wishes to thank the members of Working Group B on Food Additives and Nutrient Sources added to Food for the preparation of this opinion: D. Boskou, U.R. Charrondiere, B. Dusemund, D. Gott, T. Hallas-Møller, K.F.A.M. Hulshof, J. König, C. Le Donne, D. Parent-Massin, I.M.C.M. Rietjens, G.J.A. Speijers, P. Tobback, T. Verguieva, R.A. Woutersen.

GLOSSARY / ABBREVIATIONS

ANS	Panel on Food Additives and Nutrient Sources added to Foods
CAS	Chemical Abstracts Service
DNA	Deoxyribonucleic Acid
EC	European Commission
EFSA	European Food Safety Authority
NIST	National Institute of Standards and Technology
RNA	Ribonucleic Acid
XPS	X-ray Photoelectron Spectroscopy