European Food Safety Authority

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SCIENTIFIC OPINION

Inability to assess the safety of strontium-enriched yeast added for nutritional purposes as a source of strontium in food supplements and the bioavailability of strontium 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-2005-193)

Adopted on 13 May 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 strontium-enriched yeast added for nutritional purposes as a source of strontium in food supplements and the bioavailability of strontium from this source based on the supporting dossier following a request from the European Commission. *The EFSA Journal* (2009) 1085, 1-6.

BACKGROUND AS PROVIDED BY THE EUROPEAN 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 strontium–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 EUROPEAN 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 strontium–enriched yeast added for nutritional purposes to food supplements.

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

STATEMENT

1. Introduction

Following a request from the European Commission to the European Food Safety Authority (EFSA), the Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS) was asked to provide a scientific opinion on the safety of strontium-enriched yeast added for nutritional purposes as a source of strontium in food supplements and on the bioavailability of strontium from this source.

2. Summary of the information provided in the supporting dossier on strontium-enriched yeast

Strontium-enriched yeast is derived from cultures of specified strains of *Saccharomyces cerevisiae* grown in the presence of strontium chloride. 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.

Strontium-enriched yeast has no specific chemical identity (name, CAS No., molecular weight) but is chemically defined in terms of its strontium content, following culture of a yeast starter culture in the presence of strontium chloride. The petitioner states that strontium from strontium-enriched yeast has different characteristics to strontium chloride, the strontium being integrated by the yeast into its structure.

Strontium-enriched yeast is described by the petitioner as an amorphous hygroscopic cream powder with a slight yeast odour which is water soluble at 20 °C. The petitioner states that strontium is present at 0.2% of the yeast matrix. The majority of the remaining 99.8% is made up of enzymatically ruptured yeast cells. The petitioner also provides microbiological specifications. Specifications for lead, mercury, cadmium and arsenic are not provided. An adequate chemical characterisation of the fermentation complexes is not provided.

Additional information is given on the analytical methods used for the identification and characterisation of the source, its purity and the residual impurities of the end product. The petitioner states that the identification of the source may be ascertained by using analytical techniques such as Fourier Transform Infrared Spectroscopy (FTIR), Nuclear Magnetic Resonance (NMR) Spectroscopy, Electron Microscopy (EM) and Energy Disperse X-Ray Spectrometry (EDS), as well as pH measurement and amino acid profiling. However, only a comparative FTIR and elemental analysis for carbon, hydrogen, and nitrogen (C:H:N analysis) for both the starter yeast and the strontium-enriched yeast, is provided.

The manufacturing process is briefly described.

Analytical methods for the determination of the source in food are based on the determination of total strontium by Atomic Absorption Spectroscopy (AAS), as well as C:H:N analysis. The petitioner states that strontium-enriched yeast is stable in foods and food supplements for a minimum of three years, although no data were provided to support this statement.

Specific proposals for use levels for the strontium-enriched yeast were not provided. The petitioner indicates only that strontium-enriched yeast is intended to be used in supplements

at levels of less than 100 μg/day. The proposed use, according to the petitioner, is to provide a source of strontium supplied as a nutrient in food supplements, which mirrors its natural occurrence in food. Strontium-enriched yeast is used by food supplement manufacturers as an ingredient in tablets, caplets, capsules, chewable tablets, effervescent powders and liquids that are food supplements. The method of incorporation is determined by the individual manufacturers as appropriate for the particular type of finished product. The petitioner states that quantities added are product dependent, and are generally in the range of 0.1 mg to 3 mg/day.

No specific information is provided on the bioavailability of strontium from strontium-enriched yeast. The petitioner indicates only that strontium from strontium-enriched yeast is more bioavailable than strontium from strontium chloride.

No toxicological data are provided on the source. The petitioner indicates only that strontium is generally considered to be of low toxicity.

3. 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 yeasts in the presence of a high quantity of strontium.

According to the petitioner, strontium-enriched yeasts are safe. Although not explicitly stated in the dossier, the argument for the safety of strontium-enriched yeast appears to be based on strontium 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 organic strontium compounds, not further defined, but with a metabolic fate and biological distribution similar to that of other sources of strontium in the diet.

Further chemical characterisation of the fermentation products was not provided.

According to the petitioner, the difference in the C:H:N ratio between the starter yeast (9.8:1.5:1) and the strontium-enriched yeast (8.1:1.2:1) supports the hypothesis that changes within the yeast due to strontium incorporation 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 strontium-enriched yeast and that such a difference in the C:H:N ratio would not in any case provide a clear evidence of strontium incorporation or change in the structure of the yeast.

According to the petitioner, the differences between the FTIR spectra of strontium-enriched yeasts and the starter yeast reference spectrum suggest changes in composition and structure within the yeast. The Panel considers that the FTIR spectra provided do not demonstrate the existence of coordinate bonds between strontium and the yeast biomass.

The Panel notes that the petitioner has insufficiently chemically characterised the product and therefore has not demonstrated that strontium from strontium-enriched yeast has a metabolic fate and biological distribution similar to that of other food sources of strontium in the diet.

The Panel notes that it is not possible to assess the bioavailability of strontium from strontium-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 of strontium-enriched yeast.

The Panel notes that neither the EFSA Scientific Panel on Dietetic Products, Nutrition and Allergies (NDA) nor any other authorities have established dietary reference values for strontium. There is no evidence that strontium is essential for humans.

CONCLUSIONS

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

Key words:

Strontium, strontium chloride, strontium-enriched yeast, food supplements, yeast.

DOCUMENTATION PROVIDED TO EFSA

Technical dossier, 2005. Bio-transformed Strontium Proposed for Addition to Annex II of Directive 2002/46/EC of the European Parliament and of the Council Relating to Food Supplements. Submitted by Higher Nature Ltd, UK. Original submission June 2005. Additional information submitted January 2008 and October 2008.

REFERENCES

EFSA (European Food Safety Authority), 2008. Opinion of the Scientific Panel on Biological Hazards on the maintenance of the list of QPS microorganisms intentionally added to food or feed. *The EFSA Journal* (2008) 923, 1-48.

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GLOSSARY / ABBREVIATIONS

AAS	Atomic Absorption Spectroscopy
ANS	Scientific Panel on Food Additives and Nutrient Sources added to Food
CAS	Chemical Abstracts Service
EC	European Commission
EFSA	European Food Safety Authority
EDS	Energy Disperse X-Ray Spectrometry
EM	Electron Microscopy
FTIR	Fourier Transform Infra Red
NDA	Scientific Panel on Dietetic Products, Nutrition and Allergies
NMR	Nuclear Magnetic Resonance