European Food Safety Authority

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SCIENTIFIC OPINION

Inability to assess the safety of magnesium-enriched yeast added for nutritional purposes as a source of magnesium in food supplements, based on the supporting dossiers [1]

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

(Question No EFSA-Q-2005-092, EFSA-Q-2005-204)

Adopted on 5 June 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 magnesium-enriched yeast added for nutritional purposes as a source of magnesium in food supplements, based on the supporting dossier, following a request from the European Commission. *The EFSA Journal* (2009) 1131, 1-7.

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 magnesium-enriched yeast and bio-transformed magnesium 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 magnesium-enriched yeast and bio-transformed magnesium added 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 magnesium-enriched yeast added for nutritional purposes as a source of magnesium in food supplements and on the bioavailability of magnesium from this source.

This statement is based on the information on magnesium-enriched yeasts provided by two petitioners.

2. Summary of the information provided in the supporting dossiers on magnesium-enriched yeast

Magnesium-enriched yeasts are derived from cultures of specified strains of *Saccharomyces cerevisiae* grown in the presence of magnesium 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 to release the contents which are then spray dried.

According to one of the petitioners, magnesium in magnesium-enriched yeast is naturally integrated by the growing yeast into its own structure and occurs therefore, in the way magnesium would be present in any food material. The other petitioner describes magnesium-enriched yeast as "a complex of proteins, peptides and amino acids, resulting from the hydrolysis of *Saccharomyces cerevisiae*, which are bound to magnesium".

One of the petitioners states that during fermentation in the presence of magnesium chloride, a specific strain of *Saccharomyces cerevisiae* produces specific magnesium compounds, the metabolic fate and the biological distribution of which are similar to those of other sources of magnesium in the diet.

No specific chemical identity (name, CAS Registry Number, molecular weight) was provided by either petitioner, and the two petitioners name their products differently. One of 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".

The analytical techniques which have been used to characterise the formation of a bound magnesium-yeast complex are Fourier Transform Infrared (FTIR) Spectroscopy, a comparative elemental analysis for carbon, hydrogen, and nitrogen (C:H:N analysis) and X-ray Photoelectron Spectroscopy (XPS).

Chemical and microbiological specifications have been provided by both petitioners. In both cases, the total magnesium content in the source is in the range of 5-5.7%, the remainder of the material is made up of ruptured yeast cells.

The manufacturing process was described in detail by one petitioner and in a more limited form by the other one.

Magnesium-enriched yeast was stated by the petitioners to be used as an ingredient in tablets, caplets, capsules, chewable tablets, effervescent powders and liquids that are food supplements. Magnesium-enriched yeast was identified by one petitioner as currently used in six different products. The proposed daily intake of these products is generally 1-3 tablets resulting in a magnesium daily intake of 24-360 mg, of which up to 10-150 mg can be from magnesium-enriched yeast. The other petitioner indicated that these supplements containing magnesium-enriched yeast are intended to provide in the range of 0.75-50 mg magnesium/day.

The following limited information was provided by one of the petitioners on the bioavailability of magnesium from magnesium-enriched yeasts (unpublished Vinson, 1991). Three female and five male subjects ingested 500 mg of magnesium in the form of magnesium oxide, magnesium glycinate, magnesium amino acid chelate or 5% magnesium-enriched yeast. Magnesium excretion was measured using a 24-hour urine sample. The average 24-hour post-dose urinary magnesium content was significantly higher after ingestion of magnesium yeast compared to placebo control, magnesium oxide and magnesium glycinate but not significantly different from magnesium amino acid chelate. Vinson (unpublished 1991) concluded that magnesium from magnesium-enriched yeast was found to be more efficiently absorbed than from other sources of magnesium.

No toxicological data were provided on magnesium-enriched yeasts.

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 magnesium.

According to one of the petitioners, fermentation in the presence of magnesium chloride within eukaryotic cells will produce magnesium compounds, not further defined, but with a metabolic fate and biological distribution similar to those of other sources of magnesium in the diet.

According to the same petitioner, the difference in the C:H:N ratio between the starter yeast and the magnesium-enriched yeast supports the hypothesis that changes within the yeast due to the incorporation 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 magnesium-enriched yeast and that such a difference in the C:H:N ratio would not in any case provide a clear evidence of incorporation of magnesium or change in the structure of the yeast.

The same petitioner also stated that the XPS spectra submitted indicate that magnesium is not elemental and is also not bound to any chlorine. The Panel considers that the XPS spectra provided can give some information on the crystallinity of magnesium-enriched yeasts, but do not provide a significant contribution to its chemical characterisation.

According to the other petitioner, the differences between the FTIR spectra of magnesium-enriched yeast 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 magnesium and the yeast biomass.

According to the petitioners magnesium-enriched yeast is safe. Although not explicitly stated in the dossiers the argument for the safety of magnesium-enriched yeast appears to be based on magnesium 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 magnesium compounds with a metabolic fate and biological distribution similar to those of other sources of magnesium in the diet.

The Panel considers that the petitioners have insufficiently chemically characterised their products and therefore have not demonstrated that the magnesium from magnesium-enriched yeast has a similar metabolic fate and biological distribution to those of other sources of magnesium in the diet

Magnesium from magnesium-enriched yeasts is stated by the petitioners to be more bioavailable than magnesium from other magnesium compounds.

Based on the information provided by one of the petitioners, the Panel notes that the magnesium-enriched yeast used in the Vinson study (unpublished, 1991) is similar to one of the magnesium-enriched yeasts under consideration in this statement. The Panel therefore concludes that magnesium could be expected to be bioavailable from this magnesium-enriched yeast. In the absence of further information from the other petitioner, the Panel is unable to extrapolate this conclusion on bioavailability to the other magnesium-enriched yeast under consideration.

The Panel notes that neither safety data nor suitable supporting references were provided to support the assumption of safety of magnesium-enriched yeasts under consideration.

CONCLUSIONS

The Panel concludes that magnesium could be expected to be bioavailable from one of the magnesium-enriched yeasts under consideration. The Panel concluded that the bioavailability of the other magnesium-enriched yeast cannot be assessed due to the lack of an appropriate dossier.

The Panel also concludes that due to the lack of appropriate dossiers supporting the use of magnesium-enriched yeasts in food supplements, the safety of magnesium-enriched yeasts under consideration cannot be assessed.

Key words:

Food supplements, magnesium, magnesium chloride, yeast-transformed magnesium, magnesium-enriched yeast.

DOCUMENTATION PROVIDED TO EFSA

1. Technical dossier 2005a. Dossier on magnesium-enriched yeast (magnesium-enriched *Saccharomyces cerevisiae*) proposed for addition to Annex II of Directive 2002/46/EC of the European Parliament and of the Council Relating to Food Supplements. March 2005. Submitted by Nature's Own Limited, UK.

2. Technical dossier 2005b. Dossier on Bio-transformed magnesium 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 and November 2008. Submitted by Higher Nature Ltd, UK.

REFERENCES

EFSA (European Food Safety Authority), 2008. Scientific 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.

Vinson JA, 1991. Bioavailability of magnesium. Unpublished data

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GLOSSARY / ABBREVIATIONS

ANS	Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS)
CAS	Chemical Abstracts Service
EC	European Commission
EFSA	European Food Safety Authority
FTIR	Fourier Transform Infra Red
XPS	X ray Photoelectron Spectroscopy