European Food Safety Authority

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SCIENTIFIC OPINION

Inability to assess the safety of boron-enriched yeast added for nutritional purposes as a source of boron in food supplements and the bioavailability of boron 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-2005-187)

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 boron-enriched yeast added for nutritional purposes as a source of boron in food supplements and the bioavailability of boron from this source based on the supporting dossier following a request from the European Commission. *The EFSA Journal* (2009) 1071, 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 boron-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 boron-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 boron-enriched yeast

Boron-enriched yeast is derived from cultures of specified strains of *Saccharomyces cerevisiae* grown in the presence of boric acid. 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 boron enriched yeast are provided.

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

The petitioner states that during fermentation in the presence of boron, a specific strain of *Saccharomyces cerevisiae* produces specific forms of boron, 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 boron are present in the enriched yeast were not provided.

A comparative C:H:N analysis and the FT-IR spectra of both the starter yeast and the boron-enriched yeast are provided.

Boron-enriched yeast is described as an amorphous hygroscopic cream-coloured powder with slight yeast odour which is water soluble at 20 °C.

The petitioner states that boron is present at 1% of the source. The majority of the remaining 99% is made up of enzymatically ruptured yeast cells consisting of 40% carbohydrate, 35% protein and 6% lipid. The loss on drying is 6% and the ash content is 10 %.

The petitioner also provides microbiological specifications. Specifications for lead, mercury, cadmium and arsenic are not provided.

Use levels for the boron-enriched yeast are not provided. The petitioner only indicates that boron-enriched yeast is to be used to provide a source of boron supplied as a nutrient in food supplements. According to the petitioner, the quantities added to the food supplements are product-dependent, but because of the improved bioavailability are generally lower than those found in other sources of boron.

No data were provided on the bioavailability of boron from boron-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 boron.

According to the petitioner, fermentation in the presence of boron within eukaryotic cells will produce organic boron compounds similar to those produced *in vivo* in other species. Further characterisation of the fermentation product demonstrating that the expected organic boron compounds would be present 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 boron-enriched yeast (4.8:0.8:1), as well as the difference in carbohydrate (37.25:40) and protein (38.8:35) contents of the two materials, 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 such a difference would not in any case provide a clear evidence of complexing or change in the structure of boron-enriched yeast. The Panel also considers 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 and difference in carbohydrate and protein contents of the starter yeast and the final product.

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

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

According to the petitioner, boron from boron-enriched yeast is safe. Although not explicitly stated in the dossier the argument for the safety of boron-enriched yeast appears to be based on boron 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 boron compounds 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 boron compounds are similar to those present in the diet, 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 boron from boron-enriched yeast since neither data nor suitable supporting references were provided.

CONCLUSIONS

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

Key words:

Food supplements, boron, biotransformed boron, yeast-transformed boron, boron-enriched yeast

DOCUMENTATION PROVIDED TO EFSA

1. Dossier on Bio-transformed Boron 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 in January 2008. Submitted by Higher Nature Ltd UK.

REFERENCES

EFSA, 2004. Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the Tolerable Upper Intake Level of Boron (Sodium Borate and Boric Acid). The EFSA Journal 80, 1-22

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GLOSSARY / ABBREVIATIONS

ANS	Panel on Food Additives and Nutrient Sources added to Food
CAS	Chemical Abstracts Service
EC	European Commission
EFSA	European Food Safety Authority
FT-IR	Fourier Transform Infrared Spectroscopy