European Food Safety Authority

The EFSA Journal (2009) 1126, 1-6

SCIENTIFIC OPINION

Inability to assess the safety of vitamin B_{12}-enriched yeast added for nutritional purposes as a source of vitamin B_{12} in food supplements and the bioavailability of vitamin B_{12} from this source, based on the supporting dossier [1]

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

(Question No EFSA-Q-2005-195)

Adopted on 4 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 vitamin B_{12}-enriched yeast added for nutritional purposes as a source of vitamin B_{12} in food supplements and the bioavailability of vitamin B_{12} from this source based on the supporting dossier following a request from the European Commission. *The EFSA Journal* (2009) 1126, 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 vitamin B_{12}-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 vitamin B_{12}-enriched yeast 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 vitamin B_{12}-enriched yeast added for nutritional purposes as a source of vitamin B_{12} in food supplements and on the bioavailability of vitamin B_{12} from this source.

2. Summary of the information provided in the supporting dossier on vitamin B_{12}-enriched yeast

Vitamin B_{12}-enriched yeast is derived from cultures of specified strains of *Saccharomyces cerevisiae* grown in the presence of cyanocobalamin. 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 vitamin B_{12}-enriched yeast are provided.

According to the petitioner, vitamin B_{12} in vitamin B_{12}-enriched yeast is naturally integrated by the growing yeast into its own structure and occurs therefore, in the way vitamin B_{12} would be present in any food material.

The petitioner states that during fermentation in the presence of vitamin B_{12}, a specific strain of *Saccharomyces cerevisiae* produces specific vitamin B_{12} compounds, the metabolic fate and the biological distribution of which are similar to those from other sources of vitamin B_{12} in the diet.

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". Comparative Fourier Transform Infrared (FTIR) spectra of starter yeast, vitamin B_{12}, the vitamin B_{12}-enriched yeast, and a simple mixture of yeast and vitamin B_{12} have been provided.

Vitamin B_{12}-enriched yeast is described as an amorphous hygroscopic pink-coloured powder with a slight yeast odour which is water soluble at 20 °C.

According to the petitioner, vitamin B_{12} is present at 0.5% of the source. The remaining 99.5% is made up of enzymatically ruptured yeast cells. The petitioner also provides microbiological specifications. Specifications for lead, mercury, cadmium and arsenic are not provided.

Specific proposals for use levels for vitamin B_{12}-enriched yeast were not provided. The petitioner only indicates that vitamin B_{12}-enriched yeast is to be used to provide a source of vitamin B_{12} 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 vitamin B_{12}.

No data were provided on the bioavailability of vitamin B_{12} from vitamin the B_{12}-enriched yeast under consideration or on the safety of the source. Vinson *et al.*, (1989) reported that rats fed an unspecified vitamin B_{12} enriched yeast product had 2.56 times more vitamin B_{12} in serum and 1.6 times more vitamin B_{12} in the liver than rats given uncomplexed vitamin B_{12}.

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 yeast in the presence of a high quantity of vitamin B_{12}.

According to the petitioner, fermentation in the presence of vitamin B_{12} within eukaryotic cells will produce vitamin B_{12} complexes not further defined, but with a metabolic fate and biological distribution similar to those of other sources of vitamin B_{12} in the diet.

According to the petitioner, from the comparative FTIR spectra it can be deduced that vitamin B_{12} is in '*biological complex formation*' with yeast. The Panel considers that the FTIR spectra provided do not demonstrate the existence of such complexes.

According to the petitioner, vitamin B_{12} from vitamin B_{12}-enriched yeast is safe. Although not explicitly stated in the dossier the argument for the safety of vitamin B_{12}-enriched yeast appears to be based on vitamin B_{12} being normal constituents 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 vitamin B_{12} complexes, the metabolic fate and the biological distribution of which are similar to those from other sources of vitamin B_{12} in the diet.

The Panel notes that the petitioner has insufficiently chemically characterised the product and therefore has not demonstrated that the vitamin B_{12} complexes have a metabolic fate and biological distribution similar to those of other sources of vitamin B_{12} in the diet.

The Panel also notes that it was not possible to assess the bioavailability of vitamin B_{12} from vitamin B_{12}-enriched yeast since neither data nor suitable supporting references were provided.

The Panel further notes that neither safety data nor suitable supporting references were provided to support the assumption of safety of vitamin B_{12}-enriched yeast.

CONCLUSIONS

The Panel concludes that due to the lack of an appropriate dossier supporting the use of vitamin B_{12}-enriched yeast in food supplements, the bioavailability of vitamin B_{12} from vitamin B_{12}-enriched yeast and the safety of vitamin B_{12}-enriched yeast cannot be assessed.

Key words:

Food supplements, vitamin B_{12}, cobalamin, yeast-transformed vitamin B_{12}, vitamin B_{12}-enriched yeast.

DOCUMENTATION PROVIDED TO EFSA

1. Dossier on Bio-transformed Vitamin B_{12} 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 October 2008. Submitted by Higher Nature Ltd UK.

REFERENCES

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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, C. Le Donne, K.F.A.M. Hulshof, J. König, 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 Food
CAS	Chemical Abstracts Service
EC	European Commission
EFSA	European Food Safety Authority
FTIR	Fourier Transform Infrared