

SCIENTIFIC OPINION

Inability to assess the safety of folic acid-enriched yeast added for nutritional purposes as a source of folic acid to food supplements and the bioavailability of folic acid from this source, based on the supporting dossier¹

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

(Question No EFSA-Q-2005-197)

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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 folic acid-enriched yeast added for nutritional purposes to food supplements and the bioavailability of folic acid from this source, based on the supporting dossier following a request from the European Commission. *The EFSA Journal* (2009) 1090, 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 folic acid-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.

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 folic acid-enriched yeast added for nutritional purposes to food supplements.

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

This statement is based on the information on folic acid-enriched yeast as provided by the petitioner.

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

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

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

The petitioner states that during fermentation in the presence of folic acid, a specific strain of *Saccharomyces cerevisiae* incorporates folic acid into ‘biological complexes’ the metabolic fate and the biological distribution of which are similar to those of other sources of folates 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”. Further details on the chemical characterisation of the fermentation products to demonstrate that the expected complexes of the folic acid are present in the enriched yeast were not provided.

Comparative Fourier Transform Infrared (FTIR) spectra of the starter yeast, folic acid, folic acid-enriched yeast and a simple mixture of yeast and folic acid have been provided.

Folic acid-enriched yeast is described as a creamy powder with a slight yeast/citrus odour, soluble in water at 20°C.

According to the petitioner, folic acid is present at 1% of the source. The remaining 99% is made up of enzymatically ruptured yeast cells consisting mainly of carbohydrates, protein and lipids. The loss on drying and the ash content are also reported.

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

The petitioner states that the use levels of folic acid-enriched yeast will be in the range of 200 µg to 800 µg in capsules or tablets, to provide, depending on the product, between 100 µg and 200 µg folic acid/day.

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

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 folic acid.

According to the petitioner, fermentation in the presence of folic acid within eukaryotic cells will produce folic acid/yeast complexes similar to those of other sources of folic acid in the diet.

According to the petitioner, from the comparative FTIR spectra it can be deduced that folic acid is integrated in a 'biological complex' with yeast. The Panel considers that the FTIR spectra provided do not demonstrate the existence of such complexes.

According to the petitioner, folic acid from folic acid-enriched yeast source is safe. Although not explicitly stated in the dossier, the argument for the safety of folic acid-enriched yeast appears to be based on folates being normal constituents of the diet, and the long history of use of *Saccharomyces cerevisiae* in fermented food and beverages. The assumption is that fermentation within eukaryotic cells will produce folic acid complexes, the metabolic fate and the biological distribution of which are similar to those of other sources of folic acid in the diet.

The Panel further notes that the petitioner has insufficiently chemically characterised the product.

The Panel notes that it was not possible to assess the bioavailability of folic acid from folic acid-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 folic acid-enriched yeast.

CONCLUSIONS

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

Key words:

Food supplements, folic acid, yeast-transformed folic acid, folic acid-enriched yeast.

DOCUMENTATION PROVIDED TO EFSA

Dossier on Bio-transformed Folic Acid 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 by Higher Nature Ltd UK, June 2005. Additional information included on January 2008 and October 2008.

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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
FTIR	Fourier Transform Infrared