European Food Safety Authority

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SCIENTIFIC OPINION

Inability to assess the safety of biotin-enriched yeast added for nutritional purposes as a source of biotin in food supplements and the bioavailability of biotin 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-2005-199)

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 biotin-enriched yeast added for nutritional purposes as a source of biotin in food supplements and the bioavailability of biotin from this source, based on the supporting dossier following a request from the European Commission. *The EFSA Journal* (2009) 1134, 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 biotin-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 biotin-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 biotin-enriched yeast added for nutritional purposes as a source of biotin in food supplements and on the bioavailability of biotin from this source.

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

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

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

The petitioner states that during fermentation in the presence of biotin, a specific strain of *Saccharomyces cerevisiae* incorporates biotin into 'biological complexes', the metabolic fate and the biological distribution of which are similar to those of other sources of biotin 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 biotin are present in the enriched yeast were not provided.

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

Biotin-enriched yeast is described as an amorphous hygroscopic powder, soluble in water at 20°C.

According to the petitioner, biotin 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 were not provided.

Specific proposals for use levels for biotin-enriched yeast were not provided. The petitioner only states that biotin-enriched yeast is currently used to provide between 50 µg biotin/day up to a maximum of 300 µg biotin/day, depending on the type of supplement.

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

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

According to the petitioner, from the comparative FTIR spectra it can be deduced that biotin 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, biotin from biotin-enriched yeast source is safe. Although not explicitly stated in the dossier, the argument for the safety of biotin-enriched yeast appears to be based on biotin 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 the normal metabolic pathways, fermentation within eukaryotic cells will produce biotin complexes, the metabolic fate and the biological distribution of which are similar to those of other sources of biotin in the diet.

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

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

CONCLUSIONS

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

Key words:

Food supplements, biotin, yeast-transformed biotin, biotin-enriched yeast

DOCUMENTATION PROVIDED TO EFSA

Dossier on Bio-transformed Biotin 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.

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

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