European Food Safety Authority

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SCIENTIFIC OPINION

Inability to assess the safety of niacin-enriched yeast added for nutritional purposes as a source of niacin in food supplements and the bioavailability of niacin 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-2005-211)

Adopted on 4 June 2009

PANEL MEMBERS

F. Aguilar, U.R. Charrondiere, B. Dusemund, P. Galtier, J. Gilbert, D.M. Gott, S. Grilli, R. Guertler, G.E.N. Kass, J. Koenig, C. Lambré, J-C. Larsen, J-C. Leblanc, A. Mortensen, D. Parent-Massin, I. Pratt, I.M.C.M. Rietjens, I. Stankovic, P. Tobback, T. Verguieva, R.A. Woutersen.

[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 niacin-enriched yeast added for nutritional purposes as a source of niacin in food supplements and the bioavailability of niacin from this source based on the supporting dossier following a request from the European Commission. *The EFSA Journal* (2009) 1124, 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 niacin-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 niacin-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 niacin-enriched yeast added for nutritional purposes as a source of niacin in food supplements and on the bioavailability of niacin from this source.

The niacin-enriched yeast is prepared with niacinamide.

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

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

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

The petitioner states that during fermentation in the presence of niacin, a specific strain of *Saccharomyces cerevisiae* produces specific niacin compounds, the metabolic fate and the biological distribution of which are similar to those from other sources of niacin 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 the starter yeast, niacin, niacin-enriched yeast, and a simple mixture of yeast and niacin have been provided.

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

According to the petitioner, niacin is present at 25% of the source. The remaining 75% 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 niacin-enriched yeast were not provided. The petitioner only indicates that niacin-enriched yeast is to be used to provide a source of niacin 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 niacin.

No data were provided on the bioavailability of niacin from the niacin-enriched yeast under consideration or on the safety of the source. Vinson *et al.*, (1989) reported that rats fed an unspecified niacinamide-enriched yeast product had 3.9 times more niacin in blood and 1.7 times more niacin in the liver than rats given uncomplexed niacin.

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 niacin.

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

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

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

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

CONCLUSIONS

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

Key words:

Food supplements, niacin, yeast-transformed niacin, niacin-enriched yeast.

DOCUMENTATION PROVIDED TO EFSA

1. Dossier on Bio-transformed Niacin 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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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