European Food Safety Authority

The EFSA Journal (2009) 1087, 1-6

SCIENTIFIC OPINION

Inability to assess the safety of molybdenum-enriched yeast added for nutritional purposes as a source of molybdenum in food supplements and the bioavailability of molybdenum 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-2005-203)

Adopted on 14 May 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 molybdenum-enriched yeast added for nutritional purposes as a source of molybdenum in food supplements and the bioavailability of molybdenum from this source, based on the supporting dossier, following a request from the European Commission. *The EFSA Journal* (2009) 1087, 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 molybdenum-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 molybdenum-enriched yeast added for nutritional purposes in 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 molybdenum-enriched yeast added for nutritional purposes as a source of molybdenum in food supplements and on the bioavailability of molybdenum from this source.

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

According to the petitioner, molybdenum in molybdenum-enriched yeast is naturally integrated by the growing yeast into its own structure and occurs therefore in the way molybdenum would be present in any food material. 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 were not provided.

The petitioner provided some general information on the manufacturing process. Molybdenum-enriched yeast is derived from cultures of a specified strain of non-genetically modified *Saccharomyces cerevisiae* grown in the presence of a natural substrate and sodium molybdate (Na_2MoO_4). 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, having first determined that there is no free sodium molybdate present. The cell wall is ruptured enzymatically to release the contents which are then spray dried.

Additional information was given on the analytical methods used for the identification and characterisation of the source and the residual impurities of the end product. The results of the comparative elemental analysis for carbon, hydrogen, and nitrogen (C:H:N analysis) and Fourier Transform Infrared Spectroscopy (FTIR) analysis for the characterisation of the starter yeast and the molybdenum-enriched yeast were provided. However, information on the chemical characterisation of the fermentation complexes was not provided.

Molybdenum-enriched yeast is described by the petitioner as a tan powder with a characteristic yeast odour. The petitioner states that molybdenum is present at 0.2% of the source. The remaining 99.8% is made up of enzymatically ruptured yeast cells. The loss on drying and the ash content are also reported. The petitioner also provided microbiological specifications. Specifications for lead, mercury, cadmium and arsenic were not provided.

Analytical methods for the determination of the source are mainly based on the measurement of total molybdenum by Atomic Absorption Spectroscopy (AAS). The petitioner reports that molybdenum-enriched yeast is stable in foods and food supplements for a minimum of three years, although no data were provided to support this statement.

Specific proposals for use levels for molybdenum-enriched yeast were not provided. The petitioner only indicates that molybdenum-enriched yeast is to be used to provide a source of molybdenum supplied as a nutrient in food supplements. According to the petitioner, the quantities of molybdenum-enriched yeast added to the food supplements are product-

dependent. The petitioner also states that in currently available food supplements, molybdenum-enriched yeast is added at levels up to a maximum of 240 µg⁄day.

No data on the bioavailability of molybdenum from molybdenum-enriched yeast or on the safety of the source are provided. The petitioner states that molybdenum-enriched yeast exists in a complexed form as found naturally in yeast and is unlikely to impact on the intestinal milieu or the absorption of other nutrients in any way other than would be expected when consuming yeast derived from fermented foods. In relation to the yeast component of the source, the petitioner states that there is a long history of use of *Saccharomyces cerevisiae* in food preparation.

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 yeasts in the presence of a high quantity of molybdenum, as sodium molybdate.

According to the petitioner, molybdenum-enriched yeast is safe. Although not explicitly stated in the dossier, the argument for the safety of molybdenum-enriched yeast appears to be based on molybdenum being a normal constituent of the diet, and the long history of use of *Saccharomyces cerevisiae* in fermented foods and beverages. The assumption is that, provided there is no overload of normal metabolic pathways, fermentation within eukaryotic cells will produce organic molybdenum compounds, not further defined but with a metabolic fate and biological distribution similar to that of other sources of molybdenum in the diet.

Further chemical characterisation of the fermentation product was not provided. The petitioner states that the identification of the source may be ascertained by several fingerprinting parameters that include amino acid profiling and elemental analysis.

According to the petitioner, the difference in the C:H:N ratio between the starter yeast (9.8:1.5:1) and the molybdenum-enriched yeast (10.9:1.6:1) supports the hypothesis that changes within the yeast due to molybdenum incorporation into the internal structure of the yeast may have modified the overall composition of the yeast. However, the Panel considers that such a difference in the C:H:N ratio would not in any case provide a clear evidence of molybdenum incorporation or change in the structure of the yeast.

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

Overall, the Panel notes that the petitioner has insufficiently chemically characterised the product and therefore has not demonstrated that the molybdenum from molybdenum-enriched yeast has a metabolic fate and biological distribution similar to those of other food sources of molybdenum in the diet.

The Panel notes that it is not possible to assess the bioavailability of molybdenum from molybdenum-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 molybdenum-enriched yeasts.

CONCLUSIONS

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

Key words:

Food supplements, sodium molybdate, molybdenum, yeast-transformed molybdenum, molybdenum-enriched yeast, yeast.

DOCUMENTATION PROVIDED TO EFSA

Technical dossier, 2005. Bio-transformed Molybdenum Proposed for Addition to Annex II of Directive 2002/46/EC of the European Parliament and of the Council Relating to Food Supplements. Submitted by Higher Nature Ltd, UK. Original submission June 2005. Additional information submitted January 2008, February 2008 and November 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.

ACKNOWLEDGEMENTS

The European Food Safety Authority wishes to thank the members of Working Group A on Food Additives and Nutrient Sources for the preparation of this opinion: F. Aguilar, N Bemrah, P. Galtier, J. Gilbert, S. Grilli, R. Guertler, G.E.N. Kass, C. Lambré, J.C. Larsen, J-C. Leblanc, A. Mortensen, I. Pratt, I. Stankovic.

GLOSSARY / ABBREVIATIONS

AAS	Atomic Absorption Spectroscopy
ANS	Scientific 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 Infra Red