European Food Safety Authority

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SCIENTIFIC OPINION

Inability to assess the safety of vitamin D-enriched yeast added for nutritional purposes as a source of vitamin D in food supplements and the bioavailability of vitamin D 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-2005-198)

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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 vitamin D-enriched yeast added for nutritional purposes as a source of vitamin D in food supplements and the bioavailability of vitamin D from this source, based on the supporting dossier, following a request from the European Commission. *The EFSA Journal* (2009) 1148, 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 D-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 vitamin D-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 vitamin D-enriched yeast added for nutritional purposes as a source of vitamin D in food supplements and on the bioavailability of vitamin D from this source.

The present opinion deals with vitamin D_2-enriched yeast, a synonym used by the petitioner for vitamin D-enriched yeast. The latter terminology is used in the terms of reference provided by the European Commission.

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

Vitamin D-enriched yeast is derived from cultures of specified strains of *Saccharomyces cerevisiae* grown in the presence of vitamin D_2. 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 D-enriched yeast are provided.

According to the petitioner, vitamin D_2 in vitamin D-enriched yeast is naturally integrated by the growing yeast into its own structure and occurs therefore, in the way vitamin D would be present in any food material.

The petitioner states that during fermentation in the presence of vitamin D_2, a specific strain of *Saccharomyces cerevisiae* produces complexed forms of vitamin D_2 within the yeast, the metabolic fate and the biological distribution of which are similar to those of other sources of vitamin D 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 complexed forms of the vitamin D are present in the enriched yeast were not provided.

Comparative Fourier Transform Infrared (FTIR) spectra of the starter yeast, vitamin D_2, vitamin D_2-enriched yeast and a simple mixture of yeast and vitamin D_2 have been provided.

Vitamin D-enriched yeast is described as a brownish amorphous hygroscopic powder with a yeast-like odour, soluble in water at 20°C.

The petitioner indicates that the vitamin D_2 content in vitamin D-enriched yeast is 5% (equal to 1.10^6 IU/g) of the total material. The remaining material is made up of enzymatically ruptured yeast cells.

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

No data on use levels for vitamin D-enriched yeast were provided. The petitioner only states that vitamin D-enriched yeast is currently used to provide between 1.5 µg and up to a maximum of 5 µg vitamin D/day, depending on the type of supplement.

No data were provided on the bioavailability of vitamin D from vitamin D-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 presence of a high quantity of vitamin D_2.

According to the petitioner, fermentation in the presence of vitamin D_2 within eukaryotic cells will produce undefined vitamin D/yeast complexes, but with a metabolic fate and biological distribution similar to those of other sources of vitamin D in the diet.

The Panel notes, as already noted before by the SCF (SCF, 2002), that vitamin D_2 (ergocalciferol) is formed by UV radiation from its precursor ergosterol. Ergosterol is found in plants, yeast and fungi. The synthesis of vitamin D_2 from ergosterol hardly takes place in nature. Plants are thus a poor source of vitamin D_2.

According to the petitioner, from the comparative FTIR spectra it can be deduced that vitamin D_2 is in '*complexed form*' with the yeast. The Panel considers that the FTIR spectra provided do not demonstrate the existence of such complex.

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

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

CONCLUSIONS

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

Key words:

Food supplements, vitamin D, yeast-transformed vitamin D, vitamin D-enriched yeast, vitamin D_2, ergocalciferol

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.

SCF (Scientific Committee on Food), 2002. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Vitamin D. Available at: http://ec.europa.eu/food/fs/sc/scf/out157_en.pdf

DOCUMENTATION PROVIDED TO EFSA

Dossier on Bio-transformed Vitamin D 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 provided on January 2008 and November 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