

SCIENTIFIC OPINION

Inability to assess the safety of potassium amino acid chelate and iron amino acid chelate as sources of potassium and iron added for nutritional purposes to food supplements based on the supporting dossiers ¹

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

(Questions No EFSA-Q-2006-221, EFSA-Q-2006-222, EFSA-Q-2007-074)

Adopted on 14 May 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 potassium amino acid chelate and iron amino acid chelate as sources of potassium and iron added for nutritional purposes to food supplements following a request from the European Commission. *The EFSA Journal* (2009) 1103, 1-5.

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 potassium amino acid chelate and iron amino acid chelate 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 supplements².

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 potassium amino acid chelate and iron amino acid chelate added for nutritional purposes 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 potassium amino acid chelate and iron amino acid chelate as sources of potassium and iron added for nutritional purposes to food supplements and on the bioavailability of potassium and iron from these sources.

This statement is based on the information on potassium amino acid chelate and iron amino acid chelate as provided by the petitioner.

2. Summary of information provided by the petitioner

According to the petitioner, potassium amino acid chelate is a complex mineral chelate consisting of the potassium ion (from potassium carbonate) bonded to a mixture of ligands including glycine, aspartic acid and citric acid. The resulting material is further complexed with rice and soy protein hydrolysates. Specifications were provided for cadmium (5 mg/kg), lead (10 mg/kg) and arsenic (3 mg/kg). Microbiological specifications were also provided.

No specific information on the chemical characteristics of the iron amino acid chelate is provided. The petitioner only indicates that the specifications for this substance are identical to those of the potassium source.

The petitioner also provided some information on the general chemical properties of potassium and iron.

No data were provided on the proposed use levels, the safety of potassium amino acid chelate and of iron amino acid chelate, nor on the bioavailability of potassium or iron from the respective sources.

3. Assessment

The present statement deals only with the safety of potassium amino acid chelate and of iron amino acid chelate added for nutritional purposes to food supplements and with the bioavailability of the minerals potassium or iron from the respective sources. The safety of the minerals itself in term of amounts that may be consumed is outside the remit of this Panel.

The petitioner has not provided any information on the chemical identity of the amino acids in the amino acid chelates. No adequate description of the manufacturing process is provided explaining, for example, the role and fate of glycine, aspartic acid, citric acid and the large carbohydrate fraction derived from the rice and soy hydrolysates after production.

The petitioner has not provided any data on the toxicity of potassium amino acid chelate and iron amino acid chelate, nor on the bioavailability of potassium or iron from the respective sources.

CONCLUSIONS

The Panel concludes that due to the lack of an adequate dossier supporting the use of potassium amino acid chelate and of iron amino acid chelate, the safety of potassium amino acid chelate and of iron amino acid chelate and the bioavailability of potassium or iron from the respective sources cannot be assessed.

Key words:

Food supplements, potassium amino acid chelate, iron amino acid chelate.

DOCUMENTATION PROVIDED TO EFSA

1. Dossier on potassium amino acid chelate proposed for Addition to Annex II of Directive 2002/46/EC of the European Parliament and of the Council relating to Food Supplements. June 2005. Submitted by Kabco Pharmaceutical, Inc.
2. Dossier on iron amino acid chelate proposed for Addition to Annex II of Directive 2002/46/EC of the European Parliament and of the Council relating to Food Supplements. June 2005. Submitted by Kabco Pharmaceutical, Inc.

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GLOSSARY / ABBREVIATIONS

ANS	Scientific Panel on Food Additives and Nutrient Sources added to Food
EFSA	European Food Safety Authority