

SCIENTIFIC OPINION

Inability to assess the safety of calcium amino acid chelate, copper amino acid chelate, magnesium amino acid chelate, manganese amino acid chelate and zinc amino acid chelate added for nutritional purposes to food supplements based on the supporting dossiers ¹

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

(Questions No EFSA-Q-2006-297, EFSA-Q-2006-298, EFSA-Q-2006-299, EFSA-Q-2006-300, EFSA-Q-2006-301)

Adopted on 30 April 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 calcium amino acid chelate, copper amino acid chelate, magnesium amino acid chelate, manganese amino acid chelate and zinc amino acid chelate added for nutritional purposes to food supplements based on the supporting dossiers following a request from the European Commission. *The EFSA Journal* (2009) 1077, 1-5.

BACKGROUND AS PROVIDED BY THE 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 calcium amino acid chelate, copper amino acid chelate, magnesium amino acid chelate, manganese amino acid chelate and zinc 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 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 calcium-, copper-, magnesium-, manganese and zinc amino acid chelates added for nutritional purposes to food supplements.

² OJ L 183, 12.7.2002, p. 51.

ASSESSMENT

1. Summary of the information provided by the petitioner

According to the petitioner, calcium-, copper-, magnesium-, manganese- and zinc-amino acid chelates consist of the respective nutrient cation (Ca, Cu, Mg, Mn, Zn) and an amino acid/polypeptide/metabolic intermediate at a ratio of 1:1 or 1:2. Specifications were provided for cadmium, lead, mercury, cesium and arsenic. Microbiological specifications were also provided. However, no details are provided neither on the chemical nature of the sources nor on the origin or nature of the respective polypeptide fractions composing the sources.

No adequate description of the manufacturing process is provided explaining e.g. more in particular the role and fate of aspartic acid, citric acid and the large carbohydrate fraction derived from the rice flour in the sources after production.

No data were provided on the proposed use levels, the safety of calcium-, copper-, magnesium-, manganese- and zinc-amino acid chelates, nor on the bioavailability of calcium, copper, magnesium, manganese and zinc from these sources.

2. Assessment

The Panel notes that the petitioner has not provided any information on the nature of amino acids in the amino acid chelates.

The Panel notes that the petitioner has not provided any data on the toxicity of calcium-, copper-, magnesium-, manganese- and zinc-amino acid chelates, nor on the bioavailability of calcium, copper, magnesium, manganese and zinc from these sources.

CONCLUSIONS

The Panel concludes that due to the lack of an adequate dossier supporting the use of calcium, copper-, magnesium-, manganese- and zinc-amino acid chelates in food supplements, the safety of calcium-, copper-, magnesium-, manganese- and zinc amino acid chelates and the bioavailability of calcium, copper, magnesium, manganese and zinc from these sources cannot be assessed.

Key words:

Food supplements, copper amino acid chelate, magnesium amino acid chelate, manganese amino acid chelate, zinc amino acid chelates, calcium, copper, magnesium, manganese, zinc.

DOCUMENTATION PROVIDED TO EFSA

1. Dossier on calcium 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 Natur Energi ApS.
2. Dossier on copper 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 Natur Energi ApS.
3. Dossier on magnesium 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 Natur Energi ApS.
4. Dossier on manganese 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 Natur Energi ApS.
5. Dossier on zinc 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 Natur Energi ApS.

ACKNOWLEDGEMENTS

The European Food Safety Authority wishes to thank the members of the Working Group B on Food Additives and Nutrient Sources added to Food for the preparation of this opinion: D. Boskou, U.R. Charrondiere, B. Dusemund, D. Gott, T. Hallas-Møller, K.F.A.M. Hulshof, J. König, C. Le Donne, D. Parent-Massin, I.M.C.M. Rietjens, G.J.A. Speijers, P. Tobback, T. Verguieva, R.A. Woutersen.

GLOSSARY / ABBREVIATIONS

ANS	Panel on Food Additives and Nutrient Sources added to Foods
EC	European Commission
EFSA	European Food Safety Authority