European Food Safety Authority

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SCIENTIFIC OPINION

Inability to assess the safety of selenium amino acid chelate added for nutritional purposes as a source of selenium in food supplements and the bioavailability of selenium 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-2006-223)

Adopted on 28 January 2009

This scientific statement replaces the earlier statement published on 5 February 2009.[2]

SCIENTIFIC PANEL MEMBERS

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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 selenium 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 supplements[3].

[1] For citation purposes: Scientific Statement of the Panel on Food Additives and Nutrient Sources added to Food on a request from the Commission on selenium amino acid chelate as a source of selenium added for nutritional purposes to food supplements. *The EFSA Journal* (2009) 952, 1-4

[2] Editorial changes only: page 2 point 1, the value was changed from mg to g. The changes do not affect the overall conclusion of the scientific statement. To avoid confusion, the original version has been removed from the website.

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 selenium amino acid chelate added for nutritional purposes in food supplements.

STATEMENT

1. Summary of information provided on selenium amino acid chelate

According to the petitioner, selenium amino acid chelate is composed of selenium plus amino acid chelate (no further details provided). It is described as an off-white to tan powder. The petitioner states that the chelate is present at a level of 1 g/kg in the final product, other components being carbonate, 920 g/kg, and citrate 79 g/kg. Specifications were provided for cadmium (limit 5 mg/kg), lead (limit 3 mg/kg) and arsenic (limit 3 mg/kg) and microbiological specifications were also provided. The description of the manufacturing process used to produce selenium amino acid chelate was insufficient to characterise the compound.

Use levels for the chelate were not provided. The petitioner refers only to a daily value of 70 µg selenium per person developed by the US Food and Drug Administration (US FDA) for selenium and a tolerable upper intake level (UL) of 400 µg selenium per person per day established by the Institute of Medicine of the US National Academy of Sciences.

The petitioner states that amino acid chelates enhance the body's ability to utilise attached minerals through their affinity for other amino acids. The petitioner provides limited information on the properties and characteristics of selenium, its function in the body, its toxicity and its postulated role in prevention of cancer and heart disease. No data were provided on the bioavailability and safety of selenium amino acid chelate.

2. Assessment

The Panel notes that:

- The petitioner has not provided any information on the chemical identity of the amino acids in the amino acid chelate.
- The petitioner has not provided any data on the toxicity of selenium amino acid chelate, or on the bioavailability of selenium from this source.

CONCLUSIONS

The Panel concludes that due to the lack of an adequate dossier supporting the use of selenium amino acid chelate in food supplements, the safety of selenium amino acid chelate and the bioavailability of selenium from this substance cannot be assessed.

[3] OJ L 183, 12.7.2002, p. 51.

Key words:

Food supplements, selenium amino acid chelate

DOCUMENTATION PROVIDED TO EFSA

Dossier on selenium 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. 2005. Submitted by Kabco Pharmaceutical, Inc. (USA)

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GLOSSARY / ABBREVIATIONS

ANS Panel	The Scientific Panel on Food Additives and Nutrient Sources added to Food
EFSA	European Food Safety Authority
UL	Tolerable Upper Intake Level
US FDA	US Food and Drug Administration