Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a request from the Commission related to

Calcium sulphate for use in foods for particular nutritional uses

adopted on 10 December 2003

SUMMARY

The Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food has been asked to evaluate calcium sulphate as a source of calcium for use in the manufacture of foods for particular nutritional uses.

Calcium sulphate is an approved food additive (E 516). It was evaluated by the Scientific Committee on Food in 1990 and an Acceptable Daily Intake not specified was allocated.

The intake of calcium sulphate from the proposed use can be estimated to be from 531mg (375 mg of sulphate and 156 mg of calcium) to 1062 mg (750 mg of sulphate and 312 mg of calcium) per person per day. This intake is well below the tolerable upper intake level of 2500 mg/person/day for calcium established for adults by the SCF in 2003. The Panel does not anticipate that the additional intake of sulphate from the use of calcium sulphate in waters would result in any adverse effects.

In human studies the bioavailability of calcium from calcium sulphate in waters is comparable to that from milk and the sulphate anion does not affect the urinary excretion of calcium.

The Panel concluded that calcium sulphate as a source of calcium for use in foods for particular nutritional uses is not of concern from the safety point of view.

KEY WORDS

Calcium sulphate, foods for particular nutritional uses; CAS Registry number: 7778-18-9; CAS Registry number: 10101-41-4

http://www.efsa.eu.int/p_foodadd_en.html
BACKGROUND

The Scientific Committee on Food (SCF) was asked in November 2001 to consider the safety of a number of substances as sources of nutrients for foods for particular nutritional uses. The evaluation could not be completed under the SCF mandate and continuation of this work now falls to the EFSA Scientific Panel on Food Additives, Flavourings, Processing Aid and Materials in Contact with Food. Calcium sulphate as a source of calcium was one of the substances.

TERMS OF REFERENCE

The Commission asks the European Food Safety Authority to provide a scientific opinion, based on its consideration of the safety and bioavailability of the nutrient source, calcium sulphate, when used in the manufacture of foods for particular nutritional uses.

ASSESSMENT

Chemistry

Calcium sulphate, the calcium salt of sulphuric acid appears in two forms: as anhydrite with a chemical formula Ca SO₄, molecular weight of 136.14 and CAS Registry Number 7778-18-9 or a dihydrate with a chemical formula CaSO₄·2H₂O, a molecular weight of 172.18 and CAS Registry Number 10101-41-4. It exists either as odourless white crystals or crystalline powder. When dissolved both salts dissociate to calcium and sulphate ions. Calcium sulphate dihydrate is of limited solubility in water. The following evaluation covers both calcium sulphate and calcium sulphate dihydrate.

Specifications

According to the petitioner the purity criteria for calcium sulphate, as shown by the analysis of calcium sulphate dihydrate, comply with the specifications for the substance used as a food additive (E 516) in Commission Directive 2000/63/EC amending Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners, JECFA specifications (JECFA, 1975), and with those of European Pharmacopoeia (third edition) (Ph. Eur. 3, 1996).

Case of need and proposed uses

According to the petitioner, calcium sulphate is one of the three soluble inorganic compounds able to enrich drinks with calcium. Two other salts are calcium carbonate and calcium chloride. Calcium carbonate and calcium sulphate dihydrate are of limited solubility in water. Use of a well-balanced mixture of these salts enables higher concentrations of calcium to be achieved in a product.

According to the petitioner, calcium sulphate is intended to be used in waters and water based beverages at the level of 354.2 mg/l providing 250 mg/l of sulphate and 104.2 mg/l of calcium. This level complies with the guidance level for sulphate in Directive 98/83/EC on drinking water. It is
also in line with WHO guidelines for water quality (1996) set on the taste perception threshold for sulphate by human beings.

For comparison, the intended level of use is 4 to 5 times lower than that in certain natural mineral waters available on the market in the European Union.

**Exposure**

The intake of calcium sulphate from the proposed use can be estimated to be from 531mg (375 mg of sulphate and 156 mg of calcium) to 1062 mg (750 mg of sulphate and 312 mg of calcium) per person per day taking into account the level indicated by the petitioner and assuming that the normal daily water intake is 1.5 l to 3 l per person (25-50 ml per kg body weight for a person with body mass of 60 kg) and that these drinks comprise the sole daily fluid intake. This intake is well below the tolerable upper intake level of 2500 mg/person/day for calcium established for adults by the SCF (SCF, 2003).

**Existing authorisations and evaluations**

The use of calcium sulphate as a food additive was evaluated by SCF in 1990 and was allocated an Acceptable Daily Intake (ADI) not specified (SCF, 1990). At that time the Committee evaluated several cations and anions and established a group ADI not specified, although exhaustive systematic toxicological studies have not been carried out with the individual ions. At that time, the Committee considered that these ions were constituents of the major electrolytes in all biological material from animal and plant origin and therefore occurred in foodstuffs. Therefore, the Committee was of opinion that no safety problems were likely to arise, provided the contribution from food intake did not disturb the homeostatic mechanisms controlling the electrolyte balance of the body.

Calcium sulphate was also evaluated by JECFA and an ADI not specified was allocated (JECFA, 1986).

**Biological and toxicological data**

**Toxicological data**

No data on toxicological aspects were submitted.

**Human data on absorption of calcium from calcium-rich mineral waters**

The bioavailability of calcium from natural mineral water containing calcium sulphate was studied in 15 lactose intolerant male individuals and compared to that from milk. In eight of 15 subjects, there was a higher level of calcium absorption from mineral water than from milk. Bioavailability was similar in five of 15 subjects. The bioavailability of calcium absorption from milk was greater than that from mineral water in 2 of 15 subjects (Halperrn et al., 1991).

Calcium bioavailability from natural calcium and sulphate rich mineral water was compared with that from milk in nine healthy young women. Calcium absorption was measured in the fasting state.
Calcium sulphate

Discussion

The studies indicate that the bioavailability of calcium from calcium sulphate in mineral waters is comparable to that from milk and that the sulphate anion does not affect the urinary excretion of calcium.

The intake of calcium sulphate from the proposed use can be estimated to be from 531 mg (375 mg of sulphate and 156 mg of calcium) to 1062 mg (750 mg of sulphate and 312 mg of calcium) per person per day. This intake is well below the tolerable upper intake level of 2500 mg/person/day for calcium established for adults by the SCF (SCF, 2003). The Panel does not anticipate that the additional intake of sulphate from the use of calcium sulphate in waters would result in any adverse effects.

Given the previous approval of calcium sulphate as a food additive (JECFA, 1986; SCF, 1990) a toxicological evaluation of calcium sulphate is not needed for the present opinion.

CONCLUSIONS AND RECOMMENDATIONS

The Panel noted that the bioavailability of calcium from calcium sulphate in waters is comparable to that from milk.

The Panel concluded that calcium sulphate as a source of calcium for use in foods for particular nutritional uses is not of concern from the safety point of view.

DOCUMENTATION PROVIDED TO EFSA


Letter from the European Commission to the Chairman of the Scientific Committee on Food on “Evaluation of a number of substances added for specific nutritional purposes in foods for particular nutritional uses” dated 03/12/2002, Brussels. SCF/CS/ADD/NUT/50.

Additional submissions related with the dossier on calcium sulphate submitted by IDACE in February 2003:

- Letter Additional information on calcium sulphate: Answers to the questions 1,2, and 3 concerning the specification, intended use levels and intake estimates,
- Copy Chemische Fabrik Lehrte: Chemical analysis,
- Copy Specification Danone Group Beverages Ingredients, Mineral Salts, Appendices.
Additional submissions related with the dossier on calcium sulphate submitted by Danone-company in February 2003 consisting of the following scientific publications:

- “Calcium bioavailability from calcium- and sulphate-rich mineral water, compared with milk, in young adult women”. Couzy, F. et al., 1995.
- “Absorbability of the calcium in a high-calcium mineral water”. Heaney, R.P. et al., 1994
- “Effect of calcium supplementation as a high-calcium mineral water on bone loss in early postmenopausal women”. Cepollaro, C. et al., 1996.
- A release of the WHO dedicated to sulphates in general: Sulphate (without name of the author, date, publication details).

REFERENCES


SCIENTIFIC PANEL (AFC) MEMBERS

ACKNOWLEDGEMENTS
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