

SCIENTIFIC OPINION

Calcium fluoride as a source of fluoride added for nutritional purposes to food supplements

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

(Question No EFSA-Q-2005-088)

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PANEL MEMBERS

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SUMMARY

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 calcium fluoride added for nutritional purposes as a source of fluoride in food supplements and on the bioavailability of fluoride from this source.

The present opinion deals only with the safety of calcium fluoride as a source of fluoride and the bioavailability of the fluoride from this source. The safety of fluoride itself, in terms of amounts that may be consumed, is outside the remit of this Panel.

Most of the available toxicity data examined in this opinion comes from exposure to freely soluble forms of fluoride, such as sodium fluoride, and the results of comprehensive evaluations carried out on these substances concluded that the most sensitive effect of chronic fluoride exposure in humans is dental fluorosis. The conclusions of these evaluations also indicated that genotoxicity and carcinogenicity are not of concern for fluoride exposure in humans. Upper tolerable intake levels for fluoride have been established in Europe amounting to 1.5 mg/day for 1–3 year old children, 2.5 mg/day for 4–8 year old children, 5 mg/day for 9–15 year old children and 7 mg/day for adults (≥ 15 year old). The scarce literature available on the toxicity of calcium fluoride suggests that calcium fluoride shows less toxicity than soluble forms of fluoride at equivalent dosages.

Proposed supplementation foresees that calcium fluoride will be added to food supplements to supply approximately 1 mg calcium fluoride, corresponding to approximately 0.5 mg fluoride/day. However, due to its reported low solubility and bioavailability actual fluoride exposure from calcium fluoride supplementation should be at best about half the anticipated daily amounts (0.25 mg fluoride/day). Daily calcium exposure from this source will be very small and of no safety concern.

The Panel noticed that the foreseen supplementation with calcium fluoride will not exceed fluoride upper tolerable intake levels established in Europe for different populations. Furthermore, the potential added contribution of this supplementation for adults to the available total fluoride daily exposures' estimates will not exceed the specific upper tolerable intake level for the adult population and for children above the age of 8 year old. The Panel concludes that the use of calcium fluoride as food supplement at the proposed use levels would be of no safety concern for these populations.

However, the Panel noted that one available exposure scenario, which considers drinking water fluoride supplementation of 1 mg/l, suggests that the potential added contribution of calcium fluoride supplementation to the total estimated dietary exposure from food and drinking water could reach or exceed most upper tolerable intake level values established in Europe for children in age ranges of 1 to 3 and 4 to 8 year old.

The Panel concludes that the use of calcium fluoride as food supplement would be of no safety concern provided that fluoride upper tolerable intake level values established in Europe are not exceeded by the combined exposure from food supplements and the diet.

The Panel notes that according to Commission Regulation (EC) No 629/2008 the maximum levels of lead, mercury and cadmium in food supplements as sold should be 3 mg/kg, 0.1 mg/kg and 1 mg/kg, respectively.

Key words:

Calcium fluoride, CAS 7789-75-5, food supplements