



Risk Assessment of "Other Substances"-Beta-Alanine

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Authors' contributions

This work was carried out in collaboration between all authors. The opinion has been assessed and approved by the Panel on Nutrition, Dietetic Products, Novel Food and Allergy of VKM. All authors read and approved the final manuscript.

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ABSTRACT

The Norwegian Scientific Committee for Food Safety (Vitenskapskomiteen for mattrygghet, VKM) has, at the request of the Norwegian Food Safety Authority (Mattilsynet; NFSA), assessed the risk of "other substances" in food supplements and energy drinks sold in Norway. VKM has assessed the risk of doses given by NFSA. These risk assessments will provide NFSA with the scientific basis while regulating "other substances" in food supplements.

"Other substances" are described in the food supplement directive 2002/46/EC as substances other than vitamins or minerals that have a nutritional and/or physiological effect. It is added mainly to food supplements, but also to energy drinks and other foods. In this series of risk assessments of "other substances" the VKM has not evaluated any claimed beneficial effects from these substances, only possible adverse effects.

The present report is a risk assessment of specified doses of beta-alanine in food supplements, and it is based on previous risk assessments and articles retrieved from literature searches.

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According to information from NFSA, beta-alanine is an ingredient in food supplements sold in Norway. NSFA has requested a risk assessment of beta-alanine: 1000, 1500 and 2000 mg/day from food supplements.

Beta-alanine is a non-essential, non-proteogenic naturally occurring beta amino acid. Beta-alanine is a component of the naturally occurring peptides carnosine, anserine and balenine. Supplementation with beta-alanine leads to an increased production of the peptide carnosine, which is found in high concentrations in the skeletal muscle of both vertebrates and non-vertebrates. Data suggest that beta-alanine functions as a small molecule neurotransmitter and should join the ranks of the other amino acid neurotransmitters.

The only observed adverse effect from beta-alanin supplementation in humans is transient (1-2 hours) paraesthesia and flushing. Paraesthesia is characterised by a stinging or prickling sensation in the skin. There is no evidence that the paraesthesia in the skin is harmful in any way. Long-term studies in humans were not found. Four small human clinical studies have been included in this risk assessment. The occurrence of paraesthesia apparently is dependent on the magnitude of the individual doses that the daily dose is split into. Single doses of beta-alanine of 10 mg/kg bw (700 mg in a 70 kg person) or more provoked transient paraesthesia. Symptom occurrence and severity increased with the dose. Repeated intakes of 5 mg beta-alanine/kg bw or less taken with >2 hours intervals did not induce paraesthesia. Haematology and plasma clinical chemistry was found normal after daily doses of 2.8 g and 3.2 g for 4 weeks in healthy adults. Apart from occasional paraesthesia, a daily dose of 6.4 g for up to seven weeks did not induce any adverse clinical effects in healthy adults of 80 kg, corresponding to a dose of 5.6 g per day in a 70-kg person.

We are not aware of any data indicating that children and adolescents are more vulnerable than adults for supplementation with beta-alanine on a per kg bw basis.

No relevant animal studies were identified.

VKM concludes that:

- In adults (≥ 18 years), the specified doses 1000, 1500 and 2000 mg/day of beta-alanine in food supplements are unlikely to cause adverse health effects provided that beta-alanine is consumed with maximum 5 mg/kg bw per intake and a minimum of 2 hours between the intakes.
- In adolescents (14 to <18 years) and children (10 to <14 years) the specified doses 1000, 1500 and 2000 mg/day of beta-alanine in food supplements are unlikely to cause adverse health effects provided that beta-alanine is consumed with maximum 5 mg/kg bw per intake and a minimum of 2 hours between the intakes.

Children younger than 10 years were not within the scope of the present risk assessment.

Keywords: *Beta-alanine; food supplement; adverse health effect; negative health effect; Norwegian Food Safety Authority; Norwegian Scientific Committee for Food Safety; other substances; risk assessment; VKM.*

Available: <https://vkm.no/download/18.4fdace2015eceedf21453704/1507126572622/Risk%20assessment%20of%20beta-alanine%20-%20-%20other%20substances.pdf>

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NOTE:

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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