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Risk Assessment of "Other Substances" – L-serine

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Authors' contributions

This work was carried out in collaboration among 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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Grey Literature

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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.

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The present report is a risk assessment of specified doses of L-serine in food supplements, and it is based on previously published risk assessments and scientific papers retrieved from a comprehensive literature search.

L-serine is a non-essential amino acid which is produced endogenously and is supplied from the diet. In addition to its role in protein synthesis, L-serine has an important role as a major contributor to the one-carbon pool and is involved in the metabolism of several key compounds, including glycine, cysteine, taurine, and phospholipids and of D-serine.

According to information from NFSA, L-serine is an ingredient in food supplements sold in Norway. NSFA has requested a risk assessment of 50, 500, 1000, 1250, 1500 and 1750 mg/day of L-serine from food supplements. Most dietary proteins contain about 4-5% L-serine. Rich sources of proteins are meat, dairy products, legumes, fish, nuts, seeds, eggs and whole grains. Dietary intake of L-serine in Norway is not known, but results show an overall mean intake of L-serine from food and food supplements of 3.5 g/day in the United States (NHANES III, USA).

In the first phase of the present evaluation of "other substances", previous reports that have assessed the safety of L-serine supplementation in humans were identified. In the second phase, a systematic literature search was performed to retrieve scientific papers published before 11 May 2016 (human studies literature search) and before 28 July 2016 (animal studies literature search). Based on this search, we did not identify any long-term studies in healthy individuals that could be used for safety evaluations. On the other hand, three relevant animal studies were included in this report.

The animal studies revealed no adverse health effects as a result of the tested doses of Lserine (840-3000 mg/kg bw per day). For the risk characterisation of L-serine, in the absence of long-term studies in healthy individuals, VKM based the value of comparison on the no observed adverse effect level (NOAEL), 3000 mg/kg bw per day which was the highest dose tested in a 90-days toxicological study in rats. This value was used to calculate the Margin of Exposure (MOE) values for daily intake of 50, 500, 1000, 1250, 1500 and 1750 mg L-serine in children (10 to <14 years), adolescents (14 to <18 years) and adults (≥18 years). The MOE-values ranged from 74 to 4200, which were considered acceptable since L-serine is a nutrient that does not cause any well documented adverse effects and because studies indicate a high endogenous production (Snell, 1986) and a high dietary intake of L-serine (NHANES III, USA) compared to the doses considered in the present risk assessment.

Thus, VKM concludes that:

- In adults (≥18 years), the specified doses 50, 500, 1000, 1250, 1500 and 1750 mg/day L-serine in food supplements are unlikely to cause adverse health effects.
- In adolescents (14 to <18 years), the specified doses 50, 500, 1000, 1250, 1500 and 1750 mg/day L-serine in food supplements are unlikely to cause adverse health effects.
- In children (10 to <14 years), the specified doses 50, 500, 1000, 1500 and 1800 mg/day L-serine in food supplements are unlikely to cause adverse health effects.

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

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

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NOTE:

This work was carried out in collaboration between all authors. The opinion has been assessed and approved by the Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics of VKM. All authors read and approved the final manuscript.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.