Risk Assessment of "Other Substances" – Lycopene

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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 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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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 in food supplements and concentrations in energy drinks given by NFSA. These risk assessments will provide NFSA with the scientific basis while regulating the addition of "other substances" to food supplements and other foods.

"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. VKM has not in this series of risk assessments of "other substances" evaluated any claimed beneficial effects from these substances, only possible adverse effects.

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The present report is a risk assessment of lycopene, and it is based on previous risk assessments and articles retrieved from a literature search.

According to information from NFSA, lycopene is an ingredient in food supplements sold in Norway. NFSA has requested a risk assessment of 10 mg/day of lycopene in food supplements. The intake of lycopene was estimated for the age groups children (10 to <14 years), adolescents (14 to <18 years) and adults (≥18 years).

Other sources of lycopene, such as foods and cosmetics, have not been included in the present risk assessment.

Lycopene belongs to a large group of naturally-occurring pigments known as carotenoids, and is known to have antioxidant properties. Lycopene is a natural constituent of red fruits and vegetables and of certain algae and fungi. The major sources of natural lycopene in the human diet are tomatoes and tomato-based products. Fruits like pink grapefruit, watermelon, rosehip, papaya and guava are also sources of lycopene.

Lycopene can be obtained by solvent extraction of the natural strains of red tomatoes \( (Lycopersicon esculentum) \) with subsequent removal of the solvent. Synthetic lycopene can be produced by the Wittig condensation of synthetic intermediates commonly used in the production of other carotenoids used in food. Lycopene biosynthesis by the fungus \( B. \) trispora follows the same pathway as the synthesis of lycopene in tomatoes.

There are case reports of yellow-orange skin discoloration and/or gastrointestinal discomfort after prolonged high intakes of lycopene-rich food and supplements, those effects being reversible upon cessation of lycopene ingestion. The results from one study indicated that lycopene increased the incidence of the preterm labor and low birthweight babies. However, due to weaknesses in the reporting, VKM cannot use the results from this study in the risk characterisation.

An ADI of 0.5 mg/kg bw per day was established by EFSA in 2008. The ADI was derived from the NOAEL of 50 mg/kg bw per day from a 52-week toxicity study in rats, based on a partly reversible increased level of the liver enzyme alanine transaminase (ALT). An ADI is set to cover the general population, including children. This ADI-value was used for comparison with the estimated exposure in the risk characterization.

From a daily dose of 10 mg lycopene, the daily exposure is 0.23 mg/kg bw for children (10 to <14 years), 0.16 mg/kg bw for adolescents (14 to <18 years), and 0.14 mg/kg bw for adults (≥18 years). Thus, the intakes are below the ADI of 0.5 mg/bw per day for all age groups.

VKM concludes that it is unlikely that a daily dose of 10 mg lycopene from food supplements causes adverse health effects in children (10 to <14 years), adolescents (14 to <18 years) and adults (≥18 years).

Keywords: Adverse health effects; food supplement; lycopene; negative health effects; Norwegian Food Safety Authority; Norwegian Scientific Committee for Food Safety; other substances; risk assessment; VKM.

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NOTE:

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COMPETING INTERESTS

Authors have declared that no competing interests exist.