Risk Assessment of "Other Substances" – Coenzyme Q10

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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.

Article Information

DOI: 10.9734/EJNFS/2018/42539

Received 2nd June 2018
Accepted 28th June 2018
Published 3rd July 2018

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 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. In this series of risk

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assessments of "other substances", VKM has not evaluated any potential beneficial effects from these substances, only possible adverse effects.

The present risk assessment of coenzyme Q10 (CoQ10) is based on previous risk assessments and articles retrieved from a literature search.

According to information from NFSA, CoQ10 is an ingredient in food supplements sold in Norway. NFSA has requested a risk assessment of intake of 100 mg/day of CoQ10 in food supplements.

CoQ10 (CAS no. 303-98-0) is a naturally-occurring, lipid-soluble compound present in all tissues in humans. Ubiquinone is the totally oxidized form (CoQ10), whereas ubiquinol (CoQ10H2) is the totally reduced form. Meat and fish are the food sources richest in CoQ10. CoQ10 intake from the diet ranges between 3 and 6 mg/day in developed countries. The total body pool of CoQ10 is estimated to be approximately 0.5–1.5 g in an adult.

Several studies of CoQ10 (both oxidized and reduced form) have been performed in healthy humans (adults) and animals, showing fairly similar results. The adverse effects reported in a small number of human subjects were generally limited to mild gastrointestinal symptoms such as nausea and stomach upset. In humans, orally ingested CoQ10 was well tolerated at doses up to 900 mg/day (corresponding to 12.9 mg/kg bw per day in a 70 kg adult) over periods up to one month. With regard to animal studies, the lack of adverse effects of CoQ10 doses up to 1200 mg/kg per day in long-term toxicity studies supported and extended the results from the human studies. No studies on children (10 to <14 years) and adolescents (14 to <18 years) were identified. Based on the included literature there was no evidence indicating that age affects tolerance for CoQ10. Therefore, in this risk characterisation the same tolerance as for adults was assumed for these age groups (adjusted for body weight).

From a daily dose of 100 mg CoQ10, the daily exposure is 2.3 mg/kg bw for children (10 to <14 years), 1.6 mg/kg bw for adolescents (14 to <18 years), and 1.4 mg/kg bw for adults (≥18 years). For the risk characterization, the values used for comparison with the estimated exposure are 900 mg/day (corresponding to 12.9 mg/kg bw per day in a 70 kg adult) based on human studies (4 weeks) and the no observed adverse effect level (NOAEL) of 1200 mg/kg bw per day based on a long-term toxicity study in rats (52 weeks).

The margin of exposure (MOE) approach is used for the rat study; that is the ratio of the NOAEL to the exposure. An acceptable MOE value for a NOAEL-based assessment of CoQ10 based on an animal study is ≥100, which includes a factor 10 for extrapolation from animals to humans, and a factor 10 for interindividual human variation. Comparing the NOAEL from a long-term toxicity study in rats with the estimated exposure for the different age groups, it is unlikely that a daily dose of 100 mg/day of CoQ10 causes adverse health effects in children above 10 years, adolescents and adults.

Comparing the dose reported to be well tolerated for healthy adults directly with the estimated exposure, it is unlikely that a daily dose of 100 mg/day of CoQ10 causes adverse health effects in children above 10 years, adolescents and adults.

VKM concludes that it is unlikely that a daily dose of 100 mg of CoQ10 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; coenzyme Q10; food supplement; negative health effects; Norwegian Food Safety Authority; Norwegian Scientific Committee for Food Safety; other substances; risk assessment; ubidecarenone; ubiquinol; ubiquinone; VKM.

Available: https://vkm.no/download/18.645b840415d03a2fe8f26085/1502712503082/Risk%20assessment%20of%20"other%20substances%22%20%E2%80%93%20Coenzyme%20Q10.pdf
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.