Risk Assessment of "Other Substances" – D-Ribose

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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, Flavorings, 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 (NFSA) [Vitenskapskomiteen (VKM) for mattrygghet] 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.

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

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According to information from NFSA, D-ribose is an ingredient in food supplements sold in Norway. NFSA has requested a risk assessment of 3100 and 6200 mg/day of D-ribose in food supplements for the age groups children (10 to <14 years), adolescents (14 to <18 years) and adults (>18 years).

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

D-ribose is a component of the genetic material RNA and is synthesized in all living cells via the pentose phosphate pathway. D-ribose is also a structural component of adenosine triphosphate (ATP), the primary source of cellular energy and a key component of riboflavin (e.g. vitamin B2). The estimated endogenous synthesis of D-ribose is referred to be from 2.7 g per day (women) to 16.5 g per day (men). D-ribose is available in small amounts in the diet via ripe fruits and vegetables. It is also an ingredient in food supplements, some so-called energy drinks and in cosmetics as skin conditioner and humectant.

Orally administered D-ribose is absorbed in the small intestine by passive diffusion. Absorption rates after oral ingestion of doses up to 200 mg/kg bw per hour (administered for 5 hours) has been shown to range from 87.8 to 99.8% in humans.

No serious adverse health effects were identified at doses up to 20 g per day as reported in the human studies included in this opinion.

Based on a subchronic oral toxicity study in rats, no observed adverse effect levels (NOAELs) of 3.6 and 4.4 g/kg bw per day in males and females were derived. The NOAELs were based on a statistically significant decrease in body weight. In another study in rats, the NOAELs for embryo toxicity/teratogenicity of D-ribose were 3.6 and 4.6 g/kg bw per day based on individual females. This NOAELs were primarily based on a statistically significantly higher incidence of one or multiple wavy ribs in the mid- and high-dose groups compared to control animals.

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 D-ribose. Therefore, in this risk characterisation a tolerance as for adults, based on body weight, were assumed for these age groups.

The values used for comparison with the estimated exposure in the risk characterization are 20 g per day (corresponding to 286 mg/kg bw per day in a 70 kg adult) considered to be without appreciable health risk for most healthy adults and the NOAEL of 3.6 g/kg bw per day from the subchronic toxicity and embryotoxicity/teratogenicity studies in rats.

From a daily dose of 3100 mg or 6200 mg of D-ribose, the intake levels are 71.4, 50.6 and 44.3 mg/kg bw per day and 142.6, 101.1 and 88.6 mg/kg bw per day for for children (10 to <14 years), adolescents (14 to <18 years) and adults (≥18 years), respectively.

The calculated MOE values from the rat study for a daily intake of 3100 mg per day were 50.4, 71.1 and 81.3 for children (10 to <14 years), adolescents (14 to <18 years) and adults (≥18 years), respectively. The calculated MOE values for a daily intake of 6200 mg per day were 25.2, 35.6 and 40.6 for children (10 to <14 years), adolescents (14 to <18 years) and adults (≥18 years), respectively. In this case, MOE values below 100 are regarded as acceptable since D-ribose is present in all cells in the body and the daily doses from food supplements are in the same order as the endogenous production, which ranges from 2.7 g per day (women) to 16.5 g per day (men) (Bioenergy Life Science Inc., 2008).

VKM concludes that it is unlikely that daily doses of 3100 mg or 6200 mg D-ribose in food supplements causes adverse effects in children (10 to <14 years), adolescents (14 to <18 years) and adults (≥18 years).
Keywords: Adverse health effect; D-ribose; food supplement; negative health effect; Norwegian Food Safety Authority; Norwegian Scientific Committee for Food Safety; other substances; risk assessment; VKM.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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