Risk Assessment of "Other Substances" – Inulin

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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.

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 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", VKM has not evaluated any claimed beneficial effects from these substances, only possible adverse effects.

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

According to information from NFSA, inulin is an ingredient in food supplements sold in Norway. NFSA has requested a risk assessment of the dose 3 g/day of inulin in food supplements.

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The total exposure to inulin from other sources than food supplements and cosmetics, such as foods, is not included in the risk assessment.

Inulin is a naturally occurring carbohydrate found in a variety of vegetables and fruits such as onions, leeks, garlic, asparagus, artichokes, bananas and wheat. Chicory root is the most common source of industrially produced inulin. Inulin belongs to the nondigestible polysaccharides which are carbohydrates that resist digestion in the small intestine but are fermented by bacteria in the colon.

No serious adverse health effects were identified in the human studies included in this opinion. The reported negative health effects of inulin-type fibres are generally mild gastrointestinal symptoms and include diarrhea, abdominal rumbling, bloating, cramping and excessive flatulence. Such effects occur over a wide range of doses and may also depend on the source of inulin. Chain length influences the negative gastrointestinal effects, which will be less with long-chained inulin molecules. As a pragmatic approach, the intake of 5 g/day of inulin from agave and Jerusalem artichoke and 10 g/day of inulin from chicory root and globe artichoke were chosen as the values for comparison with the exposure to inulin from food supplements in the risk characterization. These doses were without serious adverse health effects, even though mild gastrointestinal effects may occur in some/sensitive individuals. These doses are in the same range as the estimated average consumption of inulin from food in Europe (3 – 11 g/day). Data indicates that also doses up to 20 g/day may be well tolerated by most people. However, there is a wide interpersonal variability in the doses at which gastrointestinal effects associated with the colonic fermentation will appear.

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 inulin. Therefore, in this risk assessment the same tolerance as for adults was assumed for these age groups (adjusted for body weight).

From a daily dose of 3 g inulin, the calculated intake levels are 69.1, 48.9 and 42.9 mg/kg bw per day for children (10 to <14 years), adolescents (14 to <18 years) and adults (≥18 years), respectively. In the risk characterization, the values used for comparisons with the exposure from food supplements is 5 g/day of inulin from agave and Jerusalem artichoke and 10 g/day of inulin from chicory root and globe artichoke (corresponding to 71 and 143 mg/kg bw per day, respectively, in a 70 kg adult).

Comparing the exposure of a daily dose of 3 g/day of inulin from food supplements with the inulin doses of 5 g/day and 10 g/day considered to be without appreciable risk for most healthy adults, it is unlikely that this dose in food supplements causes any adverse health effects in children above 10 years, adolescents and adults.

VKM concludes that it is unlikely that a daily dose of 3 g of inulin 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 effect; food supplements; inulin; negative health effect; Norwegian Food Safety Authority; Norwegian Scientific Committee for Food Safety; other substances; risk assessment; VKM.

Available: https://vkm.no/download/18.645b840415d03a2fe8f26046/1502711467329/Risk%20assessment%20of%20other%20substances%22%20%E2%80%93Inulin.pdf

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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