Assessment of Intake of Nicotinic Acid and Nicotinamide in Relation to Tolerable Upper Intake Levels

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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 Nutrition, Dietetic Products, Novel Food and Allergy of VKM. All authors read and approved the final manuscript.

Article Information

DOI: 10.9734/EJNFS/2018/42535

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 intake of niacin in the Norwegian population. NFSA has also requested that VKM conduct scenario calculations to illustrate the consequences of establishing separate maximum limits for nicotinic acid (1, 4, 8 or 10 mg/day) and nicotinamide (100, 500, 700 or 900 mg/day) in food supplements, by assessing these scenarios against existing tolerable upper intake levels (ULs). The current maximum limit for niacin added to food supplements is 32 mg/day, including nicotinic acid, nicotinamide and inositol hexanicotinate.

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The term niacin (vitamin B3) comprises the two main water-soluble forms nicotinic acid and nicotinamide (niacinamide). The human body can get niacin from the diet or synthesise it from the essential amino acid tryptophan. Dietary intakes are expressed as milligram niacin equivalents (NEs), which correspond to 1 mg of pure niacin or 60 mg of tryptophan.

In the body, niacin primarily functions as a component of the coenzymes NAD (nicotinamide adenine dinucleotide) and NADP (nicotinamide adenine dinucleotide phosphate) which are present in all cells. These coenzymes play essential roles for the functioning of a wide range of enzymes involved in the metabolism of carbohydrates, amino acids and fat. In addition to its function in coenzymes, niacin is involved in DNA repair and gene stability. Niacin has a half-life of 20-40 minutes in the human body.

Late symptoms of severe niacin deficiency (pellagra) include fatigue, headache, apathy, depression, memory loss, dementia, pigmented skin rash after sun exposure, bright red tongue, vomiting, diarrhoea, and constipation.

Flushing (burning and itching of the face, arms and chest) and stomach irritation are the main side effects of moderately high supplemental intake of nicotinic acid (>35 mg/day). Long-term use of high doses (≥3000 mg/day) of nicotinic acid as a cholesterol-lowering drug can also be toxic to the liver. Nicotinamide, however, does not have these effects. In general, the risk of nicotinamide toxicity appears to be quite low.

VKM proposes to adopt the ULs of nicotinic acid and nicotinamide set by the Scientific Committee for Food Safety (SCF) in 2002, which are based on one human dose-response study (nicotinic acid) and several human dose-response studies (nicotinamide), respectively. Hence, the UL for supplemental nicotinic acid is suggested to 10 mg/day for adults and the UL for supplemental nicotinamide to 900 mg/day for adults. The ULs for children and adolescents have been derived on the basis of their body weights.

The ULs set for nicotinic acid and nicotinamide concern only intake from supplements since intake of nicotinic acid and nicotinamide from regular foods is considered to be without risk of negative health effects. Therefore, VKM has not conducted or evaluated scenarios with intake from both diet and the separated new maximum limits for nicotinic acid and nicotinamide in food supplements suggested by NFSA.

Dietary calculations, however, have been performed for niacin intakes (includes both nicotinic acid and nicotinamide) in various percentiles (P5, P25, mean, P50, P75 and P95) in children (2-, 4- and 9-year-olds), adolescents (13-year-olds) and adults as background information.

Mean and median intakes of niacin from the diet alone are above or at the recommended intakes for all age groups.

Because UL for supplemental nicotinic acid is 10 mg/day for adults, none of the suggested maximum limits in food supplements (1, 4, 8, or 10 mg/day) will lead to exceedance of this UL in adults. In 13-year-olds and 9-year-olds, supplements with 8 mg nicotinic acid per day will lead to exceedance of UL, and in 4-year-olds and 2-year-olds supplementation of 4 mg nicotinic acid per day will lead to exceedance of the UL for nicotinic acid.

Because UL for supplemental nicotinamide is 900 mg/day for adults, none of the suggested maximum limits in food supplements (100, 500, 700 or 900 mg/day) will lead to exceedance of UL in adults. In 13-year-olds, supplements with 700 mg nicotinamide per day will lead to exceedance of UL. In 9-year-olds, 4-year-olds and 2-year-olds, supplementation of 500 mg nicotinamide per day will lead to exceedance of the UL for nicotinic acid.

Keywords: VKM; risk assessment; Norwegian Scientific Committee for Food Safety; niacin; nicotinamide; nicotinic acid; food supplement; upper level; exposure.
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.