European Journal of Nutrition & Food Safety

12(3): 32-34, 2020; Article no.EJNFS.55593
ISSN: 2347-5641

Risk Assessment of "Other Substances" – L-phenylalanine and DL-phenylalanine

Livar Frøyland[1*], Margaretha Haugen[2], Kristin Holvik[2], Martinus Løvik[3], Tor A. Strand[4], Grethe S. Tell[5] and Per Ole Iversen[6]

[1]Norwegian Scientific Committee for Food Safety (VKM), Institute of Marine Research (NIFES), Norway.
[2]Norwegian Scientific Committee for Food Safety (VKM), Norwegian Institute of Public Health (FHI), Norway.
[3]Norwegian Scientific Committee for Food Safety (VKM), Norwegian University of Science and Technology (NTNU), Norway.
[4]Norwegian Scientific Committee for Food Safety (VKM), Innlandet Hospital Trust (HF), Norway.
[5]Norwegian Scientific Committee for Food Safety (VKM), University of Bergen (UiB), Norway.
[6]Norwegian Scientific Committee for Food Safety (VKM), University of Oslo (UiO), Norway.

Authors' contributions

This work was carried out in collaboration among 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/2020/v12i330205

Received 02 February 2020
Accepted 08 April 2020
Published 15 April 2020

Grey Literature

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.

"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 L-phenylalanine and DL-phenylalanine and is based on previous risk assessments.

**Corresponding author: Email: tron.gifstad@vkm.no;*

According to information from the Norwegian Food Safety Authority, L- and DL-phenylalanine are ingredients in food supplements sold in Norway. NFSA has requested a risk assessment of the following doses of L-phenylalanine and DL-phenylalanine in food supplements: L-phenylalanine 100, 250, 500, 750 and 1000 mg/day and DL-phenylalanine 50 and 75 mg/day.

L-phenylalanine is an essential amino acid which means it has to be obtained from the diet. Amino acids are building blocks for proteins and present in protein rich food such as milk, meat, fish, eggs and cheese.

No data on adverse health effects after chronic ingestion of supplemental phenylalanine in apparently healthy subjects are available, thus no tolerable upper intake level (UL) can be established. Patients with phenylketonuria (PKU), a genetic disorder that impairs phenylalanine hydroxylase (PAH), an enzyme involved in the metabolism of phenylalanine, must keep plasma levels of phenylalanine low in order to maintain normal growth and brain development. In Norway, all newborns are routinely screened for PKU three days after birth.

The mean dietary intake of phenylalanine in the EU population range from 0.4-4.1 g/day corresponding to 79.0 mg/kg bw per day for adolescents (10-17 years) and 58.7 mg/kg bw per day for adults, respectively (EFSA, 2013). The sweetener aspartame contains phenylalanine. Taking the molecular weight of phenylalanine into account, the proportion of to phenylalanine exposure from aspartame is 56%. The ADI of 40 mg aspartame/day/kg bw (providing 22.4 mg phenylalanine/day/kg bw) JECFA (1981) was re-evaluated and maintained in 2013, based on the notion that elevated plasma levels of phenylalanine in pregnant women leads to developmental toxicity in their children (EFSA, 2013).

The literature search did not provide novel information on adverse health effects related to intake of L-phenylalanine and no information related to DL-phenylalanine.

VKM concludes that:

- In adults (≥ 18 years), the specified doses 100, 250, 500, 750 and 1000 mg/day L-phenylalanine in food supplements are considered unlikely to cause adverse health effects.
- In adolescents (14 to < 18 years), the specified doses 100, 250, 500, 750 and 1000 mg/day L-phenylalanine in food supplements are considered unlikely to cause adverse health effects.
- In children (10 to < 14 years), the specified doses 100, 250, 500, 750 and 1000 mg/day L-phenylalanine in food supplements are considered unlikely to cause adverse health effects. Although the highest dose provides 23 mg/kg bw per day which slightly exceeds 22.4 mg/kg bw per day, it is considered unlikely to cause adverse health effects in healthy children 10 to < 14 years.
- None of the above conclusions are applicable for patients with phenylketonuria (PKU).
- No conclusion can be made regarding DL-phenylalanine.

Children below 10 years were not included in the terms of reference.

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

Available:https://vkm.no/download/18.645b840415d03a2fe8f26065/1502799816007/Risk%20assessment%20of%20%22other%20substances%22%20%E2%80%93%20L-phenylalanine%20and%20DL-phenylalanine.pdf

ISBN: 978-82-8259-196-6

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.

Competence of VKM experts: Persons working for VKM, either as appointed members of the Committee or as external experts, do this by virtue of their scientific expertise, not as representatives for their employers or third party interests. The Civil Services Act instructions on legal competence apply for all work prepared by VKM.

Suggested citation: VKM. (2016). Risk assessment of "other substances" – L-phenylalanine and DL-phenylalanine. Opinion of the Panel on Nutrition, dietetic products, Novel Food an Allergy of the Norwegian Scientific Committee for Food Safety, ISBN: 978-82-8259-196-6, Oslo, Norway.

COMPETING INTERESTS

Authors have declared that no competing interests exist.