EPA and DHA in food supplements for children and adolescents

Background

"Other substances" are substances that have a nutritional or physiological effect but are not vitamins or minerals. Examples of "other substances" include fatty acids, amino acids, coenzyme Q10 and caffeine. Excessive intake of certain "other substances" may be associated with health risks.

In the European Economic Area (EEA), the provisions on the addition of “other substances” to foods are currently only partially harmonised in Regulation (EC) No 1925/2006. This means that Member States may lay down national supplementary provisions on the aspects that are not harmonised. Any national supplementary provisions must comply, inter alia, with the general principles of EEA law on the free movement of goods, "mutual recognition" and the legal exceptions to these EEA principles.

In Norway new supplementary national provisions regarding the addition of certain “other substances” to foods including food supplements entered into force on 1 January 2020. The new national supplementary provisions are included in the Norwegian regulation “Forskrift 26. februar 2010 nr. 247 om tilsetning av vitaminer, mineraler og visse andre stoffer til næringsmidler”, which also implements Regulation (EC) No 1925/2006 in Norwegian internal law.

A so-called “positive list” for the addition of certain "other substances", was introduced as an Annex to the regulation. The intention is to reduce health risks that can occur when consuming certain "other substances" in foods, including food supplements.

The new national supplementary provisions only apply to the addition of “other substances” that a) have a purity of at least 50% or are concentrated 40 times or more, and b) are not normally consumed as a food in themselves and not normally used as an ingredient in foods.

Furthermore, the supplementary national provisions do not apply to the addition of the following “other substances”: a) plants or parts of plants in fresh, dried, chopped, cut or powdered form, b) extracts of plants or parts of plants exclusively made through basic aqueous extraction, possibly followed by dehydration, c) enzymes and microorganisms and d) "other substances" listed in Parts A and B of Annex III to Regulation (EC) No 1925/2006.

It is only permitted to add “other substances” that are listed in the “positive list” in Annex 3 to foods, including food supplements. Such addition to foods must be in accordance with the terms and conditions set in the “positive list”, including the limits that are set for the different substances. Substances regulated by other legislations like those for novel foods, food additives, flavourings, Foods for Specific Groups, etc. is outside the scope of the national supplementary provisions.

If a food business operator wants to add different quantities or use different conditions of a substance that is included in the “positive list”, the food business operator must notify the Norwegian Food Safety Authority (NFSA). If a food business operator wants to add new substances, not currently included in the “positive list”, the food business operator must apply for authorisation to the NFSA.

When needed for the NFSA to process an application or notification, the Norwegian Scientific Committee for Food and Environment (VKM) is requested to perform a risk assessment so

that new substances or higher amounts of substances listed in the “positive list” are risk assessed.

Terms of references

The NFSA hereby asks the Norwegian Scientific Committee for Food and Environment (VKM) to examine whether the exposure to EPA (CAS registry number 10417-94-4) and DHA (CAS registry number 6217-54-5) in food supplements to children and adolescents, that is covered by the national supplementary provision, might constitute a health risk for Norwegian children and adolescents (both sexes) in the age group from 3 to 18 years.

In the report «Risk assessment of «other substances» - eicosapentaenoic acid, docosapentaenoic acid and docosahexaenoic acid VKM Report 2015:27»[1] it is assessed as unlikely that the daily dose of 1290 mg DHA in food supplements will cause negative healtheffects in the age group 10-18 years. The NFSA needs a similar assessment of DHA given to children in the age from 3-10 years, of EPA for all ages (3-18 years), and an assessment of a total daily intake of DHA and EPA for all ages (3-18 years).

EPA and DHA in food supplements for children and adolescents

1) The NFSA asks the Norwegian Scientific Committee for Food and Environment (VKM) to assess if a daily intake of a food supplement containing 1100 mg DHA can consitute a health risk for Norwegian children and adolescents (both sexes) in the ages from 3 to 18 years.

2) The NFSA asks VKM to assess if a daily intake of a food supplement containing 1550 mg EPA can consitute a health risk for Norwegian children and adolescents (both sexes) in the ages from 3 to 18 years.

3) The NFSA asks VKM to assess if a daily intake of a food supplement containing both 1550 mg EPA and 1100 mg DHA can constitute a health risk for Norwegian children and adolescents (both sexes) in the ages from 3 to 18 years.

4) If these daily doses of EPA and DHA (the doses specified in question 1-3) not are considered as safe: Which doses can be assessed as safe?

This includes:

- Identify and characterise adverse health effects.
  - o Identify and describe toxicological reference point(s).
  - o Describe uncertainty related to the toxicological reference point(s).
- Estimate the exposure
  - o Estimate exposure for the dose(s) and age groups given above.
  - o Describe uncertainty related to the exposure estimates.

[1] Risk assessment of "other substances" - eicosapentaenoic acid, docosapentaenoic acid and docosahexaenoic acid VKM Report 2015:27

- Characterise health risks associated with exposure to EPA and DHA, and describe uncertainty that may have an impact on the conclusions.
- Identify and describe main knowledge gaps that may have an impact on the conclusions.