Background

According to Norwegian food legislation foods and drinks fortified with vitamins and minerals could until January 1. 2020 not be placed on the market without special permission from the Norwegian Food Safety Authority (NFSA). This was regulated in the supplementary Norwegian provisions on the addition of vitamins, minerals and certain «other substances» in the regulation (EF) 1925/2006.

In 2006 the Norwegian Scientific Committee for Food and Environment adapted a Danish model for assessing applications concerning food fortification with vitamins and minerals into Norwegian conditions. The NFSA also requested the Norwegian Scientific Committe for Food and Environment to assess whether the model can represent a safe assessment of fortification. The Norwegian Scientific Committee for Food and Environment updated the model in 2009[1] and in 2013[2], and the model was used in the NFSA as a tood in the management of applications on food fortification.

From January 1. 2020, amendmends regarding the national provisions on the addition of vitamins, minerals and «other substances» entered into force and a so-called positive list was introduced in the regulation Forskrift om tilsetning av vitaminer, mineraler og visse andre stoffer til næringsmidler - Lovdata.
This implies that food business operators may add vitamins and minerals that appear in the positive list to relevant food categories (i.e. in accordance with the requirements in Annex 1).

If a food business operator wants to add vitamins and minerals to foods in different quantities or to other categories of food from those stated in the positive list, the food business operator must notify the NFSA according to the relevant procedures described in the regulation. As a basis to assess these notifications, the NFSA requests an updated model. The model will be fully explained below.

Thiamine, riboflavin, vitamin B_{12}, biotin, pantothenic acid, potassium, chloride and sodium
The addition of thiamine, riboflavin, vitamin B_{12}, biotin, pantothenic acid, potassium, chloride and sodium is excepted from the obligation of notification, provided that the addition not represents a health risk, with reference to footnote 1 in Annex 1 in Forskrift om tilsetning av vitaminer, mineraler og visse andre stoffer til næringsmidler - Lovdata

Iodine
Currently there are several food categories in Annex 1 in Forskrift om tilsetning av vitaminer, mineraler og visse andre stoffer til næringsmidler - Lovdata where iodine may be added i.e. «vegetarian alternatives to milkbased drinks», «carbohydrate-electrolyte drinks», «carbohydrate-electrolyte drinks also containing protein/fat», «meal replacements for weight control», «juniormilk», «bars etc.». The NFSA therefore requests that iodine is included in the fortification model as it can be used as a basis to assess future notifications on the addition of iodine.

Terms of reference

The Norwegian Scientific Committee for Food and Environment is requested to update the model for food fortification. The updating of the model should be based upon data from the following food consumption surveys: Ungkost 3 (2015), Småbarnskost 3 (2015) and

[1] VKM. Modell for vurdering av berikingssaker - revidert versjon 25. februar 2009

[2] Revurdering av modell for beriking av mat og drikke - Vitenskapskomiteen for mat og miljø

Spedkost 3 (2020). The updating should include new calculations for energy and vitamins and minerals from the diet and from food supplements.

The following is requested included as part of updating the model

- assessment of the consequences of the amended classification of products such as gluten free foods, sportproducts, meal replacements for weight control[3] etc.
    - to which degree are these products included in the fortification model, and could the intake of vitamins and minerals from these products, in the future, be included in the model?
- if sufficient scientific data, - assessment of possible inclusion of the additional vitamins and minerals in the model: vitamin K, chromium, fluoride, iodine, molybdenum, manganese, phosphorus (with reference to relevant assessments from the Norwegian Scientific Committee for Food and Environment)
- inclusion of the recommended Tolerable Upper Intake Levels (UL-levels) from relevant assessments from the Norwegian Scientific Committee for Food and Environment (published after 2013)
- if available data – inclusion of the age group «70 years and older»
- a presentation of various versions of the model, based on assumptions that 5%,10 %, 15%, 20 % and 25 % of the energy in the diet is derived from fortified foods
- inclusion of the estimated intake of energy and nutrients from the 95th percentile from foods and drinks in each age group

Additionally, if sufficient scientific data:

- is there a risk that healthy persons (children/adults) on a gluten free diet can exceed UL/GL[4] for any nutrients?

The Norwegian Food Safety Authority requests that the following dietary surveys are used:

- Spedkost 3 (2020)
- Småbarnskost 3 (2020)
- Ungkost 2015
- Norkost 3 2010-2011
- and if available: relevant intake data from other Nordic countries or other European countries etc.

[3] The products were until July 2016 classified as foods for particular nutritional uses and are now classified as regular foods.
[4] GL: Guidance Level