Vitenskapskomiteen for mat og miljø
Norwegian Scientific Committee for Food and Environment

VKM Bulletin 2025:13

New update of a fortification model

Lene Frost Andersen, Inger Therese L Lillegaard, Bente Mangschou, Anine C Medin, Inger Aakre, Knut Tomas Dalen, Lars T Fadnes, Ingrid Kvestad, Lise Madsen, Gry I G Schultz, Vibeke H Telle-Hansen, Tor A Strand

Scientific Opinion of the Panel on Nutrition, Dietetic Products, Novel Food and Allergy of the Norwegian Scientific Committee for Food and Environment

New update of a fortification model

Preparation of the opinion

The Norwegian Scientific Committee for Food and Environment (Vitenskapskomiteen for mat og miljø, VKM) appointed a project group to draft the opinion. The project group consisted of three VKM members and two VKM staff members. The Committee, by the Panel on Nutrition, Dietetic Products, Novel food and Allergy assessed and approved the final opinion.

Authors of the opinion

The authors have contributed to the opinion in a way that fulfils the authorship principles of VKM (VKM, 2023). The principles reflect the collaborative nature of the work, and the authors have contributed as members of the project group and/or the VKM Panel on nutrition, dietetic products, novel food and allergy.

Members of the project group

Lene Frost Andersen – Chair of the project group, vice-chair of the Panel on Nutrition, Dietetic Products, Novel food and Allergy in VKM. Affiliation: 1) VKM; 2) University of Oslo.

Inger Therese L Lillegaard – VKM staff. Affiliation: VKM

Bente Mangschou – Project leader, VKM staff. Affiliation: VKM.

Anine C Medin– Member of the Panel on Nutrition, Dietetic Products, Novel food and Allergy in VKM. Affiliation: 1) VKM; 2) University of Agder.

Inger Aakre– Member of the Panel on Nutrition, Dietetic Products, Novel food and Allergy in VKM. Affiliation: 1) VKM; 2) Institute of Marine Research.

Members of the Panel on Nutrition, Dietetic Products, Novel Food, and Allergy

(in alphabetical order before chair of the Panel):

Lene Frost Andersen – Vice Chair of the Panel on Nutrition, Dietetic Products, Novel Food, and Allergy in VKM. Affiliation: 1) VKM; 2) University of Oslo.

Knut Tomas Dalen – Member of the Panel on Nutrition, Dietetic Products, Novel Food, and Allergy in VKM. Affiliation: 1) VKM; 2) University of Oslo.

Lars T Fadnes – Member of the Panel on Nutrition, Dietetic Products, Novel Food, and Allergy in VKM. Affiliation: 1) VKM; 2) University of Bergen, Haukeland University Hospital.

Ingrid Kvestad – Member of the Panel on Nutrition, Dietetic Products, Novel Food, and Allergy in VKM. Affiliation: 1) VKM; 2) NORCE; 3) Innlandet Hospital Trust.

Lise Madsen – Member of the Panel on Nutrition, Dietetic Products, Novel Food, and Allergy in VKM. Affiliation: 1) VKM; 2) University of Bergen.

Anine C Medin – Member of the Panel on Nutrition, Dietetic Products, Novel Food, and Allergy in VKM. Affiliation: 1) VKM; 2) University of Agder.

Gry I G Schultz – Member of the Panel on Nutrition, Dietetic Products, Novel Food, and Allergy in VKM. Affiliation: 1) VKM; 2) Nes municipality.

Vibeke H Telle-Hansen – Member of the Panel on Nutrition, Dietetic Products, Novel Food, and Allergy in VKM. Affiliation: 1) VKM; 2) OsloMet.

Inger Aakre – Member of the Panel on Nutrition, Dietetic Products, Novel Food, and Allergy in VKM. Affiliation: 1) VKM; 2) Institute of Marine Research.

Tor A Strand – Chair of the Panel on nutrition, Dietetic Products, Novel Food, and Allergy in VKM. Affiliation: 1) VKM; 2) Innlandet Hospital Trust, 3) University of Bergen.

Acknowledgement

VKM would like to thank Tue Christensen and co-workers for providing data for vitamin K1 and chromium from the Danish National Survey of Diet and Physical Activity (DANSDA) 2011-2013.

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.

Table of Contents

Summary

VKM has updated the fortification model with new estimates for intakes of preformed vitamin A, β-carotene, vitamin D, tocopherol, niacin, vitamin B6, folic acid, vitamin C, calcium, magnesium, iron, zinc, copper, selenium, iodine, phosphorus and energy in adults (18-80 years), and implemented the new tolerable upper intake levels for vitamin D, vitamin B6, iron, zinc, selenium, and magnesium in all or most age groups. The estimated intakes of nutrients are based on data from the national food consumption surveys: Norkost 4 (2022-2023), Ungkost 3 (2015), Småbarnskost 3 (2020), and Spedkost 3 (2020). The intake data for 13-, 9-, 4-, 2- and 1-year-olds are the same as in the 2021 version (VKM, 2021). Data for vitamin K, chromium, and manganese is not available in the Norwegian Food Composition Table, and the estimated intakes of vitamin K1, chromium, and manganese in adults, 13-, 9- and 4-year-olds are calculated from the Danish National Survey of Diet and Physical Activity (2011-2013). Intake estimates could not be calculated for molybdenum or fluoride due to lack of data.

All calculations have been made according to the model and include intakes of vitamins and minerals in the 95th percentile from foods/drinks alone in addition to mean intakes from foods and supplements (users only). As value for comparison of these intakes we have used tolerable upper intake levels (ULs), safe levels of intake (SLs) or guidance levels (GLs). The SLs and GLs must be considered as more uncertain values than the ULs.

The results of the calculations are given in the Tables 1.5-1 to 1.5-3. The column to the right in these tables shows the most vulnerable and limiting age group.

The maximum of each nutrient that may be added to 100 kcal of foods or drinks according to the most vulnerable and limiting population groups is given in Table 1.5-4 for the assumptions that 20, 15, or 10% of the energy in the diet is derived from fortified foods or drinks.

The model does not include fortification of foods such as salt, seasonings, water or foodstuffs that do not naturally contain energy. Furthermore, the model does not account for the risk of low nutrient intake.

If light products are assessed in the same manner as their equivalent non-light products, this leads to a higher content of added nutrients per unit of energy for light products.

Sammendrag på norsk

VKM har oppdatert berikningsmodellen med nye estimater for inntak av predannet vitamin A, β-karoten, vitamin D, tokoferol, niacin, vitamin B6, folsyre, vitamin C, kalsium, magnesium, jern, sink, kobber, selen, jod, fosfor og energi hos voksne (18-80 år), og nye øvre tolerable inntaksnivåer (UL) for vitamin D, vitamin B6, jern, sink, selen og mangan i alle, eller de fleste aldersgruppene. Inntaksdata for 13-, 9-, 4-, 2- og 1-åringer er de samme som i 2021-versjonen (VKM, 2021). De estimerte inntakene av næringsstoffene er basert på data fra de nasjonale kostholdsundersøkelsene: Norkost 4 (2022-2023), Ungkost 3 (2015), Småbarnskost 3 (2020) og Spedkost 3 (2020). Data for vitamin K, krom og mangan er ikke tilgjengelig i den norske matvaretabellen, og estimerte inntak av vitamin K1, krom og mangan hos voksne, 13-, 9- og 4-åringer er beregnet fra Danmarks nasjonale undersøkelse av kost og fysiske aktivitet (2011-2013). Estimert inntak kunne ikke beregnes for molybden eller fluor på grunn av mangel på data.

Vi har sammenliknet de beregnede inntaksestimatene med tolerable øvre inntaksnivåer (UL), trygge øvre nivåer (SL) eller veiledende nivåer (GL). SL og GL må betraktes som mer usikre verdier enn UL, da de er basert på et dårligere datagrunnlag.

Alle beregninger er gjort i henhold til modellen, og inkluderer inntak av vitaminer og mineraler i 95 persentilen fra mat/ drikke alene i tillegg til gjennomsnittlig inntak fra kosttilskudd (bare brukere).

Resultatene fra alle beregningene er presentert i tabellene 1.5-1 til 1.5-3. Kolonnen ytterst til høyre i disse tabellene viser den mest sårbare og begrensende aldersgruppen.

Maksimum av vitaminer og mineraler som kan tilsettes 100 kcal mat eller drikke for den mest sårbare og begrensende befolkningsgruppen er gitt i tabell 1.5-4, og for antakelsene om at henholdsvis 20, 15 eller 10 % av energien i kostholdet kommer fra beriket mat eller drikke.

Modellen kan ikke brukes for tilsetning av vitaminer og mineraler til for eksempel salt, krydder, vann eller matvarer som ikke naturlig inneholder energi. Modellen omfatter ikke risiko for lavt inntak av næringsstoffer.

Hvis lettprodukter vurderes på samme måte som de tilsvarende ikke-lettproduktene, vil dette medføre et høyere innhold av tilsatte næringsstoffer per energienhet.

Abbreviations

ALA - acceptable level of addition
DANSDA - Danish National Survey of Diet and Physical Activity
EFSA - European Food Safety Authority
EI95 - the 95th percentile energy intake
EVM – Expert Group on Vitamins and minerals (UK)
GL – guidance level (set by other authorities than EFSA)
KBS - kostberegningssystemet
IOM – Institute of Medicine (US)
MA – maximal allowance
NASEM - National Academies of Sciences, Engineering, and Medicine (US)
NFC – Nutri Food Calc
NNR – Nordic nutrition recommendations
OIM – observed individual means
PFF - proportion of energy from fortified foods
SL – safe level of intake (set by EFSA)
UL – tolerable upper intake level (set by EFSA)
VKM – Vitenskapskomiteen for mat og miljø (Norwegian Scientific Committee for Food and Environment)

Background as provided by the Norwegian Food Safety Authority

In 2006 the Norwegian Scientific Committee for Food and Environment adapted a Danish model for assessing applications concerning food fortification into Norwegian conditions. The Norwegian Food Safety Authority (NFSA) also requested the Norwegian Scientific Committee for Food and Environment to assess whether the model would represent a safe assessment of fortification (VKM, 2006). Based on new data, VKM has revised this fortification model in 2009, 2013, and 2021 (VKM, 2009; VKM, 2013; VKM, 2021).

From January 1. 2020, amendments regarding the national provisions on the addition of vitamins, minerals and «other substances» entered into force and two so-called positive lists were introduced in the regulation Forskrift om tilsetning av vitaminer, mineraler og visse andre stoffer til næringsmidler - Lovdata, one for the addition of vitamins and minerals, and the other concerning the addition of certain “other substances”.

According to this regulation, 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 for vitamins and minerals (Annex 1 in the regulation), the food business operator must notify the NFSA according to the relevant procedures described in the regulation. As basis to assess these notifications, the NFSA requests an updated model.

For some vitamins and minerals, there is an exception to the notification procedure. This applies to the addition of thiamine, riboflavin, vitamin B12, biotin, pantothenic acid, potassium, chloride and sodium, provided that the addition does not pose a risk to human health, cf. footnote 1 in Annex 1 to the Forskrift om tilsetning av vitaminer, mineraler og visse andre stoffer til næringsmidler. NFSA has therefore not included these vitamins and minerals in this assignment.

Since the latest update of the fortification model in 2021, new relevant scientific documentation has been published. A new national dietary survey (Norkost 4) was published in November 2024, and EFSA opinions updating tolerable upper intake levels (hereinafter UL) for several vitamins and minerals have been published in 2023 and 2024.

Terms of reference as provided by the Norwegian Food Safety Authority/ Norwegian Environment Agency

The NFSA requests that VKM update the fortification model with calculations from Norkost 4 and updated EFSA opinions on the tolerable upper intake level (UL) for vitamin B6, vitamin D, preformed vitamin A and β-carotene, vitamin E, iron, manganese and selenium. The update of the fortification model should include new data for intake of energy, vitamins and minerals both from the diet in general and from dietary supplements.

As part of the assessment, NFSA requests VKM to

- update the model for the scenarios where 10%, 15% and 20% of the energy intake in the population is derived from fortified products.

- calculate estimates for intake in the 95th percentiles.

As basis for the new update of the fortification mode, NFSA requests that the following new national dietary surveys and EFSA opinions on tolerable upper intake level should be used:

- Norkost 4 (2022-2023)
- Scientific opinion on the tolerable upper intake level for vitamin B6. (Published 17. May 2023)
- Scientific opinion on the tolerable upper intake level for vitamin D, including the derivation of a conversion factor for calcidiol monohydrate. (Published 8. august 2023)
- Scientific opinion on the tolerable upper intake level for preformed vitamin A and β-carotene (Published 6. June 2024)
- Scientific opinion on the tolerable upper intake level for vitamin E (Published 2. August 2024)
- Scientific opinion on the tolerable upper intake level for folate (Published November 2023)
- Scientific opinion on the tolerable upper intake level for iron (Published 12. June 2024)
- Scientific opinion on the tolerable upper intake level for manganese (Published 8. December 2023)
- Scientific opinion on the tolerable upper intake level for selenium (Published 20. January 2023)

1 Update of the fortification model

This VKM-bulletin is based on the text and calculations in the VKM-report of a previous version of the fortification model (VKM, 2021). In this updated version, the following changes have been made in the calculations, and the text has been revised according to these changes:

- Calculations for adults have been replaced with data from the national dietary intake survey in adults aged 18 to 80 years, Norkost 4 (Myhre et al., 2024).
- New tolerable upper intake levels/ safe upper levels have been included for the vitamins and minerals from the latest EFSA opinions on tolerable upper intake levels for preformed vitamin A (retinol and retinyl esters) and β-carotene (EFSA, 2024a), vitamin D (EFSA, 2023a), vitamin E (EFSA, 2024b), folic acid (EFSA, 2023b), vitamin B6 (EFSA, 2023c), iron (EFSA, 2024c), selenium (EFSA, 2023d) and manganese (EFSA, 2023e).

1.1 The fortification model

The fortification model is based on a model suggested by Danish authorities in 2006 (Rasmussen et al., 2006), but some adaptions have been made by VKM. VKM first published a report on this fortification model in 2006, and it has also been revised and updated in 2009, 2013 and 2021 (VKM, 2006; VKM, 2009; VKM, 2013; VKM, 2021).

The fortification model is based on the intake of vitamins and minerals and energy from the diet at the 95th percentile level in various age groups. As for the additional intakes of vitamins and minerals from food supplements, the mean values among those who have used such supplements are added.

The total intake from regular foods plus supplements is deducted from the UL/SL/GL for the relevant age group, giving the maximum amount of nutrients that can be "allocated" for food fortification. The maximum amount of a nutrient that can be "allocated" is distributed over the energy intake at the 95th percentile level for the same age group. Based on these inputs, an estimate is made showing which age group is most likely to have an excessive intake of each nutrient.

This fortification model does not apply to non-caloric products such as e.g. salt or "light products". "Light products" should be assessed in the same manner as their equivalent "non-light products".

VKM does not have access to any information on how much of present energy intakes that are derived from fortified foods or drinks at an individual level. As requested in the terms of reference, VKM has calculated for the assumptions that 10, 15, or 20% of the energy intakes are derived from fortified foods/drinks.

Finally, the accepted level of addition of vitamins or minerals in the most sensitive age group is listed in Table 1.5-4.

The formula for the model is as follows:

$$ALA = \frac{MA}{EI95 \times PFFn}$$

ALA: acceptable level of addition

MA (maximal allowance for intake of micronutrients from fortified foods) = (UL, SL or GL) – (intake from food for the 95th percentile level + mean intake from food supplements among food supplement users).

EI95: the 95th percentile energy intake

PFFn: proportion of energy from fortified foods.

UL (set by EFSA): tolerable upper intake level.

SL (set by EFSA): safe level of intake is a value for upper intake in EFSA in cases where the UL has not been set (see below).

GL (set by other VKM or other authorities, not by EFSA): guidance level is a value for upper intake in cases where the UL or SL has not been set (see below).

Rasmussen et al. (2006) estimated that "about half of the Danish diet consists of foods which are potentially fortifiable. Among these, not all foods will be fortified. Even consumers who prefer fortified foods will probably not be able to get more than 25% of their total energy intake from fortified foods. This fraction (PFFn) should be adjusted according to the future development in market shares from fortified foods." In this update of the fortification model, NFSA has requested VKM to present calculations as if 10, 15, and 20% of the energy is derived from fortified products.

To illustrate with an example:

If you want to fortify a product with vitamin D, and assume that 10% or 20% of the energy intake comes from fortified products:

The most vulnerable group for vitamin D intake is 1-year-old children. For this group, the 95th percentile intake of vitamin D from food is 17 µg per day, and the intake from food supplements is 10 µg, giving a total intake of 27 µg/day. The UL for this age group is 50 µg, i.e. an MA of vitamin D is 23 µg. EI95 is 2000 kcal/day for this age group.

For 1-year-olds ALA_{20}= [23 µg/ (2000 kcal x 0.20)] x 100 = 5.75 µg vitamin D per 100 kcal

(meaning that ~6 µg vitamin D could be added to 100 kcal of a fortified product)

For 1-year-olds ALA_{10}= [23 µg/ (2000 kcal x 0.10)] x 100 = 11.5 µg vitamin D per 100 kcal (meaning that ~12 µg vitamin D can be added to 100 kcal of a fortified product)

1.2 Vitamins and minerals included in this update of the fortification model

The Norwegian Food Safety Authorities has requested VKM to include the following nutrients in the latest update of the fortification model: preformed vitamin A, β-carotene, vitamin D, vitamin E, niacin, vitamin B6, folic acid, vitamin C, vitamin K, calcium, magnesium, iron, zinc, copper, selenium, iodine, phosphorus, chromium, molybdenum, manganese and fluoride.

According to the Norwegian Regulation on the addition of vitamins, minerals and certain other substances to foods, thiamine, riboflavin, vitamin B12, biotin, pantothenic acid, potassium, chloride and sodium are not covered by the notification procedure, and the NFSA have not included these substances in the terms of reference.

For vitamin K, chromium, molybdenum, manganese, and fluoride no intake estimations could be conducted from national dietary surveys due to lack of concentration data in food and drinks in the Norwegian Food Composition Table. VKM has used data from exposure calculations from the Danish DANSDA (the Danish National Survey of Diet and Physical Activity) (DANSDA 2011-2013), for vitamin K1, chromium, and manganese for age groups at or above 4 years. It should be noted that data on vitamin K1, chromium, and manganese is not available for 1- and 2-year-olds.

1.3 UL/ SL/ GL-values

Health risks associated with high intakes of vitamins and minerals are described in assessments of Tolerable Upper Intake Levels (ULs) for foods by EFSA and will not be further described in this report.

References to the specific ULs/SLs/GLs used for this revised version of the fortification model are given in Appendix 1 *Tolerable Upper Intake Levels (ULs), Safe Levels of intake (SL) and Guidance Levels (GLs) used for this fortification model*.

The Scientific Committee on Food (SCF) and EFSA have set ULs for the preformed vitamin A, vitamins D, E, niacin (nicotinamide and nicotinic acid), vitamin B_6 and folic acid and for the minerals calcium (only for adults), magnesium (not for the youngest age groups), zinc, copper, iodine, selenium, and molybdenum. For iron and manganese, EFSA have suggested safe levels of intake (SL). Overview table of published ULs from SCF/EFSA is given here, updated 2024 (EFSA, 2024d).

In a series of opinions from VKM on maximum limits for dietary supplements, VKM has also made separate assessments of several ULs/GLs based on previous reports not only from SCF/EFSA, but also from IOM/NASEM, NNR or EVM. In this fortification model we have used the ULs/GLs suggested by VKM for vitamin C, vitamin K1, calcium (children and adolescents), magnesium (children and adolescents), phosphorus, and chromium (VKM, 2016a, 2016b, 2017, 2018a, 2018b).

The UL for vitamin A includes retinol and retinyl esters in µg retinol equivalents per day.

No UL has been established for β-carotene (EFSA, 2024a). However, the EFSA Panel “considers that the use of supplemental β-carotene (i.e., in fortified foods and/or food supplements) by the general population should be limited to the purpose of meeting vitamin A requirements”. Vitamin A requirements are assumed to be met in the general Norwegian population, and for the purpose of this fortification model a GL=0 is suggested for supplemental β-carotene. Consequently, β-carotene is not calculated in this update of the fortification model but merely included in the summary table 1.5-4.

The ULs for folic acid and magnesium are only applicable for the amount of nutrients added as fortifying agents or in food supplements, and not for folates and magnesium that are naturally present in foods/drinks.

In this update of the fortification model as compared to the 2021-version, ULs have been changed for β-carotene, vitamin D, vitamin B6, iron, zinc, and selenium in all or most age groups. All ULs are decreased, except from vitamin D which is significantly increased.

1.4 Intake calculations

The Panel has made use of consumption data from the nationwide Norwegian dietary surveys conducted on various age groups: Adults (Norkost 4, 18-80 years), children and adolescents (Ungkost 3, 4-, 9-, and 13-year-olds), 2-year-olds (Småbarnskost 3) and infants 12 months (Spedkost 3). For vitamin K1, and chromium, we have used data from the Danish National Survey of Diet and Physical Activity (DANSDA) for 4-, 9- and 13-year-olds and adults.

1-year-old children: the exposure in 1-year-olds was estimated from Spedkost 3, conducted in 2019 (Paulsen et al., 2020). Spedkost 3 was carried out by the University of Oslo and the Norwegian Institute of Public Health. The food consumption survey was based on a semi-quantitative food frequency questionnaire (FFQ). The caregiver was asked to have the last two weeks in mind when answering the questionnaire. In addition to predefined household units, food amounts were also estimated from photographs. A total of 1957 1-year-olds participated. The participation rate was 65%. Only children that did not receive breastmilk were included in this assessment (n=1024).

2-year-old children: The intake in 2-year-olds was estimated from Småbarnskost 3, conducted in 2019 (Astrup et al., 2020). Småbarnskost 3 was carried out by the University of Oslo and the Norwegian Institute of Public Health. This food consumption survey was based on a semi-quantitative food frequency questionnaire (FFQ). The caretaker was asked to have the last two weeks in mind when answering the questionnaire. In addition to predefined household units, food amounts were also estimated from photographs. A total of 1413 2-year-olds participated. The participation rate was 47%.

4-, 9- and 13-year-old children/adolescents: The intake in 4-, 9- and 13-year-old children was estimated from the national food consumption survey Ungkost 3 (Hansen et al., 2016; Hansen et al., 2015). The Ungkost 3 study was carried out by the University of Oslo, the Norwegian Food Safety Authority, the Norwegian Directorate of Health and the Norwegian Institute of Public Health in 2015 for 4th and 8th graders (8-9-year-olds and 12-13-year-olds), and in 2016 for 4-year-old children. The dietary assessment tool was a 4 days validated web-based food diary. A total of 399 4-year-old, 636 9-year-old and 687 13-year-old children participated. The participation rates were 20, 55 and 53%, respectively.

Adults 18-80 years: Norkost 4 was based on two 24-hour recalls by telephone at least two weeks apart. Food amounts were presented in household measures or estimated from photographs (Myhre et al., 2024). The Norkost 4 study was carried out by the University of Oslo, the Norwegian Directorate of Health, and the Norwegian Institute of Public Health in 2022-23. A total of 1964 adults aged 18-80 years participated. The participation rate was 40%.

DANSDA 2011-2013: Intake of food and drink was collected from a representative sample of 3946 individuals aged 4-75 years with a participation rate of 54% (Pedersen et al., 2015). The data collection period was 2011-2013. The participants kept a food record for seven consecutive days in a pre-coded (semi-closed) questionnaire with answering categories for the most commonly consumed foods and dishes in the Danish diet. The participants in the results presented in this report were grouped (4 to 9-years-olds, 10 to 17-years-olds and 18 to 75-years-olds).

The food and nutrient calculation systems KBS/NFC were used in intake calculations. The food database upgraded for each survey were used, Ungkost 3 – AE-14, Sped- and Småbarnskost 3 –

AE-18, and Norkost 4 used N4. One exception for Ungkost 3, which used the AE-18 for updated iodine values.

The intake of nutrients from fortified foods and drinks that are already available on the Norwegian market are included only to a limited extent in the calculations. The intake of vitamins A and D from fortified butter, margarine and milk for which have been recommended over several years by the Norwegian Directorate of Health are included in our exposure estimates, whereas few other fortifications are included.

The intake estimates are based on unweighted data and means of survey days (OIMs) from Norkost 4, Ungkost 3, DANSDA, whereas data for 1- and 2-year-olds are based on FFQs.

VKM has estimated the 95th percentile of intake of each included nutrient from regular foods and drinks (not including food supplements) in each age group.

The 95th percentile is commonly used, as a conservative approach, in risk assessments and covers most of the consumers. It should be noted that there is a higher uncertainty associated with the intakes in the higher percentiles than the mean value, and the 95th percentile is more likely an overestimation than underestimation of intake.

With use of the dietary and supplement intake calculations the amount of nutrients that can be allocated for fortification have been estimated. Tables 1.5-4 accounts for the most vulnerable groups, i.e. the age group that tolerates the lowest addition per 100 kcal before a risk of exceeding the UL/SL/GL arises. The age groups that (at the 95th percentile level) already have an intake from diet and food supplements that exceeds the UL/SL/GL will have a tolerance for fortification after the calculations that is below zero (a negative number). In practice this means that fortification with this nutrient cannot be done without exceeding UL/SL/GL. The negative numbers have been changed to zero in the column on the extreme right in Table 1.5-4.

1.4.1 Food supplements

In the fortification model, the mean values of nutrient intake from food supplements (users only) are added to the intakes from regular foods and drinks to estimate the total intake of nutrients.

In the model, the number of supplement users are not taken into account. For each vitamin and mineral, the mean intakes from supplement users are given equal weight independent of number of supplement users. The use of food supplements in Norway is common among adults (50% among the men, and 62% among the women) (Myhre et al., 2024). In children and adolescents, the intake of food supplements ranges from 43% among the 13-year-olds to 67% in non-breastfed 1-year olds (Astrup et al., 2020; Paulsen et al., 2020; Hansen et al., 2016; Hansen et al., 2015).

The precision level for the food supplement data varies across the national dietary surveys due to methodological differences. In Norkost 4, each participant was asked for name and amount of each supplement taken. In Ungkost 3 and Sped- and Småbarnskost 3 the respondents could choose from a predefined lists of food supplements but could also use a free text alternative. In Ungkost 3 the list contained 11 predefined supplements (including aggregated alternatives) and in Spedkost 3 and Småbarnskost 3 the list contained 10 predefined supplements (including aggregated alternatives).

1.5 Results of the calculations

All the calculations are given in Appendix 2 *All calculations in the fortification model*.

All calculations have been made according to the model formula – with Norwegian dietary data and Norwegian data for the intake of food supplements, except for vitamin K1, and chromium, and manganese in which Danish data was used.

The maximum amounts of nutrients that can be added per 100 kcal of foodstuff according to the calculations in the fortification model are given in the Tables 1.5-1 to 1.5-3 below. The column to the right in these tables shows the most vulnerable and limiting age group.

Summary table 1.5-4 shows how much of various nutrients that may be added to food products in Norway (per 100 kcal) in different age groups, assuming 20%, 15%, or 10% of the energy in the diet is derived from fortified products. The negative numbers in Tables 1.5-1 to 1.5-3 have been changed to zero in Table 1.5-4.

As can be seen from the Summary table 1.5-4, the assumptions of 10, 15 or 20% of the energy derived from fortified foods affect how much vitamin or mineral that may be added per 100 kcal of food products. The assumptions do however not affect which nutrients that may be added to foods or drinks.

Inclusion of the youngest age groups affects both which nutrients that may be added (especially for vitamin D and several of the minerals) and the amount that could be added without exceeding the ULs/SLs/GLs.

Table 1.5-1 Amount of nutrients that can be added per 100 kcal of foodstuff for each included age group according to the calculations in the fortification model assuming that 20% of the energy in the diet is derived from fortified foods.

20% of the energy	Men 18-80 y	Women, 18-80 y	Adolescents, 13 y	Children, 9 y	Children, 4 y	Children, 2 y	Infants, 1 y	Most sensitive age group
Retinol, µg	129	276	53	32	-43	-335	-452	**1-year-olds**
Vitamin D, µg	8	11	13	7	8	8	6	**1-year-olds**
Tocopherol, mg	34	46	32	28	25	20	18	**1-year-olds**
Niacin, mg	110	146	75	64	48	32	30	**1-year-olds**
Vitamin B6, mg	1	1	1	1	0	0	0	**1-, 2-, and 4-year-olds**
Folic acid, µg	99	121	80	66	61	31	28	**1-year-olds**
Vitamin C, mg	209	276	166	209	121	56	36	**1-year-olds**
Calcium, mg	24	85	86	222	224	169	223	**Adult men**
Magnesium, mg	9	12	29	38	29	6	5	**1-year-olds**
Iron, mg	1	0	1	0	-2	-2	-7	**1-year-olds**
Zinc, mg	-1	0	0	-1	-2	-3	-3	**1- and 2-year-olds**
Copper, mg	0,2	0,4	0	0	0	0	0	**1-13-year-olds**
Selenium, µg	11	20	16	11	4	-2	-2	**1- and 2-year-olds**
Iodine, µg	1	6	25	3	-3	-37	-43	**1-year-olds**
Phosphorus, mg	-20	96	120	201	209	266	338	**Adult men**
Vitamin K1, µg	106	140	89	81	69	NA	NA	**4-year-olds**
Chromium, µg	2752	3609	2090	1377	1721	NA	NA	**9-year-olds**
Manganese, mg	0	0	0	0	-1	NA	NA	**All age groups**

NA: not available

Table 1.5-2 Amount of nutrients that can be added per 100 kcal of foodstuff for each included age group according to the calculations in the fortification model assuming that 15% of the energy in the diet is derived from fortified foods.

15% of the energy	Men 18-80 y	Women, 18-80 y	Adolescents, 13 y	Children, 9 y	Children, 4 y	Children, 2 y	Infants, 1 y	Most sensitive age group
Retinol, µg	172	368	70	42	-57	-446	-603	**1-year-olds**
Vitamin D, µg	10	15	17	9	11	11	8	**1-year-olds**
Tocopherol, mg	45	61	42	37	33	26	24	**2-year-olds**
Niacin, mg	147	195	99	85	64	42	41	**1-year-olds**
Vitamin B6, mg	1	2	1	1	1	0	0	**1-year-olds**
Folic acid, µg	133	161	107	89	82	41	37	**1-year-olds**
Vitamin C, mg	278	368	222	279	162	74	48	**1-year-olds**
Calcium, mg	32	113	115	296	299	225	297	**Adult men**
Magnesium, mg	12	16	38	51	38	8	7	**1-year-olds**
Iron, mg	1	1	2	0	-2	-3	-9	**1-year-olds**
Zinc, mg	-1	0	-1	-2	-2	-4	-4	**1- and 2-year-olds**
Copper, mg	0,2	0,6	0	0	0	0	0	**1-13-year-olds**
Selenium, µg	15	27	22	15	6	-2	-3	**1-year-olds**
Iodine, µg	1	8	33	4	-4	-50	-57	**1-year-olds**
Phosphorus, mg	-26	128	160	268	279	355	451	**Adult men**
Vitamin K1, µg	141	187	119	108	92	NA	NA	**4-year-olds**
Chromium, µg	3669	4812	2787	1836	2295	NA	NA	**9-year-olds**
Manganese, mg	0	0	0	0	-1	NA	NA	**All age groups**

NA: not available

Table 1.5-3 Amount of nutrients that can be added per 100 kcal of foodstuff for each included age group according to the calculations in the fortification model assuming that 10% of the energy in the diet is derived from fortified foods.

10% of the energy	Men 18-80 y	Women, 18-80 y	Adolescents, 13 y	Children, 9 y	Children, 4 y	Children, 2 y	Infants, 1 y	Most sensitive age group
Retinol, µg	258	553	105	63	-86	-669	-905	**1-year-olds**
Vitamin D, µg	15	22	26	14	16	16	12	**1-year-olds**
Tocopherol, mg	68	91	63	56	50	39	36	**1-year-olds**
Niacin, mg	221	292	149	128	96	64	61	**1-year-olds**
Vitamin B6, mg	2	2	2	1	1	0	0	**1-and 2-year-olds**
Folic acid, µg	199	242	161	133	123	62	56	**1-year-olds**
Vitamin C, mg	417	552	333	418	243	112	72	**1-year-olds**
Calcium, mg	48	169	172	444	448	338	446	**Adult men**

10% of the energy	Men 18-80 y	Women, 18-80 y	Adolescents, 13 y	Children, 9 y	Children, 4 y	Children, 2 y	Infants, 1 y	Most sensitive age group
Magnesium, mg	18	24	58	76	57	13	10	**1-year-olds**
Iron, mg	2	1	3	1	-4	-5	-13	**1-year-olds**
Zinc, mg	-2	0	-1	-3	-4	-5	-6	**1-year-olds**
Copper, mg	0,4	0,8	1	1	0	0	0	**1-, 2- and 4-year-olds**
Selenium, µg	22	40	33	22	9	-4	-4	**1- and 2-year-olds**
Iodine, µg	1	12	50	6	-6	-75	-86	**1-year-olds**
Phosphorus, mg	-39	192	240	402	418	533	676	**Adult men**
Vitamin K1, µg	212	280	178	162	138	NA	NA	**4-year-olds**
Chromium, µg	5504	7218	4180	2754	3442	NA	NA	**9-year-olds**
Manganese, mg	-1	0	-1	0	-1	NA	NA	**All age groups**

NA: not available

The maximum of each nutrient that may be added to 100 kcal of foods or drinks according to the most vulnerable and limiting population groups is given in Table 1.5-4 for the assumptions that 20, 15, or 10% of the energy in the diet is derived from fortified foods or drinks. It should be noted that for vitamin K1 and chromium, data for 1- and 2-year-olds are not available.

Table 1.5-4 Summary of maximum amount of nutrients that can be added per 100 kcal of foodstuff according to the calculations in the fortification model assuming 20, 15, or 10% of the energy intake is derived from fortified foods. Results for the most vulnerable and limiting age group for each vitamin and mineral.

Nutrients	20 E%	15 E%	10 E%
Retinol, µg	0	0	0
β-carotene, µg	0	0	0
Vitamin D, µg	6	8	12
Tocopherol, mg	18	24	36
Niacin, mg	30	41	61
Vitamin B6, mg	0	0	0
Folic acid, µg	28	37	56
Vitamin C, mg	36	48	72
Calcium, mg	24	32	48
Magnesium, mg	5	7	10
Iron, mg	0	0	0
Zinc, mg	0	0	0
Copper. mg	0	0	0
Selenium, µg	0	0	0
Iodine, µg	0	0	0
Phosphorus, mg	0	0	0
Vitamin K1*, µg	69	92	138
Chromium*, µg	1721	1836	2754

Nutrients	20 E%	15 E%	10 E%
Manganese*, mg	0	0	0

*Data for 1- and 2-year-olds are not available.

1.6 Limitations of the model

The model does not include the risk of low nutrient intake. Furthermore, the model does not include fortification of foods such as salt, seasonings, water or foodstuffs that do not naturally contain energy.

Since light products are to be assessed in the same manner as their equivalent non-light products, this leads to a higher content of added nutrients per unit of energy for light products than those included in the calculations in the model. If light products (including products that provide no energy) become a major source of a nutrient, the prerequisites for the calculations in the model will no longer apply. E.g. a light yogurt containing 43 kcal per 100 g may be fortified with the same amount of vitamins and minerals as a regular yogurt containing 86 kcal per 100 g. Accordingly, one serving of regular yogurt contributes with the same amount of energy as two servings of light yogurt, despite being equally fortified which will allow more vitamins/minerals per energy unit. This principle also applies to the fortification of bottled waters (e.g. vitamin waters), salt and spices, containing no energy.

The model includes mean intakes of vitamins and minerals from supplements (users only). Individuals with higher supplement intakes than the means, may not be sufficiently protected from exceedance of ULs/SLs/GLs.

Consumers with high energy intakes from a few single food or drink items may not be sufficiently protected from high intakes if their energy sources are fortified above the energy percent given in the model.

Nutritional policy authorities require special measures to be implemented for some nutrients in order to increase the intake in certain sections of the population. The model does not assess the risk of a low intake of nutrients (only high intakes) and does not take into account the fact that food fortification targeted directly at certain groups of the population may be desirable e.g. population groups with intakes of iron and vitamin D below recommended levels.

2 Uncertainties

Section 1.6 describes the main limitations in the model itself, e.g. what the model does not include or cover, and certain population groups that might not be protected from exceeding ULs/SLs/GLs with this model. In this chapter we describe uncertainties underlying the data inputs in the model.

The data for establishing ULs are often scarce, especially in children and adolescents. For nutrients in the model that have been estimated based on SLs (iron) or GLs (vitamin C, vitamin K1, phosphorus and chromium) the uncertainty is higher than for those with established ULs.

In the model, we have used intakes in the 95th percentiles as estimates for nutrients and energy from foods and drinks. The food consumption data used in this fortification model are from four different dietary surveys with three different dietary assessment methods. Overestimation of intakes based on OIMs in the 95th percentiles is more likely in dietary surveys based on 2x24 h recall (Norkost 4), and food diaries (Ungkost 3), than in surveys based on food frequency questionnaires (Spedkost 3 and Småbarnskost 3). These overestimations could potentially influence the model for those nutrients in which adults are the most vulnerable groups, i.e. calcium and phosphorus.

As described in section 1.4.1, the precision level of food supplement intakes varies between the different dietary survey methods. The most precise estimates are given in Norkost 4, while the younger age groups were given a list of predefined supplements to choose from. Some of the supplements were generic like “cod liver oil” or “multi-vitamins”, where one common food code was used for all entries, independent of the actual brand and content of the supplement taken. For intakes of nutrients from food supplements we have used mean intakes among supplement users of the specific nutrient only. The input data for supplements that contain nutrients not commonly found in supplements   is associated with uncertainty. For some nutrients, especially in the younger age groups, these means are based on very few individuals e.g. from one to ten subjects.

The intake of nutrients from fortified foods and drinks that are already available on the Norwegian market are included only to a limited extent in the calculations. The intake of vitamins A and D from fortified butter, margarine and milk for which general permission has been granted by the Norwegian Food Safety Authority are included in our exposure estimates as are infant formulas and baby porridges, whereas few other fortifications are included.

3 The need for monitoring

To ensure that food fortification does not represent a health risk, the prerequisites on which the model is based must be monitored:

- Surveillance of intake of fortified products on the Norwegian market, including intake of fortified light products and products without energy, e.g. fortified salt, waters etc. Without good knowledge of available fortified products on the market, and good consumption data of these products, intake estimates for vitamins and minerals will be associated with uncertainty in the whole population.
- The intake of nutrients and energy from food/drinks and vitamin and mineral supplements in different groups of the population.

4 Answer to the terms of reference

Maximum amount of nutrients that can be added per 100 kcal of foodstuff according to the calculations in the fortification model assuming 20, 15, or 10% of the energy intake from fortified foods is given in Summary Tables 1.5-1 to 1.5-3 and Table 1.5-4. All the calculations are given in Appendix 2.

The tolerable upper intake levels/ safe levels of intake/ upper guidance levels VKM have used for this opinion are given in Appendix 1.

Due to lack of data on tolerable upper intake levels/ safe levels of intake/ upper guidance levels or exposure data, molybdenum, and fluoride could not be included in the model. For vitamin K and chromium exposure data was not available for 1- and 2-year-olds.

Dietary patterns develop and change over time. To keep up with the changes, the fortification model needs to be updated along with new national dietary surveys.

5 Data gaps

The following data gaps have been identified:

- Intake of nutrients derived from fortified products.
- More knowledge about supplement use, especially in certain age groups such as children, and adolescents.
- Updated ULs for several nutrients with emphasis on studies in the younger age groups. Several nutrients lack ULs, and studies investigating negative health effects from high intakes are scarce, especially in children and adolescents.
- Food composition data for vitamin K, chromium, molybdenum, manganese and fluoride.

References

Astrup H., Myhre J.B., Andersen L.F., Kristiansen A.L. (2020) Småbarnskost 3, Landsomfattende undersøkelse av kostholdet blant 2-åringer i Norge, National Institute of Public Health, Oslo Norway. ISBN: 978-82-8406-100-9.

EFSA Panel on Nutrition, N. F., Food, A., Turck, D., Bohn, T., Castenmiller, J., de Henauw, S., Hirsch-Ernst, K. I., Knutsen, H. K., Maciuk, A., Mangelsdorf, I., McArdle, H. J., Pentieva, K., Siani, A., Thies, F., Tsabouri, S., Vinceti, M., Lietz, G., Passeri, G., Craciun, I., . . . Naska, A. (2024a). Scientific opinion on the tolerable upper intake level for preformed vitamin A and beta-carotene. *EFSA J*, *22*(6), e8814. https://doi.org/10.2903/j.efsa.2024.8814

EFSA Panel on Nutrition, N. F., Food, A., Turck, D., Bohn, T., Castenmiller, J., de Henauw, S., Hirsch-Ernst, K. I., Knutsen, H. K., Maciuk, A., Mangelsdorf, I., McArdle, H. J., Pentieva, K., Siani, A., Thies, F., Tsabouri, S., Vinceti, M., Traber, M. G., Vrolijk, M., Bercovici, C. M., . . . Naska, A. (2024b). Scientific opinion on the tolerable upper intake level for vitamin E. *EFSA J*, *22*(8), e8953. https://doi.org/10.2903/j.efsa.2024.8953

EFSA Panel on Nutrition, N. F., Food, A., Turck, D., Bohn, T., Castenmiller, J., de Henauw, S., Hirsch-Ernst, K. I., Knutsen, H. K., Maciuk, A., Mangelsdorf, I., McArdle, H. J., Pentieva, K., Siani, A., Thies, F., Tsabouri, S., Vinceti, M., Aggett, P., Fairweather-Tait, S., de Sesmaisons Lecarre, A., . . . Naska, A. (2024c). Scientific opinion on the tolerable upper intake level for iron. *EFSA J*, *22*(6), e8819. https://doi.org/10.2903/j.efsa.2024.8819

EFSA. (2024d) Overview on Tolerable Upper Intake Levels as derived by the Scientific Committee on Food (SCF) and the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), Summary of Tolerable Upper Intake Levels – version 10 (June 2024), European Food Safety Authority.

EFSA Panel on Nutrition, N. F., FoodAllergens, Turck, D., Bohn, T., Castenmiller, J., de Henauw, S., Hirsch-Ernst, K. I., Knutsen, H. K., Maciuk, A., Mangelsdorf, I., McArdle, H. J., Pentieva, K., Siani, A., Thies, F., Tsabouri, S., Vinceti, M., Lanham-New, S., Passeri, G., Craciun, I., . . . Naska, A. (2023a). Scientific opinion on the tolerable upper intake level for vitamin D, including the derivation of a conversion factor for calcidiol monohydrate. *EFSA J*, *21*(8), e08145. https://doi.org/10.2903/j.efsa.2023.8145

EFSA Panel on Nutrition, N. F., Food, A., Turck, D., Bohn, T., Castenmiller, J., de Henauw, S., Hirsch-Ernst, K. I., Knutsen, H. K., Maciuk, A., Mangelsdorf, I., McArdle, H. J., Pentieva, K., Siani, A., Thies, F., Tsabouri, S., Vinceti, M., Crous-Bou, M., Molloy, A., Ciccolallo, L., . . . Naska, A. (2023b). Scientific opinion on the tolerable upper intake level for folate. *EFSA J*, *21*(11), e08353. https://doi.org/10.2903/j.efsa.2023.8353

EFSA Panel on Nutrition, N. F., Food, A., Turck, D., Bohn, T., Castenmiller, J., de Henauw, S., Hirsch-Ernst, K. I., Knutsen, H. K., Maciuk, A., Mangelsdorf, I., McArdle, H. J., Pelaez, C., Pentieva, K., Siani, A., Thies, F., Tsabouri, S., Vinceti, M., Fairweather-Tait, S., Vrolijk, M., . . . Naska, A. (2023c). Scientific opinion on the tolerable upper intake level for vitamin B6. *EFSA J*, *21*(5), e08006. https://doi.org/10.2903/j.efsa.2023.8006

EFSA Panel on Nutrition, N. F., Food, A., Turck, D., Bohn, T., Castenmiller, J., de Henauw, S., Hirsch-Ernst, K. I., Knutsen, H. K., Maciuk, A., Mangelsdorf, I., McArdle, H. J., Pelaez, C., Pentieva, K., Siani, A., Thies, F., Tsabouri, S., Vinceti, M., Aggett, P., Crous Bou, M., . . . Naska, A. (2023d). Scientific opinion on the tolerable upper intake level for selenium. *EFSA J*, *21*(1), e07704. https://doi.org/10.2903/j.efsa.2023.7704

EFSA Panel on Nutrition, N. F., Food, A., Turck, D., Bohn, T., Castenmiller, J., de Henauw, S., Hirsch-Ernst, K. I., Knutsen, H. K., Maciuk, A., Mangelsdorf, I., McArdle, H. J., Pentieva, K., Siani, A., Thies, F., Tsabouri, S., Vinceti, M., Bornhorst, J., Cubadda, F., Dopter, A., . . . Naska, A. (2023e). Scientific opinion on the tolerable upper intake level for manganese. *EFSA J*, *21*(12), e8413. https://doi.org/10.2903/j.efsa.2023.8413

EFSA. (2012). Tolerable upper intake level of calcium. *EFSA J*. https://doi.org/https://doi.org/10.2903/j.efsa.2012.2814

EFSA. (2006). Tolerable upper intake levels of vitamins and minerals. In: Scientific Committee on Food. ISBN: 92-9199-014-0

EVM. (2003) Safe Upper Levels for Vitamins and Minerals, in: Expert Group on Vitamins and Minerals (Ed.), Food Standard Agency, London, UK.

Hansen L.B., Myhre J.B., Andersen L.F. (2016) Ungkost 3, Landsomfattende kostholdsundersøkelse blant 4-åringer i Norge, National Institute of Public Health, Oslo, Norway.

Hansen L.B., Myhre J.B., Johansen A.M.W., Paulsen M.M., Andersen L.F. (2015) Ungkost 3, Landsomfattende kostholdsundersøkelse blant elever i 4. -og 8. klasse i Norge, National Institute of Public Health, Oslo, Norway.

Myhre J.B., Brodin M.M.A., Andersen L.F. (2024). Norkost 4 [nettdokument]. Oslo: Helsedirektoratet, 2024. Tilgjengelig fra www.helsedirektoratet.no/rapporter/norkost-4

Paulsen M.M., Myhre J.B., Andersen L.F., Kristiansen A.L. (2020) Spedkost 3, Landsomfattende undersøkelse av kostholdet blant spedbarn i Norge, 12 måneder, National Institute of Public Health, Oslo, Norway. ISBN: 978-82-8406-099-6.

Pedersen A.N., Christensen T., Matthiessen J., Knudsen V.K., Rosenlund-Sørensen M., Biltoft-Jensen A., Hinsch H.-J., Ygil K.H., Kørup K., Saxholt E., Trolle E., Søndergaard A.B., Fagt S. (2015) Dietary habits in Denmark 2011-2013, Main results, DTU Fødevareinstituttet, Søborg, Denmark. ISBN: 978-87-93109-39-1.

Rasmussen S.E., Andersen N.L., Dragsted L.O., Larsen J.C. (2006) A safe strategy for addition of vitamins and minerals to foods. European Journal of Nutrition 45:123-135. DOI: DOI 10.1007/s00394-005-0580-9.

VKM. (2021) Assessment and updating of a fortification model, Opinion of the Panel on nutrition, dietetic products, novel food and allergy of the Norwegian Scientific Committee for Food Safety Norwegian Scientific Committee for Food Safety, Oslo, Norway. ISBN: 978-82-8259-366-3.

VKM. (2018a) Assessment of dietary intake of chromium (III) in relation to tolerable upper intake level, Opinion of the Panel on Nutrition, Dietetic Products, Novel Food and Allergy of the Norwegian Scientific Committee for Food and Environment, Norwegian Scientific Committee for Food and Environment, Oslo, Norway. ISBN: 978-82-8259-303-8.

VKM. (2018b) Assessment of dietary intake of vitamin K and maximum limits for vitamin K in food supplements, Opinion of the Panel on Nutrition, Dietetic Products, Novel Food and Allergy of the Norwegian Scientific Committee for Food and Environment, Norwegian Scientific Committee for Food and Environment, Oslo, Norway. ISBN: 978-82-8259-300-7.

VKM. (2017) Assessment of dietary intake of phosphorus in relation to tolerable upper intake levels, Opinion of the Panel on Nutrition, Dietetic Products, Novel Food and Allergy of the Norwegian Scientific Committee for Food Safety, Norwegian Scientific Committee for Food Safety, Oslo, Norway. ISBN: 978-82-8259-275-8.

VKM. (2016a) Assessment of dietary intake of vitamin C and calcium in the Norwegian population, Opinion of the Panel on Nutrition, Dietetic Products, Novel Food and Allergy of the Norwegian Scientific Committee for Food Safety, Norwegian Scientific Committee for Food Safety, Oslo, VKM. ISBN: 978-82-8259-206-2.

VKM. (2016b) Risk assessment of magnesium in food supplements, Opinion of the Panel on Nutrition, Dietetic Products, Novel Food and Allergy of the Norwegian Scientific Committee for Food Safety, Norwegian Scientific Committee for Food Safety, Oslo, Norway. ISBN: 978-82-8259-205-5.

VKM. (2013) Assessment and updating of the fortification model from 2006, Opinion of the Panel on nutrition, dietetic products, novel food and allergy of the Norwegian Scientific Committee for Food Safety Norwegian Scientific Commettee for Food Safety, Oslo, Norway. ISBN: 978-82-8259-069-3.

VKM. (2009) Modell for vurdering av berikningssaker – revidert versjon. Statement from the Panel on nutrition, dietetic products, novel food and allergy of the Norwegian Scientific Committee for Food Safety, Norwegian Scientific Commettee for Food Safety, Oslo, Norway.

VKM. (2006) Model for assessing applications concerning food fortification, Opinion of the Panel on nutrition, dietetic products, novel food and allergy of the Norwegian Scientific Committee for Food Safety, Norwegian Scientific Commettee for Food Safety, Oslo, Norway.

Appendix 1

Tolerable upper intake levels (ULs), safe levels of intake (SLs), and upper guidance levels (GLs) used for this fortification model

Nutrients	Unit		Men ≥ 18 years	Women ≥ 18 years	Adolescents 13 years	Children 9 years	Children 4 years	Children 2 years	Infants 1 year	Reference
Preformed vitamin A	µg RE	UL	3000	3000	2000	1500	1100	800	800	EFSA, 2024a
β-carotene[1]	µg	No UL	0	0	0	0	0	0	0	EFSA, 2024a
Vitamin D	µg VDE	UL	100	100	100	50	50	50	50	EFSA, 2023a
Tocopherol	mg	UL	300	300	220	160	120	100	100	EFSA, 2024b
Nicotinamide Nicotinic acid	mg mg	UL	900 10	900 10	500 6	350 4	220 3	150 2	150 2	EFSA, 2006 (SCF, 2002)
Vitamin B6	mg	UL	12	12	8.6	6.1	4.5	3.2	3.2	EFSA, 2023c
Folic acid[2]	µg	UL	1000	1000	600	400	300	200	200	EFSA, 2023b
Vitamin C	mg	UL	2000	2000	1200	1200	650	400	400	IOM, 2000 for adults, VKM, 2016a for children and adolescents
Calcium	mg	UL	2500	2500	2500	2500	2500	2500	2500	EFSA, 2012 for adults, VKM, 2016a for children and adolescents
Magnesium[2]	mg	UL	250	250	250	250	250	85	85	EFSA, 2006 (SCF, 2001); VKM, 2016b for young children
Iron	mg	SL	40	40	30	20	15	10	10	EFSA, 2024c
Zinc	mg	UL	25	25	18	13	10	7	7	EFSA, 2006 (SCF, 2002)
Copper	mg	UL	5	5	4	3	2	1	1	EFSA, 2006 (SCF, 2003)
Selenium	µg	UL	255	255	180	130	95	70	70	EFSA, 2023d
Iodine	µg	UL	600	600	450	300	250	200	200	EFSA, 2006 (SCF, 2003)
Phosphorus[3]	mg	GL	3000	3000	3000	3000	3000	3000	3000	VKM, 2017; No UL established by EFSA, 2006
Vitamin K1[3]	µg	GL	1000	1000	670	500	370	270	270	VKM, 2018b; No UL established by EFSA, 2006 (SCF, 2003)
Chromium[3]	µg	GL	21000	21000	13020	6930	6930	3570	3570	VKM, 2018a; No UL established by EFSA, 2006 (SCF, 2003)
Manganese[4]	mg	UL	8	8	6	6	5	4	4	EFSA, 2023e

1) No UL was set for β-carotene. The EFSA Panel “considers that the use of supplemental β-carotene (i.e., in fortified foods and/or food supplements) by the general population should be limited to the purpose of meeting vitamin A requirements” and for the purpose of this fortification model, a guidance level=0 is used for fortification and supplement use.
2) The ULs for folic acid and magnesium are only applicable for the amount of nutrients added as fortifying agents or in food supplements, and not for those that are naturally present in foods/drinks.
3) Guidance levels used in previous VKM reports derived from various sources, see VKM reports for details.
4) Safe levels of intake from EFSA.

Appendix 2

All calculations in the fortification model

Intakes in the 95th percentile in all included age groups

Table Appendix 2-3: Intakes in the 95th percentile in men 18-80 years from Norkost 4 and DANSDA 2011-2013 (for vitamin K1, chromium, and manganese). Energy intake in the 95th percentile is approximately 3800 kcal in Norkost 4 and 3900 kcal in DANSDA.

Norkost 4, men 18-80 y (data for vitamin K1 and chromium is from DANSDA)	UL/SL/GL	95P intake from food/ drink	Intake from suppl. (mean, users only)	Maximal amount (MA)	Max addition pr. 100 kcal (FA) Energy from fortified foods		
					20%	15%	10%
Retinol, µg	3000	1681	340	979	129	172	258
Vitamin D, µg	100	19	24	57	8	10	15
Tocopherol, mg	300	29	13	258	34	45	68
Niacin, mg	900	48	14	838	110	147	221
Vitamin B6, mg	12	3,9	1,7	6,4	1	1	2
Folic acid, µg	1000	0	244	756	99	133	199
Vitamin C, mg	2000	216	198	1586	209	278	417
Calcium, mg	2500	2071	247	182	24	32	48
Magnesium, mg	250	0	183	67	9	12	18
Iron, mg	40	20	14	6,6	1	1	2
Zinc, mg	25	22	11	-8	-1	-1	-2
Copper, mg	5	2,3	1,3	1,3	0,2	0,2	0,4
Selenium, µg	255	120	51	84	11	15	22
Iodine, µg	600	487	109	5	1	1	1
Phosphorus, mg	3000	3126	24	-150	-20	-26	-39
Vitamin K1, µg	1000	187	8	805	106	141	212
Chromium, µg	21000	64	21	20915	2752	3669	5504
Manganese, mg	8	9	1	-2	0	0	-1

Table Appendix 2-4: Intakes in the 95th percentile in women 18-80 years from Norkost 4 and DANSDA 2011-2013 (for vitamin K1, chromium, and manganese). Energy intake in the 95th percentile is approximately 2900 kcal in both Norkost 4 and DANSDA.

Norkost 4, women 18-80 y (data for vitamin K1 and chromium is from DANSDA)	UL/SL/GL	95P intake from food/ drink	Intake from suppl. (mean, users only)	Maximal amount (MA)	Max addition pr. 100 kcal (FA) Energy from fortified foods		
					20%	15%	10%
Retinol, µg	3000	1090	307	1603	276	368	553
Vitamin D, µg	100	13,2	24	63	11	15	22
Tocopherol, mg	300	23	13	264	46	61	91
Niacin, mg	900	34	18	848	146	195	292
Vitamin B6, mg	12	2,8	2,5	7	1	2	2
Folic acid, µg	1000	0	298	702	121	161	242

Norkost 4, women 18-80 y (data for vitamin K1 and chromium is from DANSDA)	UL/SL/GL	95P intake from food/ drink	Intake from suppl. (mean, users only)	Maximal amount (MA)	Max addition pr. 100 kcal (FA) Energy from fortified foods		
					20%	15%	10%
Vitamin C, mg	2000	213	186	1601	276	368	552
Calcium, mg	2500	1613	397	490	85	113	169
Magnesium, mg	250	0	179	71	12	16	24
Iron, mg	40	15	22	2,8	0	1	1
Zinc, mg	25	16	9,7	-0,7	0	0	0
Copper, mg	5	2	0,55	2,4	0,4	0,6	0,8
Selenium, µg	255	89	50	116	20	27	40
Iodine, µg	600	448	118	34	6	8	12
Phosphorus, mg	3000	2369	74	557	96	128	192
Vitamin K1, µg	1000	179	9	812	140	187	280
Chromium, µg	21000	46	21	20933	3609	4812	7218
Manganese, mg	8	7	1	0	0	0	0

Table Appendix 2-5: Intakes in the 95th percentile in 13-year-olds from Ungkost 3 and DANSDA 2011-2013 (for vitamin K1, chromium, and manganese). Energy intake in the 95th percentile is approximately 3100 kcal in Ungkost 3 and 3600 kcal in DANSDA.

Ungkost 3, 13-year-olds (data for vitamin K1 and chromium is from DANSDA)	UL/SL/GL	95P intake from food/ drink	Intake from suppl. (mean, users only)	Maximal amount (MA)	Max addition pr. 100 kcal (FA) Energy from fortified foods		
					20%	15%	10%
Retinol, µg	2000	1486	187	327	53	70	105
Vitamin D, µg	100	10,7	8	81	13	17	26
Tocopherol, mg	220	16	8,2	196	32	42	63
Niacin, mg	500	28	9,6	462	75	99	149
Vitamin B6, mg	8,6	2,1	0,87	6	1	1	2
Folic acid, µg	600	0	102	498	80	107	161
Vitamin C, mg	1200	117	51	1032	166	222	333
Calcium, mg	2500	1592	375	533	86	115	172
Magnesium, mg	250	0	71	179	29	38	58
Iron, mg	30	14	7,4	9	1	2	3
Zinc, mg	18	17	3,9	-3	0	-1	-1
Copper, mg	4	1,5	0,29	2	0	0	1
Selenium, µg	180	62	17	101	16	22	33
Iodine, µg	450	230	65	155	25	33	50
Phosphorus, mg	3000	2257	0	743	120	160	240
Vitamin K1, µg	670	111	6	553	89	119	178
Chromium, µg	13020	49	14	12957	2090	2787	4180
Manganese, mg	6	7	1	-2	0	0	-1

Table Appendix 2-6: Intakes in the 95th percentile in 9-year-olds from Ungkost 3 and DANSDA 2011-2013 (for vitamin K1, chromium, and manganese). Energy intake in the 95th percentile is approximately 2500 kcal in Ungkost 3 and 2600 kcal in DANSDA.

Ungkost 3, 9-year-olds (data for vitamin K1 and chromium is from DANSDA)	UL/SL/GL	95P intake from food/ drink	Intake from suppl. (mean, users only)	Maximal amount (MA)	Max addition pr. 100 kcal (FA) Energy from fortified foods		
					20%	15%	10%
Retinol, µg	1500	1154	188	158	32	42	63
Vitamin D, µg	50	8,8	6,7	35	7	9	14
Tocopherol, mg	160	13,7	6,7	140	28	37	56
Niacin, mg	350	22,3	7,1	321	64	85	128
Vitamin B6, mg	6,1	1,7	0,7	3,7	1	1	1
Folic acid, µg	400	0	68	332	66	89	133
Vitamin C, mg	1200	116	39	1045	209	279	418
Calcium, mg	2500	1389	0	1111	222	296	444
Magnesium, mg	250	0	59	191	38	51	76
Iron, mg	20	12,3	6	2	0	0	1
Zinc, mg	13	16	4	-7	-1	-2	-3
Copper, mg	3	1,4	0,3	1	0	0	1
Selenium, µg	130	58	17	55	11	15	22
Iodine, µg	300	217	69	14	3	4	6
Phosphorus, mg	3000	1996	0	1004	201	268	402
Vitamin K1, µg	500	89	5	406	81	108	162
Chromium, µg	6930	37	8	6885	1377	1836	2754
Manganese, mg	6	6	1	-1	0	0	0

Table Appendix 2-7: Intakes in the 95th percentile in 4-year-olds from Ungkost 3 and DANSDA 2011-2013 (for vitamin K1, chromium, and manganese). Energy intake in the 95th percentile is approximately 2000 kcal in Ungkost 3 and 2600 kcal in DANSDA.

Ungkost 3, 4-year-olds (data for vitamin K1 and chromium is from DANSDA)	UL/SL/GL	95P intake from food/ drink	Intake from suppl. (mean, users only)	Maximal amount (MA)	Max addition pr. 100 kcal (FA) Energy from fortified foods		
					20%	15%	10%
Retinol, µg	1100	1079	193	-172	-43	-57	-86
Vitamin D, µg	50	10	7	33	8	11	16
Tocopherol, mg	120	14	7	99	25	33	50
Niacin, mg	220	20	8	192	48	64	96
Vitamin B6, mg	4,5	1,9	0,8	1,8	0	1	1
Folic acid, µg	300	0	55	245	61	82	123
Vitamin C, mg	650	121	44	485	121	162	243
Calcium, mg	2500	1243	361	896	224	299	448
Magnesium, mg	250	0	136	114	29	38	57
Iron, mg	15	10	12	-7	-2	-2	-4
Zinc, mg	10	12	5	-7	-2	-2	-4
Copper, mg	2	1,2	1	-0,2	0	0	0

Ungkost 3, 4-year-olds (data for vitamin K1 and chromium is from DANSDA)	UL/SL/GL	95P intake from food/ drink	Intake from suppl. (mean, users only)	Maximal amount (MA)	Max addition pr. 100 kcal (FA) Energy from fortified foods		
					20%	15%	10%
Selenium, µg	95	51	27	17	4	6	9
Iodine, µg	250	198	64	-12	-3	-4	-6
Phosphorus, mg	3000	1662	502	836	209	279	418
Vitamin K1, µg	370	89	5	276	69	92	138
Chromium, µg	6930	37	8	6885	1721	2295	3442
Manganese, mg	5	6	1	-2	-1	-1	-1

Table Appendix 2-8: Intakes in the 95th percentile in 2-year-olds from Småbarnskost 3. Energy intake in the 95th percentile is approximately 2000 kcal.

Småbarnskost 3, 2-year-olds	UL/SL/GL	95P intake from food/ drink	Intake from suppl. (mean, users only)	Maximal amount (MA)	Max addition pr. 100 kcal (FA) Energy from fortified foods		
					20%	15%	10%
Retinol, µg	800	1922	216	-1338	-335	-446	-669
Vitamin D, µg	50	8	10	32	8	11	16
Tocopherol, mg	100	13	9	79	20	26	39
Niacin, mg	150	15	8	127	32	42	64
Vitamin B6, mg	3,2	1,7	0,7	0,8	0	0	0
Folic acid, µg	200	0	77	123	31	41	62
Vitamin C, mg	400	138	39	223	56	74	112
Calcium, mg	2500	1574	251	675	169	225	338
Magnesium, mg	85	0	60	25	6	8	13
Iron, mg	10	12	7	-9	-2	-3	-5
Zinc, mg	7	12	6	-11	-3	-4	-5
Copper, mg	1	1,1	0,4	-0,5	0	0	0
Selenium, µg	70	53	24	-7	-2	-2	-4
Iodine, µg	200	253	96	-149	-37	-50	-75
Phosphorus, mg	3000	1935	0	1065	266	355	533

Table Appendix 2-9: Intakes in the 95th percentile in 1-year-olds from Spedkost 3 (non-breastfed). Energy intake in the 95th percentile is approximately 2000 kcal.

Spedkost 3 (non-breastfeds only), 1-year-olds	UL/SL/GL	95P intake from food/ drink	Intake from suppl. (mean, users only)	Maximal amount (MA)	Max addition pr. 100 kcal (FA) Energy from fortified foods		
					20%	15%	10%
Retinol, µg	800	2394	215	-1809	-452	-603	-905
Vitamin D, µg	50	17	10	24	6	8	12
Tocopherol, mg	100	20	8	72	18	24	36
Niacin, mg	150	19	9	122	30	41	61

Spedkost 3 (non-breastfeds only), 1-year-olds	UL/SL/GL	95P intake from food/ drink	Intake from suppl. (mean, users only)	Maximal amount (MA)	Max addition pr. 100 kcal (FA) Energy from fortified foods		
					20%	15%	10%
Vitamin B6, mg	3,2	1,9	0,8	0,5	0	0	0
Folic acid, µg	200	0	89	111	28	37	56
Vitamin C, mg	400	217	40	143	36	48	72
Calcium, mg	2500	1358	250	892	223	297	446
Magnesium, mg	85	0	65	20	5	7	10
Iron, mg	10	22	14	-26	-7	-9	-13
Zinc, mg	7	13	6	-12	-3	-4	-6
Copper, mg	1	1,3	0,4	-0,7	0	0	0
Selenium, µg	70	52	26	-8	-2	-3	-4
Iodine, µg	200	267	104	-171	-43	-57	-86
Phosphorus, mg	3000	1648	0	1352	338	451	676