Vitenskapskomiteen for mattrygghet
Norwegian Scientific Committee for Food Safety

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

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Summary

In 2006 the, the Panel on Nutrition, Dietetic Products, Novel Food and Allergy in the Norwegian Scientific Committee for Food Safety (VKM) adapted a Danish model for assessing applications concerning food fortification into Norwegian conditions. The fortification model is presently used by the Norwegian Food Safety Authorities as a tool in the management of applications on food fortification.

The model from 2006 was based on intake calculations from dietary surveys from 1997-2000. Since then, new national dietary surveys have been published. These are the comprehensive nationwide Norwegian dietary surveys among adults (Norkost 3, 2010-2011), among young children (Småbarnskost, 2007) and infants (Spedkost, 2006-2007). The Norwegian Food Safety Authority has requested VKM to implement the new data into the fortification model from 2006.

In the model from 2006 it is assumed that 25% of the energy in the diet can be derived from fortified foods and drinks. Information from the Norwegian Food Safety Authority, including about a pilot study for Norkost 3 suggested that the overall intake of fortified foods and drinks was marginal. From management of applications for fortified foods, the Norwegian Food Safety Authority also experienced that there are few fortified foods on the market in Norway. The Norwegian Food Safety Authority has therefore requested VKM to evaluate whether the assumption that 25 energy percent (E%) deriving from fortified foods can be reduced to 15 E%, and if such a reduction will have health implications. In addition, the Norwegian Food Safety Authority has asked VKM to perform an evaluation of the safety factors in the model.

VKM argues that the model for fortification should be based on the dietary intake of vitamins and minerals at the 95th percentile level in various age groups. This is in accordance with risk assessments performed in European Food Safety Authority (EFSA), and will assure that the dietary intake in a majority of the population will be covered, still within a reasonable secure use of dietary exposure calculations. Mean intake of vitamins and minerals from food supplements (among users only) was chosen, in an attempt to reduce the impact of those with a high intake of supplements. The intake at 95th percentile from the diet plus the mean nutrient intake from supplements is deducted from the tolerable upper intake level (UL) for each nutrient in each 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 then distributed over the energy intake at the 95th percentile level. In this manner an estimate is made showing which age group is most likely to have an excessive intake of a certain nutrient.

VKM does not have access to any other information about available fortified foods on the Norwegian market than the information given by the Norwegian Food Safety Authority. However, based on this information, VKM considers that it seems reasonable that the energy intake from fortified foods is reduced to 15 E%. In this revised fortification model the assumption from 2006 that 25 E% of the total energy intake will be derived from fortified foods, have therefore been reduced to 15 E%. This adjustment implies that the addition of e.g. vitamin D, vitamin E, thiamine, riboflavin, niacin, folic acid, vitamin B_{12}, vitamin C and calcium per 100 kcal can be increased without risk of exceeding UL. No changes are made for e.g. vitamin A, beta-carotene, magnesium, iron, zinc or copper. A more summary is presented in Table 1 and Appendix 1.

The Panel on nutrition, dietetic products, novel food and allergy considers that this model for management of fortification will reduce health risk that could be caused by unauthorised food fortification.

Norsk sammendrag

Faggruppen for ernæring, dietetiske produkter, ny mat og allergi foretok i 2006 en norsk tilpasning av en dansk modell som Mattilsynet bruker til vurdering av berikningssaker – altså tilsetning av vitaminer og mineraler til matvarer. Berikningsmodellen fra 2006 er basert på inntaksberegninger fra kostholdsundersøkelser fra blant annet 1997-99. Nyere kostholdsundersøkelser er nå tilgjengelig. På denne bakgrunn har Mattilsynet bedt Vitenskapskomiteen for mattrygghet (VKM) om en oppdatering av berikningsmodellen fra 2006.

I berikningsmodellen fra 2006 er det tatt utgangspunkt i inntaksberegninger fra kostholdsundersøkelser fra 1997-2000. Nye landsrepresentative kostholdsundersøkelser er publisert etter den tid; for voksne (Norkost 3, 2010-11), for 2-åringer (Småbarnskost, 2007) og for spedbarn (Spedkost, 2006-2007). Mattilsynet har derfor bedt om at VKM å gjøre nye inntaksberegninger basert på de seneste kostholdsundersøkelsene i berikningsmodellen fra 2006.

I modellen fra 2006 ble det forutsatt at 25% av energien i kosten kan komme fra beriket mat og drikke. I henhold til informasjon fra Mattilsynet antyder imidlertid en pilotstudie til Norkost 3 at inntak av beriket mat og drikke er marginalt. Mattilsynet har også erfart dette i sin håndtering av berikningssaker. Mattilsynet har derfor bedt VKM om å vurdere om forutsetningen om at 25% av energien kommer fra beriket mat kan reduseres til 15 energiprosent (E%), og hvilken helsemessig betydning dette eventuelt vil ha. I tillegg har Mattilsynet bedt om at VKM foretar en vurdering av sikkerhetsfaktorene som inngår i modellen.

VKM mener at berikningsmodellen bør baseres på inntak av vitaminer og mineraler fra vanlig mat og drikke hos 95 persentilen i ulike aldersgrupper. Dette samsvarer med inntaksberegninger i risikovurderinger i European Food Safety Authority (EFSA), og vil sikre at inntaket hos de aller fleste i befolkningen er dekket samtidig som det er en rimelig trygg bruk av dataene fra ytterkantene i kostholdsundersøkelsene. Til inntaket av vitaminer og mineraler fra vanlig mat og drikke hos 95 persentilen adderes det gjennomsnittlige inntaket av vitaminer og mineraler fra kosttilskudd (blant de som bruker tilskudd). For tilskudd er altså det gjennomsnittlige inntaket valgt for å unngå at storkonsumenter av kosttilskudd skal få for stor innvirkning på resultatene i modellen. Summen av inntaket av vitaminer og mineraler fra mat og kosttilskudd blir trukket fra det tolerable øvre inntaksnivået for de respektive vitaminene og mineralene, og resultatet blir da den maksimumsmengden som kan fordeles til berikning. Denne maksimumsgrensen blir fordelt på energiinntaket til 95 persentilen hos de respektive aldersgruppene. På den måten blir det synliggjort hvilken aldersgruppe som er mest sårbar for å overskride de fastsatte øvre tolerable inntaksnivåene for de ulike vitaminene og mineralene.

VKM har ikke tilgang på annen informasjon om tilgjengelig beriket mat og drikke på det norske markedet enn informasjonen som er gitt fra Mattilsynet. Basert på informasjonen fra Mattilsynet, anser imidlertid VKM at det er rimelig at forutsetningen om at 25% av energien i kosten vår kan reduseres til 15 E%. I denne oppdaterte berikningsmodellen er det derfor forutsatt at 15% av energien kommer fra beriket mat. Denne justeringen medfører at tilsetningen av blant annet vitamin D, vitamin E, tiamin, riboflavin, niacin, folat, vitamin B12, vitamin C og kalsium per 100 kcal kan økes uten risiko for overskridelse av UL for de respektive næringsstoffene sammenlignet med resultatene fra 2006. Ingen forandringer er foreslått for blant annet vitamin A, betakaroten, magnesium, jern, sink og kopper. En mer detaljert oppsummering er gitt i tabell 1 og vedlegg 1.

Faggruppen for ernæring, dietetiske produkter, ny mat og allergi anser at denne modellen for risikohåndtering av berikning vil redusere eventuell helserisiko forbundet med ukritisk berikning av mat og drikke.

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Background

According to Norwegian food legislation foods and drinks fortified with vitamins and minerals cannot be placed on the market without special permission from the Norwegian Food Safety Authority. A national authorization is required[1], and will be upheld until common maximum limits for addition of vitamins and minerals have been established in EU and implemented in Norwegian legislation. The time schedule for the setting of such limits in EU is at present not known.

In 2006 the, the Panel on Nutrition, Dietetic Products, Novel Food and Allergy in the Norwegian Scientific Committee for Food Safety adapted a Danish model for assessing applications concerning food fortification with vitamins and minerals into Norwegian conditions. This adapted model is presently used in the Norwegian Food Safety Authorities as a tool in the management of applications on food fortification.

The model is based on intake calculations vitamins and minerals and energy from the diet at the 95th percentile in various age groups. The model will be fully explained below. In the model from 2006 it is assumed that 25% of the energy in the diet can be derived from fortified foods and drinks. A pilot study for Norkost 3 suggested that the overall intake of fortified foods and drinks in the Norwegian population is marginal. From management of applications for fortified foods, the Norwegian Food Safety Authority also experienced that there are few fortified foods on the market.

The model from 2006 was among others based on intake calculations from diets surveys from 1997-99 which now have been replaced by more recently published national food consumption surveys.

Terms of reference

VKM is requested to update a model for assessing applications concerning food fortification with vitamins and minerals from 2006.

The updating of the model should be based upon data from the following food consumption surveys; Norkost 3 (2010-2011), Småbarnskost (2007) and Spedkost (2006-2007). The updating should include new intake calculations for energy and vitamins and minerals from the diet and from food supplements.

The Norwegian Food Safety Authority (Mattilsynet) has requested that the updating of the model includes an evaluation of all the factors incorporated in the model. Especially the assumption that up to 25% of the energy in the diet (E%) can be derived from fortified foods and drinks, and the impact on health if this assumption is reduced to 15 E%.

A general explanation of the model and an overall evaluation of the safety margins in the model, including Tolerable Upper Intake Levels and special (vulnerable) groups should be included.

[1]Forskrift 26. februar 2010 nr. 247 om tilsetning av vitaminer, mineraler og visse andre stoffer til næringsmidler §§ 4 og 6 (berikingsforskriften) implementing regulation (EC) No 1925/2006 of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods.

Assessment

In the evaluation from 2006, the Panel on Nutrition, Dietetic Products, Novel Food and Allergy, concluded that the Danish model is providing a good basis for assessment of the addition of vitamins and minerals to food, and considered that the use of the Danish model/formula for food fortification will reduce the risk of the nutrient intake of certain groups in the population exceeding the Upper Limit (UL) or the Guidance Level (GL) value. In this revised and updated assessment of the fortification model, VKM is requested to conduct an overall evaluation of the safety factors in the model.

1 Risks associated with a high intake of vitamins and minerals

Health risks associated with a high intake of vitamins and minerals are described in the assessments of the Scientific Committee for Food (SCF) in Tolerable Upper Intake Levels for Foods, published on http://europa.eu.int/comm/food/fs/sc/scf/out80_en.html, and by the European Food Safety Authority (EFSA), published on http://www.efsa.eu.int/science/nda/nda_opinions/454_en.html.

Adverse health effects resulting from an excessive intake of individual nutrients are also described in Nordic Nutrition Recommendations 2004 (Nord 2004:13) (NNR 2004).

2 The revised fortification model

The Panel has made use of consumption data from the comprehensive nationwide Norwegian dietary surveys conducted on various age groups: Adults (Norkost 3, 2010-2011), children and adolescents (Ungkost, 2000), young children (Småbarnskost, 2007) and infants (Spedkost, 2006-2007). 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. The 95th percentile of intake is commonly used for exposure estimates in risk assessments, and it is assumed that the data at this level is reasonably valid. Higher percentiles often represent unreliable data. The Danish model which we use is also based on the 95th percentile for intake of nutrients from the diet (Rasmussen *et al*. 2006)[2].

In this updated version, mean intake of vitamins and minerals from food supplements (among users only) is used[3]. The mean value of nutrient intake from food supplements is used in order to prevent that those with high use of food supplements will have too high impact on the total nutrient intake calculations. Calculations from Norkost 3 indicate that approximately 75% of the adult population has an intake of nutrients from food supplements at or below the mean intake. The intake of nutrients from supplements in the 95th percentile is approximately twice the intake compared to mean intake (from supplements) for many of the nutrients. If these high intakes should be used, the margin between intake and UL would be very narrow for nutrients such as vitamin D.

[2]Rasmussen SE, Andersen NL, Dragsted LO and Larsen JC. A safe strategy for addition of vitamins and minerals to foods. Eur J Nutr (2006) 45:3, 123-125.
[3]Different data were used for food supplements in the opinion from 2006.

The total intake from regular foods plus supplements is deducted from the UL/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. On the basis of these criteria an estimate is made showing which age group is most likely to have an excessive intake of a certain nutrient.

VKM does not have access to any other information about available fortified foods on the Norwegian market than the information given by the Norwegian Food Safety Authority. However, based on this information, VKM considers that it seems reasonable that the energy intake from fortified foods is reduced to 15%.

The formula for the model then is as follows:

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

$$ALA15 = \frac{MA}{EI95 \times 0.15}$$

ALA = Acceptable level of addition

ALA_{15} : It is presumed that a maximum of 15 % of the energy in the diet will be derived from fortified foods and drinks. . This presumption is used in all computations with regard to the level that can be "allocated" per 100 kcal.

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

UL = Upper Tolerable Intake Level. SCF and EFSA have set ULs for the vitamins A, D, E, niacin, vitamin B_6 and folic acid and for the minerals Ca, Mg, Zn, Cu, I and Se.

GL: Guidance Level: a value for upper intake in cases where the UL has not been set by SCF (see below).

EI_{95} = The 95th percentile energy intake

PFF_n = proportion of energy from fortified foods.

The Danish authorities suggest that the calculations are always based on the most vulnerable group. Most often this will be children between the ages of one and three.

Danish authorities suggest that "light" products be assessed in the same manner as their analogous non-light products. The Panel supports this principle, but draws attention to the fact that the intake of fortified light products must also be monitored.

Uncertainty is attached to a number of factors that are included in the model, and the data in the *Summary Table* in Appendix 1 are therefore limited to two significant figures.

3 UL/GL values

The SCF and EFSA has set ULs for the vitamins A, D, E, niacin, vitamin B_6 and folic acid and for the minerals calcium, magnesium, zinc, copper, iodine and selenium. For nutrients where no UL values are available from SCF/EFSA or NNR, the Danish authorities have applied so-called GL values. The Danish assessment is to a large extent based upon the report Safe Upper Levels for Vitamins and Minerals, 2003 from the UK Expert Group on Vitamins and Minerals (EVM). This report can be viewed on the website of the Food Standards Agency, UK http://www.food.gov.uk/. In the (Danish) model, GLs that correspond to the conclusions of the UK report are used for riboflavin, vitamin B_{12}, biotin, pantothenic acid and vitamin C.

GLs set by the Danish authorities have been used for the other vitamins and minerals that are included in the model – thiamine, beta-carotene and iron.

Some of the substances do not have a UL for all the age groups. The Danish authorities have extrapolated values for the various age groups from values for adults (UL or GL) on the basis of body surface area (body weight$^{0.75}$).

In 2006, The Panel reviewed the data basis for the Danish assessment, examined the Danish references, and appraised the extent to which other assessments should be made for GLs in Norway. The Panel supports the assessment from the UK and Denmark, and is of the opinion that the GL values given in the Danish fortification model can be used in a fortification model adapted to Norwegian conditions in cases where a UL has not been set by SCF or EFSA. An overview of the UL/GL for each age group is given in Appendix 2.

It should be emphasised that in general GL values are set where the data from human and animal studies are insufficient to set an UL. It is, however, not possible to evaluate how this affects the overall safety margins in the fortification model.

The ULs for folic acid and magnesium are only applicable for nutrients added as fortifying agents or in food supplements, and not for those that are naturally present.

4 Intake calculations

In the model for fortification, the intake at the 95th percentile (for food intake of the individual nutrients) in the most vulnerable age group for each nutrient forms the basis for the maximum limits in Table 1. The 95th percentile is commonly used in risk assessments, and covers most of the consumers. It should be noted that there is a higher uncertainty associated with the 95th percentile than the mean value, especially among the age groups with a low number of participants. However, the new national dietary surveys provide relative valid intake also at the 95th percentile.

1-year-old children; Spedkost 2006-2007 is based on a semi-quantitative food frequency questionnaire. In addition to predefined household units, food amounts were also estimated from photographs. The study was conducted in 2007, and a total of 1635 1-year-old children participated (Øverby *et al.*, 2009).

2-year-old children; Småbarnskost 2007 is based on a semi-quantitative food frequency questionnaire. In addition to predefined household units, food amounts were also estimated from photographs. The study was conducted in 2007, and a total of 1674 2-year-olds participated (Kristiansen, Andersen & Lande, 2009).

4-year-old children; Ungkost 2000 is based on a 4-day food intake registration with a precoded food diary. Food amounts were presented in predefined household units or as portions estimated from photographs (Pollestad *et al.*, 2002). The study was conducted in 2001, and 391 4-year-olds participated.

9- and 13-year-old children/adolescents; Ungkost 2000 is based on a 4-day food intake registration with a precoded food diary. Food amounts were presented in predefined household units or as portions estimated from photographs (Øverby & Andersen, 2002). The study was conducted in 2000 and 810 9-year-old children and 1005 13-year-old adolescents participated.

Adults; Norkost 3 is based on two 24-hour recalls by telephone at least one month apart. Food amounts were presented in household measures or estimated from photographs (Totland *et al*., 2012). The study was conducted in 2010/2011, and 1787 adults (925 women and 862 men) aged 18-70 participated.

The intake of nutrients from fortified foods that are already available on the Norwegian market are included to some extent in the calculations – for example 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.

With use of the dietary and supplement intake calculations the amount of nutrients that can be allocated for fortification have been estimated. The *Summary Table* in Appendix 1 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/GL arises. The age groups that (at the 95th percentile level) already have an intake from diet and food supplements that exceeds the UL/GL will have a tolerance for fortification after the calculations that is below zero (a minus figure). In practice this means that fortification with this nutrient cannot be done without exceeding UL/GL. The minus figures have been changed to zero in the column of figures on the extreme right in the Summary Table in Appendix 1.

In Norway, no data exist for calculating the intake of pantothenic acid and biotin for all age groups. In Ungkost 2000 (4-, 9- and 13-year olds) data is also lacking for vitamin B_6 and B_{12}. The Panel is of the opinion that for the time being Norwegian authorities can use Danish dietary intake data for biotin and pantothenic acid. However, the Panel has also noted that the Danish values constitute uncertain estimates. Average figures from the Norwegian mother and child survey have been used to estimate the intake of biotin and pantothenic acid from food supplements.

With regard to niacin, zinc, copper and selenium, the food composition data are insufficient to allow for validated intake calculations, but have still been used for the calculations. Data of these nutrients may be lacking for several food and drink items. They are marked as NS=not sufficient in Table 1. Nutrients marked as NS may be regarded as underestimates of the real intake and therefore contribute to lowering the overall safety margin in the fortification model. The magnitude of underestimation may vary from nutrient to nutrient.

With regard to iodine, the data are too inadequate to allow intake calculations to be made for children and young people in Norway. Iodine is therefore not included in the Norwegian adaptation of the model, but should be incorporated when data are available for all age groups.

4.1 Food supplements

The use of food supplements in Norway is common (47% among the men, and 58% among the women) (Totland *et al*., 2012).

Mean value of nutrient intake from food supplements is used in order to prevent that individuals with high use of food supplements will have too high impact on the total nutrient intakes. Calculations from Norkost 3 indicate that approximately 75% of the adult population has an intake of nutrients from food supplements at or below the mean intake. The intake of nutrients from supplements in the 95th percentile is approximately twice the intake compared to mean intake (from supplements) for many of the nutrients. If these high intakes (95th percentile) should be used, the margin between intake and UL would be narrow for nutrients such as vitamin D.

As the calculations are based on mean intake among food supplement users, the estimates do not account for high intakes of food supplements.

5 Not all foodstuffs will in practice be fortified

In the evaluation of the fortification model in 2006 it was presumed that for technical and practical reasons maximum 25% of the energy in food will be derived from fortified foods. The amount of fortified foods and drinks on the Norwegian market is, however, lower than expected in 2006 (based on information from the Norwegian Food Safety Authority, including from a pilot for Norkost 3). Because of this, the Panel considers that it will be of no safety concern to lower this to 15 E%.

6 Results of the calculations

All calculations have been made according to the model formula – with Norwegian dietary data and Norwegian data for the intake of food supplements. A summary of the calculations can be viewed in the *Summary Table* in Appendix 1. The column to the right in the *Summary Table* shows the amount of the various nutrients that can be added to foodstuffs in Norway (per 100 kcal) without exceeding UL/GL in 95th percentile of the population at the various age groups.

Example:

The most vulnerable group for vitamin D intake is one-year-old children. For this group, the 95th percentile intake of vitamin D from food is 13.6 µg per day, and the intake from food supplements is 6.6 µg, giving a total possible intake of 20.2 µg vitamin D/day. The UL for this age group is 25 µg, i.e. an MA of 4.8 µg. EI_{95} is 1900 kcal/day for this age group.

ALA_{15} = [4.8 µg/ (1900 kcal x 0.15)] x 100 = approx. 2 µg vitamin D per 100 kcal

Table 1 below has been extracted from *Summary Table* in Appendix 1 and shows the amounts of the various nutrients that according to the calculations in the model can be added per 100 kcal foodstuff/beverage in Norway. These figures are based on 15% of the total energy being derived from fortified foods

Table 1: **Maximum amount of nutrients that can be added per 100 kcal of foodstuff according to the calculations in the fortification model assuming 15 E% from fortified foods.**

Nutrient	Maximum addition per 100 kcal
Vitamin A (retinol), µg	0
Beta-carotene, µg	0
Vitamin D, µg	2
Vitamin E, mg	28
Vitamin B_1, mg	4
Vitamin B_2, mg	3
Niacin*, mg	43
Vitamin B_6*, mg	1
Folic acid, µg	53
Vitamin B_{12}*, µg	173
Pantothenic acid[1], mg	16
Biotin[1], µg	76
Vitamin C, mg	24
Calcium, mg	49
Magnesium, mg	0
Iron, mg	0
Zinc*, mg	0
Copper*, mg	0
Selenium*, µg	1

[1)]Danish data for dietary intake have been used for pantothenic acid and biotin, and Norwegian data for intake from food supplements.
*NS=not sufficient data.

7 Limitations of 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.

Data on content of several nutrients are lacking in numerous foods and drinks in the food and nutrition database system – kostberegningssystemet (KBS).

Another limitation of the model is the fact that new dietary surveys will most probably lead to changes in the calculation results and thus also to the amounts of the various nutrients that the model indicates could be added per 100 kcal of foodstuff/beverage in Norway

In addition, 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 analogous non-light products, this leads to a higher content of added nutrients per unit of energy for light products than that which the model has included in the calculations. 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.

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.

8 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:

- The intake of nutrients and energy from food and food supplements in different groups of the population
- The intake of energy from fortified foods should not exceed 15%
- Fortification of light products
- Surveillance of fortified products on the Norwegian market

9 Conclusion

This assessment and updating of the fortification model from 2006 suggests the amounts of the various nutrients that according to the calculations can be added per 100 kcal of foodstuff/beverage in Norway without risk of exceeding UL. A summary is presented in Table 1.

The factors in the model (i.e. the selected percentile for dietary intake of nutrients, selected intake of nutrients from food supplements, the percentage of energy from fortified foods and the UL for the various nutrients) are evaluated as sufficiently high for all investigated age groups, but do not take into account high consumers of food supplements.

VKM considers that it seems reasonable that the energy intake from fortified foods is reduced from 25 to 15%. This adjustment implies that the addition of e.g. vitamin D, vitamin E, thiamin, riboflavin, niacin, folic acid, vitamin B12, vitamin C and calcium per 100 kcal can be increased without risk of exceeding tolerable upper intake levels for these nutrients compared to the 2006 figures. No changes are made for e.g. vitamin A, beta-carotene, magnesium, iron, zink or copper.

Monitoring is required to ensure the relevance of the prerequisites in the model. The intake of energy from fortified foods must not exceed 15%, and the data basis for the intake of energy and nutrients in the various groups of the population must be improved.

10 Data gaps

A general problem is the lack of intake data for several relevant nutrients in Norway. Another difficulty is that Upper Tolerable Intake Levels (ULs) have not been set for all nutrients in SCF/EFSA or NNR 2004.

Appendix 1 Summary Table, all age groups

Maximum amount of nutrients that can be added per 100 kcal of foodstuff in the various age groups according to the calculations in the fortification model assuming 15 E% from fortified foods.

	Men	Women	Infants, 12 months	2 year olds	4 year olds	9 year olds	B13 year olds	Most vulnerable group	Max. fortification per 100 kcal
Vitamin A (ret.), µg	137	306	-147	**-201**	-189	-96	42	**-189**	**0**
Beta carotene, µg	-631	**-6890**	-45	544	77	-261	-314	**-6890**	**0**
Vitamin D, µg	11	18	**2**	12	12	9	7	**2**	**2**
Vitamin E, mg	43	62	30	**28**	35	34	39	**28**	**28**
Thiamin, mg	7	11	5	**4**	6	5	6	**4**	**4**
Riboflavin, mg	6	9	3	**3**	4	4	5	**3**	**3**
Niacin, mg	136	197	46	**43**	66	76	91	**43**	**43**
Vitamin B_6, mg	3	5	1	**1**	1	1	2	**1**	**1**
Folic acid, µg	135	195	57	**53**	54	60	86	**53**	**53**
Vitamin B_{12}, µg	321	454	183	**173**	240	235	258	**173**	**173**
Pantothenic acid, mg	30	43	17	**16**	20	20	24	**16**	**16**
Biotin, µg	139	199	80	**76**	78	85	104	**76**	**76**
Vitamin C, mg	99	146	**24**	41	70	71	81	**24**	**24**
Calcium, mg	**49**	166	341	316	351	208	135	**49**	**49**
Magnesium, mg	28	32	**-4**	6	65	47	37	**-4**	**0**
Iron, mg	3	4	**-19**	-3	-2	-1	0	**-19**	**0**
Zink, mg	-1	0	-2	-2	**-3**	-2	-2	**-3**	**0**
Copper, mg	0	0	0	**0**	0	0	0	**0**	**0**
Selenium, µg	21	39	5	2	**1**	7	17	**1**	**1**

Appendix 2 List Upper Tolerable Intake Levels (UL) from SCF and EFSA and Guidance levels (GL)

Preformed vitamin A, µg (SCF, 2002)	
Infants 12 months	800
2 year olds	800
4 year olds	1100
9 year olds	1500
13 year olds	2000
Women	3000
Men	3000

Beta carotene, µg (DK, 2005)	
Infants 12 months	5000
2 year olds	5000
4 year olds	5000
9 year olds	5000
13 year olds	5000
Women	5000
Men	5000

Vitamin D, µg (EFSA, 2012)	
Infants 12 months	25
2 year olds	50
4 year olds	50
9 year olds	50
13 year olds	100
Women	100
Men	100

Vitamin E, mg (SCF, 2003)	
Infants 12 months	100
2 year olds	100
4 year olds	120
9 year olds	160
13 year olds	220
Women	300
Men	300

Thiamin, mg (EVM,UK, 2003/DK, 2005)	
Infants 12 months	15
2 year olds	15
4 year olds	20
9 year olds	25
13 year olds	34
Women	50
Men	50

Riboflavin, mg (EVM,UK, 2003/DK, 2005)	
Infants 12 months	12
2 year olds	12
4 year olds	16
9 year olds	22
13 year olds	29
Women	43
Men	43

Niacin, mg (SCF, 2002)	
Infants 12 months	150
2 year olds	150
4 year olds	220
9 year olds	350
13 year olds	500
Women	900
Men	900

Vitamin B6, mg (SCF, 2000)	
Infants 12 months	5
2 year olds	5
4 year olds	7
9 year olds	10
13 year olds	15
Women	25
Men	25

Folic acid, µg (SCF, 2000)	
Infants 12 months	200
2 year olds	200
4 year olds	300
9 year olds	400
13 year olds	600
Women	1000
Men	1000

Vitamin B12, µg (EVM,UK, 2003/DK, 2005)	
Infants 12 months	530
2 year olds	530
4 year olds	730
9 year olds	1000
13 year olds	1330
Women	2000
Men	2000

Pantothenic acid, mg (EVM,UK, 2003/DK, 2005)	
Barn 12. mnd	55
Barn 2 år	55
Barn 4 år	75
Barn 9 år	100
Barn 13 år	135
Kvinner	200
Men	200

Biotin, µg (EVM,UK, 2003/DK, 2005)	
Barn 12. mnd	270
Barn 2 år	270
Barn 4 år	370
Barn 9 år	500
Barn 13 år	670
Kvinner	1000
Men	1000

Vitamin C, mg (EVM,UK, 2003/DK, 2005)

Infants 12 months	270
2 year olds	270
4 year olds	370
9 year olds	500
13 year olds	670
Women	1000
Men	1000

Calcium, mg (EFSA, 2012)

Infants 12 months	2500
2 year olds	2500
4 year olds	2500
9 year olds	2500
13 year olds	2500
Women	2500
Men	2500

Magnesium, mg (SCF, 2001)

Infants 12 months	65
2 year olds	65
4 year olds	250
9 year olds	250
13 year olds	250
Women	250
Men	250

Iron, mg (DK, 2005)

Infants 12 months	10
2 year olds	10
4 year olds	14
9 year olds	20
13 year olds	30
Women	50
Men	50

Zinc, mg (SCF, 2002)

Infants 12 months	7
2 year olds	7
4 year olds	10
9 year olds	13
13 year olds	18
Women	25
Men	25

Copper, mg (SCF, 2003)

Infants 12 months	1
2 year olds	1
4 year olds	2
9 year olds	3
13 year olds	4
Women	5
Men	5

Selenium, µg (SCF, 2000)

Infants 12 months	60
2 year olds	60
4 year olds	90
9 year olds	130
13 year olds	200
Women	300
Men	300

SCF: Scientific Committee for Food
EVM, UK: Expert Group on Vitamins and minerals i Food Standard Agency, UK
EFSA: European Food Safety Authority
DK: Danish authorities

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