Vitenskapskomiteen for mattrygghet
Norwegian Scientific Committee for Food Safety

Assessment of vitamin A and D in food supplements

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

The Norwegian Food Safety Authority has requested the Norwegian Scientific Committee for Food Safety (VKM) to evaluate the national maximum limits for vitamin A and vitamin D in food supplements. The existing maximum limit for vitamin A is 1500 µg RE[1]/daily dose, and 10 µg/daily dose for vitamin D. This VKM assessment is based upon tolerable upper intake levels (UL) for vitamin A and D, recommended intakes of vitamin A and D, the intake of retinol and vitamin A and D and includes children above three years, adolescents and adults.

The UL for retinol is 3000 µg/day for adults and between 1100 µg/day and 2600 µg/day for children and adolescents. Recommended intake of vitamin A is 900 and 700 µg/day for men and women, respectively, and between 350 µg/day and 600 µg/day for children and adolescents. The existing maximum limit for vitamin A in food supplements exceeds the recommended intakes in all age groups, and some age groups already have an intake of retinol that exceeds the UL. In all of the investigated population groups except for women, the intake in the 95th percentile without supplements would exceed the UL if 1500 µg retinol (the existing maximum limit for vitamin A in food supplements) is added to the intake. Furthermore, because of the risk of exceeding an intake associated with increased risk of osteoporosis, it is concluded that the maximum limit for vitamin A in food supplements should not be increased.

The UL for vitamin D is 100 µg/day for children and adolescents above 10 years and adults, and 50 µg/day for children 1-10 years. Recommended intake of vitamin D is 10 µg/day for children above two years, adolescents and adults, and 20 µg/day for elderly above 75 years.

Less than 50% of the adult population meets the recommended intake of vitamin D. The existing maximum limit for vitamin D in food supplements is equivalent to the recommendation for daily intake for children and adults under 75 years. To ensure intake of 20 µg vitamin D per day in elderly, a daily dosage of 20 µg from food supplements is justified. If the maximum limit for vitamin D in supplements is increased to 20 µg per daily dosage, all age groups including elderly above 75 years can cover the recommended intake without any risk of exceeding UL. A new maximum limit at 20 µg per recommended daily doses in food supplements is therefore suggested. It is also recommended that the minimum limit for vitamin D in food supplements is evaluated.

[1]Retinol equivalents, 1RE=1 µg retinol or 6 µg beta carotene.

Sammendrag

Mattilsynet har bedt om en risikovurdering av de nasjonale maksimumsgrensene for vitamin A og vitamin D i kosttilskudd. Maksimumsgrensen for vitamin A er i dag 1500 µg RE[2] per anbefalt døgndose, og maksimumsgrensen for vitamin D er 10 µg/dag. VKMs vurdering er basert på tolerable øvre inntaksnivåer (UL), anbefalt daglig inntak for vitamin A og D samt inntak av retinol og vitamin A og D blant barn og unge over tre år og voksne. UL for retinol er 3000 µg/dag for voksne, og fra 1100 til 2600 µg/dag for barn og unge. Anbefalt daglig inntak av vitamin A er 900 µg for menn og 700 µg for kvinner, og fra 350 til 600 µg/dag for barn og unge. De eksisterende maksimumsgrensene for vitamin A i kosttilskudd overskrider anbefalt inntak for alle aldersgrupper, og noen av de undersøkte aldersgruppene har allerede et inntak som overskrider UL. I alle de undersøkte gruppene av befolkningen, unntatt kvinner, vil inntaket hos de i 95 persentilen uten kosttilskudd overskride UL dersom man plusser på 1500 µg som tilsvarer eksisterende maksimumsgrense for vitamin A i kosttilskudd. En høyere maksimumsgrense enn det vi har i dag, vil i tillegg medføre økt risiko for et inntak av vitamin A som er forbundet med økt risiko for osteoporose. Faggruppen har derfor konkludert med at maksimumsgrensen for vitamin A i kosttilskudd ikke bør økes.

UL for vitamin D er 100 µg/dag for barn og unge over 10 år og voksne. For barn 1-10 år er UL satt til 50 µg/dag. Anbefalt daglig inntak av vitamin D er 10 µg for barn over to år, unge og voksne, og 20 µg/dag for eldre over 75 år.

Under halvparten av den voksne befolkningen har et inntak av vitamin D som svarer til anbefalt inntak. Den eksisterende maksimumsgrensen for vitamin D i kosttilskudd tilsvarer anbefalt daglig inntak for barn og voksne under 75 år. For å sikre et inntak av vitamin D på 20 µg/dag hos eldre, kan det være nødvendig å få tilførsel fra kosttilskudd. Dersom maksimumsgrensen for vitamin D i kosttilskudd økes til 20 µg per anbefalt døgndose, vil alle aldersgrupper, inkludert eldre over 75 år, kunne få dekket sitt vitamin D behov uten risiko for overskridelse av UL. Faggruppen foreslår derfor at maksimumsgrensen for vitamin D i kosttilskudd økes til 20 µg per anbefalt døgndose. Faggruppen foreslår videre at det blir foretatt en vurdering av om eksisterende minimumsgrense for vitamin D i kosttilskudd også bør økes.

[2]Retinolekvivalenter, 1RE=1µg retinol eller 6 µg betakaroten.

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Background

Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements and regulation 1925/2006/EC of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods are both implemented in the Norwegian legislation. According to 2002/46/EC (food supplement directive) and 1925/2006/EC (fortification regulation) common minimum and maximum limits for addition of vitamins and minerals in food supplements and regular foods will be adopted. However, the process has halted, and the time schedule for finalisation of common limits is unknown.

Until common limits are adapted in EU, the national limits from the previous regulation of food supplements from 1986[3] apply. Maximum limit for vitamin A in food supplements is 1500 µg RE[4]/daily dose, and the maximum limit for vitamin D in food supplements are 10 µg/daily dose[5].

The previous national authorisation for fortification is also continued until common minimum and maximum limits for addition of vitamins and minerals to foods are adapted in EU. The national regulation for fortification is based on VKM's opinion Model for assessing applications concerning food fortification from 2006, an adaption of a Danish model for fortification with Norwegian food consumption data. The opinion from 2006 suggests a maximum limit for vitamin D fortification at 1.1 µg/100 kcal and no fortification with vitamin A or retinol. An updating of the fortification model from 2013 suggests a new maximum limit for vitamin D at 2 µg/100 kcal and no changes for vitamin A or retinol.

New Norwegian dietary surveys are available since 2006.

The Norwegian Food Safety Authority considers revising the existing maximum limits for vitamin A and D in food supplements in the context of the following criteria:

- Tolerable upper intake levels for vitamins and minerals
- Intake of vitamins and minerals
- Recommended daily intake of vitamins and minerals

Terms of reference

The Norwegian Food Safety Authority has requested the Norwegian Scientific Committee for Food Safety to evaluate the existing national maximum limits for vitamin A and D in food supplements.

The assessment should include children above three years, adolescents and adults, and should be based upon:

[3]Forskrift 25. september 1986 nr. 1918 for produksjon og frambud m.v. av vitamin- og mineraltilskudd (kosttilskuddforskriften).
[4]Retinol equivalent, 1 RE=1 µg retinol or 6 µg beta carotene.
[5]Vedlegg 1 til kosttilskuddforskriften: Maksimums- og minimumsgrenser for innhold av vitaminer og mineraler i kosttilskudd.

- Tolerable upper intake levels for vitamin A and D
- Intake of vitamin A and D from all sources (including fortified foods and food supplements) in the Norwegian population
- Recommended intake of vitamin A and D

Assessment

1 Tolerable Upper Intake Levels for vitamin A and vitamin D

1.1 Establishment of Tolerable Upper Intake Levels

Tolerable upper intake level (UL) is an estimate of the highest level of intake which is not associated with an appreciable risk of adverse health effects. According to Guidelines for the development of tolerable upper intake levels for vitamins and minerals (SCF 2000), UL is defined as the maximum level of total chronic daily intake of a nutrient (from all sources) judged to be unlikely to pose a risk of adverse health effects to humans. *Tolerable intake* in this context connotes what is physiologically tolerable and is a scientific judgment as determined by assessment of risk, i.e. the probability of an adverse effect occurring at some specified level of exposure. ULs apply to all groups of the general population (excluding those receiving the nutrient under medical supervision), and may be derived for various life stage groups in the population (SCF 2000).

Where possible, ULs should be derived for total intake of nutrients from all sources. It should be noted that added nutrients may sometimes differ from endogenous nutrients in foods in a number of ways, e.g. chemical form, timing of intake and amount consumed in a bolus dose, effect of the food matrix and interaction of the nutrient with other constituents of the diet.

Equivalent method for establishing UL has been adopted by the Scientific Committee for food (SCF), the European Food Safety Authority (EFSA), the Nordic Nutrition Recommendations (NNR Project Group 2004) and the Institute of Medicine (IOM 1998).

1.1.1 Tolerable Upper Intake Levels for Vitamin A

SCF established an UL at 3000 µg RE/day of preformed vitamin A (retinol) for adults, based on the risk to women of child-bearing age (SCF 2002). This value was about 2.5-fold lower than the lowest daily intake associated with hepatotoxicity during chronic intake. The ULs for infants and children were based on the adult value at 3000 µg/day with correction for differences in basal metabolic rate compared to adults (body weight$^{0.75}$). Provitamin A carotenoids are not known to cause vitamin A toxicity, and therefore ULs are expressed in terms of preformed vitamin A (retinol) (EFSA 2008).

The SCF further considered that the UL may not provide an adequate margin of safety in relation to the possible decrease in bone density and the risk of bone fracture, and that it would be advisable that postmenopausal women, who are at greater risk of osteoporosis and bone fracture, should restrict their intake of preformed vitamin A (retinol) to 1500 µg RE/day.

The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) published a scientific opinion on the consequences for the consumer of the use of vitamin A in animal nutrition in 2008 (EFSA 2008). The EFSA opinion reviewed two recent reports on the safety of retinol performed by the UK Scientific Advisory Committee on Nutrition (2005) and the Agence Francaise de Securite Sanitaire des Aliments (2005). VKM has recently published a risk assessment of retinol and retinyl esters in cosmetics (VKM 2012).

The FEEDAP Panel was of the opinion that new available data published later than the SCF opinion from 2002 would not substantially alter the risk assessment for preformed vitamin A (retinol). Consequently, EFSA still considered the UL of 3000 µg RE/day from preformed vitamin A (retinol) as being appropriate. The FEEDAP Panel further referred to the advice from SCF that a maximum intake of 1500 µg RE/day from preformed vitamin A (retinol) would serve as a guidance level (GL) for individuals at a greater risk of osteoporosis and bone fracture, until new data indicates the necessity of a re-evaluation.

Retinol toxicity is an important issue in the Nordic countries where the dietary intake is relatively high, and similar conclusions regarding UL for retinol have been made in the Nordic Nutrition Recommendations and by IOM (IOM 2001; NNR Project Group 2004).

Table 1: Tolerable Upper Intake Level for preformed vitamin A (retinol) for different age groups (SCF, 2002).

Age	µg/day
4–6 year olds	1100
7–10 year olds	1500
11-14 year olds	2000
15-17 year olds	2600
>18 years	3000

1.1.2 Tolerable Upper Intake Levels for vitamin D

EFSA has recently established an UL at 100 µg/day for vitamin D for adults, based on the risk for hypercalcaemia (EFSA 2012). In two studies in men, intakes between 234 and 275 µg/day were not associated with hypercalcaemia, and a no observed adverse effect level (NOAEL) at 250 µg/day was established. Taking into account uncertainties associated with these studies, the UL for adults including pregnant and lactating women was set at 100 µg/day, and thereby a safety of margin at 2.5 for the UL. The ULs for infants and children were additionally based on effect on growth (EFSA 2012).

IOM established an UL at 100 µg/day for adults in 2010 (IOM 2010). In The Nordic Nutrition Recommendations from 2004 UL is 50 µg/day for adults and 25 µg/day for children (NNR Project Group 2004). New NNR evaluations are due in 2013.

Table 2: Tolerable Upper Intake Level for vitamin D for different age groups (EFSA, 2012; NNR, 2004).

Age	EFSA, 2012 µg/day	NNR, 2004 µg/day
1-10 year olds	50	25
Children > 10 years and adults	100	50

2 Recommended daily intake of vitamin A and vitamin D

2.1 Methods for establishment of recommendations for nutrient intake

The main object of the nutrient recommendations is to ensure a diet that provides energy and nutrients for optimal growth, development, function and health during the whole life. The establishment of a recommended daily intake for nutrients consists of two main steps: The first step includes evaluation of average requirement for the population group in question, judged by individual criteria for each nutrient. The establishment of these criteria includes considerations about clinical and biochemical deficiency symptoms, body stores, body pool turn-over and tissue levels. The nutritional requirements are influenced by age, sex, growth, height, weight, pregnancy and lactation. In the second step an evaluation of a safety margin covering individual variations is made. The size of the safety margin depends on variations in requirements between individuals, and on variations in bioavailability and potential negative effects of high intakes.

In NNR the term *recommended intake* refers to the amount of a nutrient that according to present knowledge can meet the known requirement and maintain a good nutritional status among practically all healthy individuals (NNR Project Group 2004).

2.1.1 Recommendations for vitamin A (RE)

The Nordic Nutrition recommendations from 2004 are the basis for the Norwegian recommendations. The recommended intake of vitamin A (RE) is 700 µg for women and 900 µg for men (NNR Project Group 2004). Vitamin A includes retinol and carotenoids e.g. beta carotene.

Table 3: Recommended intakes for vitamin A (RE) for different age groups (NNR, 2004).

Vitamin A, RE/d	2-5 years	6-9 years	10-13 years	Women	Men
Recommended intake	350	400	600	700	900

2.1.2 Recommendations for vitamin D

The Nordic Nutrition recommendations from 2004 are the basis for the Norwegian recommendations. The new Nordic recommendation for intake of vitamin D (presented in Reykjavik) is 10 µg for children above two years and adults and 20 µg for elderly (≥ 75 years). In 2010 IOM established Recommended Dietary Allowance for vitamin D at 15 µg/day for adults < 70 years, and 20 µg/day for adults > 70 years (IOM 2010).

Table 4: New recommendations for intake of vitamin D for different age groups (NNR, Conference information, Reykjavik).

Vitamin D, µg/d	Children > 2 y and adults	Elderly ≥ 75 y
Recommended intake	10	20

In 2006, The Norwegian Council on Nutrition recommended intake of fatty fish, vitamin D fortified foods in addition to use of cod liver oil or other food supplements containing vitamin D as measures to ensure an adequate vitamin D-status in the Norwegian population (Nasjonalt råd for ernæring 2006).

3 Exposure

3.1 Intake of retinol and vitamin A and D from regular food and fortified foods and food supplements

The intakes of retinol and vitamin A and D in adults are calculated from the national food consumption survey Norkost 3. 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). Norkost 3 was conducted in 2010/2011 and 1787 adults aged 18-70 years participated. The participation rate was 37%. Unfortunately no national dietary information among the older population (> 70 years) exists.

The intake of retinol and vitamin A and D in children and adolescents are calculated from the national food consumption survey Ungkost. 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. The study in 4-year olds was conducted in 2001, and 391 4-year olds participated (Pollestad *et al.,* 2002). The study in 9- and 13-year olds was conducted in 2000 and 810 9-year old children and 1005 13-year old adolescents participated (Øverby & Andersen 2002).

Consumption data on fortified foods are limited. Consumption of fortified butter (with 1093 µg retinol and 10 µg vitamin D per 100g) and margarines (with 900 µg retinol and 10 µg vitamin D per 100 g) and low fat milk (0.4 µg vitamin D per 100 g) can however be calculated[6], and is included in the intakes showed in Tables 5-9 and Figures 1-8. Consumption

[6]VKM report from 28.06.2012 Consumption of fortified foods, and intake of vitamins and minerals from all foods.

of butter/margarine includes both fat spreads on bread and in cooking, and low fat milk include both milk for drinking and in cooking.

Consumption of fortified foods and drinks and intake of vitamins and minerals were computed by the software system (KBS) developed at the Institute of Basic Medical Sciences, Department of Nutrition, at the University of Oslo. The food databases are mainly based on various versions of the official Norwegian food composition table (Rimestad *et al.,* 2000).

Retinol and vitamin A and D are calculated with and without supplements and cod liver oil. The recommendation for intake is given in Vitamin A (RE) and UL is given for retinol. Both vitamin A and retinol are therefor included in the intake calculations.

Mean and median intake of retinol and vitamin A and D and in the 95th and 5th percentile from regular foods and fortified foods and supplements are given in Table 5 for men, Table 6 for women and Table 7, 8 and 9 for children and adolescents.

Table 5: Total intake of retinol and vitamin A and D in men (18-70 years).

	Vitamin A, RE/d		**Retinol, µg/d**		**Vitamin D, µg/d**	
	Including supplements Users only (n=293)	Without supplements (n=862)	Including supplements Users only (n=275)	Without supplements (n=862)	Including supplements Users only (n=325)	Without supplements (n=862)
Mean	1635	1003	1350	793	20.7	6.7
Median	1387	847	1127	622	17.1	5.3
95th percentile	3280	2188	2691	1691	45.3	17.2
5th percentile	617	293	508	208	5.1	1.2

Table 6: Total intake of retinol and vitamin A and D in women (18-70 years).

	Vitamin A, RE/d		**Retinol, µg/d**		**Vitamin D, µg/d**	
	Including supplements Users only (n=339)	Without supplements (n=925)	Including supplements Users only (n=296)	Without supplements (n=925)	Including supplements Users only (n=394)	Without supplements (n=925)
Mean	1499	766	983	561	16.5	4.9
Median	1135	663	841	463	12.1	3.8
95th percentile	2402	1581	1983	1285	33.1	12.3
5th percentile	540	269	360	162	4.0	0.5

Table 7: Total intake of retinol and vitamin A and D in 4-year olds.

	Vitamin A, RE/d		Retinol, µg/d		Vitamin D, µg/d	
	Including supplements Users only (n=235)	Without supplements (n=391)	Including supplements Users only (n=235)	Without supplements (n=391)	Including supplements Users only (n=235)	Without supplements (n=391)
Mean	1183	754	1019	603	9.8	2.6
Median	1055	633	914	492	8.5	2.1
95th percentile	2034	1489	1711	1259	20.9	6.5
5th percentile	526	296	434	237	3.5	0.9

Table 8: Total intake of retinol and vitamin A and D in 9-year olds.

	Vitamin A, RE/d		Retinol, µg/d		Vitamin D, µg/d	
	Including supplements Users only (n=360)	Without supplements (n=810)	Including supplements Users only (n=360)	Without supplements (n=810)	Including supplements Users only (n=360)	Without supplements (n=810)
Mean	1247	817	1060	643	9.3	2.8
Median	1171	710	959	530	8.0	2.3
95th percentile	2184	1661	2015	1475	18.9	6.9
5th percentile	480	279	412	206	3.3	0.6

Table 9: Total intake of retinol and vitamin A and D in 13-year olds.

	Vitamin A, RE/d		Retinol, µg/d		Vitamin D, µg/d	
	Including supplements Users only (n=297)	Without supplements (n=1005)	Including supplements Users only (n=297)	Without supplements (n=1005)	Including supplements Users only (n=297)	Without supplements (n=1005)
Mean	1275	774	1087	615	8.5	2.5
Median	1126	590	919	439	6.6	1.9
95th percentile	2443	1586	2184	1278	21.1	6.6
5th percentile	444	210	375	156	2.5	0.4

3.1.1 Main sources to retinol and vitamin D in the diet

The main sources to retinol in the diet among Norwegian adults are butter, margarine and oils, meat and meat products from offals such as liver pate and food supplements. Similar pattern is seen in the younger age groups, and in the youngest age group food supplements presumably is the major source to retinol. The main sources to retinol in different age groups are presented in Figures 1-4.

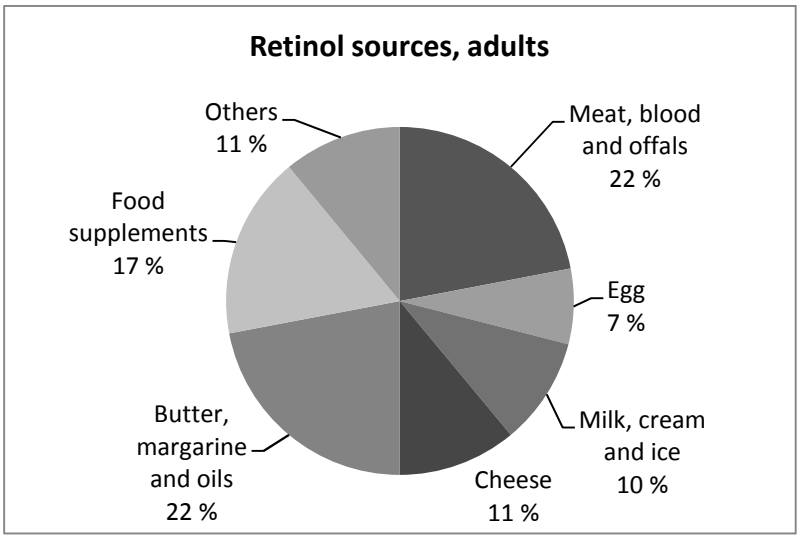

Figure 1: Main sources to retinol among Norwegian adults.

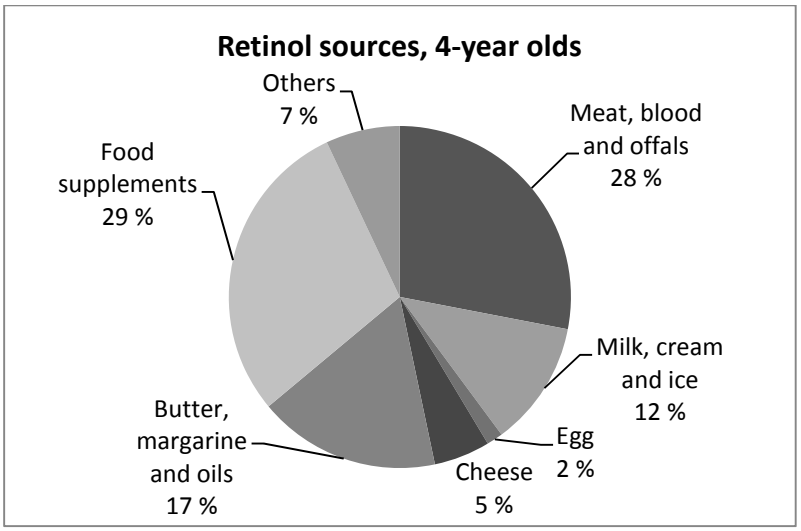

Figure 2: Main sources to retinol among 4-year olds.

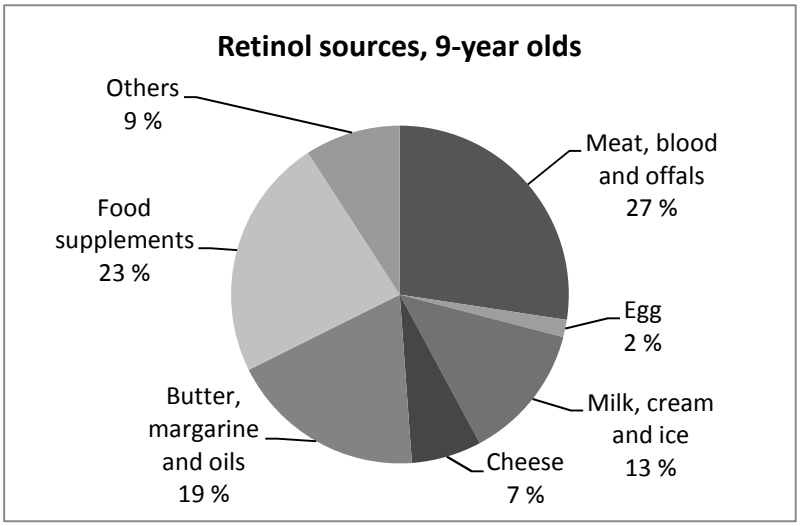

Figure 3: Main sources to retinol among 9-year olds.

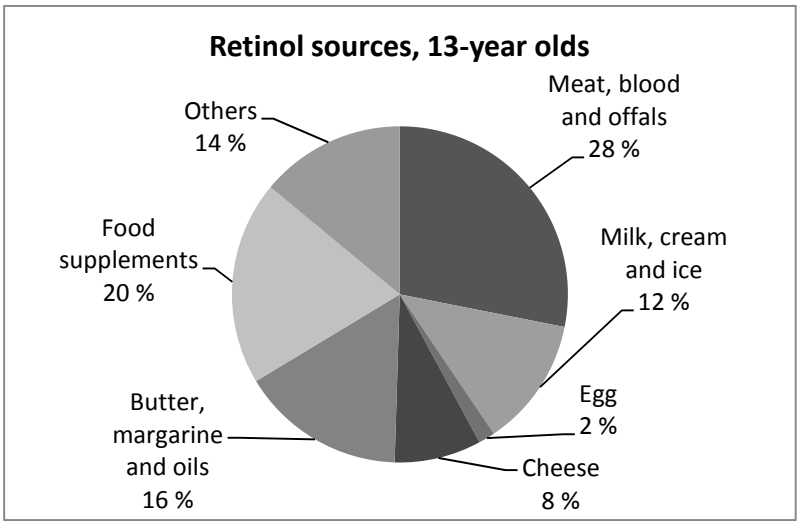

Figure 4: Main sources to retinol among 13-year olds.

The main sources to vitamin D in the diet among Norwegian adults are food supplements, fish and shellfish, and butter and margarine. In the younger age groups food supplements are the major source, and contribution from fish and seafood less significant. The main sources to vitamin D in different age groups are presented in Figure 5-8.

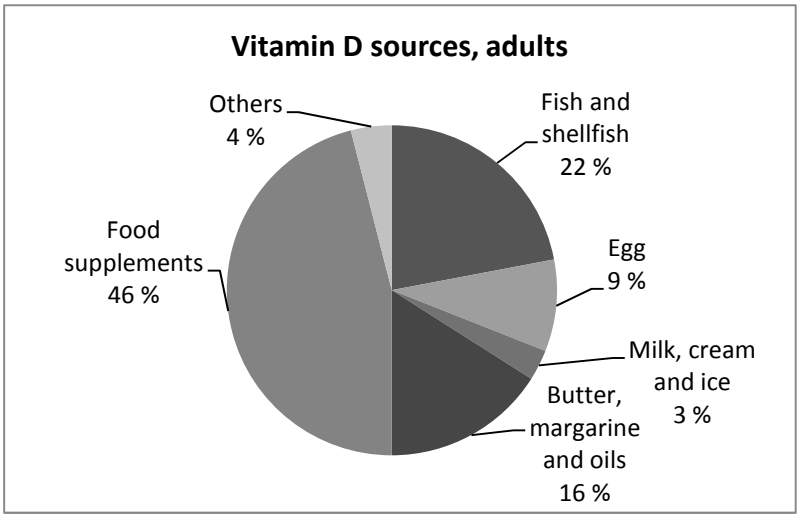

Figure 5: **Main sources to vitamin D among Norwegian adults.**

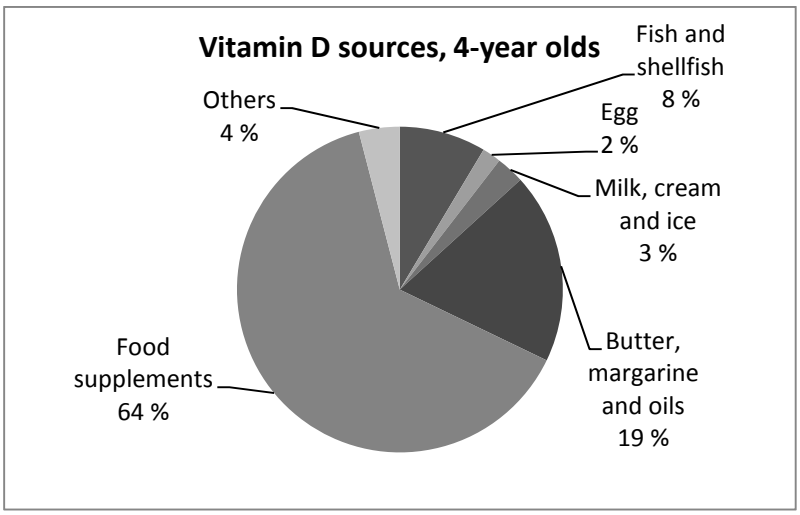

Figure 6: **Main sources to vitamin D among 4-year olds.**

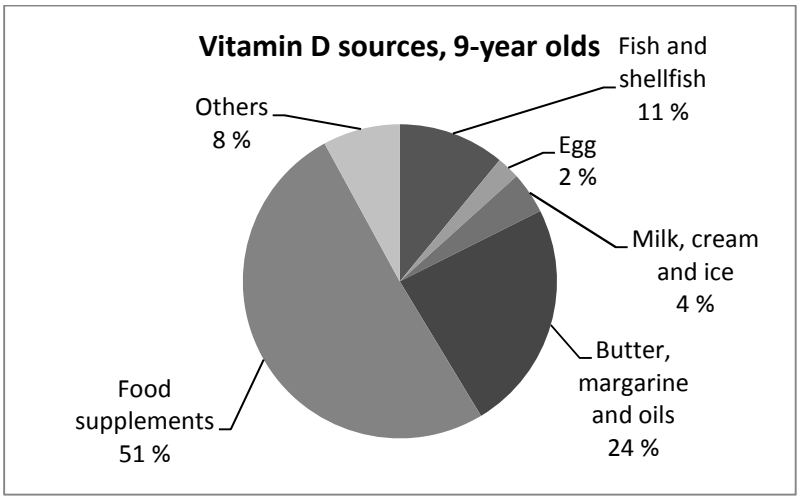

Figure 7: **Main sources to vitamin D among 9-year olds.**

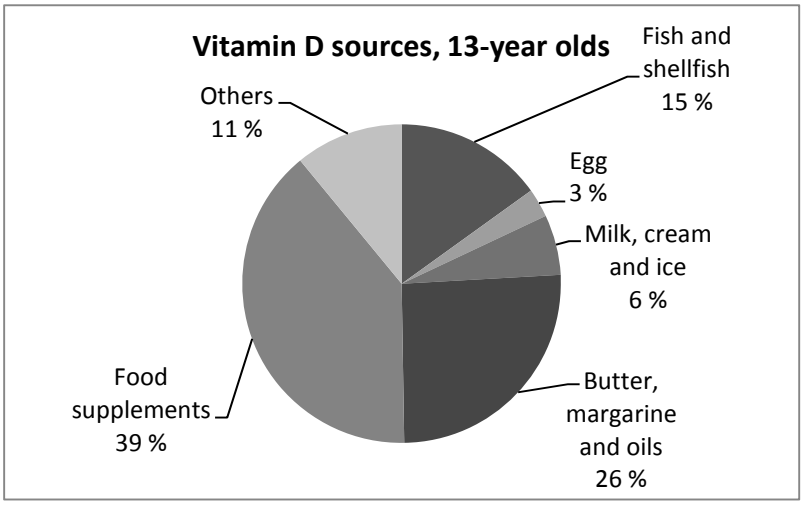

Figure 8: Main sources to vitamin D among 13-year olds.

3.1.2 Uncertainty factors in exposure assessment of vitamin A and D

As present, there is no available method that measures dietary exposure among individuals or groups of individuals without error (Andersen 2000). The uncertainty related to over- or under-estimation of consumption of foods and supplements with A and D vitamins are the most important. Furthermore, there is uncertainty connected to the analysed and calculated values of vitamin A and D in foods and supplements. Since A and D vitamins are present in large quantities in a few foods, a correct portion size assessment is important, for instance for cod liver oil or roe paste.

To obtain an accurate estimate of individual vitamin A and D intakes a large number of repeated measurements are needed, since the day-to-day variation is large (Willett 1998). This implies that there is a higher uncertainty associated with the 95th and 5th percentile than the mean value.

4 Evaluation of maximum limits in food supplements

Maximum limit for vitamin A in food supplements is 1500 µg RE/daily dose, and the maximum limit for vitamin D in food supplements are 10 µg/daily dose.

4.1 Special groups

Recommended intake of vitamin A is set to be 700 and 900 µg/day for women and men, respectively (NNR Project Group 2004). No increased risk of retinol associated birth defects have been observed among women consuming retinol in doses below 3000 µg/day, and this dose is set as the UL for adults (EFSA 2008; SCF 2002). However, long-term intakes of retinol in excess of 1500 µg/day have been associated with increased risk of osteoporosis in postmenopausal women. Therefore, this level serves as a guidance level (GL) for individuals at greater risk of osteoporosis and bone fracture e.g. elderly. The UL for retinol applies to intakes from both foods and food supplement, whereas an additional contribution from cosmetic products has not been included.

4.2 General population, different age groups

The maximum limit for vitamin A in food supplements is 1500 µg per daily dose. In the following it is assumed that supplements contain 1500 µg only as preformed vitamin A (retinol). The UL for 4-6 year olds of preformed vitamin A (retinol) is 1100 µg per day. In this age group food supplements containing maximum level of preformed vitamin A (retinol) exceed the UL. The UL for 7-10 year olds is equivalent to the existing maximum limit for vitamin A in food supplements. Intake of retinol in men (95th percentile) without supplements is approximately 1700 µg and exceeding GL at 1500 µg/day for older men. Additional intake of 1500 µg retinol from supplement adds up to an intake of 3200 µg/day, and exceeds the UL at 3000 µg/day. In women and 13 year olds, the intake in the 95th percentile without supplements is approximately 1300 µg. Additional intake of 1500 µg retinol from supplement adds up to an intake of t 2800 µg/day – slightly below the UL for women, but exceeding the GL at 1500 µg/day for postmenopausal women and individuals at greater risk of osteoporosis and the UL for 1-14 year olds at 2000 µg/day. Furthermore, the existing maximum limit for vitamin A in food supplements exceeds the recommended intakes in all age groups (see Table 3). Higher dosage than the exciting maximum limit for vitamin A or retinol in food supplements will increase the risk of exceeding the UL or GL in the various age groups. Among women and men not using food supplements more than 50% do not reach the recommended intake of vitamin A, while intake among children seems more adequate (Table 5-9). Supplementation lowers the percentage not reaching the recommended intake. However, because of the increased risk of exceeding GL in elderly, the Panel on nutrition, dietetic products, novel food and allergy suggests not to increase the existing national maximum limits for vitamin A in food supplements.

In the evaluation of maximum limits for vitamin D in food supplements, the Panel on nutrition, dietetic products, novel food and allergy has used the UL of 100 µg/day for children >10 years and adults and 50 µg/day for children 1-10 years (established by EFSA and IOM). Less than 50% of the adult population have an adequate/recommended intake of vitamin D, see Tables 5-9. The existing maximum limit for vitamin D in food supplements is 10 µg per daily dosage e.g. equivalent to the recommendation for daily intake for children and adults under 75 years. To cover the increased recommended intake of 20 µg/day of vitamin D for the adult population >75 years, supplementation is necessary. Although no national data of dietary intake in this population group exists, it is generally known that the food intake is low among the elderly (Nes *et al.,* 1992). To ensure intake of 20 µg vitamin D per day in this group of elderly a daily dosage of 20 µg from food supplements is justified. If the maximum limit for vitamin D in supplements is increased to 20 µg per daily dosage, all age groups including elderly above 75 years can cover the recommended intake without risk of exceeding UL. Increasing the maximum limit to e.g. 50 µg as suggested as an example by the Norwegian Food Safety Authority implies that all age groups under 10 years will exceed the UL (UL 1-10 years=50 µg/day). Increasing the maximum limit to e.g. 90 µg as suggested as another example by the Norwegian Food Safety Authority implies that all age groups will exceed the UL (UL > 10 years=100 µg/day). The Panel on Nutrition, dietetic products, novel food and allergy therefore suggests a new maximum limit of 20 µg of vitamin D per recommended daily doses in food supplements.

The main concern of the Norwegian Directorate of Health is low intakes of vitamin D from food, and vitamin D supplementation is recommended in infants, young children and elderly to ensure adequate intake. The existing minimum limit is 1 µg per daily dosage. This will not contribute to a sufficient intake for the population with lower intakes. The Panel on Nutrition, dietetic products, novel food and allergy recommends that the existing minimum limit for vitamin D in food supplements is evaluated.

Conclusion

The maximum limit for vitamin A in food supplements should not be increased for any age group.

Based on the increased recommended intake for adults above 75 years to 20 µg per day and calculations of exposure from food showing no exceeding of UL for vitamin D in any of the age groups, the Panel on nutrition, dietetic products, novel food and allergy concludes that the maximum limit for vitamin D in food supplements can be increased to 20 µg per recommended daily dosage for children (above 3 years) and adults.

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