# Fortification of Food in Europe

- with specific emphasis on vitamin D

*Summary of the conference, held June 4-5 2004 in Copenhagen, Denmark.*

Around 70 participants representing food industry, policy makers, consumer groups and the scientific community attended the conference that had 16 scientific presentations performed by invited speakers.

*Prof. Kevin Cashman: "The importance and the effects of vitamin D".*
The effect of vitamin D on serum calcium level is the most well known effect, but receptors for vitamin D have been detected in many tissues throughout the body, which almost certainly tells that the vitamin has an effect there. The population can be divided in 3 receptor gene groups, and a key question is whether there is an increased susceptibility to osteoporosis associated with particular genotypes, and if it is mediated through diet related processes. Correlations between vitamin D status and several diseases like some cancers, high blood pressure, psoriasis and others are most likely. Cut-off values for plasma 25-dihydroxyvitamin D (25OHD) as a marker for vitamin D deficiency was discussed and it was concluded that if 80 nmol/l is the limit, almost all Irish are deficient, and even with a cut-off of 40 nmol/l many people throughout Europe (almost half the population) will be regarded as deficient, especially during winter.
It was pointed out that data on vitamin D intake in most European countries are sparse, but it was estimated that 90% of Europeans have intakes below recommendations.
It was stated that even if we can't *prove* that an optimal vitamin D status in the populations will reduce the occurrence of osteoporosis, it is irresponsible not to act on the widespread low status among populations, especially concerning the knowledge gained lately about the correlation between vitamin D status and other diseases. Greater awareness of the consequences of vitamin D deficiency is needed.

*Assistant professor Christel Lamberg-Allardt: "What influences the vitamin D status and what is the current vitamin D status in Europe?"*
A sufficient vitamin D status can be obtained if people spend some time in the sun, in order to gain enough UV-B irradiation for the skin to synthesise the vitamin. However, in the Northern Europe in the months October to February there is not enough UV-B radiation for the skin to produce vitamin D, and in order to maintain sufficient vitamin D status, the body depends on the stores build up during summer or on vitamin D supplementation from food or supplements. Surprisingly, an overview of data on vitamin D status among different populations in Europe reveals higher status in people from Northern countries compared with Southern countries. This could be due to sampling time, as it is assumed that during summer people from Northern countries spend more time in the sun than people from Southern countries but other explanations were given, for example dietary habits, intake of supplements, and high calcium intake. Vegans have lower vitamin D status during winter but reach the same summer-status as others. Studies of status in the Finnish population (healthy adolescents, adults, and elderly) during winter reveal high frequency of low status or deficiency, reflected in low bone mineral density.
It was shown that a low vitamin D status can be corrected by supplementation but after about 6 weeks of supplementation plasma 25OHD reaches a plateau, which depends on the magnitude of the supplement. It was questioned, if 5-10 μg/day vitamin D really is

enough. Fish and fish products are the best food sources for vitamin D, but access to fortified foods will increase availability of vitamin D containing food for those not eating fish. Many countries recommend vitamin D prophylaxis for small children.

*Dr. Paul Lips: "What is the effect of lower and higher vitamin D intake?"*
Vitamin D deficiency and high bone turnover (secondary hyperparathyroidism) is common (>20%) among patients with hip fracture. There is a negative relationship between serum 25OHD and serum parathyroid hormone (PTH), if serum 25OHD is below a threshold, which may be around 50 nmol/l. Below the threshold serum 25OHD, a vitamin D supplement decreases serum PTH. Calcium intake also has a marked effect on the serum level of PTH. If the calcium intake is low, the PTH-level is high and the half-life of 25OHD is short, which may be corrected by supplementation with vitamin D.
Again, data showed that a plateau in vitamin D status was reached within 3 month of supplementation. It was shown that the difference between effect of supplements with 400 IU /day and 800 IU/day was marginal, though, but effect of vitamin D supplementation depended on the baseline vitamin D status.
Vitamin D supplementation with or without calcium had a moderate effect in some studies on the occurrence of bone fractures. The effect, though, depended on baseline vitamin D status, calcium intake, and level of supplements. Vitamin D supplement could be given as daily doses between 400 IU and 800 IU, or as equivalent doses once per month or per three month.
It was concluded that supplementation with vitamin D can be safely done with doses between 400 IU and 800 IU/day and that a greater effect on bone fracture of higher doses has not been proven but the effect depends on baseline vitamin D status. The effect of combined calcium and vitamin D on parathyroid function, bone loss and fractures is greater than of either administered alone. If, on the other hand, the calcium intake is high (>1000 mg/d) – as it is in some European countries – only vitamin D fortification may be necessary, but otherwise it is recommended to fortify with both nutrients.

*Professor Jadwiga Charzewska: "Contribution of sun exposure for vitamin D status across Europe".*
Small amounts of UV radiation are beneficial to people because of its role for vitamin D production in the skin. The radiation is influenced by sun elevation, latitude, cloud cover, ground reflections, and time of day. Vitamin D production in skin depends on degree of pigmentation/tanning. For example tanning reduces the vitamin D production $\geq$ 50%.
In the OPTIFORD study, summer sun exposure across European populations were very similar among girls, but differed among women, probably due to different sun exposure habits. Especially Spanish women seemed to avoid the sun. The sun exposure was reflected in vitamin D status expressed by the serum 25OHD and correlated well with the participant's own statements about sunbath habits. It was established that in young girls each additional hour spent outdoors between 11-15 hours resulted in 5% increase in serum 25OHD concentration, and in women each hour spent outdoors between 15-20 hours increased serum 25OHD by 7%. Adequate serum 25OHD concentration generated during summer significantly correlated with a high serum 25OHD level in winter. Therefore a need to promote reasonable use of solar radiation is suggested.

*Professor Carmen Cuadrado: "Contribution of diet for vitamin D status across Europe".*
Dietary habits vary across Europe and are influenced by several economical, social, physical, and physiological factors. In the OPTIFORD project the intake of vitamin D (and calcium) from food was assessed using a common database on chemical composition of foods and a common food survey method. Difficulties were identified when creating the common database on vitamin D content in foods: variation in vitamin D content from different food databases due to differences in analytical methods, fortification policy, and cooking and industrial processes which affect results.
In many European countries fish contributes most to vitamin D intake, although big differences are seen between countries. The same goes for red meat and poultry, eggs, and dairy products. Also, intakes of vitamin supplements vary across Europe; mainly people from northern countries take supplements. Preliminary data from the OPTIFORD project shows that several population groups have vitamin D intakes from food below recommendations, especially adolescent girls.

*Professor Leif Mosekilde: "What is the minimum effective level of vitamin D intake?"*
Actually, vitamin D is only a vitamin when we avoid sunshine. Otherwise it is a hormone, which can be synthesised sufficiently in the body. This creates a major problem in assessing the minimum effective level of vitamin D intake. Besides, the minimum effective level depends of what conditions/diseases we are going to prevent!
A plasma 25OHD of >50 nmol/l is considered sufficient. At this level both plasma PTH and bone turnover is normal.
Population based studies indicate fracture prevention by 10 μg/day vitamin D given in combination with 1000 mg calcium, or 2500 μg vitamin D three times a year (equivalent to 20 μg/day) if given without calcium. Studies on institutionalised elderly living in nursing homes indicate fracture prevention by 20 μg/day vitamin D if given in combination with 1200 mg calcium.
Population based studies indicate that severe falls are prevented by 10 μg/day vitamin D in combination with 1000 mg calcium, while studies on institutionalised elderly living in nursing homes indicate fall prevention by 20 μg/day vitamin D + 1200 mg calcium compared with 1200 mg calcium alone.

*Dr. Michael F. Holick: "Risk groups of vitamin D deficiency".*
The importance of sun exposure for vitamin D production was demonstrated, and it was suggested that elderly people spend 15-30 minutes/day in the sun (without sun screen). Pigmented skin requires 5-6 times more UV-B radiation than un-pigmented skin for comparable vitamin D production. Application of sunscreen reduces the vitamin D production considerably (90-99%), and people should be informed about this. During winter there is not enough sun for vitamin D production in the skin if you live at high latitude, and a vitamin D supplement from food or supplements is recommended. Foods need not have a high fat content to be an efficient vitamin D vehicle; actually the vitamin is better absorbed from a non-fat diet! New on the American marked is calcium-fortified juice with vitamin D.
The speaker stated that he had participated in establishing the American vitamin D recommendations, but that he now knew, they are too low – recommendations for people avoiding the sun should be 25 μg/day.
The plasma 25OHD level as a marker for vitamin D status was discussed, and cut of values of 50-80 nmol/l were suggested.

*Associate professor Christian Mølgård: "Adolescent girls – Impact of vitamin D on bone accretion".*
Severe prolonged vitamin D deficiency during growth results in rickets, a problem that is again being revealed in many industrialised countries. Late rickets/adolescent rickets are seen during the pubertal growth spurt. The few foods containing vitamin D in more than small amounts (mainly fish) are not the most popular among teen-agers! Therefore they are dependent on skin vitamin D production to obtain a sufficient status. This is clearly reflected in the fluctuations in vitamin D status throughout the year, the status being very low during winter, where about 90% had plasma 25OHD below 50 nmol/l. In an intervention study in the OPTIFORD project it was shown that the vitamin D status could be improved significantly by supplementing with 5 μg/day vitamin D for one year, while 10 μg/day had an additional small but insignificant effect. However, bone accretion (expressed as bone mass density and bone mineral concentration) was not affected by the supplement.

*Ph.D. student Heli Viljakainen: "The elderly – Determination of lowest beneficial dose that effects calcium metabolism".*
In the elderly, skin vitamin D production is reduced, they spend less time outdoor, and they often cover their body from sun exposure, resulting in low vitamin D status. To investigate what intake of vitamin D was necessary to obtain a sufficient status in this age group, an intervention study was performed in the OPTIFORD project. Elderly men and women (65-81 years) were selected for the study. Their baseline vitamin D intake was on average 10 μg/day, and their calcium intake 1064 mg/day. During the intervention, participants were given vitamin D supplements containing either 0, 5, 10 or 20 μg/day for 12 weeks during winter. After about 6 weeks intervention, serum 25OHD reached a plateau in all intervention groups, indicating balance between intake and utilisation. The final 25OHD level obtained depended on the amount of vitamin D in the supplement. However, if groups were subdivided into low and high baseline vitamin D status, it was shown that subjects with initially lower plasma 25OHD reached lower final 25OHD concentration than subjects with initially higher 25OHD.
It was concluded that during winter an intake of 11 μg/day vitamin D is required to reach a sufficient plasma 25OHD-level, while an intake of 20 μg/day is needed to maintain the same level as during summer.

*M.Sc. Rikke Andersen: "Immigrants – Vitamin D, bone accretion and lack of sun exposure".*
Immigrants from the Middle East often maintain traditions from their home culture when moving to countries at higher latitudes. The dress-code, dark skin pigmentation and low fish intake often lead to very low vitamin D status in this population resulting in several deficiency symptoms, mainly rickets in the children and muscle weakness in adult and elderly. In the OPTIFORD project a randomised, placebo controlled intervention study was performed on girls, women and men with Pakistani origin living in Denmark. Recruitment of participants appeared a major hurdle(!). Despite this the anticipated number of women and men were recruited, but group size of girls became lower than anticipated. Baseline vitamin D status was extremely low: 95-97% of all age groups had serum 25OHD below 50 nmol/l, while 40-46% of girls and women, and 13% of men had serum 25OHD below 10 nmol/l, indicating severe vitamin D deficiency. Intervention with 0, 10 or 20 μg/day vitamin

D was performed during 1 year. Vitamin supplementation resulted in a marked increase in vitamin D status after 6 months, while no further increase was observed during the next 6 months. Supplementation with 10 μg/day vitamin D seemed to replenish status in girls and women, while 20 μg/day replenished status in men. No effects were observed on any of the measured bone markers and bones. However, this could be due to low group sizes. Besides, further statistical analyses are needed.

*Mrs. Aileen Robertson: "WHO strategy on food fortification".*
New global guidelines from WHO on fortification are just finished, but not yet published. The guidelines state that fortification should provide about 97.5% of individuals in a population with an intake that meets their requirement for specific micronutrients without exceeding the Tolerable Upper Intake Levels. Previously, nutrition deficiency was a problem solely for less developed countries, but the tendency with poor eating habits (diets high in fat and sugar and low in nutrients) brings the problem to industrialised countries too. It is estimated that at present about 2% of Europeans have nutritional deficiencies. Supplementation is important in the most vulnerable population groups, where fortification proves insufficient. If fortification is opted for, regulation is necessary. To predict effects of fortification it is of great advantage to have access to dietary surveys, which makes it possible to evaluate which nutrients to add, which foods to fortify, and how much to add (level of fortification). Besides, target groups and risk groups can be identified. As it is often difficult to finance dietary surveys, it was suggested that food industry support such surveys financially, and helps update chemical food databases.
WHO is of the opinion that foods high in sugar, fat and salt should not be fortified.
Efficacy trials in connection with fortification programs are most wanted.

*Dr. Dominique Taeymans: "Current European situation of fortification of food".*
Two consumer surveys were cited. Results revealed that 77% of European consumers are confident that their diet provides the required micronutrients, but only 42% of Nordic consumers have that opinion, and therefore about 50% of consumers from Nordic countries eat vitamin supplements. Many consumers know that there are fortified foods on the marked but less than 50% say they eat fortified foods (large variation between countries) because they do not rely on fortified foods as a means of achieving daily nutritional needs. However, many consumers recognise the contribution of fortified foods in the context of a balanced diet.
Safety was a key concern in relation to food fortification, and consumers affirm their right to select between fortified and unfortified foods.
It was suggested that health benefits from fortified foods should be communicated to consumers (claims).
CIAA welcomes the European Commission proposal to harmonise EU legislation on fortified foods and supports the proposed common regulatory framework based on safety grounds. However, CIAA thinks the proposal raises concerns about the level of harmonisation and any restrictions on the addition of vitamins and minerals to specific food categories not justified on public safety grounds.

*Dr. Mairead Kiely: "Modelling of food consumption data to estimate the impact of fortification on the vitamin D supply".*
Even though the sun gives the most important contribution to our vitamin D supply, food provides an important part too, especially during winter. Food supplements contribute

significantly to the vitamin D intake as well, and supplement users have the same vitamin D status during winter as non-users have during summer. However, recommendations to specific population groups about use of food supplements have been without effect in Ireland (folic acid). Therefore fortification could be considered.
If fortification is considered, information about food intake in the population is very useful. Results from dietary surveys can be used to identify appropriate vehicles for the fortification, and to calculate effects of different fortification strategies, for example the impact in different population groups of fortification of different foods at different levels. When evaluating food consumption data for exposure assessments, factors such as time frame, population groups and representativeness, food groups for which data are available, and quantity and quality of data, determine the quality and relevance of the outcome. It is very important that calculation models are composed of many single components, for example cod liver oil should be a single food among other foods. Also, dividing complex foods into ingredients allow for detailed calculations.
One must be aware that if fortification is optional and not mandatory, it gets more complicated to calculate nutritional intakes, as marked shares of different products must be known as well as level of intakes.

*Assistant professor Christel Lamberg-Allardt: "Technological aspects and problems of vitamin D fortification – Fortification of bread – Bioavailability of vitamin D from a non-fatty food".*
Bread was identified as a possible vehicle for vitamin D fortification, and different types of fortified bread (white wheat bread and dark fibre rich rye bread) were developed. Extensive analysis were performed to verify stability and evenly distribution of vitamin D through the breads.
Afterwards intestinal absorption of vitamin D from the two bread types was studied in healthy, young women with a relatively low vitamin D status, and the results compared to intestinal absorption of vitamin D from a supplement. Both bread and supplement provided 10 μg/day vitamin D, and was given to the participants for three weeks. After three weeks an increase in serum 25OHD was observed in participants eating fortified bread, and the increase was of the same magnitude as for those taking a vitamin D supplement, showing that vitamin D from bread was as bio-available as vitamin D from a supplement.
The fortification level used in this study (10 μg/85 g bread), however, was too high for ordinary fortification. Based on data from the national dietary survey realistic strategies for food fortification in Finland were illustrated, and it was suggested that bread is fortified with 2 μg vitamin D/100 g bread.

*Dr. Klaus Krämer: "Optimising vitamin supply in relation to bone health".*
Factors related to bone strength and risk of osteoporosis were reviewed with special emphasis on nutritional factors. Not only vitamin D was mentioned, but also several other vitamins (A, K, C, and B vitamins) and minerals (Ca, Mg, P, Zn, and others). Besides effects of protein, sugars, alcohol, caffeine, and fruits and vegetables were pointed out.
It was suggested that vitamin B12 gets more attention in relation to osteoporosis, and the effect of vitamin D in connection with vitamin A also deserves a closer look, as does vitamin K. Distinguish between vitamin D2 and D3!

*Ph.D. Ram Chaudhari: "Application of custom designed nutrients systems as a practical approach to fortification".*
It was stated that addition of nutrients to foods should only be done if it is safe, the nutrients are bioavailable, and the fortification is cost-effective.
The importance of loss of vitamin activity during storage was illustrated. This must be kept in mind, when for example vitamin premixes are produced. Vitamins must still be present/active by the end of shelf life.

*Concluding remarks (expressed by dr. Lars Ovesen).*
Very few people in Europe receive anywhere near the recommended dietary intake of vitamin D, and a low vitamin D status is found both in adolescents, adults and the elderly (men and women). A vitamin D status equivalent to serum 25OHD of 50-80 nmol/l is desirable. This puts most of the European population in the risk group. A low vitamin D status can be improved by intake of vitamin D in a dosage that is relevant for fortification.

Controlled clinical trials indicate that vitamin D plus calcium decreases bone fracture risk. However, clinical trials comparing vitamin D alone and vitamin D plus calcium are lacking.

Fortification – together with other strategies – can be a useful tool in increasing vitamin D intake and vitamin D status. Fortified bread is a possible vehicle for vitamin D. However, there are no field studies performed that verifies that vitamin D food fortification will increase status in (all) the target population. Neither do we know if vitamin D fortification decreases occurrence of osteoporoses or decreases fracture rates.
If fortification is decided, a strong political commitment and ability to enforce regulations in a facilitative manner is needed. Involvement and willingness in the private sector to comply with regulations is needed, as is public sector backing, including the endorsement by professional medical organisations.
A sound scientific basis in the design of the fortification programme is necessary:

- documentation of the severity and effects of the insufficiency
- good data on food consumption on the individual level
- measures to monitor and evaluate the implementation of the fortification
- timely and effective corrective actions where needed

Several times during the debate it was mentioned that sun exposure of 5-15 minutes per day without sunscreen is beneficial for vitamin D status and should be recommended.

Consumer attitudes towards fortification were not discussed during the conference, but a representative for the Danish consumer organisation mentioned that in general the consumers accepted fortification if both safety and a necessity were stated.