
Request for advice

Date of request: 26 January 2006

Letter reference: VGP/VV 2646726

It is important for public health that the population has an adequate supply of essential micronutrients. We know that a habitual diet does not contain enough of some of these essential micronutrients to meet the needs of (certain groups of) the population. The Ministry of Health, Welfare and Sport therefore follows an active policy with regard to these essential micronutrients. This policy covers both the use of supplements (vitamin D for young children, folic acid for pregnant women and women who want to have a baby) and fortification of foodstuffs. The addition of vitamins A and D to margarine, butter, and oil is permitted and encouraged under the Agreement on the vitamin fortification of spreadable fats. The addition of iodine to table salt (and alternative products), bread and bread substitutes (via salt used in breadmaking) and meat products (via nitrite pickle) is also permitted.

On the other hand it is important to ensure that people do not consume too much of certain essential micronutrients, as this could be harmful to health. That is why foodstuffs cannot in principle be fortified with essential micronutrients that have a 'narrow margin'. The micronutrients in question are vitamin A, vitamin D, folic acid, selenium, copper and zinc. A 'narrow margin' in this context means that the recommended dietary allowance (RDA) and the safe upper level of intake are relatively close to one another, which means that people can easily run the risk of consuming too much of a certain vitamin, mineral or trace element. The addition of iodine to foodstuffs is prohibited for the same reason. There are however exceptions to these rules: iodine can be added to salt (used in breadmaking

and preparing meat products) and vitamins A and D can be added to spreadable fats. Controlled additions seek to ensure that consumers do not ingest too much or too little. As far as the other essential micronutrients that do not have a narrow margin are concerned, fortification of foodstuffs is permitted up to 100% of the recommended dietary allowance per daily intake.

Three developments are taking place at the moment leading to a need to review micronutrient policy. They are set out below.

Following the judgement of the Court (2 December 2004, EC Commission v. Netherlands, C-41 102), the Netherlands has had to give up its absolute ban on fortification with substances such as folic acid. Requests for exemption from the ban on adding micronutrients can only be rejected if it can be demonstrated that placing the specific product on the market would endanger public health. According to the Court's judgement, the absence of a nutritional need for the fortification of foodstuffs, which has in the past been an important argument used by the Netherlands in rejecting requests for exemption, no longer constitutes adequate grounds. The EU regulation on voluntary fortification of foodstuffs with vitamins, minerals and some other substances will take effect in the course of the next year or two. Policy on the fortification of foodstuffs with micronutrients will then be harmonised throughout the EU. This regulation will set minimum and maximum amounts of vitamins and minerals that can be added. The same procedure will be carried out for dietary supplements in order to minimise the risk of overdoses of micronutrients by people consuming fortified foodstuffs and taking dietary supplements. It is true that the regulation deals with voluntary fortification and therefore by definition does not resolve the problem of possible deficits in the supply of essential micronutrients. But the regulation does allow EU member states to continue or introduce mandatory fortification of foodstuffs if this is necessary on public health grounds. The question is whether the Netherlands should maintain its current system of voluntary fortification of spreadable fats with vitamins A and D and the fortification of table salt, salt used in breadmaking and nitrite pickle with iodine or whether it should move to a system of mandatory fortification. Another point is that science is producing new findings. Increasingly, researchers are discovering that the health benefits of a supply of certain micronutrients at levels (far) above the current dietary reference values. As this might also lead to a risk of excessive intake, which needs to be considered in the light of the other effects, the Ministry's policy could be based on a risk-benefit analysis. Risk-benefit analysis models are being devised. One example is the role that folic acid is thought to play in preventing cardiovascular diseases. The United States has examined the advantages and disadvantages of extra folic acid supply and has decided to introduce mandatory fortification of flour (for use in bread making and other applications). Ireland and the United Kingdom are currently considering whether to follow suit.

The challenge facing me is to devise a policy, within the context of the new European regulation, under which the largest possible proportion of the population will receive sufficient essential

micronutrients while the smallest possible proportion of the population will run the risk of consuming more than the safe upper level of intake.

In the light of this, I am asking the Health Council to address the questions set out below.

For what essential micronutrients for which dietary reference values have been established in the Netherlands and in what situation does the habitual diet not offer sufficient guarantees that the population, or groups of the population, will have an adequate supply? Please use food consumption data, nutritional status data and other relevant scientific information when addressing this issue. What is the best way of ensuring an adequate supply of essential micronutrients in these situations? The Council is requested to look at all available policy instruments for each essential nutrient in its deliberations. What might the health benefits of an active fortification policy (whether with mandatory fortification or not) be for (groups of) our population in the light of a risk-benefit analysis for essential micronutrients such as folic acid and vitamin D (and any other relevant vitamins and/or minerals)?

I would very much appreciate receiving your advisory report around the middle of 2007.

(signed)

The Minister for Health, Welfare and Sport

H. Hoogervorst

Additional questions

Date of request: 17 July 2006

Letter reference: VGP/VV 2700094

Dear Professor Knottnerus,

In January 2006, I requested that you draft an advisory report on essential micronutrients (advisory report request VGPIVV 2646726). At the time, in outlining the request, I mentioned various points for attention. Following a question in parliament* concerning vitamin D deficiencies in specific sections of the population in the Netherlands, I now request you to pay particular attention in the aforementioned advisory report to the vitamin D intake of pregnant women and people with a non-Western background.

I trust I have provided you with sufficient information.

The Director-General of Public Health,
J.I.M. de Goeij, M.Sc.

* See annex 1: parliamentary question 2050609210 concerning severe vitamin D deficiency of people with a non-Western background.

Annex 1

Answers to parliamentary questions from Arib (PvdA) on severe vitamin D deficiency of people with a non-Western background (2050609210).

1.

Have you read the article on the severe vitamin D deficiency of people with a non-Western background? 1)

1.

Yes

2.

What is your opinion of the article, which states that half of pregnant women with non-Western backgrounds in the Netherlands and their offspring have a severe vitamin D deficiency? What do you think of the fact that 10% of women with a Dutch background and their offspring had a vitamin D deficiency?

2.

The article concerns a fairly small random sample of Dutch/European and non-Western pregnant women. However, the results of this study conducted in Amersfoort display similarities with a previous study of an midwifery practice in The Hague. As a result of these studies amongst others, a random survey is currently underway of the prevalence of vitamin D deficiency. The aim of these more extensive studies is to achieve a better insight into the factors that have the greatest effect on the occurrence of vitamin D deficiency. The studies are also looking at different ethnic groups separately. The study results are expected this year. Other research has indicated that men and non-pregnant women with a non-Western background are more likely to have a vitamin D deficiency. This is connected with factors that affect vitamin D status, such as skin colour, amount of exposure of uncovered skin to sunlight and dietary patterns. A vitamin D supply below the recommended level has been brought to my attention and needs to be further studied (see the following questions).

3.

Were you aware that a previous study in The Hague of 240 pregnant women also demonstrated similar low vitamin D levels? If so, what did you do with the findings of the study? 2)

3.

Yes, see question 2.

My nutritional policy is based on the Guidelines for a Healthy Diet and the Health Council's dietary reference values (including those pertaining to vitamin D).

New information has recently emerged from studies. This information makes it necessary to review the micronutrients policy. I have requested an advisory report from the Health Council on, amongst other things, which essential micronutrients, such as vitamin D, according to a risk-benefit analysis, would provide health benefits in the event of adopting an active fortification policy, possibly with mandatory addition of nutrients. I also request the Health Council to consider groups of the popula-

tion. In a supplementary letter, I shall specifically refer to pregnant women and groups of the population with a non-Western background as a point for attention in connection with this.

Information on vitamin D intake is currently disseminated via various information media. On its website the Netherlands Nutrition Centre recommends extra vitamin D for certain groups, including children aged 0-4 and pregnant women. The importance of an adequate vitamin D supply is also regularly stressed in news bulletins and other reports on the website and in publications such as the vitamin guide. Within the scope of the folic acid campaign, which is being conducted in cooperation with Erfocentrum (Dutch national genetic resource and information centre) and with funding from the Ministry of Health, Welfare and Sport, a brochure published by the Netherlands Nutrition Centre specifically refers to the use of vitamin D during pregnancy. The brochure specifically targets women from ethnic minorities and women with a low level of education. As part of the same project, to encourage women in ethnic minorities and women with a low socio-economic status to take folic acid, pilots are currently underway in which midwives are actively attempting to provide the women concerned with information via their practices and networks. If the pilots produce good results, I shall certainly be examining the possibility of including information on vitamin D intake in this initiative. Various initiatives are underway at the local level, such as one in which midwifery practices in Amsterdam involve information officials of VETC (which produces information for specific language and cultural groups) to improve communication with women of non-Western background. Pre-conception healthcare is also scheduled to start soon in Amsterdam with the aim of informing women about measures they can take to have a healthy pregnancy, and to aid early identification of women with an increased risk of problems during pregnancy.

Finally, advice on supplements, including vitamin D, for children aged 0-4 already has a firm place in dietary advice provided in child healthcare through child healthcare centres.

4.

What is your opinion of the finding of epidemiological studies that it is likely that a low vitamin D level is one of the factors contributing to the existence of disorders with a long latency period, such as osteoporosis, diabetes mellitus type I, multiple sclerosis, cardiovascular diseases, and prostate, breast and colorectal cancers?

4.

The dietary reference values for vitamin D published by the Health Council in 2000 for the population of the Netherlands had the aim of establishing peak bone mass by the age of 30 and thereafter to delay bone deterioration for as long as possible. At the time of drafting the dietary reference values (2000) there were few indications that vitamin D might have a protective effect against diseases. A recent literature review by the National Institute of Public Health and Environmental Protection, RIVM, has also shown that evidence is only convincing for osteoporosis that a low vitamin D status in men and women older than 50-60 is associated with a higher risk of fractures. The Health Council's advisory report referred to in question 3 will therefore also examine the relationship between vitamin D and various diseases. The Health Council will conduct a risk-benefit analysis taking into

account the achievable health benefits and any adverse effects. This will form the basis for determining the advisable intake for various population groups.

5.

Did you know that it has been scientifically demonstrated 3) that vitamin D deficiency in the last trimester of pregnancy adversely affects bone development in the child? If so, what action did you take in the light of this knowledge? How did you translate the knowledge into your policy on disease prevention in respect of pregnant women?

5.

I am aware of a recent publication in the Lancet concerning a study that showed a definite link between vitamin D status during pregnancy and the bone mass of children aged 9.

I am not aware of what the effect of supplements, as recommended in the Netherlands for children aged 0-4, would be on the child's bone mass at a later age.

Further, see answers to questions 2 and 3.

6.

Why have Devaron tablets, 400 E, and depot injections silently been withdrawn from pharmacies?

6.

The 400 E (10 ug) Devaron tablets and the depot injections (Neo-Dohyfral D3) were withdrawn from the market for economic reasons by the manufacturers concerned. Devaron tablets were mainly used in the indication (prevention of) osteoporosis (brittle bone disease). Sales declined sharply with the arrival of combination preparations that contained calcium and Devaron.

7.

Can you remember the Health Council's advisory report of 2000 4) on dietary reference values?

What did you do with the recommendations made in the advisory report? Could you indicate exactly how you have encouraged vitamin D use in the vulnerable groups?

7.

Further, see my answers to questions 2 and 3.

Elderly people (male and female) may have an increased risk of vitamin D deficiency because reduced mobility prevents some elderly people from going outdoors and because the skin of elderly people is less capable of producing vitamin D when exposed to sunlight. The group is also specifically mentioned in the information produced by the Netherlands Nutrition Centre. Spreadable fats and products used for baking and frying can be fortified with vitamin A and D. Furthermore, the Commodities Act Exemption for Vitamin Preparations has been amended following the Health Council's report. Vitamin preparations containing a higher amount of vitamin D may now be marketed for consumption by people aged 60 and older. This was already possible for children up to the age of 6, pregnant women and breastfeeding women. It may also be clearly stated on the packaging that the product is suitable for people aged 60 and older.

Following the Health Council's advisory report, a number of requests for knowledge were also submitted to RIVM (Ministry of Health, Welfare and Sports, project V/340230: status determination for folate and micronutrients). This concerns research into the vitamin D status of 4,400 pregnant women from various ethnic groups and a status determination of, amongst other things, vitamin D among 1,400 people from various ethnic groups. The results of this will be published before the end of the year.

The results will be included in the review of the vitamin D fortification policy. Following the publication of the Health Council's report on dietary reference values, it was discussed and the possibility was considered of granting permission for the fortification of various products, in addition to spreadable fats and fats used in baking and frying. No priority was stated at the time in connection with scheduled European regulations on the subject. While awaiting the European regulations and the requested advisory report, I have no plans for any voluntary or compulsory fortification of additional products.

The subject has my attention and I will take the appropriate measures in due course.

8.

What specifically will you be doing to motivate general practitioners to take this problem more seriously and actively provide information in their guidance, especially of risk groups, such as pregnant women with a non-Western background, and to enable vitamin D supplements to be provided? Would you be willing to arrange for the Dutch College of General Practitioners to draw up clear guidelines to encourage the use of vitamin D?

8.

See also questions 3 and 7.

I see general practitioners, midwives and gynaecologists as important links in the information chain concerned with pregnancy.

I am therefore eager to hear the response of the Dutch College of General Practitioners (NHG), the Royal Dutch Organisation of Obstetricians (KNOV) and the Dutch Society for Obstetrics and Gynaecology (NVOG) to recent developments (including the article by Wielders of 4 March 2006 in NTvG) and I expect to be able to read their response soon in *Nederlands Tijdschrift voor Geneeskunde* (NTvG).

A request has been submitted to the Health Council for an advisory report on preconception care. The Council will examine whether it would be advisable to integrate preconception care in pregnancy healthcare and child healthcare centres. I look forward to receiving the results and to see whether they jointly lead to a good proposal for information for ensuring vitamin D intake, amongst other things, during pregnancy. My assessment will also include the results of the requests to RIVM for knowledge (see question 7) and other more detailed studies (see question 2). Reports on this will also include information on the determinants of a vitamin D deficiency and on why, for example, women from ethnic minorities do not take supplements during pregnancy.

- 1) Nederlands Tijdschrift voor Geneeskunde, 4 March last. 150 (9).
- 2) Karamali NS, Meer IM van der, Wuister JD, Verhoeven I. Vitamine D-tekort bij zwangere vrouwen: gegevens van een verloskundigenpraktijk uit Den Haag. Epidemiological Bulletin 2004;39:10-4.
- 3) See note 1
- 4) Dietary reference values: calcium, vitamin D, thiamine, riboflavin, niacin, pantothenic acid and biotin. The Hague: Health Council of the Netherlands; 2000.