

**EC Health & Consumer Protection Directorate-General Discussion
June 2006 Discussion Paper on
The setting of maximum and minimum amounts for
vitamins and minerals in foodstuffs**

Comments submitted 28 September 2006 by

Dr Soja John Thaikattil, Student: M Med (Cli Epi)
School of Public Health, The University of Sydney, Australia

Westmead PO Box 114, Sydney NSW 2145, Australia
Email: s_j_thaikattil@yahoo.com.au (s underscore j underscore)
Tel: +49 421 107 087 (mobile)

I wish to take this opportunity to submit my comments to the discussion paper on setting of maximum and minimum levels for vitamins and minerals to foodstuffs.

- I share the view with many others that the current recommended levels for intake of minerals and vitamins based on prevention of deficiency states should be reviewed and revised in order to make provision for levels of nutrients required for optimum health characterised by genomic stability as proved by emerging DNA studies. For example Fenech in his study found that healthy young adults required 700 µg of folic acid and seven µg of B12 *in addition to a healthy diet* to maintain genomic stability [1]. The 1991 UK MRC clinical trial which established conclusive evidence of the association between folic acid and neural tube defects (NTD) proves the same point, namely the level of folic acid required to prevent NTD is much higher than the current recommended levels based on prevention of deficiency disease. Genomic stability contributes to prevention of cancer development. Higher levels of folic acid than currently recommended is required also for optimum reduction of homocysteine levels, which in turn is deemed a risk factor in cardiovascular disease and reduction in bone density. Vitamin B12 acts in conjunction with folic acid in all of the above.
- Since some European countries are currently considering mandatory fortification of staple food with folic acid, and it is hoped that all European countries would follow suit to introduce mandatory fortification, and some of the opposition from the general public seems to be based on the notion: 'If I'm not about to have a baby, what does folic acid have to do with me?', the role of higher levels of the nutrients required for the optimum health of the general population needs to be communicated while setting maximum and minimum levels of vitamins and minerals.
- The determination of the safe upper limit for folic acid based on masking of megaloblastic anaemia of B12 deficiency is obsolete. The new safe upper limit should be determined based on risk of cancer development instead. Until the availability of data determining the safe upper level in relation to cancer development, 1 mg of synthetic folic acid per day should be considered as

recommended upper level of intake, rather than safe upper limit. Considering that 700 µg of folic acid is required in addition to a healthy diet for genomic stability, in a healthy young adult, it would cause the public unnecessary concern if 1 mg were set as safe upper limit.

- Synthetic vitamin B12 is particularly important to the elderly population, since they suffer from mild deficiency due to several reasons. Most of the mild deficiency could be easily reversed with low level supplementation in fortified staple foods.
- While optimum health is the goal, it is also prudent not to overload the human metabolism with excessive amounts of synthetic vitamins and minerals. It would hence be necessary to set a reasonable upper limit even in cases where there is no scientifically established level for tolerable upper limit. For example, a daily intake of 15 µg of B12 would adequately meet the needs for genomic stability in a healthy young adult. There is no need to expose the same young adult to a hundred times that amount. Mega doses of vitamins and minerals are made available in some supplements. In the best interests of the public, there needs to be a way to regulate the amounts added, which far exceeds the levels required for optimum health.
- It would be ideal if supplements of vitamins and minerals with greater potential risk at excessive intakes (eg Vit A, beta carotene, Calcium, Copper, Fluoride, Iodine, Iron, Manganese, and Zinc) were marketed separately from those which have low or almost no risk. That would ensure that the mix and match of supplements which is often required to get all the nutrients in the right doses, does not lead to overdose of the nutrients with potential risk.
- It is advisable to set the maximum levels for fortified foods and supplements separately because consumption of fortified foods is far more common than supplements. It should be possible for the normal population to get all their nutrient requirements met without the need for supplements, as many people can't afford them.
- Dietary habits of all population groups should be taken into account while setting of maximum levels of vitamins and minerals. However intake of supplements should not be allowed to determine the levels in fortified food.
- It is necessary to keep in mind that industry is driven by competition and motivated by profit, may not always act in the best interests of public health, and hence may oppose moves which do not serve their self-interest [4]. The benefits of mandatory fortification of staple foods with nutrients like folic acid and vitamin B12 for the general population is immense, not only in terms of better health for all but also in cutting the cost of health care.

References

1. Fenech M. The role of folic acid and vitamin B12 in genomic stability of human cells. *Mutation Research* 2001; 475:57-67.
2. Thaikattil SJ. Comments on SACN draft report 'Folate and disease prevention' 23 November 2005.

(Comments posted under Sydney West Area Health Service, Australia)

http://www.sacn.gov.uk/pdfs/health_service_australia.pdf

http://www.sacn.gov.uk/pdfs/folic_sacn_06_02.pdf

http://www.sacn.gov.uk/meetings/subgroups/folic/2006_02_10_responses.html

3. Thaikattil SJ. Comments on Foodstandards Australia New Zealand Proposal P295: Consideration of mandatory fortification with folic acid 31 July 2006.

[Proposal P295: Consideration of mandatory fortification with folic acid – Final Assessment Report 8 September 2006; to view FSANZ abstract of 3, please click on [pdf] of attachments 1-6: Ref P13, pages 162-164 (pages 169-171 of pdf file) of main document dated 4 October 2006.]

<http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp295consider2600.cfm>

4. Nestle M. Food industry and health: mostly promises, little action. *Lancet* 2006; 368:564-65.