

# Office of Population Health Genomics

Submission to FSANZ

Proposal P295  
CONSIDERATION OF MANDATORY  
FORTIFICATION WITH FOLIC ACID

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04-02945

Food Standards Australia and New Zealand  
Standards Management Officer  
PO Box 7186  
Canberra BC ACT 2610

Dear Standards Management Officer

Re: Proposal P295 - Consideration of mandatory fortification with folic acid

The specific objective of this Proposal is to introduce mandatory fortification of the food supply with folic acid to reduce the incidence of NTDs in Australia and New Zealand. In May 2004, Mr McGinty, the Minister for Health (WA) proposed mandatory fortification of staple foods at the Australian and New Zealand Food Regulation Ministerial Council, where all State and Federal Health Ministers supported the proposal for consideration by Food Standards Australia & New Zealand (FSANZ). Therefore, the Office of Population Health Genomics as part of the Department Of Health Western Australia strongly supports the proposal for the introduction of mandatory fortification of bread making flour with folic acid to decrease the incidence of NTDs and considers the other option of maintaining the status quo, presented in the draft assessment report as unsatisfactory in achieving this aim.

The international experience is that over forty countries have implemented mandatory fortification, including the United States, Canada, Indonesia and South Africa<sup>1</sup>. The food industry in Australia has been able to utilise permissions for voluntary fortification of food with folate for over 10 years. Voluntary fortification alone has achieved an approximately 7% decrease in the incidence of NTDs in Australia<sup>2</sup>. States that have undertaken extensive education campaigns have achieved a 30% reduction in NTD incidence<sup>3,4,5</sup>. In Western Australia health promotion programs have been run to increase awareness of the need to increase folate consumption amongst women and medical professionals. While these interventions have resulted in a modest but limited, reduction

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<sup>1</sup> Food Safety Authority of Ireland (2006). Report of the National Committee on Folic Acid Food Fortification. Dublin.

<sup>2</sup> Lancaster, P. and T. Hurst (2001). Trends in neural tube defects in Australia. Australian Institute of Health and Welfare, National Perinatal Statistics Unit. Commonwealth Department of Health and Aged Care (ed). Canberra.

<sup>3</sup> Chan, A., Pickering, J., Haan, E., Netting, M., Burford, A., Johnson, A., and Keane, R. J. (2001). "Folate before pregnancy": the impact on women and health professionals of a population-based health promotion campaign in South Australia. Medical Journal of Australia, **174** (12): 631-6.

<sup>4</sup> Bower, C., Ryan, A., Rudy, E. and Miller, M. (2002). Trends in neural tube defects in Western Australia. Australian and New Zealand Journal of Public Health **26**(2): 150-151.

<sup>5</sup>Riley, M. and Halliday, J. (2004). Birth Defects in Victoria in 2001-2002. Victorian Perinatal Data Collection Unit. Melbourne, Victorian Government Department of Human Services.

in the overall incidence of NTDs in Western Australia (approximately 27%), the indigenous population, single women, those with lower levels of education and lower socio-economic status have not realised the same reduction in NTDs<sup>6</sup>. The use of folic acid supplements in the periconceptual period has been correlated with education and socio-economic status<sup>6</sup> and data from Western Australia show an increasing disparity in NTD rates between Aboriginal and non-Aboriginal infants, with Aboriginal infants now twice as likely to have an NTD as non-Aboriginal infants<sup>7</sup>.

Extensive education campaigns fail to reach fifty percent of women of reproductive age due to the equivalent rate (50%) of unplanned pregnancies and socio-economic factors<sup>8</sup>.

In preparation for this submission, the Office of Population Health Genomics has supported the work undertaken by Carol Bower and Nick de Klerk, with Siobhan Hickling, Elizabeth Milne, Helen Bailey, Gina Ambrosini and Leon Flicker on the scientific evidence of benefits and risks of an increase in folic acid intake in Australia and New Zealand:

- Quantification of primary benefits: reduction of NTD risk;
- Potential secondary benefits – risk reduction of cardiovascular, cancer diseases and of impaired cognitive function;
- Estimates of risk: increase in risk of some cancers and the evidence of an association between the intake of folic acid with the development of cancer.

We agree with their conclusions that

- An increase of folate intake of 0.2mg/day would prevent 10 NTD in infants of supplemented mothers and 39 in infants of unsupplemented mothers (Bower C & de Klerk N, Part 1).
- There is probable evidence that increase folate intake protects against cardiovascular disease (Hickling S, Part 2), and could reduce the risk of rectal cancer (Ambrosini G, Part 2), possible evidence that high levels of folate intake protect against breast cancer (Milne E, Part 2) and an association between folate and a risk of cognitive decline (Flicker L, Part 2).

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<sup>6</sup> Bower, C., Knowles, S., and Nicol, D. (1997). Changes in folate supplementation, and in serum and red cell folate levels in antenatal patients over the course of a health promotion project for the prevention of neural tube defects. *Aust N Z J Obstet Gynaecol* 37, 267-271.

<sup>7</sup> Bower, C., Eades, S., Payne, J., D'Antoine, H., and Stanley, F. (2004). Trends in neural tube defects in Western Australia in Indigenous and non-Indigenous populations. *Paediatr Perinat Epidemiol* 18, 277-280.

<sup>8</sup> Ray, J. G., Singh, G., and Burrows, R. F. (2004a). Evidence for suboptimal use of periconceptual folic acid supplements globally. *BJOG* 111, 399-408.

- As yet, there is little evidence from studies in humans of an adverse effect of folate on the incidence of cancers (Milne E & Bailey H, Part 3).

The recent report of the Food Safety Authority of Ireland on Folic Acid Fortification indicated increasing voluntary fortifications may “increase the range of foods fortified with folic acid or the amount of folic acid added to these foods”, that “could lead to over-consumption by some groups of the population and would not cover the needs of those women who choose not to eat these foods.” (page 8)<sup>1</sup>.

With regard to *Section 10 of the FSANZ Act 1991* and the objectives FSANZ is required to consider in this process the following comments are made:

1. The protection of public health and safety

The scientific evidence presented in the Draft Assessment Report demonstrates the significant public health benefits that can be achieved by this policy approach. There are no demonstrable safety issues involved in the fortification of bread making flour with folic acid.

The international activities in mandatory fortification of food with folic acid make this an imperative for FSANZ, to ensure Australians are not disadvantaged due to inconsistencies between domestic and international food supplies.

As evidenced above mandatory fortification of staple foods with folate is the only option that increases the folate intake of women regardless of socio-economic, education or indigenous status, family planning or geographical location.

There have been no reported adverse effects from mandatory fortification. No cases of masking of vitamin B12 deficiency have been reported in any country where mandatory fortification has been implemented<sup>9,10,11</sup>.

2. The provision of adequate information relating to food to enable consumers to make informed choices

The Draft Assessment Report sets out the information about folic acid, public health risks and benefits in a manner that should enable consumers to make informed choices.

The Proposal does not contradict, but enhances the Australian Guidelines for Healthy Eating (2003), which encourages consumption green, leafy vegetables for folate<sup>12</sup>.

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<sup>9</sup> Hirsch, S., de la Maza, P., Barrera, G., Gattas, V., Petermann, M., and Bunout, D. (2002). The Chilean Flour Folic Acid Fortification Program Reduces Serum Homocysteine Levels and Masks Vitamin B-12 Deficiency in Elderly People. *J Nutr* 132, 289-291.

<sup>10</sup> Liu, S., West, R., Randell, E., Longrich, L., O'Connor, K. S., Scott, H., Crowley, M., Lam, A., Prabhakaran, V., and McCourt, C. (2004). A comprehensive evaluation of food fortification with folic acid for the primary prevention of neural tube defects. *BMC Pregnancy Childbirth* 4, 20.

<sup>11</sup> Mills, J. L., Von Kohorn, I., Conley, M. R., Zeller, J. A., Cox, C., Williamson, R. E., and Dufour, D. R. (2003). Low vitamin B-12 concentrations in patients without anemia: the effect of folic acid fortification of grain. *Am J Clin Nutr* 77, 1474-1477.

3. The prevention of misleading or deceptive conduct

The introduction of mandatory fortification is more likely to prevent misleading or deceptive conduct than maintaining the status quo or extending the permissions for voluntary fortification.

Further to this, individuals with Coeliac disease are unlikely to have improved folate status as a result of mandatory fortification and specific promotional activities regarding supplementation should be considered for this group.

Our estimates agree with the independent health economic analysis conducted by Access Economics that predict, based on the Burden of Disease cost of \$7.0 million, the benefits to the Australian health system would exceed \$30 million per year.

Yours sincerely



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<sup>12</sup> NHMRC (2003). Dietary Guidelines for Australian Adults. Canberra.