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Re: Submission on the Ministry of Primary Industries Discussion Document  
*The Future of Folic Acid Fortification in New Zealand.*

To the Food Policy Team,

Thank you for the opportunity to make a submission on the *Future of Folic Acid Fortification in New Zealand* Discussion Document. This submission is made on behalf of the New Zealand College of Public Health Medicine.

Yours sincerely,

A handwritten signature in blue ink that reads "Julia Peters".

Dr Julia Peters  
President, NZCPHM

A handwritten signature in blue ink that reads "Richard Hoskins".

Dr Richard Hoskins  
NZCPHM Council, Chair Policy Committee

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# Submission on the Discussion Document

## *The Future of Folic Acid Fortification in New Zealand*

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### EXECUTIVE SUMMARY

#### Introduction

This submission is made on behalf of the New Zealand College of Public Health Medicine (NZCPHM). The NZCPHM is the professional body of doctors with specific expertise and interest in the practice of Public Health Medicine. NZCPHM membership includes 181 fully qualified specialists in public health medicine, and 32 registrars who are doctors in advanced training in the speciality.

Public Health Medicine is the branch of medicine concerned with the epidemiological analysis of the health and health care of populations and population groups. It involves the assessment of health and of health care needs, the development of policy and strategy, the promotion of health, the control and prevention of disease and the organisation of services to best meet those needs.

The NZCPHM commends the Ministry of Primary Industries (MPI) on the clear and evidence-based Discussion Document <sup>1</sup> and companion Monitoring and Evaluation Report <sup>2</sup> provided for comment. The NZCPHM appreciates the opportunity to submit on this important public health issue in New Zealand.

#### OPTION 1

The NZCPHM **strongly recommends option 1**, the introduction of mandatory fortification as planned per the Food Standard 2007. While the NZCPHM recommends immediate adoption of mandatory fortification from September 2012, we would support a phased in approach over a one year period. This period may be required for industry to prepare and to minimise industry change-over costs. The NZCPHM believes that option 1 preserves sufficient consumer choice through the exemption of organic and unleavened bread and through ingredient labelling.

Mandatory folic acid fortification is **safe and cost-effective**, and is the only policy option able to reach the whole population in order to **protect those women most at risk** of having a neural tube defect-affected pregnancy. The NZCPHM supports the MPI assessment that the evidence overwhelmingly shows that there is either no link, or no significant link, between folic acid and increased cancer rates. No safety concerns have been raised regarding the current voluntary folic acid fortification regime in New Zealand.

This important public health issue has been deferred since 2007, and New Zealand is now lagging behind more than 70 other countries that have replenished the food supply with folic acid, an essential B vitamin, through mandatory fortification. These countries are receiving the health, social and economic benefits of improved folate status and reduced NTDs.

NTD prevention for New Zealand women, babies and whānau is **not currently being maximised** via policies of supplementation and voluntary fortification. The burden of this harm falls on those groups most at risk, particularly young mothers and women with unplanned pregnancies. Mandatory fortification of bread with folic acid will address this inequality.

## OPTION 2

If consumer choice was considered to be excessively constrained by option 1 (only allowing organic and unleavened products to be exempt) then the NZCPHM would not oppose limited mandatory fortification (option 2). However the NZCPHM would recommend a very high threshold of fortification (for example 95%) of bread product. This would allow maintenance of consumer choice and reduced compliance for smaller bakeries, while improving the uptake of folic acid to those most at risk of NTD (although to a lesser extent than with mandatory fortification).

## OPTIONS 3 and 4

The NZCPHM strongly holds that should mandatory fortification be rejected, then voluntary **fortification must be maintained**. The NZCPHM would not oppose option 3 in this scenario. The NZCPHM actively opposes revocation of the Standard (option 4), because there is no assurance that the current level of voluntary fortification (and associated limited health gains) would be maintained.

The NZCPHM strongly recommends that any continuation of voluntary fortification should be supported (through funding, subsidies or incentives) to improve efforts to fortify the products most likely to be consumed by the target group (for example low cost white and multigrain breads). While not achieving the maximal possible preventative benefit for NTDs, this would enhance the folate status of a greater proportion of the target population.

## Additional recommendations

For any of the options 1-3, the NZCPHM also recommends:

- Ongoing review of the scientific literature about benefits and harms of folic acid.
- Increasing public awareness of folic acid among women of child-bearing age with a comprehensive education campaign.
- Making folic acid supplements free-at-point of use for pregnant women and women planning pregnancy.
- A monitoring programme is put in place to evaluate the impact of folic acid fortification policies. This should include monitoring the overall incidence of NTDs (including termination data to capture all NTD-affected pregnancies) as well as monitoring folate status in the target population.

## OPTION 1

The NZCPHM strongly recommends option 1, the introduction of mandatory fortification as planned in September 2012 (per the Food Standard 2007). The NZCPHM would support a phased in approach over a one year period, to allow industry time to prepare and to minimise industry change-over costs.

### Rationale

#### 1. Neural tube defects are an important public health problem

Neural tube defects (NTDs) are serious birth defects due to the failure of the neural tube to close, for example in the head region (anencephaly) or the spine (spina bifida). Infants born with anencephaly are usually stillborn or die within a few days of birth, and those with spina bifida have life-long disabilities with varying degrees of paralysis <sup>3</sup>.

The number of NTD-affected pregnancies should be expressed as an overall rate which includes terminations, stillbirths (fetal death >20weeks), and live births, in order to compare rates, and to monitor and evaluate the impact of folic acid policies. Due to the difficulty in reporting of termination-related NTDs (including in New Zealand, where changes in reporting mean this data has not been collected since 2004), many jurisdictions report NTD birth prevalence (stillbirth and live birth). This latter measure significantly underestimates the true NTD prevalence. For example in Australia, where robust termination data is available for three regions, it is estimated that more than 50% (up to 70% in some areas) of NTD pregnancies are terminated prior to 20 weeks gestation <sup>4</sup>.

The NZCPHM would like to ensure that any discussion of NTD in New Zealand, such as the average birth prevalence reported in the MPI Discussion Document <sup>1</sup> of 5.4/10,000 (2001-2008), should clearly state the caveat that if 50-70% of NTD-affected pregnancies have been terminated then the true prevalence of NTD-affected pregnancies in New Zealand could be up to 12-14/10,000. This overall rate would equate to around 70-90 NTD-affected pregnancies in New Zealand per year. It is important to make this distinction for monitoring purposes, as several countries have noted a plateau of NTD birth prevalence, but an ongoing downward trend for NTD-affected pregnancies overall <sup>4,5</sup>. It is also important when quantifying the potential gain in preventing NTD affected pregnancies in New Zealand with mandatory fortification (over voluntary fortification). Mandatory fortification can result in further NTD reductions, possibly to a 'floor level' <sup>6</sup> of 6-9/10,000 (40-50 NTD affected pregnancies per year including those terminated). This would **prevent approximately 20-30 NTD affected pregnancies a year in New Zealand**.

Australian data demonstrates that **NTD rates vary in the population**. Those women most at risk include younger women (particularly teenagers), indigenous women, women in remote areas, and women with multiple pregnancies were more likely to have a NTD-affected pregnancy <sup>4,7</sup>.

Termination, stillbirth, perinatal death and life-long disability are all hugely significant harms to women, babies, whānau and society. These outcomes also have significant healthcare, social and economic costs associated, which have been well documented (see point 9 below).

#### 2. Most NTD are preventable with adequate folate levels

Poor nutrition, specifically folate insufficiency, has been associated with NTDs since as early as the 1930s<sup>8</sup>. Evidence has accumulated since the 1960s that improving folate status during the peri-conception period could reduce the risk of NTDs. Both observation and intervention studies have demonstrated that adequate consumption of folic acid (at a level of 400mcg per day) can

prevent NTDs. The landmark 1991 Medical Research Council Vitamin Study, a randomised controlled trial published in the Lancet<sup>9</sup>, further established that folic acid supplementation can prevent more than 70% of all NTDs. This finding was endorsed in a Cochrane systematic review<sup>10</sup>. In populations where voluntary folic acid fortification was already occurring, decreases of 40-50% in NTDs have still been recorded after mandatory fortification was introduced<sup>11,12</sup>.

### **3. Targeted approaches to improving folate status are insufficient**

Three approaches have been taken to improve folate status in the target population group of women of childbearing age. These strategies are:

- Improved dietary intake of folate rich foods.
- Supplementation with folic acid tablets.
- Fortification of commonly consumed foods such as breakfast cereal, orange juice and flour (bread products and pasta).

Dietary modification and supplementation are public health strategies **targeted** at women of childbearing age (specifically pregnant women and women planning to become pregnant). These strategies are implemented through health education, health promotion and antenatal care. While these approaches have improved rates of NTD, they have not been successful alone or in combination because:

- Dietary improvement requires behavioural change. There are many barriers to behavioural change including lack of knowledge, financial constraints, health beliefs and behaviours, and busy lives. This happens in a number of spheres of public health activity, beyond just dietary changes. In addition, improving folate status to the level required to reduce the risk of NTD is very difficult to achieve with diet alone, partly due to the lower bioavailability of folate compared with folic acid. Evidence to date suggests dietary change initiatives are ineffective<sup>13,14</sup>.
- The Ministry of Health recommends beginning folic acid supplementation (800mcg tablets) at least 4 weeks before conception and continuing until 12 weeks gestation. Supplementation is effective at preventing NTDs<sup>15</sup>, however large numbers of pregnancies are unplanned. This has been identified as a significant issue limiting the efficacy of supplementation as a strategy. In New Zealand the most recent evidence suggests 40% of pregnancies are unplanned. Of women with unplanned pregnancies, 28% did not take folic acid at all during their pregnancy<sup>16</sup>.
- Adherence to the Ministry of Health recommendation is low even in women with planned pregnancies; only 58% of women with planned pregnancies in New Zealand fully meet this recommendation, and a further 7% did not take folic acid at all<sup>16</sup>. Similar patterns are seen in other high income countries<sup>17,18</sup>. Some women cannot afford to pay the pharmacy part-charge for supplements (they are not free on prescription or over-the-counter), they do not like to take supplements, or they forget to take them<sup>4,19</sup>.

### **4. Voluntary fortification provides some improvement in folate status but is not completely successful**

There is a trend to reducing NTD rates internationally since the 1980s (although the rates and methods of reporting are variable), from the order of 45/10,000 live and still births, to 10-15/10,000 in the United Kingdom<sup>20</sup>. Authors speculate that this reduction is a combination of improved nutrition, voluntary folic acid fortification of a variety of products, and variable levels of supplementation<sup>4,5</sup>. Voluntary fortification produces improvement in folate status and reduction in NTDs. The MPI-commissioned New Zealand research supports this improvement in blood folate levels. The research showed that optimum folate range (906nmol/L) increased from 26% of women in 2008/2009 to 59% in 2011<sup>21</sup>. However, the Bradbury et al research also shows that 41% of women in the survey had inadequate folate levels, and were at risk of NTD<sup>21</sup>.

In Canada the prevalence of NTD reduced from 15.8/10,000 (1993-1997) to 10.9/10,000 (1997-2000) after the introduction of voluntary fortification in 1996<sup>12</sup>. However the impact of voluntary fortification falls short of what could be achieved with a universal fortification programme<sup>22</sup>, for example in Canada the NTD prevalence then dropped further to 8.6/10,000 (2000-2002) after the introduction of mandatory fortification in 1998<sup>12</sup>. The aim of a public health approach to this issue should be the **prevention of all folate preventable NTD affected pregnancies**. It has been suggested, as noted above, that this might mean achieving a 'floor effect' of an overall NTD prevalence of approximately 6-9/10,000<sup>6</sup>. These non-folate sensitive NTDs may be related to other environmental or genetic factors.

#### **5. Mandatory fortification is a universal approach which reaches those most at risk**

Mandatory fortification of commonly consumed items (like bread) with folic acid reaches those women not reached through targeted approaches. These groups of women are those most at risk of NTD affected pregnancies: young women, ethnic minority groups, women living in high areas of deprivation and women with low educational attainment<sup>7</sup>. This situation is exacerbated by the targeted measures, as dietary improvements and supplements are likely to be taken up more frequently by older and more highly educated women<sup>16, 23</sup>. In New Zealand these inequalities maybe further exacerbated by the current voluntary fortification regime (in place since 2009) where multigrain bread has been the predominant choice for folic acid fortification to date; it has been suggested that this bread is less likely to be consumed by vulnerable population groups.

In contrast to dietary modification, supplementation and voluntary fortification, mandatory fortification is a **universal approach**. This approach seeks to replenish the levels of folate at a population level, and thus to maximise the preventative benefit of folate for the target group regardless of dietary intake, supplementation use and pregnancy planning. This is an important way to address health inequalities. The efficacy of this approach in addressing inequalities is supported by evidence. Mandatory fortification in the United States (US) has resulted in near uniform 100mcg/day serum folate levels across the whole distribution of the population<sup>24</sup>, and has resulted in a similar 30-40% reduction in NTD prevalence for African-American and Hispanic women as that recorded for white women<sup>3</sup>.

#### **6. Mandatory folic acid fortification is effective**

Evidence has been available for decades on the safety and efficacy of folic acid in countries that have introduced mandatory fortification. At present there are more than 70 countries<sup>25</sup> that mandate folic acid fortification of bread; New Zealand is lagging behind comparable countries such as the United States, Canada, South Africa and Australia in this important initiative. In the United States (US) more than a decade of outcome data indicates that at the low dose population level folic acid (140mcg per 100g) is effective at reducing the incidence of NTDs and is harmless to the population<sup>5</sup>. In countries where mandatory fortification with folic acid has been introduced this has resulted in a substantial increase in blood concentrations of folate, and a concomitant decrease in NTD. Evidence of this efficacy is provided in the table overleaf.

Impact of fortification with folic acid: Blood folate and NTD trends					
		United States	Canada	Australia	Chile
Introduced		1996 Enforced from 1998	Phased in from 1998-2000	2007 Enforced from 2009	2000
Level fortified		140mcg/100g	150mcg/100g	135mcg/100g (2-3mg/kg flour)	220mcg/100g
Folate status	Measure	Population survey (NHANES)	Population survey (CHMS)	Laboratory samples tested for folate status	
	Pre-fortification	21% Proportion of population with low serum folate (<3ng/mL) (1988-1994)		9.1% Proportion of samples with low serum folate (<7nmol/L)  3.4% Proportion of samples with low RBC folate (<310nmol/L)  (2007-2010)	
	Post-fortification	<1% (1999-2000)	Folate deficiency is virtually non-existent.	2.1%  0.5%(Indicating that folate deficiency is virtually non-existent) (2009-2010)	
	Proportion reaching the RBC folate level of 906nmol/L*	10% Mean RBC folate 590nmol/L	78% of childbearing women achieved optimal RBC folate level	64% in 2010	
NTDs	Decline in prevalence	19-36%	46-50%	Awaited	43%
	Pre-fortification	10.8/10,000 (1995-1996)	15.8/10,000 (1993-1997)	10.1/10,000 (2005)	17.1/10,000 (1999-2000)
	Post-fortification	6.9/10,000 (2006)	Voluntary 10.9/10,000 (1997-2000)  Mandatory 8.6/10,000 (2000-2002)	Awaited	9.7/10,000 (2001-2002)
References		3, 26-29	12, 30, 31	4, 22	11, 32, 33

Notes: Serum folate is a measure of folate in the diet, while Red Blood Cell (RBC) folate refers to folate stores. \* The level of >906nmol/L is considered to significantly reduce NTDs. NTDs indicate overall NTD prevalence (NTD affected pregnancies where possible: terminations, stillbirths, perinatal deaths and live births), rather than NTD affected births, to capture the full range of folate preventable NTDs.

## **7. Mandatory folic acid fortification is safe**

There is a substantial body of evidence examining the range of benefits and potential adverse effects of folate. This body of literature is well documented and discussed in relation to the issue of folic acid fortification of food in the Foods Standards Australia and New Zealand (FSANZ) Discussion Document<sup>34</sup> produced for the 2007 move to mandatory fortification (where Australia proceeded based on the weight of this evidence, and New Zealand did not). The evidence has been updated and reviewed in the most recent MPI documents<sup>1,2</sup>, including a number of new randomised control trials, systematic reviews, meta-analyses, and papers with longer follow-up periods. The same conclusions (the levels of folic acid in fortified foods are safe for the population) were drawn from this re-analysis. The issues are also thoroughly documented in several recent publications, including the World Health Organization (WHO) guidelines on food fortification<sup>5, 32, 35</sup>.

Concerns have been raised about the intake of folic acid causing potential adverse effects, including cancer initiation/promotion, late diagnosis of the neurological effects of vitamin B12 deficiency (including nerve damage and cognitive decline) in the elderly, and the unknown effects of the accumulation of unmetabolised folic acid. There are multiple large scale observational and interventional trials, systematic reviews and meta-analyses that address these issues.

Most concerns have been associated with consumption of high levels of folic acid from supplementation, not from dietary consumption of fortified foods<sup>24, 31</sup>. The 2010 results of the US National Health and Nutritional Examination Survey (NHANES) indicated that 6% of the US adult population had consumed more than 400mcg/day (from supplements), and half of these people exceed the recommended upper limit of 1000mcg/day; none of the remaining 94% of adults consuming ≤400mcg/day exceeded the upper limit regardless of folic acid intake from fortified foods<sup>24</sup>.

A review of the evidence by the NZCPHM confirms that no conclusive evidence exists to indicate that, folic acid is contributory to any of these conditions, including cancer at the levels achieved by fortification<sup>36-42</sup>. The studies, which reported borderline increase in cancer (prostate and lung), were in groups with very high folic acid supplementation (1000mcg/day) and with high proportions of smokers; the authors themselves suggested their borderline findings required further examination<sup>41</sup>. Long term follow-up for the randomised trials have not yet been completed, so continued monitoring and research are needed to ensure that public health recommendation regarding folic acid do not have unintended negative consequences; this evidence should be regularly reviewed. Both the Cancer Society of New Zealand and Cancer Council Australia have considered the available evidence and do not oppose mandatory fortification<sup>44</sup>. More recent concerns about the possible increase in respiratory symptoms (wheeze) have also been refuted<sup>43</sup>.

## **8. Folic acid fortification is not medication**

Folate is necessary for body processes involving the production and maintenance of new cells, particularly during periods of time of rapid growth, such as infancy and pregnancy. Folate is the generic term for the two different forms of the vitamin B9 and includes both folic acid (the synthetic form) and naturally occurring forms in food. Dietary sources of folate include green leafy vegetables, liver, some fruits, beans and whole grains. Folic acid is used in supplements and fortified goods. Folic acid is converted to folate in the body, and folic acid is more readily absorbed than folate. Folic acid should not be referred to as 'medication;' it is the synthetic form of an essential vitamin.



## 9. Folic acid fortification is cost effective

Benefits of fortification include reduction of healthcare and economic costs (lost productivity), pain and suffering, and the indirect and intangible costs to NTD affected individuals, whānau and society. Preventing NTD affected pregnancies mean that the benefits are associated with reduced termination, stillbirth and ongoing disability. Costs include setup and maintenance costs for industry (noting some infrastructure is in place with voluntary fortification), costs to consumers (estimated to be negligible at 0.5c a loaf), and costs to the government for monitoring compliance and effectiveness.

Economic evaluations are variable between countries, and depend on the parameters included, particularly the estimates of industry costs and the costs included on monitoring and compliance for mandatory fortification<sup>14</sup>. Several published economic evaluations have indicated that fortification with folic acid confers substantial cost-savings. In the US there is a reported saving of US\$100 for each \$1 invested in fortification<sup>45</sup>. Chile has reported savings of \$11 for each \$1 invested in international dollars<sup>46</sup>. The two FSA NZ calculations, in the MPI report<sup>2</sup>, based on New Zealand estimates indicate that the economic costs of NTD affected pregnancies far outweighs industry and government cost.

## 10. There are other possible benefits to the population

### • Virtual elimination of folate deficiency anaemia

As noted in the table above, many studies have examined the remarkable upwards shift in the mean (and distribution) folate serum and RBC folate levels in the population pre and post fortification. Even at the low levels of fortification (<150mcg/100g) folate deficiency anaemia is virtually eliminated<sup>32</sup>.

### • Stroke reduction

Multiple studies have investigated the possible preventative benefits of folate on reducing homocystine levels, improving blood pressure and reducing cardiovascular disease. The evidence suggests homocystine levels reduce (25%) with increased folate intake<sup>37,47</sup>, and there are population level benefits in reduced hypertension and stroke (11% reduction in stroke risk in populations with voluntary fortification), although there appears to be no benefit for myocardial infarction<sup>48-50</sup>.

### • Reduction in some childhood cancers

Contrary to the concern about the potential cancer promoting effect of folate (which the evidence does not support), there is emerging evidence that some childhood cancers (for example Wilms tumours) have declined in association with mandatory folic acid fortification<sup>51,52</sup>.

### • Cognitive effects

The potential concern of folate on 'masking' vitamin B12 induced dementia and cognitive decline have not been supported at the level of folic acid achieved with fortification<sup>5</sup>. Recent early evidence points to some protective effect for folate in Parkinsons disease<sup>53</sup> and improvement in depressive symptoms<sup>54</sup>; this requires further research.

## OPTION 2

If the consumer choice was considered to be too constrained by only allowing organic and unleavened products to be exempt with option 1, then the NZCPHM would not oppose limited mandatory fortification (option 2). However the NZCPHM would recommend a very high threshold of fortification (for example 95%) of bread product. This would allow maintenance of consumer choice and reduced compliance for smaller bakeries, while improving the uptake of folic acid to those most at risk of NTD (although to a lesser extent than with mandatory fortification). The issues of consumer choice and compliance costs are of lesser importance, in our view, than effective prevention of a significant risk to public health.

## OPTION 3

NZCPHM would only not oppose option 3, mandatory reporting of voluntary fortification, if mandatory fortification (in any form) was rejected, in order to preserve folic acid fortification in the New Zealand food supply for the target group. This option would not maximise the preventative benefits of folic acid for NTDs.

## OPTION 4

The NZCPHM actively opposes option 4, the revocation of mandatory fortification with allowance (but no requirement) for voluntary fortification. This option would not provide assurance of maintenance of current levels of voluntary fortification, and undermines the importance of folic acid in preventing NTDs.

## ADDITIONAL RECOMMENDATIONS

For any of the options 1-3, the NZCPHM strongly recommends the following adjunct strategies to maximise improvement in folate status for the target group:

1. Ongoing review of the scientific literature about benefits and harms of folic acid.
2. Increasing public awareness of folic acid among women of child-bearing age with a comprehensive education campaign by MPI to:
  - Increase public awareness of the benefits of folic acid.
  - Increase women's awareness of fortified products
  - Increase uptake of peri-conception supplementation according to Ministry of Health recommendations.
3. Making folic acid supplements free-at-point of use for pregnant women and women planning pregnancy.
4. A monitoring programme is put in place to evaluate the impact of folic acid fortification policies. This should include monitoring the overall incidence of NTDs (including termination data to capture all NTD-affected pregnancies) as well as monitoring folate status in the target population.

In addition, the following misinformation should be dismissed:

- Some recent reports reviewing potential harms associated with folic acid inappropriately elevate results of borderline significance<sup>55,56</sup>. Reviews of published evidence should follow appropriate and robust scientific methodologies, as established in peer-reviewed and internationally recognised journals.
- Cost to industry should be considered as part of the cost benefit analyses, as presented in the MPI discussion paper, but should not be considered as a factor in isolation. Cost to industry should not include the hypothesis of reduced consumer demand for folate fortified product, as this effect has not been shown elsewhere in the world where mandatory fortification has been introduced, including Australia.
- Folic acid should not be referred to as 'medication;' it is the synthetic form of an essential vitamin.

## CONCLUSION

Targeted approaches and voluntary fortification have improved folate levels, however the maximal preventative benefit of folate for reducing the incidence of NTDs requires a universal approach such as mandatory fortification. New Zealand is lagging behind other countries, including early adopters like the US and Canada (who now have evidence of efficacy and safety over substantial time periods); and Australia, which through policy discussion, monitoring and evaluation, has supported mandatory fortification since 2007. More than 70 countries now fortify the food supply with this essential B vitamin. Continued delay for the implementation of this policy, which is overwhelmingly supported by evidence, means that pregnancies continue to be affected by preventable birth defects are occurring for women, babies, whānau, and society in New Zealand.

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