



November 12 2019

**Submission to the Ministry for Primary Industries:  
*Review of folic acid fortification of food***

The New Zealand College of Public Health Medicine would like to thank the Ministry for Primary Industries for the opportunity to make a submission on the *Review of folic acid fortification of food*.<sup>1</sup>

The New Zealand College of Public Health Medicine (the College) is the professional body representing the medical specialty of public health medicine in New Zealand. We have 222 members, all of whom are medical doctors, including 185 fully qualified Public Health Medicine Specialists with the majority of the remainder being registrars training in the specialty of public health medicine.

Public Health Medicine is the branch of medicine concerned with the assessment of population health and health care needs, the development of policy and strategy, health promotion, the control and prevention of disease, and the organisation of services. The College partners to achieve health gain and equity for our population, eliminating inequities across socioeconomic and ethnic groups, and promoting environments in which everyone can be healthy.

**General points**

In New Zealand (NZ), women of child-bearing age are not consuming an adequate level of folic acid resulting in a significant number of neural tube defect (NTD)-affected pregnancies, including spontaneous miscarriages and the need for medical terminations (both which should be included in the accounting of NTDs' health losses and costs to New Zealand), and inequalities between Māori and non-Māori.

Current approaches to improving folic acid intake, including supplementation for planned pregnancies and voluntary fortification by large bread makers are insufficient to address this health need.

The introduction of mandatory folic acid fortification in NZ has great potential to positively impact on the number of NTDs.

The College supports MPI's proposal to introduce mandatory fortification of all non-organic wheat flour for bread-making purposes (Option 3b in the MPI discussion document),<sup>1</sup> as a sensible, feasible, highly cost-effective, safe, and equitable approach to reducing NTDs in NZ.

Thank you for the opportunity for the NZCPHM to submit on the Review of folic acid fortification of food. We hope our feedback is helpful and are happy to provide further clarification on matter covered in this submission.

Sincerely,

A handwritten signature in dark ink, appearing to read 'F Dumble'.

Dr Felicity Dumble, President, NZCPHM

# Submission Form

## Introduction

Folic acid is an essential B vitamin important for the healthy development of babies early in pregnancy. There is overwhelming evidence that consuming sufficient folic acid before conception and during early pregnancy can prevent many cases of neural tube defects (NTD) such as spina bifida.

New Zealand's rate of NTDs is higher than it could be, and Māori women have higher rates of affected live births than other groups. The financial, social, and emotional impact from these birth defects can be significant for many families, whānau, and communities across New Zealand.

MPI recognises the importance of this issue and is seeking feedback on whether the government should:

- continue with the current voluntary approach of fortifying up to 50% of packaged sliced bread
- ask industry to enhance the voluntary approach to fortify 80% of packaged sliced bread, or
- introduce mandatory fortification of bread, bread-making wheat flour, or all wheat flour.

There is no consistent evidence that folic acid, when fortified in food at the recommended level, has any harmful health effects.

All options would exclude organic products.

We are seeking your feedback on these options. Hearing the views of the public will help us understand the possible impacts of the proposals.

## Once you have completed this form

Email to: [Food.Policy@mpi.govt.nz](mailto:Food.Policy@mpi.govt.nz)

While we prefer email, you can also post your submission to:

Consultation: Folic Acid Fortification  
Ministry for Primary Industries  
PO Box 2526  
Wellington 6104

**Submissions must be received no later than 5:00pm on 12 November 2019.**

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## Submitter details:

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## Official Information Act 1982

All submissions are subject to the Official Information Act and can be released (along with personal details of the submitter) under the Act. If you have specific reasons for wanting to have your submission or personal details withheld, please set out your reasons in the submission. MPI will consider those reasons when making any assessment for the release of submissions if requested under the Official Information Act.

## The problem

The number of folic acid-sensitive NTD-affected pregnancies in New Zealand could be reduced if the blood folate levels of women of childbearing age was improved. Most women of childbearing age cannot get enough folate from natural food sources to ensure optimal blood folate levels for the prevention of NTDs.

Supplementation only works for women who plan their pregnancies and know about the importance of taking folic acid tablets during the critical period of at least one month before and for the three months following conception. Around 53% of New Zealand pregnancies are unplanned.

Some foods are voluntarily fortified with folic acid. This is not enough, however, to sufficiently reduce the risk of NTD-affected pregnancies across the New Zealand population.

### 1. DO YOU AGREE WITH THE PROBLEM AS STATED?

- Agree.
- Disagree.
- Unsure.

Please explain why:

The College broadly agrees with the problem statement. NTDs, such as spina bifida or anencephaly, can lead to miscarriage, stillbirth and major disabilities. NZ experiences a significant burden of NTDs; using global burden of disease data,<sup>2</sup> the College estimates that in NZ about 1064 disability-adjusted life years are lost yearly to NTDs.

NTDs place an enormous emotional stress and a huge financial burden on whānau and communities. In 2019, the average lifetime cost of an NTD-affected live-birth, compared with that of the general population, was estimated at \$938,000, (which includes costs such as that of caregivers, health care educational support and lost productivity).<sup>3</sup>

The College is committed to a vision of a fair and just society that accords with te Tiriti o Waitangi and where Māori and non-Māori have equitable health outcomes, and supports initiatives that will prioritise the needs of the most disadvantaged.<sup>4, 5, 6</sup>

NTDs affect Māori communities disproportionately. From 2000 to 2015, the rate of NTD-affected live births was 4.58/10,000 live births among Māori women, compared with 2.81/10,000 live births among NZ European women.<sup>7</sup> NTD-affected births place tremendous stress on the child's iwi and hapu. We note with concern that, although the information provided by MPI includes data about this inequity, there is no reference to it in the problem statement.

## The objective of the review

The objective of this review is to increase the consumption of food containing folic acid by women of childbearing age, thereby reducing the number of NTD-affected pregnancies, while considering consumer choice, increasing equity of health outcomes, and minimising impacts on industry.

## 2. DO YOU AGREE WITH THE OBJECTIVE OF THE REVIEW?

- Agree.
- Disagree.
- Unsure.

Please explain why:

The College supports the review's objective to 'increase the consumption of food containing folic acid by women of childbearing age, thereby reducing the number of NTD-affected pregnancies...while increasing equity in health outcomes'. Fortification is a low-cost, wide-reaching public health intervention with the potential to reach even the most vulnerable populations when implemented reasonably. As acknowledged in the MPI discussion paper,<sup>1</sup> fortifying a staple food can be an efficient and equitable way to ensure everyone benefits regardless of socioeconomic status, age, gender or (health) literacy.

### 'Consumer choice' vs. the rights of people and their families/whānau born with, or unable to be born because of, NTDs

The College is concerned that previous attempts to introduce folic acid fortification have not been successful, due in part to concerns about the limitations being placed on consumer choice. Whilst we recognise that consumer choice and industry impact are criteria that are important to some sections of society, we believe that these considerations should always be secondary to potential health and equity benefits. We believe that the significant benefits to babies, mothers and society that can be gained through folate fortification, especially in addressing the disproportionate burden of NTDs amongst Māori, outweigh the advantages of consumer choice and industry convenience. For those who argue autonomy and wanting the right to eat baked goods not fortified with folic acid, we note that children born with NTDs, and the many more families/whānau of children who don't survive to be born with NTDs, in a folate-depleted food and public policy environment, have little choice to even lose in the first place.

In terms of arguments pitched as the rights of many over the rights of a few (in Appendix 3 of the MPI discussion paper<sup>1</sup>), the College considers these egregious. Many people and families are affected by NTDs. The College estimates that New Zealand has lost nearly 18,000 disability-adjusted life years from NTDs since 2009, which is appreciable. New Zealand already accepts the rights of fewer people very badly affected overriding the lesser impacts on many people's 'autonomy', eg. the fluoridation of community water supplies,<sup>8</sup> or very recently with firearm control measures following the terror attacks in Christchurch.<sup>9</sup>

### Modelling the costs and benefits

The College has reservations about the Cost-Benefit Analysis (CBA) methodology used by Sapere Research Group,<sup>3</sup> and considers the CBA's assumptions much too conservative.

As indicated in the MPI discussion paper, the CBA measured only the benefits for NTD-affected live births and stillbirths, and not NTD-affected terminations (for what Sapere considered both excessive difficulties quantifying the financial impact of terminations and ethical challenges). We consider the CBA should have considered all NTD-affected live births and foetal deaths, including not only still births but also **NTD-induced terminations**.<sup>10</sup> The MPI discussion paper<sup>1</sup> (p.57) provides a relatively high rate for induced terminations for NTDs – an average of 29 per year (between 2011 and 2015), which is significant in addition to the yearly averages of 26 NTD-affected live births and 9 NTD-affected stillbirths. While the inclusion of induced terminations is potentially contentious, given the high number of average yearly terminations, we submit that NTD-associated terminations should at a

minimum have been included in the sensitivity analysis. The termination number is high and provides even more incentive to prevent NTDs.

Other factors mentioned in the Sapere report, but not measured in the CBA and which nevertheless should have been counted, are:

- Wider impacts on family and whānau of caring etc. for children surviving with NTDs. These impacts are considerable. (Wider impacts are captured in frameworks such as [PHARMAC's Factors for Consideration](#) and [Treasury's Wellbeing Framework](#).)
- Health impacts on parents and family from foetal deaths and from medical terminations forced by unsalvageable NTDs in pregnancy.
- Possible reductions in the severity of remaining NTDs (aside from decreased incidence).
- Decreasing rates of folate deficiency in adults and children across the population, with associated health effects.

Even more importantly, the Sapere CBA also excludes **spontaneous miscarriages** likely amenable to dietary folate. The above 64 annual NTD-associated live birth/stillbirth/termination counts are small when compared with possible spontaneous miscarriages likely amenable to dietary folate. We estimate that there are 15 to 21 times as many NTD-affected cases of spontaneous miscarriages each year as there are live births or foetal deaths (including induced terminations),<sup>i 11</sup> which is a significant amount. Spontaneous miscarriages carry trauma for expecting mothers, parents and whānau, alongside extra costs to the health sector, and should have also been included in the CBA.

Other factors not mentioned in the Sapere report, which should have been counted, are the other health benefits from better dietary folate intake catalogued in the 2018 joint report by the Office of the Prime Minister's Chief Science Advisor and the Royal Society of New Zealand Te Apārangi,<sup>7</sup> where dietary folic acid reduces or potentially reduces the risks of:

- Non-NTD birth defects such as orofacial (lip/palate) clefts, heart defects, urinary tract defects, Down Syndrome.
- Adverse pregnancy and birth outcomes such as pre-eclampsia, placental detachment from the uterine wall, spontaneous abortion, pre-term delivery, and low birth weight.<sup>12,13</sup>
- Diseases of age eg. strokes, cardiovascular diseases, specific cancers, osteoporosis, and cognitive dysfunction.<sup>7</sup>

Given the exclusion of NTD-affected spontaneous miscarriages and later medical terminations with wider impacts likely amenable to dietary folate, and other factors, the College considers the Sapere CBA considerably underestimates the population benefits, and undercounts the cost-effectiveness of the various folate fortification proposals.

The College does however support Sapere CBA's use of the 3.5% discount rate<sup>14</sup> in the CBA. The College strongly supports an investment approach to health, which takes a long-term view and accounts for full long-term costs.<sup>15</sup> The NZCPHM considers that discounting of non-budgetary costs and benefits over time should use a social rate of time preference with a long-term rate of return that is riskless (i.e. risk-free) rather than risk-adjusted, and which considers intergenerational impacts.<sup>14</sup> This means using a lower discount rate than was used and promoted years ago.<sup>15</sup> As an example, PHARMAC's cost-effectiveness analyses for pharmaceuticals and medical devices discount uses a

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<sup>i</sup> The College calculates that annually 970 to 1380 spontaneous miscarriages are excess when comparing total folate levels in pregnant women (calculated relative risk (RR) 1.08 for history of folate intake preconception for quintiles with folate <800 ug/day vs. quintile with folate >800 ug/day (Q5) in the Nurses Health Study-II ([Gaskins et al. Obstet Gynecol. 2014](#) Table 2, hence with 1.3% risk of spontaneous miscarriages due to folate deficiency ÷ all pregnancies, applied to NZ vital statistics hence imputed pregnancy counts (calculated algebraically from: 58020 live births, 288 still births, 13282 terminations ([HSQC PMMRC data 2019](#)); 15-20% rates of spontaneous miscarriages/clinically-confirmed pregnancies)). Calculations available on request.

riskless rate of return, set by PHARMAC in 2007 at 3.5% (based on the then 5-year average real risk-free long-term government bond rate). PHARMAC says that it does not incorporate risk into the discount rate for cost-effectiveness analyses, as discounting represents individuals' time preferences and any risk (or future uncertainty) is taken into account elsewhere in modelling.<sup>14</sup>

## Option 1: Maintaining the status quo

Option 1 would involve continued voluntary support by large bread bakers through their Code of Practice. Their goal is to fortify up to 50% of their packaged sliced bread, by volume.

MPI has assessed option 1 against the criteria for health impacts, cost effectiveness, equity, consumer choice, and other impacts on pages 19 – 21 in the discussion paper.

### 3. DO YOU AGREE WITH THE ASSESSMENT OF THE STATUS QUO AGAINST THE CRITERIA?

- Agree.
- Disagree.
- Unsure.

Please explain why and provide any evidence you may have:

Under Option(s) 1 (and 2), compliance would be achieved through internal auditing by signatories to the Code of Practice and sampling of supermarket products by the Baking Industry Research Trust. MPI's monitoring of industry compliance would continue once every five years. The College notes that, despite a 50% target, after six years of working to the voluntary code, in 2017, the volume of bread being fortified increased to only 38%, from a starting point of 14%. Furthermore, only 54% of fortified bread tested in 2017 was within the range of 150 to 250 micrograms per 100 grams. This signals that when fortification is left to the industry it is unlikely to be implemented to target and the College is doubtful of the bread industry's level of commitment and compliance.

As a principle, the College is generally opposed to strategies that involve partnership with industry to implement. Historically, industry groups have attempted to be 'potential collaborators' in order to reduce harm, despite obvious vested interests.<sup>16</sup> The profit goals of commercial companies are in conflict with their desired role as partners in efforts to reduce harm and makes their involvement in public health interventions 'ethically questionable' with potential to delay government interventions.<sup>16</sup> Examples of such industries include alcohol, big tobacco and big oil.<sup>17, 18</sup>

Therefore, we agree with the assessment that continuing the status quo would do little to reduce rates of NTD-affected pregnancies, and that this approach would not help achieve health equity.

## Option 2: Asking industry to enhance voluntary fortification

Option 2 would involve asking industry (currently the large plant bakers) to voluntarily increase the volume of packaged sliced bread being fortified under the Code of Practice from the 2017 level of 38% to a new goal of 80%.

MPI has assessed option 2 against the criteria for health impacts, cost effectiveness, equity, consumer choice, and other impacts on pages 22 – 24 in the discussion paper.

**4. DO YOU AGREE WITH THE ASSESSMENT OF THE ENHANCED VOLUNTARY FORTIFICATION OPTION AGAINST THE CRITERIA AND LIKELY IMPACTS?**

- Agree.
- Disagree.
- Unsure.

Please explain why and provide any evidence you may have:

We agree with the assessment of option 2 and note that while this approach has the potential to prevent a number of future NTDs and result in substantial taxpayer savings, the approach relies completely on the voluntary participation of large plant bakers. It is therefore unlikely to achieve the objective set by this review.

**Option 3a: Mandatory fortification of non-organic bread**

Option 3a would see bread fortified with folic acid at the bread-making stage. It would apply to all non-organic bread products, and include bread made from cereals other than wheat (e.g. corn and rice bread).

The Australia New Zealand Food Standards Code would continue to permit the voluntary fortification of folic acid in other specified foods (such as breakfast cereals).

MPI has assessed option 3a against the criteria for health impacts, cost effectiveness, equity, consumer choice, and other impacts on pages 26 – 29 in the discussion paper.

**5. DO YOU AGREE WITH THE ASSESSMENT OF MANDATORY FOLIC ACID FORTIFICATION OF BREAD AGAINST THE CRITERIA AND LIKELY IMPACTS?**

- Agree.
- Disagree.
- Unsure.

Please explain why and provide any evidence you may have:

We agree with the assessment of Option 3a and note that this option would have significant positive health impacts and would be more effective than a voluntary fortification approach. We also note that this approach does not pose a public health risk to non-target groups such as children.

However, we note that the compliance and monitoring costs in operationalising this approach would be high due to the high number of bakeries that would be affected and foresee that this option would be difficult to monitor and may not be the most cost-effective approach. Therefore, we do not support this option to achieve the review's objective.

### **Option 3b: Mandatory fortification of non-organic bread-making wheat flour**

Under option 3b, all non-organic wheat flour for bread-making would be fortified with folic acid at the flour-milling stage. In general, folic acid is best added late in the milling process and at a point that ensures thorough and consistent mixing with the flour.

Cereals other than wheat that are processed into flour for bread-making purposes would not be required to be fortified with folic acid (such as rice).

Flour used for purposes other than bread making would not be required to be fortified.

The Australia New Zealand Food Standards Code would continue to permit the voluntary fortification of folic acid in other specified foods (such as breakfast cereals).

MPI has assessed option 3b against the criteria for health impacts, cost effectiveness, equity, consumer choice, and other impacts on pages 30 – 34 in the discussion paper.

#### **6. DO YOU AGREE WITH THE ASSESSMENT OF MANDATORY FOLIC ACID FORTIFICATION OF BREAD-MAKING WHEAT FLOUR AGAINST THE CRITERIA AND LIKELY IMPACTS?**

- Agree.
- Disagree.
- Unsure.

Please explain why and provide any evidence you may have:

The College agrees that Option 3b would have better health benefits than Options 1, 2 and 3a, although it will not prevent as many NTDs as Option 3c. We note that a small percentage of children may exceed the upper limit for folic acid intake at this level, but at a population level this proportion is considered acceptable.

We note that Option 3b provides the greatest value for money compared with Options 1, 2 and 3a. Compliance and monitoring costs will not be as significant as Option 3a due to the number of mills affected being small.

Like Options 3a and 3c, Option 3b will work to achieve health equity in NTD outcomes between Māori and non-Māori. This is because mandatory fortification removes the element of chance inherent in a voluntary approach and is not reliant on the health literacy of consumers. Option 3b also provides a high level of consumer certainty that all non-organic wheat bread is fortified.

Additionally, Option 3b is likely to result in greater certainty of consistently achieving the target folic acid range, given the small number of mills, compared with the large number of bakeries (as per Option 3a).

Finally, it is likely that of all the mandatory options, Option 3b offers the greatest choice, as consumers can still choose between organic or non-wheat breads.



### **Option 3c: Mandatory fortification of all non-organic wheat flour**

Option 3c would require the fortification of all non-organic wheat flour, whether milled in New Zealand or imported from overseas.

The Australia New Zealand Food Standards Code would continue to permit the voluntary fortification of folic acid in other specified foods (such as breakfast cereals).

MPI has assessed option 3c against the criteria for health impacts, cost effectiveness, equity, consumer choice, and other impacts on pages 35 – 39 in the discussion paper.

#### **7. DO YOU AGREE WITH THE ASSESSMENT OF MANDATORY FOLIC ACID FORTIFICATION OF NON-ORGANIC WHEAT FLOUR AGAINST THE CRITERIA AND LIKELY IMPACTS?**

- Agree.
- Disagree.
- Unsure.

Please explain why and provide any evidence you may have:

We agree with the assessment of Option 3c. Option 3c expands on the range of food products that would contain fortified flour over option 3b, and we note that there may be some potential safety risks associated with this.

The Institute of Medicine set the Tolerable Upper Intake Level for folic acid (from supplementation and fortification) at 1000µg (1 mg) per day, for adults.<sup>7</sup> The consequences of exceeding the upper limit for children are unknown as the upper limit was only set for adults, and then adjusted for body weight.<sup>7</sup> As the level of fortification increases, the likelihood of people exceeding the upper limit also increases.<sup>3</sup> The College is wary that fortification of all non-organic wheat flour (as per Option 3c) may result in a proportion of children exceeding this upper limit. We note MPI's modelling estimate that up to 36% of 5 to 8 year olds would consume too much folic acid under this approach, and for this reason cannot provide unqualified support for Option 3c.

### **Implementation**

MPI provides information on the proposed approaches to implementation for the three options presented on pages 40 – 43 in the discussion paper.

#### **8. DO YOU AGREE WITH THE APPROACH TO IMPLEMENTATION?**

- Agree.
- Disagree.
- Unsure.

Please explain why and provide any evidence you may have. Note: if you are one of the businesses that could be affected, what do you estimate the increased costs to be?

The College does not support the implementation of the voluntary approaches (Options 1 and 2) for the reasons provided above.

The College is supportive of the implementation of the mandatory approaches (options 3a, 3b and 3c). We agree with the proposed plan for monitoring folic acid levels and health impacts of fortification (in conjunction with the Ministry of Health) as well as the plan for dealing with non-compliance.

## General comments

If you have any other general comments or suggestions for the *Folic acid fortification: Increasing folic acid availability in food* discussion paper, please let us know.

The College does not consider the voluntary approaches (Options 1 and 2) would achieve the review's objective or have meaningful nor sufficient population health and health equity impacts. For the reasons provided above the College supports Option 3b as the best approach to achieve the review's objective, reduce sufficiently the number of NTDs in NZ and work to safely achieve health equity in NTD outcomes between Māori and non-Māori.

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