# 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

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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|---|---|
| Name of submitter or contact person: | Jackie Mayne |
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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:

As a Public Health Unit (PHU) we are charged with protecting the health of our resident population including minimising the impacts of nutrition-related diseases.

As such, Regional Public Health (RPH) supports the mandatory fortification of folic acid in bread but **we disagree with the problem stated, as we consider there is an insufficient focus on equitable outcomes in the problem statement, particularly for Māori whānau**.

We would welcome the opportunity to talk with you more about the equity analysis of mandatory fortification on folic acid in bread. RPH has offices in the Wellington region and could easily host a meeting.

Neural tube defects (NTD) are experienced more commonly in Māori whānau. Māori women, have a statistically significant higher live birth prevalence of NTDs compared to New Zealand European women.[i] The long-term health impacts of NTDs has the greatest impact on Māori[ii], their whānau and hapū who already disproportionately experience higher rates of inadequate housing, lower socioeconomic status and are over represented in poor health outcomes.

NTDs are not a one-off health event, analogous to an infectious disease (e.g. measles),a heart attack or a hip operation. An NTD has significant impacts on the child's health, wellbeing, social and educational opportunities across their whole lifespan and that of their whānau.

Effective lifetime management of NTD's may include house remodelling, on-going doctor and hospital visits, wheelchair and mobility supports, modified vehicles, education and social support amongst other things. The financial impact of these extra daily needs will impact the whole whānau in an on-going way. The financial pressures associated with NTDs will have a multiplier effect for whānau who may already be experiencing other significant financial and social pressures.

The higher rates of NTDs experienced by Māori whānau, means they carry the greater burden of this preventable condition in Aotearoa. This is counter to the intent of Te Tiriti o Waitangi. To achieve equity, the prevalence of NTDs needs to decrease for Māori women to rates equivalent to those for New Zealand European women.

We consider the appropriate goal of any population wide health policy, should be the targeted reduction of the health impact on those who experience it the most. Given that over 50% of births are unplanned, we consider that counting and comparing the number of projected NTDs experienced with the options presented is an inappropriate policy goal.

We **recommend** the analysis should focus on how to best reduce or eliminate NTDs in Māori whānau. We believe a focus on Māori whānau and their experience of NTDs (analogous to developing a wahakura and pēpē pods to address SUDI in Māori whānau[iii]) would be a more appropriate policy goal.

The United Nations affirmed the rights to both sovereignty and health for indigenous people in *The declaration on the Rights of Indigenous Peoples,* New Zealand[iv] ratified this declaration in 2010. Māori carry a disproportionate burden of preventable disease, NTDs being one.

Evidence has demonstrated based on outcomes of mandatory folic acid fortification in Australia and the United States, indigenous population have the greatest to gain.[v]

Therefore we **support** the further analysis you have committed to undertake as a key outcome following the feedback on this consultation.

## 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:

RPH disagrees with the objective of this review.

As a population health agency we consider the appropriate focus for all population health interventions should be increasing the equity of health outcomes.

We consider that the weighting of equity against consumer choice and industry impacts is an inappropriate objective of this review.

Given that approximately half of all pregnancies in New Zealand are unplanned, and women are unlikely to take folic acid supplement until late into their first trimester, consumer choice is not a relevant consideration in seeking to reduce the numbers of NTDs experienced in Aotearoa. Likewise, weighting health outcomes equivalently with industry impact creates a bias towards short term industry impact and away from the lifetime impacts of NTD's on children and their whānau.

Governments should adopt the least burdensome measure from the measures that are available and reasonable to mitigate the risks in question[vi]. Whilst governments must strive to ensure there is a reasonable fit between the coercive measure imposed on individuals, and the public health benefit they seek to achieve, the objective should appropriately be addressing the public health impact not the needs of industry or consumers. In our opinion, the legal principle of measuring the proportionate level of risk to that of this intervention has not been weighted equitably. Again we would welcome the opportunity to discuss this with you.

## 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:

RPH considers that the assessment of the status quo is not currently fulfilling treaty obligations and is not equitable for Māori woman and unplanned pregnancies.

The status quo has not effectively reduced the rate of NTDs. We consider that the weighting of equity against consumer choice and industry impacts is an inappropriate objective of this review.

## 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:

RPH considers that the weighting of consumer choice, equity and industry impacts in this assessment framework should be reviewed. The assessment of the enhanced voluntary fortification option is not currently fulfilling treaty obligations and is not equitable for Māori woman and unplanned pregnancies.

We note the paper states enhanced voluntary fortification is unlikely to be taken-on by industry, therefore the result will be close to status quo. As Māori are noted as experiencing higher rates of NTDs, along with many other disparities, this approach suggests that Māori are being denied their equal rights to health, as enshrined in Te Tiriti o Waitangi.

The 2017 audit by the Baking Industry Research Trust[vii] reported the mean folic acid content for all bread under the current status quo was 164ug per 100g, below the target of 200ug. This is in addition to only 38% of fortified packaged bread being achieved instead of the 50% goal. The goals and targets have not been achieved with the status quo therefore increasing these goals with enhanced fortification means further reductions in NTD incidence will be minimal, with little health outcome improvements for Māori and their whānau.

## 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:

RPH considers that the weighting of consumer choice, equity and industry impacts in this assessment framework should be reviewed. The assessment of mandatory fortification of non-organic bread option is not currently fulfilling treaty obligations and is not equitable for Māori woman and unplanned pregnancies.

Whilst RPH strongly supports mandatory fortification, option 3a would be our least preferred choice of the mandatory options proposed.

As a PHU we consider the appropriate focus for all population health interventions should be increasing the equity of health outcomes.

We consider option 3a will not equitably reduce NTD incidence as evidenced by the greater projected NTD saving with options 3b and 3c and the higher NTD incidence rates experienced by Māori whānau. Additionally the technical challenges to industry and the net cost rather than savings makes this option the least favourable.

## 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:

RPH considers that the weighting of consumer choice, equity and industry impacts in this assessment framework should be reviewed. The assessment of mandatory fortification of non-organic bread option is not currently fulfilling treaty obligations and is not equitable for Māori woman and unplanned pregnancies.

We consider the appropriate goal of any population wide health policy should be the targeted reduction of the health impact on those who experience it the most, therefore the focus should be on how to best reduce or eliminate NTD's in Māori whānau.

As an effective population health measure option 3b Mandatory fortification of non-organic bread-making wheat flour is our second preffered choice as this still has an unacceptable projected rate of NTDs.

Although this is the MPI preferred option, we believe the basis for this is based on expediency instead of a population health and equity lens. In our opinion, we believe that by MPI indicating that this is ***your preferred option***, you will have created a strong bias for responders, severely influencing their submission responses, and that responses to this submission will be skewered towards Option 3b.

As you have outlined within Option 3b, the 'Health impact' of NTDs prevented over 30 years is between 162 to 240 pregnancies, with net savings of $32.2 to $54.6 million over the same 30 year period. When Compared to Option 3c, which outlines that the 'Health impact' of NTDs prevented would be 252 to 405 pregnancies (almost double) with net savings of between $54 to $97.9 million (again, almost double) over the same 30 year time period, it is difficult to determine why Option 3c is not recommended as your preferred choice, given that all wheat based products would be fortified (leaving little to chance).

We consider the preferred option 3b as presented has an insufficient focus for equitable health outcomes for Māori and their whānau.

Upper Limit Uncertainty:

We consider the focus on the upper limit (UL) for folic acid end point as being questioned in the PMCSA[viii] report is a distraction from the key issue. A 'recent re-analysis' suggests that data originally used to set the upper levels (UL) was incorrectly interpreted. After the correct adjustment, no association between higher doses of folic acid and the health outcome was evident. In addition, it is noted that exceeding the UL is not considered as a health risk due to the wide safety margin.

We need to take preventative action in the face of uncertainty. AS outlined above, we that option 3c would have almost double the number of preventable NTDs and almost double net savings. What we can't be certain of due to lack of evidence is the impact of some individuals exceeding the upper limit of folic acid. However, the known impact of not fortifying all wheat flour, of around 200 more NTDs over a 30 year time period, is very likely to have a greater negative impact on the health of the population compared with projected exceedances of the upper limit, especially considering the unreliability of the upper limit.

## 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:

As a population health agency we consider the appropriate focus for all population health interventions should be increasing the equity of health outcomes.

We consider that the weighting of equity against consumer choice and industry impacts is an inappropriate objective of the review.

RPH supports the mandatory fortification of folic acid in bread but we disagree with the problem as stated. There is an insufficient focus on equitable outcomes in the problem statement, particularly for Māori whānau.

We **recommend** that the *Mandatory fortification of all non-organic wheat flour (regardless of end purpose)* is implemented, as this would provide the greatest benefit for all pregnancies, planned and unplanned throughout NZ and would provide a greater equitable outcome.

NTDs are experienced more commonly in Māori whānau. Māori women have a statistically significant higher live birth prevalence of NTDs compared to New Zealand European women.[ix] The long-term health impacts of NTDs has the greatest impact on Māori[x], their whānau and hapū who already disproportionately experience higher rates of inadequate housing, lower socioeconomic status and are over represented in poor health outcomes.

RPH **strongly recommends** Option 3c – Mandatory fortification of all non-organic wheat flour (regardless of end purpose) as **OUR** preferred option.

Throughout the consultation document you have outlined that the Option 3c modelling demonstrated that the 'Health impact' of NTDs prevented would be almost double of Option 3b, with net savings again almost double over the same 30 year time period, than that of Option 3b.

**Therefore option 3c Mandatory fortification of all non-organic wheat flour is our preferred option as it:**

- Will improve equity for Māori and will fulfil our treaty obligations. This option will result in less burden of disease for Māori and therefore more equitable health outcomes.
- Has the greatest cost saving of up to 97 million over 30 years, compared to 73 and 55 for option a) and b) respectively.
- The greatest health impact, reducing up to 405 NTDs over 30 years compared to 270 and 240 for a) and b) respectively.
- Broadens the folic acid vehicle to include all wheat based products, therefore allowing for changing demographics and food consumption patterns in NZ.

**Recommendations**:

- Reduce the quantity of folic acid added to wheat flour to lower the likelihood of exceeding UL and repeat modelling scenarios for this level.
- Ensure Māori are involved in this decision-making process and that this is not seen as a reduction in power and control. Increase understanding that mandated fortification would provide the greatest benefit for Māori, whānau and hapū. In the US and Australia where folic acid fortification is mandated indigenous populations have proportionately at the greatest reduction in NTD rates [xi]

**RPH would like to re-iterate the following**:

The recent re-analysis of the UL level suggests the data originally used to set the UL were incorrectly interpreted, and the UL therefore lacks a scientific basis. As stated in the report by the PMCSA 'Wald *et al* found that in determining the Lowest Observed Adverse Effect Level, the IOM failed to take into account the numbers of patients in each folic acid dose group. When this factor was included, higher doses were no longer associated with higher rates of neuropathological progression, and no dose-response relationship could be observed.' This means the basis on which the UL was determined is invalid.

In addition there is a lack of evidence of adverse clinical effects in children, and the UL for children has been derived from the adult level adjusted for body weight.
Therefore the current UL is not evidence based and is a very tenuous measure on which to eliminate a population health intervention. As the PMSCA report states re-evaluation and possibly abolition of the UL will have major implications for health risk assessments of folic acid.

RPH also note the science modelling used to estimate intakes for different age groups was based on the worst case scenario that all flour based goods consumed would be domestically produced fortified flour and the flour would be fortified to the maximum level. New Zealanders consume a significant number of imported products. We propose to reduce the folic acid added to flour to the minimum level or less to mitigate this overconsumption for 5-8 year olds.

## 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?

No comment, as this is not our area of expertise

## 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.

[i] Ministry of Primary Industries (2018), Voluntary Folic Acid Fortification- Monitoring and Evaluation Report. ISBN No: 978-1-77665-764-3 (o) (https://www.mpi.govt.nz/dmsdocument/27121/direct)

[ii] PMCSA (Office of the Prime Minister's Chief Science Advisor and the Royal Society Te Apārangi) (2018). The health benefits and risks of folic acid fortification of food [Internet]. https://www.pmcsa.org.nz/wp-content/uploads/The-health-benefits-and-risks-of-folic-acid-fortification-of-food.pdf

[iii] https://pediatrics.aappublications.org/content/139/2/e20160162 **Wahakura Versus Bassinet for Safe Infant Sleep: A Randomized Trial** Sally A. Baddock, David Tipene-Leach, Sheila M. Williams, Angeline Tangiora, Raymond Jones, Ella Iosua, Emily C. Macleod and Barry J. Taylor**.** Pediatrics February 2017, 139 (2) e20160162; DOI:

[iv] https://www.un.org/development/desa/indigenouspeoples/declaration-on-the-rights-of-indigenous-peoples.html

[v] PMCSA (Office of the Prime Minister's Chief Science Advisor and the Royal Society Te Apārangi) (2018). The health benefits and risks of folic acid fortification of food [Internet]. https://www.pmcsa.org.nz/wp-content/uploads/The-health-benefits-and-risks-of-folic-acid-fortification-of-food.pdf

[vi] http://www.euro.who.int/__data/assets/pdf_file/0003/91173/E83079.pdf

[vii] https://www.bakeinfo.co.nz/files/file/747/2017+Voluntary+fortification+of+bread+with+folic+acid+annual+report+FINAL.pdf

[viii] PMCSA (Office of the Prime Minister's Chief Science Advisor and the Royal Society Te Apārangi) (2018). The health benefits and risks of folic acid fortification of food [Internet]. https://www.pmcsa.org.nz/wp-content/uploads/The-health-benefits-and-risks-of-folic-acid-fortification-of-food.pdf

[ix] Ministry of Primary Industrie (2018), Voluntary Folic Acid Fortification- Monitoring and Evaluation Report. ISBN No: 978-1-77665-764-3 (o) (https://www.mpi.govt.nz/dmsdocument/27121/direct)

[x] PMCSA (Office of the Prime Minister's Chief Science Advisor and the Royal Society Te Apārangi) (2018). The health benefits and risks of folic acid fortification of food [Internet]. https://www.pmcsa.org.nz/wp-content/uploads/The-health-benefits-and-risks-of-folic-acid-fortification-of-food.pdf

[xi] The Health Benefits and Risks of Folic Acid Fortification of Food, A Report by the Office of the Prime Ministers Chief Science Advisor and the Royal Society Te Apārangi