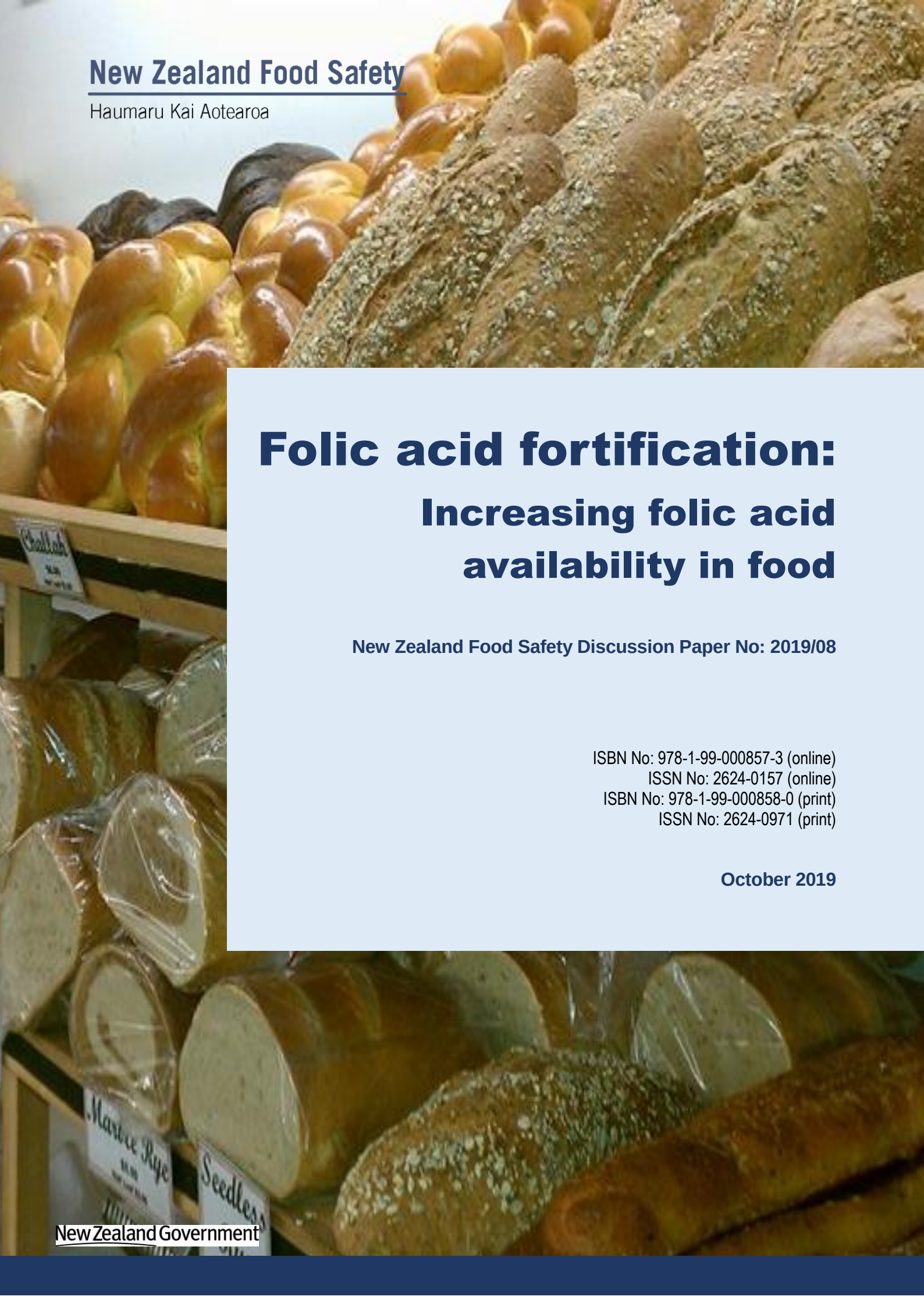

New Zealand Food Safety

Haumaru Kai Aotearoa

Folic acid fortification:

Increasing folic acid availability in food

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This publication is available on the Ministry for Primary Industries website at:
https://www.mpi.govt.nz/news-and-resources/consultations/review-of-folic-acid-fortification

Contents

Making submissions

The Ministry for Primary Industries (MPI) is seeking feedback on the proposed options for folic acid fortification to further reduce neural tube defects such as spina bifida.

Having your say

You can send your submission to us in any of the following ways:

Online	Submissions can be made using the online submission template: https://www.mpi.govt.nz/news-and-resources/consultations/review-of-folic-acid-fortification
Email	Please email your feedback to: Food.Policy@mpi.govt.nz
Letters	While we prefer email, or online submissions, you can send your response by post to: Consultation: Folic Acid Fortification Ministry for Primary Industries PO Box 2526 Wellington 6104

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

Please include the following information:

- your name and title
- your contact details (your phone number, address, and email)
- your organisation's name (if you are submitting on behalf of an organisation).

Your feedback is public information

Any submission you make becomes public information. Anyone can ask for copies of all submissions under the Official Information Act 1982. The Official Information Act says we must make the information available unless there is a good reason for withholding it. You can find those grounds in sections 6 and 9 of the Official Information Act.

Tell us if you think there are grounds to withhold specific information in your submission. Reasons might include that it is commercially sensitive or personal information. Any decision MPI makes to withhold information can, however, be reviewed by the Ombudsman, who may require the information be released.

1 | Summary

Neural tube defects and folic acid

Neural tube defects (NTDs), such as spina bifida, are a serious health problem, affecting on average 64 pregnancies a year in New Zealand. In 2019 the financial cost alone of a single NTD live birth was estimated at $938,000.[1] However, the burden is not spread equitably, with Māori women having a higher rate of NTD live births than other population groups.[2] Each NTD-affected pregnancy has a high social cost for families, whānau, and the wider community.

Folic acid, the synthetic form of the essential B vitamin folate, is essential for reducing the risk of NTDs if consumed in sufficient amounts at least one month before and for the first three months following conception. It is difficult to get enough folate through natural sources to prevent NTDs. In New Zealand, blood folate levels amongst women of childbearing age are currently insufficient to prevent NTD-affected pregnancies,[3] and reductions in NTDs could be achieved if more folic acid was consumed by this group.

Folic acid supplementation only works for women who plan their pregnancies and are aware of the importance of taking folic acid during the critical period. Around 53% of pregnancies in New Zealand are unplanned.[4]

Why we are reviewing our fortification approach

New Zealand has had a voluntary folic acid fortification scheme in place since 2009 with limited success. MPI is reviewing the voluntary fortification approach because:

- evidence suggests the current policy in New Zealand is not increasing folate status adequately for the optimal reduction of NTDs, and
- of the strong advice to introduce mandatory fortification in a 2018 report by the Prime Minister's Chief Science Advisor and the Royal Society Te Apārangi.[5]

A reduction in NTDs would see a reduction in social harm caused by these pregnancies and result in significant cost savings. But this needs to be considered against restrictions in consumer choice and the impact on the industry sector that would be responsible for fortifying their products.

[1] Discounted at 3.5% per annum (2.6 million is the undiscounted estimated). *Folic acid fortification: both society and individuals benefit. A report prepared for the Ministry of Primary Industries*. Sapere Research Group. May 2019.

[2] Voluntary Folic Acid Fortification: Monitoring and Evaluation Report. MPI technical paper no: 2018/02.

[3] 2014/15 New Zealand Health Survey (data supplied by the Ministry of Health).

[4] Bryndl E. Hohmann-Marriott. *Unplanned pregnancies in New Zealand*. Aust NZ J Obstet Gynacol 2018: 247-250.

[5] *The Health Benefits and Risks of Folic Acid Fortification of Food*: A report by the Prime Minister's Chief Science Advisor and the Royal Society Te Apārangi (June 2018)

What is fortification

Fortification is the addition of nutrients such as vitamins and minerals to a food. It has been used internationally for more than 80 years as a public health intervention to correct micronutrient deficiencies, and has contributed to reducing the incidence of diseases and disorders such as rickets (vitamin D deficiency), beriberi (vitamin B1 deficiency), vitamin A deficiency, iron deficiency anaemia, and goitre and cretinism (iodine deficiency).

Fortifying a staple food can be an efficient and equitable way to ensure everyone benefits regardless of socioeconomic status, age or gender, and does not rely on the knowledge or motivation of consumers to make a difference to health outcomes. According to the World Health Organisation:

> '[It] requires no change in food habits, does not alter the characteristics of the food, can be introduced quickly, can produce nutritional benefits for the target population quickly, is safe, and can be a cost-effective way of reaching large target populations that are at risk of micronutrient deficiency'.[6]

Fortification is often integrated with other interventions, such as education or supplementation programmes, when there is a population-wide issue.

Folic acid fortification policies

New Zealand has permitted folic acid to be added to a range of foods since 1996 and has a rate of NTD-affected pregnancies of 10.6 per 10,000 total births (live births, stillbirths, and terminated pregnancies). This is similar to the rate in Europe,[7] which also has a voluntary approach to fortification, but higher than comparable countries where mandatory fortification has been introduced, such as Australia (with a rate of 8.7), Canada (with a rate of 8.6), and the United States (with a rate of 7).[8] Internationally, 81 countries require certain staple foods to be fortified with folic acid to reduce the rates of NTDs.

In June this year, the Government of the United Kingdom released a public consultation on a proposal to introduce mandatory fortification of flour with folic acid "to help reduce neural tube defects (NTDs) in foetuses by raising the folate levels of women who could become pregnant". The outcome of the review is expected by early 2020.

[6] Guidelines on Food Fortification with Micronutrients. World Health Organisation. 2006.

[7] Khoshnood B, Loane M, Walled Hd, Arriola L, Addor M-C, Barisic I, et al. Long term trends in prevalence of neural tube defects in Europe: Population based study. BMJ 2015; 351.

[8] Centers for Disease Control & Prevention: https://www.cdc.gov/ncbddd/birthdefectscount/data.html

Why we fortify bread

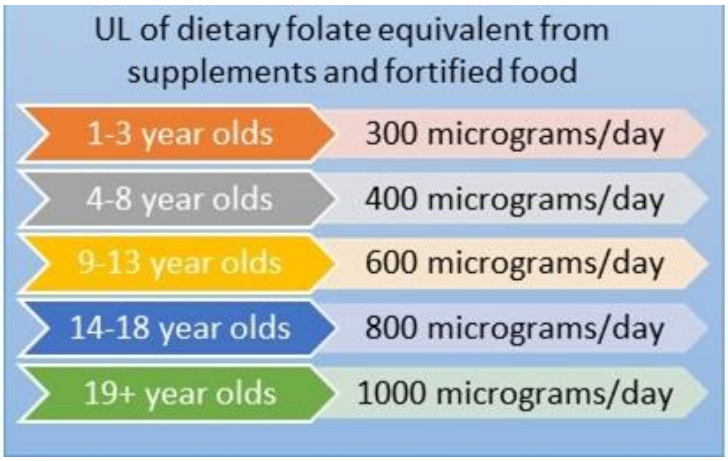
Many countries fortify bread, or bread-making flour with folic acid as it is consumed regularly by a large proportion of women of childbearing age across all ages and socio-economic groups and is relatively low cost.

Safety considerations

There is no consistent evidence from clinical trials or observational studies that folic acid fortification is associated with increased risk of developing cancers, diabetes, heart attacks, or cognitive decline. On the other hand, there is categorical evidence that folic acid fortification reduces the prevalence of NTD-affected pregnancies, and shifts those NTD births that do occur to the less severe end of the scale.

It is very difficult for people to get too much folate from naturally occurring sources of food.

The Nutrient Reference Values for Australia and New Zealand[9] recommends daily maximums (based on age) for many vitamins and minerals, including for folic acid. These are called the upper level of intake (UL).



The UL incorporates a fivefold safety margin. It is based on evidence that high intakes of folic acid can potentially conceal vitamin B12 deficiency and delay diagnosis of neurological damage in the elderly. This is unlikely to be an issue as the risk of masking vitamin B12 deficiency is now considered minimal.

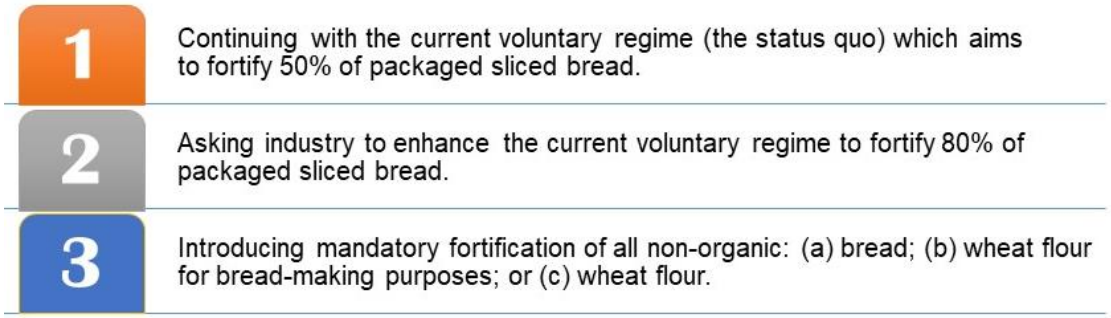
Most recently in 2018, the Prime Minister's Chief Science Advisor and the Royal Society Te Apārangi advised that there is no conclusive evidence that folic acid in the amount recommended for fortification purposes has any harmful effects on health.[10]

[9] Nutrient reference values for Australia and New Zealand. Available here: https://www.nrv.gov.au/nutrients/folate

[10] *The Health Benefits and Risks of Folic Acid Fortification of Food*: A report by the Prime Minister's Chief Science Advisor and the Royal Society Te Apārangi. June 2018.

Options for fortification

MPI has identified, and is seeking feedback on, three viable options for an ongoing folic acid fortification approach (option 3 is further divided into three possible approaches):



Note: option 3 excludes all organic products, as folic acid is a synthetic form of folate and does not meet standards for 'organic'.

Option 1 (the status quo) is already in place. This option involves the least cost to industry and maintains the current consumer choice. However, if the 50% target was achieved there would only be a small increase in the amount of folic acid being consumed and little further reduction in the number of NTD-affected pregnancies compared to current levels.

Option 2 (asking industry to enhance the current regime to 80% fortification) would require agreement from the bakers to increase the volume of bread being fortified, as it is dependent on a modification of the current voluntary Code of Practice. This would likely be difficult to implement given industry has only increased the volume of packaged sliced bread to 38% in 2017 (from 14% in 2012). Equity could become a significant issue between those bakers who would be fortifying to the standard in the Code of Practice and those not fortifying.

However, if industry did fully implement to 80%, this option has the potential to prevent an additional 82 to 233 NTD-affected pregnancies over 30 years compared to the status quo.[11] It is estimated this would have a net monetary benefit of $12.6 to $40.1 million over the same period.[12]

Option 3 (introducing mandatory fortification) would be the most effective in increasing blood folate levels and therefore reducing NTDs and their associated health and financial impacts. With greater benefits come greater costs to the industry responsible for fortifying and less choice for those consumers who want to opt out of foods containing folic acid.

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[11] MPI modelled the impact of fortification options on the estimated reduction in NTD-affected pregnancies (live birth, stillbirth and terminated pregnancies) compared to status quo. No discount rate is applied. Folic acid fortification: technical supporting document. New Zealand Food Safety. October 2019.

[12] A 30 year time period has been chosen for modelling the costs and benefits associated with the options. All costs and benefits are discounted at 3.5% per annum. Only NTDs that resulted in live births or foetal deaths were costed, but not terminations. Folic acid fortification: both society and individuals benefit. A report prepared for the Ministry of Primary Industries. Sapere Research Group. May 2019.

Mandatory fortification makes higher and more consistent levels of folic acid available from food than can be provided by voluntary approaches to fortification, and sets clear expectations for who is responsible for fortifying. There are three feasible options for implementing mandatory fortification:

- 3a (mandatory fortification of all non-organic **bread**) would result in all non-organic bread (including non-wheat breads) being fortified through activities carried out by the baking industry. This option would prevent an extra 144 to 270 NTD-affected pregnancies[13] over 30 years compared to the status quo. However, because of the high costs associated with 2,500 to 3,500 bakeries having to test folic acid levels in their products, this option would result in an estimated net financial cost of $33 to $69.1 million for the 30 year timeframe.[14]
- 3b (mandatory fortification of all non-organic **wheat flour for bread-making**) would result in all non-organic wheat bread being fortified through fortification carried out by the wheat-flour milling industry. This option would prevent an additional 162 to 240 NTD-affected pregnancies for the 30 year period compared to the status quo,[13] and have a net financial benefit over the same period of $32.2 to $54.6 million.[14]
- 3c (mandatory fortification of all non-organic **wheat flour**) would result in a wide range of non-organic flour-based products being fortified through fortification carried out at the mill. This option would fortify a greater range of foods (not just bread), resulting in more NTDs being prevented than with any other option. Over 30 years, this could be an additional 252 to 405 NTD-affected pregnancies prevented compared to the status quo, [13] saving taxpayers between $54 and $97.9 million.[14] However, this option could also expose a proportion of children to the risk of over-consuming folic acid because of the wide range of foods being fortified.

Voluntary vs mandatory fortification

Voluntary fortification allows food manufacturers to add certain vitamins and minerals to food, while mandatory fortification is a legal requirement to do so. Voluntary fortification preserves a consumer's choice to opt out of consuming folic acid, with access to a wide range of unfortified products. Costs imposed on manufacturers are lower under a voluntary approach than a mandatory one (e.g. the cost of implementation, operations, and compliance).

Studies investigating the comparative impact of mandatory and voluntary folic acid fortification on health outcomes have been conducted in Australia, the United States, Canada and the

[13] MPI modelled the impact of fortification options on the estimated reduction in NTD-affected pregnancies compared to status quo. No discount rate is applied. Folic acid fortification: technical supporting document. New Zealand Food Safety. October 2019.

[14] For the purpose of modelling costs and benefits, results are based on 30 years of fortification and are discounted at 3.5% per annum. Only NTDs that resulted in a live births or foetal deaths were costed, terminations were excluded. *Folic acid fortification: both society and individuals benefit. A report prepared for the Ministry of Primary Industries*. Sapere Research Group. May 2019.

United Kingdom. They continue to demonstrate that mandatory fortification is the most effective fortification option (including cost effective) for preventing NTDs[15].

In 2011, the United States' Centres for Disease Control found that:

> 'Mandatory folic acid fortification of cereal grain products […] beginning in 1998 contributed to a 36% reduction in NTDs from 1996 to 2006 and prevented an estimated 10,000 NTD-affected pregnancies in the past decade, resulting in a savings of $4.7 billion in direct costs.'[16]

The Australian experience provides good evidence of what can be achieved when mandatory fortification of bread-making flour is introduced. After mandatory fortification was introduced in Australia, NTD rates decreased from 10.2 per 10 000 total births (2006-2007) to 8.7 per 10 000 total births (2009-2011), with an estimated 14 of the 32 fewer NTDs per year being directly attributable to mandatory fortification.

In Australia, the mandatory fortification of bread-making flour has also led to improved equity in health outcomes, particularly for indigenous communities (with a 74% decline in the NTD rate) and teenage mothers (a 55% decline in the NTD rate).[17] Māori women in New Zealand have significantly more live NTD births than non-Māori women and would therefore likely benefit more from a mandatory approach.

Your feedback

We are seeking your feedback on whether to continue with a voluntary approach to folic acid fortification or change to mandatory fortification in order to reduce New Zealand's rate of NTD-affected pregnancies. Your submissions will be used as one of the inputs to further inform our policy work.

[15] Atta C.A.M., Fiest K., Frolkis A.D., et al. (2016). Global birth prevalence of spina bifida by folic acid fortification status: a systematic review and meta-analysis. AM J Public Health 106 (159):e24-e34.

[16] *Ten Great Public Health Achievements – United States, 2001-2010*. Morbidity and Mortality Weekly Report. (2011). 60(19);619-623

[17] Ministerial Council (Australia and New Zealand Food Regulation Ministerial Council) (2017). The effectiveness and cost-effectiveness of mandatory folic acid and iodine fortification. Online ISBN: 978-1-76007-323-7.

2 | Introduction

About this review

This consultation document looks at whether New Zealand would benefit from a different approach to folic acid fortification. It seeks your feedback on the options proposed to reduce NTD-affected pregnancies by increasing the volume of food fortified with folic acid.

The consultation is in response to two recent publications in New Zealand:

- An MPI monitoring report in 2018 that indicated that blood folate levels in New Zealand in women of childbearing age are too low and further reduction in birth defects could be achieved if blood folate levels were increased. You can access the report here.
- A review of the health benefits and risks of folic acid fortification by the Prime Minister's Chief Science Advisor and the Royal Society of Te Apārangi in 2018 (PMCSA report). The report concluded that the benefits of mandatory fortification of packaged bread with folic acid outweigh any potential adverse health effects. The report is available here.

What is in scope for this review?

This consultation looks at proposed changes to New Zealand's current approach to folic acid fortification of the food supply.

What is out of scope?

Dietary education and the Ministry of Health's subsidised supplementation programme are not part of this review. Notwithstanding the outcome of this review, and whether or not more of the food supply is fortified with folic acid, women planning a pregnancy, or in the first 12 weeks of a pregnancy should continue to use folic acid supplements as recommended by their healthcare professionals.

Also out of scope for this review is the current fortification permissions in the Australia New Zealand Food Standards Code, which has allowed folic acid to be voluntarily added to a range of food products since 1996.

3 | Background

Neural tube defects in New Zealand

The neural tube is a hollow structure from which the brain and spinal cord form in a developing baby. This tube closes and fuses very early in pregnancy (15-28 days after conception), often before a woman is aware she is pregnant. If it fails to close, NTDs can occur. These include spina bifida, which affects the spine, and anencephaly, in which little to no brain develops.

The average rate of NTD-affected pregnancies from the years 2011 to 2015 was 10.6 per 10 000 total births (live births, still births and terminations). This equates to 64 NTD-affected pregnancies every year. Each has a high social cost affecting families, whānau, and the wider community.

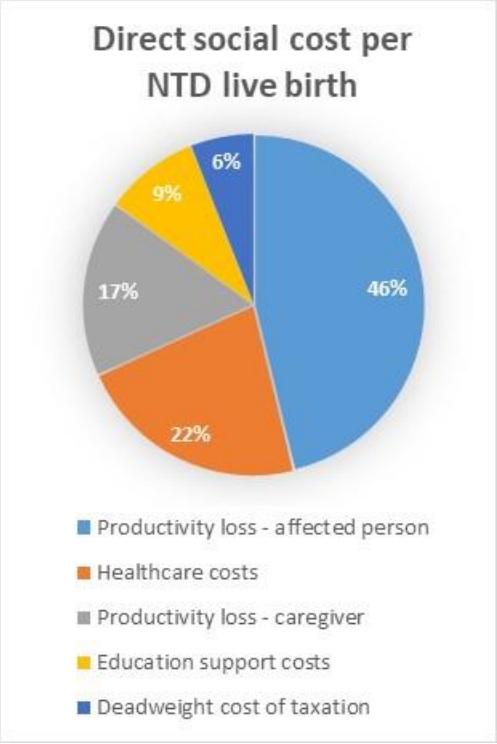
NTDs cost New Zealand more than $24 million every year

The additional average lifetime societal cost of an NTD-affected live birth, compared to the general population, was estimated in 2019 to be $938,000 (discounted rate).[18] This includes lost productivity of the affected person and their caregivers, health care costs, educational support, and the deadweight cost of taxation.

More than 60% of this cost is for productivity loses, with the majority of this due to decreased employment from higher mortality and morbidity. Healthcare costs are also significant, contributing more than 20% to the lifetime cost of a NTD.

There were, on average, 26 NTD-affected live births every year between 2011 and 2015. While the NTD rate (as a proportion of births) has been declining, this is offset by an increase in the number of births as New Zealand's population grows.

Multiplying the average cost by the number of NTDs gives an annual cost of just over $24 million. This likely underestimates the total financial cost to society of NTDs as it only includes the impact of live births and not the cost of stillbirths or terminations due to NTDs.



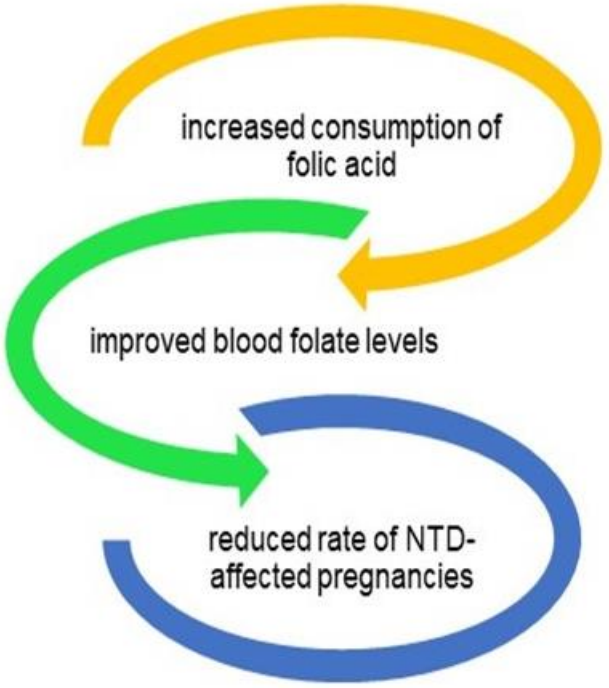
[18] The discounted rate is 3.5% p.a. $2.6 million is the undiscounted estimate, *Folic acid fortification: both society and individuals benefit. A report prepared for the Ministry of Primary Industries*. Sapere Research Group. May 2019.

Folic acid can help reduce neural tube defects

Folic acid, the synthetic form of folate, an essential B vitamin, is especially important for reducing the risk of NTDs – a link first confirmed in clinical trials in the 1990s. There is considerable scientific evidence showing that consuming folic acid for at least four weeks prior to and 12 weeks following conception can reduce the risk of NTDs.

Limits of natural food sources

It is difficult to get enough folate from natural food sources alone to reduce the risk of an NTD-affected pregnancy. For example, if a woman relied on leafy green vegetables and fruit (good sources of folate), she would have to eat nearly half a kilo of cooked spinach or raw broccoli every day to get the amount needed to reduce the risk of having a baby affected by an NTD.



Limits of supplementation programmes

Women are advised to take folic acid tablets at least four weeks before conception and for the first 12 weeks after conceiving. Subsidised folic acid supplementation tablets are available on prescription from doctors and midwives.

However, folic acid tablets only work for women who plan their pregnancies and are aware of the importance of taking folic acid during the critical period. Around 53% of New Zealand pregnancies are unplanned.[19]

Unplanned pregnancies not evenly spread

The rate of unplanned pregnancies is not evenly spread across all population groups. Māori and Pacifica women have the highest rates (75% and 71% respectively) while Europeans have the lowest (40%). For women aged 24 and younger, 83% of pregnancies are unplanned compared to an average of 41% for women who are 25 or older.

Fortification of foods with folic acid is therefore an important part of the public health strategy to reduce the prevalence of NTDs and address health inequities.

[19] Bryndl E. Hohmann-Marriott. *Unplanned pregnancies in New Zealand*. Aust NZ J Obstet Gynacol 2018: 247-250.

Increased folate can't prevent all NTDs

Not every NTD can be prevented by increasing consumption of folic acid. Other known risk factors for NTD pregnancies include family history, type 1 diabetes and obesity.

The United States' Centre for Disease Control has estimated the lowest feasible NTD rate from folic acid based interventions at 5-6 per 10 000 total births (live births, stillbirths, and terminated pregnancies). New Zealand's current rate is 10.6 per 10 000 total births.

Folic acid is permitted in New Zealand foods

Folic acid has been permitted in a range of foods (such as breakfast cereals, bread and juices) since 1996. Analysis comparing what people eat has identified that bread remains a suitable food vehicle for fortification, with 87% of women of child bearing age stating they eat bread in 2017. It is a staple food consumed widely and regularly (most, if not every day) by women of childbearing age. The percentage of women reporting consumption of other foods which can be fortified was approximately 30% for breakfast cereals, 20% for pasta, and 16 to 19% for juice.[20]

Key milestones

1996	fortification with folic acid first permitted for some foods
2007	New Zealand opts out of trans-Tasman mandatory fortification of bread
2009	public consultation on mandatory fortification
2012	public consultation on options to fortify bread with folic acid
2014	bread makers commit to voluntary fortification
2018	release of report looking at health benefits and risks of folic acid fortification (the PMCSA report)
2018	MPI monitoring report

Previous reviews of folic acid fortification

Voluntary folic acid fortification has been considered by the Government in 2006/07, 2008/09, and again in 2012. Each time there was extensive consultation with industry, health professionals, and consumers.

Monitoring since 2012

Since 2012, MPI and the Ministry of Health have monitored the level of folic acid in the food supply, blood folate levels, and the prevalence of NTDs to determine the long term impact of a committed regime to voluntary fortification of bread with folic acid. The bread industry has also

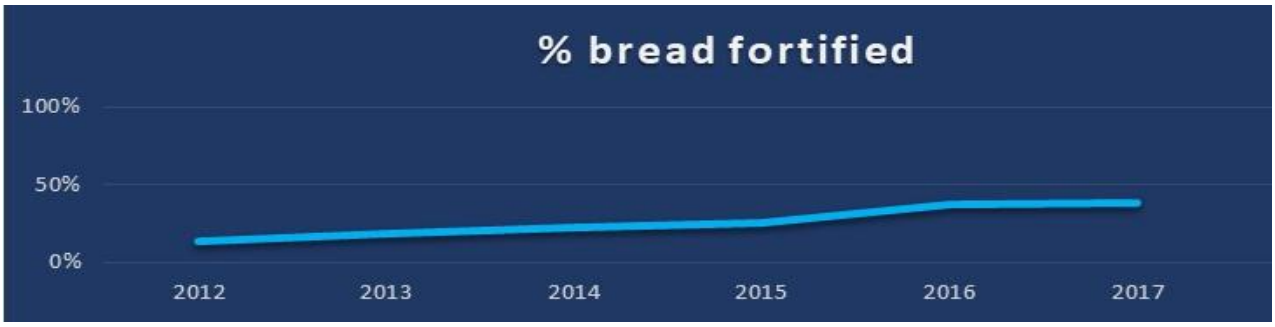
[20] Smith, C; Gray A; Mainvil, L.A., Fleming, E.A. 2015 Secular changes in intakes of foods among New Zealand adults from 1997 to 2008/09. Public Health Nutrition 18(18):3249-3259.

monitored and reported on folic acid added to bread.

By 2017 only 38% of packaged sliced bread was fortified

In 2014, the New Zealand Association of Bakers and Private Label Partners developed a Code of Practice for Voluntary Folic Acid Fortification of Bread (the Code of Practice), with assistance from MPI.

The Code of Practice committed the five signatories (large bread makers in New Zealand) to an aspirational goal of 50% fortification by volume of packaged sliced bread. From 2012 to the end of 2017, the volume of fortified packaged sliced bread increased from 14% to 38%[21].



The maximum amount of folic acid permitted in bread is 250 micrograms per 100 grams. Bread makers are asked to use a target level of 200 micrograms per 100 grams of bread. In the 2017 audit of folic acid fortification levels of bread[21], the results show that the average folic acid level of fortified bread sampled was 166 micrograms per 100 grams of bread.

Fortified breads are available in a range of prices, with 28 of the 67 varieties in 2017 costing two dollars or less a loaf, and nine of them at a dollar or less.

Consumer attitudes to folic acid fortification

In response to a general consumer study commissioned by MPI in 2017, just under a quarter of all participants (23%) thought that adding folic acid to bread should be compulsory, with women who are currently pregnant (and their partners) being the most supportive of compulsory fortification. The main reasons were that it benefited babies (participants were specifically told this before being asking their attitudes) and that it was good for health in general.

[21] Voluntary fortification of bread with folic acid: Annual Report 2017. New Zealand Baking Industry Research Trust. May 2018.

Just over half of participants (56%) considered folic acid fortification should be optional because they wanted consumers to have a choice. Women of childbearing age were more likely to believe this than other women.

A relatively high proportion of consumers (45%) said they would choose a fortified food product over a non-fortified product if price is not an issue. An additional 35% did not have a particular view, and only 19% said they would not choose the fortified product. Of those who would choose a fortified food product, women who were pregnant (and their partners) and women of childbearing age were more likely to choose the fortified product.

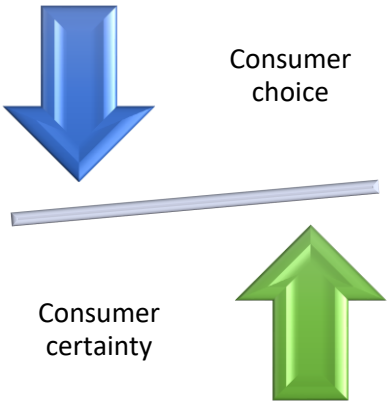
Despite the above, only two percent of those surveyed said they would avoid a product because it contains folic acid.

A 2013 survey commissioned by Food Standards Australia New Zealand indicated that almost half the surveyed population supported mandatory fortification when the potential benefits were explained to them.[22]

Providing a balance for consumers

Stakeholders must consider the significant public health benefits associated with mandatory fortification against the wider choice offered to individual consumers by a voluntary approach to fortification.

Mandatory fortification provides a high degree of consumer certainty that the bread they select will be fortified, but by providing this level of certainty it restricts an individual's choice to opt out of folic acid fortification.



By contrast, voluntary fortification provides greater choice but less certainty that any given product is fortified. Instead it relies on the target group having sufficient knowledge in respect of the importance of folic acid fortification, such as:

- understanding the important role folic acid plays in preventing NTDs;
- knowing how difficult it is to get sufficient folic acid through a normal diet to protect against NTDs;
- knowing which breads are fortified; and
- choosing a bread because it is fortified (regardless of other consumer pressures, such as whether a bread might be on special at a supermarket in any given week).

[22] Food Standards Australia New Zealand. Consumers' awareness, attitudes and behaviours towards food fortification in Australia and New Zealand. Canberra: FSANZ, 2013

Any increase in consumer choice to opt out of products containing folic acid is offset by a corresponding cost to society due to NTD-affected pregnancies.

International approaches to folic acid fortification

New Zealand and most European countries (including the United Kingdom and Ireland) have adopted voluntary fortification programmes. However, data suggest that public health approaches promoting folic acid supplementation and/or voluntary fortification have not been effective in decreasing the prevalence of NTDs in Europe.[23] The United Kingdom is currently reviewing its voluntary approach with a public consultation document recommending mandatory folic acid fortification of flour.

The United States and Canada were the first countries to introduce mandatory fortification of a staple food or foods with folic acid. By the end of 2018, 81 countries, including Australia, had implemented mandatory folic acid fortification as a result of international evidence demonstrating its effectiveness.[24] All of them fortify wheat flour, either alone or in combination with maize flour and/or rice. The extent of fortification, however, varies. For example, Australia fortifies all wheat flour used for bread making, while the United States fortifies enriched cereal grain products (such as bread, pasta, rice, and cereal), and Canada fortifies enriched flour and bread.[25]

The different approaches to folic acid fortification taken in Australia, the United States, Canada, the United Kingdom, and Ireland are set out in the MPI Technical Supporting document.[26]

[23] Khoshnood B, Loane M, Walled Hd, Arriola L, Addor M-C, Barisic I, et al. Long term trends in prevalence of neural tube defects in Europe: Population based study. BMJ. 2015; 351.

[24] Food Fortification Initiative. 15 Years of Partnering for Success. FFI: Atlanta, USA 2018. http://ffinetwork.org/about/stay_informed/publications/documents/FFI2017Review.pdf

[25] 'Enrichment' refers to the process of restoring specific nutrients to a food that were lost during processing.

[26] *Folic acid fortification: technical supporting document*. MPI New Zealand Food Safety. October 2019.

4 | Review objective

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.

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.

Criteria used to assess the proposals

1. **Health impact: overall health outcomes are improved**
    - does the intervention have the potential to reduce NTD-affected pregnancies?
    - will the intervention risk overconsumption of folic acid by any non-target group?
2. **Cost effectiveness: the intervention is cost effective**
    - will the intervention achieve the objective with minimal costs to government and industry?
    - will the intervention provide a positive cost/benefit result?
3. **Equity: equitable outcomes for all women of childbearing age are achieved**
    - will the intervention reach all parts of the target group regardless of age, cultural background, or socioeconomic status?
    - is the intervention likely to reduce inequities in NTDs?
4. **Consumer choice: the intervention maximises consumer choice while addressing the health objective**
    - does the intervention provide some consumer choice for those wanting to opt out of consuming folic acid?

Modelling the costs and benefits of the options

Two models were used to estimate the costs and benefits of the proposed options.

MPI modelled the health impact of each option. This included estimating the total number of NTD-affected pregnancies (live births, stillbirths and terminations) reduced and whether any population groups would overconsume folic acid.[27]

The economic model was used to assess the cost effectiveness of each option. Benefits were calculated using data derived from the MPI health impact model.

The economic model looks at the benefits for NTD-affected live births and stillbirths, but not NTD-affected terminations. The financial impact of terminations of pregnancies due to NTDs are difficult to quantify and ethically challenging.[28]

The economic model is based on a 30-year timeline to allow for some of the longer-term infrastructure costs associated with fortifying at the mill (e.g. options 3b or 3c) and for consistent comparison across all the options. It also provides a sufficiently long period to assess the costs and benefits over time.

The economic model uses a discount rate of 3.5% per year. Discounting is widely accepted and used in economic modelling to compare interventions that have costs and benefits that occur at different times.

Stakeholder feedback during consultation will help complete the final cost-benefit analysis.

1. DO YOU AGREE WITH THE PROBLEM AS STATED?
2. DO YOU AGREE WITH THE OBJECTIVE OF THE REVIEW?

PLEASE PROVIDE ANY EVIDENCE YOU MAY HAVE FOR YOUR REASONING.

[27] *Folic acid fortification: technical supporting document*. New Zealand Food Safety. October 2019.

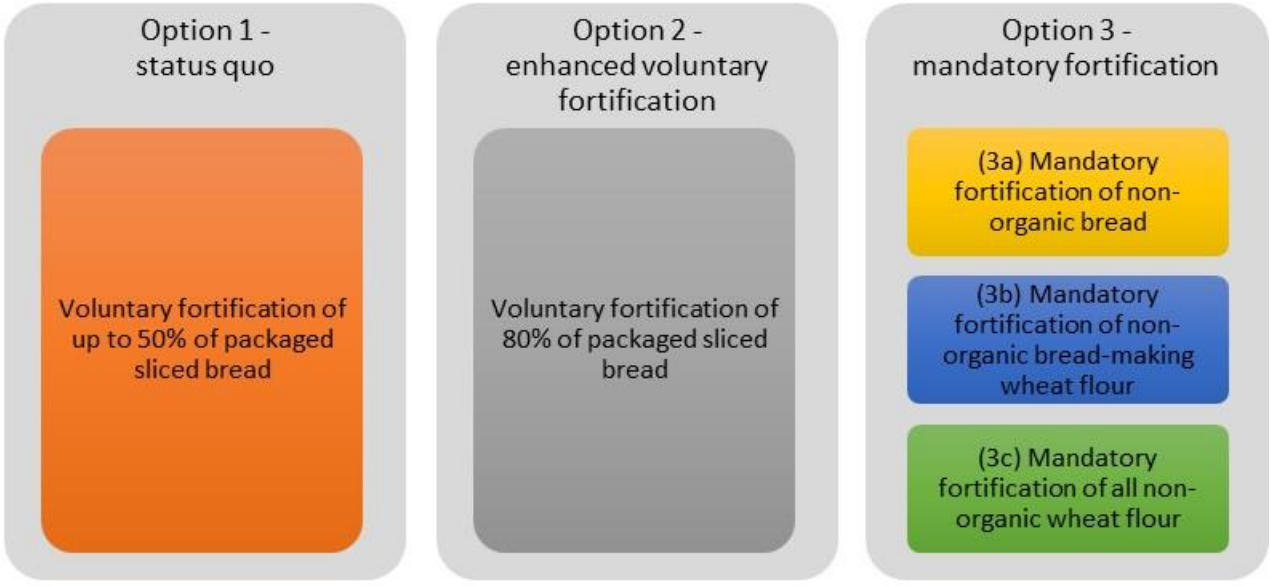
[28] *Folic acid fortification: both society and individuals benefit. A report prepared for the Ministry of Primary Industries*. Sapere Research Group. May 2019.

5 | Proposed fortification options

MPI considered options for strengthening folic acid in the food supply, and possible future regulation. This consultation document describes the feasible options and examines them against the criteria provided in part 4. A full and final analysis will take place following stakeholder submissions and include further science and cost-benefit work.

The proposed options are:

- Option 1 – continuation of the current voluntary approach, with large bread makers aiming to fortify up to 50% of packaged sliced bread by volume.
- Option 2 – asking industry to enhance the voluntary option so that 80% of packaged sliced bread is fortified.
- Option 3 – the introduction of mandatory folic acid fortification. This option is further divided into sub-options to provide for the different ways in which a mandatory approach could be put into practice:
  - 3a – mandatory fortification of all non-organic bread;
  - 3b – mandatory fortification of all non-organic wheat flour for bread making; and
  - 3c – mandatory fortification of all non-organic wheat flour.



An option to fortify a food other than bread or flour was considered by MPI, but assessed as not feasible. This option, and the reasons why it is not being progressed is discussed more fully in Appendix 2.

Option 1: Maintaining the status quo

What this option covers

Under option 1, large bread makers would continue to be encouraged to voluntarily fortify bread with folic acid within the range of 150 to 250 micrograms per 100 grams of bread (with a target level of 200 micrograms per 100 grams), in accordance with the existing New Zealand food standard.

This option would continue to be supported by the industry's Code of Practice. The goal for large plant bakers is to fortify up to 50% of their packaged sliced bread, by volume, at the level described above and to achieve this across a range of price points. This approach relies on ongoing voluntary participation by industry.

OPTION 1 SUMMARY

- only applies to packaged sliced bread
- 50% (max) of packaged sliced bread is fortified
- target level of fortification is 200µg folic acid/100g bread
- limited further reduction in NTD rates from the fortification of bread
- current costs sit with large commercial bakers
- requires ongoing voluntary participation by the bakers
- wide consumer choice of unfortified bread

How it would work

The New Zealand Association of Bakers and Private Label Partners are responsible for adding the right amount of folic acid to their bread as set out in the Code of Practice.

The Baking Industry Research Trust would continue to undertake random testing every six months to help ensure the levels are within a certain range and, where issues arise, changes are made. It would also continue to conduct an independent audit and ensure a wide range of bread, including low cost breads, is fortified.

Adding the folic acid

Under this option, folic acid is added to bread at the bakery by large commercial bakeries only. This approach would not ensure consistent levels of folic acid in bread as only 54% of fortified bread tested in 2017 was within the range of 150-250 micrograms per 100 grams of bread (noting a target of 200 micrograms per 100 grams).

Labelling requirements

Breads fortified with folic acid need to declare folic acid (or folate) in the ingredient list in addition to all other labelling requirements (Standard 1.2.4 – Labelling of Ingredients of the Australia New Zealand Food Standards Code). The status quo gives bakers control over when any new labelling and packaging would be required for new products being fortified.

Assessing option 1 against the criteria

Health impacts

The commitment made in 2012 by the bread industry to increase folic acid fortification to 50% by volume has yet to be achieved and avoidable NTDs continue.[29]

Continuing with the status quo would have little effect on further reducing the rate of NTD-affected pregnancies. The current NTD prevalence is 10.6 per 10 000 total births. This is higher than rates in comparable countries, such as Australia (with a rate of 8.7), Canada (with a rate of 8.6), and the United States (with a rate of 7). It is also higher than countries such as Chile (with a rate of 8.5).[30]

There is no risk of overconsumption of folic acid from the status quo fortification approach.

Cost effectiveness

The estimated cost of continuing with the current approach is $3.7 million over 30 years. This comprises the annual cost of the folic acid premix, ongoing internal compliance costs and annual audits by the Baking Institute Research Trust.

Equity

The status quo approach is not equitable. Māori women would continue to have a significantly higher prevalence of NTD-affected live births compared to other population groups.[31] Babies born to teenage mothers and those born into the most economically deprived areas are also disproportionately represented in overseas statistics.

Consumer choice

There would be significant consumer choice under this option, with at least 50% of packaged sliced bread remaining unfortified. Other bread types such as rolls and buns, organic bread, bread supplied by in-store or specialist bakers, and bread sold through fast food restaurants would also remain largely unfortified, providing a choice for those wanting to opt out of consuming folic acid.

This option would also continue to present a correspondingly high degree of consumer uncertainty as to which products are fortified, and relies on women of childbearing age having prior knowledge of which products are fortified and the importance of taking folic acid.

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[29] After six years of working to the voluntary Code, the latest reported annual statistics from 2017 shows the volume of bread being fortified has only increased to 38% (from a starting point of 14%).

[30] Centers for Disease Control and Prevention: https://www.cdc.gov/ncbddd/birthdefectscount/data.html

[31] Ministry for Primary Industries (2018). Voluntary Folic Acid Fortification: Monitoring and Evaluation Report. MPI technical paper no: 2018/02.

Other impacts

Impact on industry

The New Zealand Association of Bakers has indicated an ongoing commitment to meeting the 50% target in the Code of Practice for the volume of packaged sliced bread to be fortified.

The cost burden for voluntary fortification is met entirely by the large commercial bakers and includes the cost of purchasing the additional folic acid (as a flour pre-mix), training staff, testing and auditing.

Impact on government

MPI would continue to support the food industry to increase the volume of bread fortified with folic acid to 50%.

There would be no additional costs to government for ensuring industry's compliance with the status quo.

Transitional requirements

No transition is required for this option.

3. DO YOU AGREE WITH THE ASSESSMENT OF THE STATUS QUO AGAINST THE CRITERIA? WHY/WHY NOT?

Option 2: Asking industry to enhance voluntary fortification

What this option covers

This option 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%.

How it would work

If this option was introduced, the New Zealand Association of Bakers and Private Label Partners would need to agree to the new maximum target for the volume of bread to be fortified, before planning how to implement the change across their bread ranges.

As with the current voluntary scheme, each bread manufacturer would be responsible for adding the right amount of folic acid to their bread. It is hoped that industry would continue to ensure a wide range of bread is fortified so that folic acid is widely distributed across a range of price points.

Adding the folic acid

Enhanced voluntary fortification would see the New Zealand Association of Bakers and Private Label Partners doing more of what they are already doing. Folic acid would be added to bread at the bakery. Given the history of under- or over-fortification with the voluntary approach, it may take some time before the additional volume of bread consistently meets the target concentration level.

OPTION 2 SUMMARY

- only applies to packaged sliced bread
- large plant bakers would need to agree to fortify 80% of packaged sliced bread
- target level of fortification would be 150µg folic acid/100g bread
- 82 to 233 further NTDs prevented over 30 years compared to the status quo, but only if there is full compliance with the target volume
- $12.6 to $40 million in taxpayer savings over the 30 year period from when the target is reached
- 310 to 870 quality adjusted life years gained over 30 year horizon
- $2.9 million over 30 years in additional fortification costs for large commercial bakers
- unlikely to achieve the objective because it relies on greater voluntary participation than status quo
- some consumer choice maintained

Folic acid concentration

This option proposes a fortification target of 150 micrograms per 100 grams of bread. This is lower than the status quo target because more folic acid would be available for consumption.

Labelling requirements

Breads fortified with folic acid need to declare folic acid (or folate) in the ingredient list on foods (Standard 1.2.4 – Labelling of Ingredients of the Australia New Zealand Food Standards Code) in addition to all other labelling requirements. An enhanced status quo approach would give bakers control over when any new labelling and packaging would be required as they work towards fortifying 80% by volume of their breads

Assessing option 2 against the criteria

Health impacts

It is estimated that the higher amount of folic acid available for consumption would prevent an additional 82 to 233 NTD-affected pregnancies across the 30 year horizon compared to the status quo. This is the equivalent of society gaining 310 to 870 quality-adjusted life years.

Cost effectiveness

Once implemented, this option would save money compared to the status quo. The increased costs to industry for on-going purchasing of folic acid and compliance costs would be offset by much greater savings associated with a relatively lower prevalence of NTDs.

However, it is unlikely this option would increase the availability of folic acid in a timely manner, and costs associated with NTDs would continue to accrue until the new target is reached. Delays to full implementation would include the time it is expected to take to work with industry to increase the maximum target, the time and resources to redevelop the Code of Practice to reflect any changes, and the delay before any benefit from this option would start to flow through.

The net monetary benefit from 80% voluntary fortification, if fully implemented, is estimated at $12.6 to $40.1 million over 30 years.

Equity

Higher folic acid fortification could achieve greater equity compared to status quo as it would help reduce the significantly higher live birth prevalence of NTDs for Māori women compared to other population groups.

Consumer choice

Consumers would have less access to unfortified packaged sliced bread under this option when compared to status quo. Choice would still be available through the 20% of packaged sliced breads remaining unfortified as well as buns and fruit breads, organic bread, bread supplied by in-store or specialist bakers, and bread sold through fast food restaurants.

Given more bread would be fortified under this option, there would be more certainty that a bread selected would be fortified compared to the status quo. Women of childbearing age would still need to be well informed on the importance of taking folic acid when planning a pregnancy and know which bread products are fortified and choose to eat those products.

Other impacts

Impact on industry

There is a strong likelihood that industry would be reluctant to fortify above the current 50% maximum target. The language used in the current Code of Practice talks about an aspirational level of 50% (in other words, this is already believed to be a high level of fortification). The large plant bakers, who are fortifying, also see voluntary fortification as imposing a commercial disadvantage on them compared to those bakers who are not fortifying (i.e. supermarket bakeries, fast food chains and small bakers).

Implementing this option would mean additional ongoing costs compared to status quo for large plant bakers (e.g. purchasing additional folic acid premix, staff training, and testing and administration). Signatories of the Code of Practice would likely continue incurring the costs, rather than pass them on to consumers, given price competitiveness across the industry.

Impact on government

MPI would continue to support signatories of the Code of Practice to increase fortification of bread with folic acid with the new target. However, there would be no control or certainty of achieving the desired outcome.

Proposed transition period

As this is a voluntary solution, there would be no legislated time limits. MPI would work with the large commercial bakers to set annual targets for moving from current fortification levels to the proposed 80% by volume of packaged sliced bread.

This option may take some time, years rather than months, to implement, with the first task being the up-front work with the affected part of the sector to renegotiate the fortification volume in the Code of Practice. It took two years to develop the original Code of Practice, and five years to fortify from 14% of packaged sliced bread in 2012 to 38% in 2017, with little change seen between 2015 and 2017.

4. DO YOU AGREE WITH THE ASSESSMENT OF THE ENHANCED VOLUNTARY FORTIFICATION OPTION AGAINST THE CRITERIA AND LIKELY IMPACTS? WHY/WHY NOT?

Option 3: Changing to mandatory fortification

The option to change from the status quo to mandatory fortification is presented here as three sub-options, mostly characterised by which type of business would be most affected.

Commonalities of the proposed mandatory approaches

Compared to the status quo, the mandatory options would share the common benefits of preventing additional NTD-affected pregnancies, reducing health inequalities and introducing the element of consumer certainty around the consumption of folic acid.

All three mandatory options would limit consumer choice and cost more for the industry compared to the status quo.

Differences between the proposed mandatory approaches

The first two options would ultimately result in all non-organic bread being fortified, with 3a seeing fortification carried out by the baking industry (mandatory fortification of non-organic bread) and 3b seeing it carried out by the flour milling industry (mandatory fortification of non-organic bread-making wheat flour).

Option 3c broadens fortification by the flour milling industry to include all non-organic wheat flour, not just non-organic bread-making wheat flour.

Options 3b and 3c propose fortifying wheat flour only, to maintain some consumer choice for unfortified flour through the availability of non-wheat flours (such as rice or rye).

- Option 3a, mandatory fortification of all non-organic bread:
  - pros – prevents NTDs; costs are spread across the whole bread-making industry;
  - cons – large net financial cost because of the large number of bakeries; affects many small businesses; limits consumer choice to organic or home baked bread.
- Option 3b, mandatory fortification of all non-organic bread-making wheat flour:
  - pros – prevents NTDs; saves taxpayer dollars; low compliance costs because of small number of mills;
  - cons – quite significant set up costs for millers; consumer choice is limited to organic or non-wheat breads (but widest choice for consumers of the three mandatory options).
- Option 3c, mandatory fortification of all non-organic wheat flour:
  - pros – prevents NTDs; saves taxpayer dollars; low compliance costs because of small number of mills;
  - cons – quite significant set up costs for millers; consumer choice is limited to organic products across a wide range of flour-based foods; introduces risk of overconsumption of folic acid for non-target groups.

(3a) Mandatory fortification of non-organic bread

What this option covers

This option 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.

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).

Organic bread would be exempt

Bread that is represented as organic would be exempt from mandatory folic acid fortification.

OPTION 3a SUMMARY

- applies to all non-organic leavened bread, including bread made from cereals other than wheat (e.g. rye, rice)
- target level of fortification would be 150 µg folic acid/100g bread
- 144 to 270 further NTDs prevented over 30 years compared to the status quo
- net financial cost of $33 to $69.1 million over the 30 year period
- 840 to 1,570 quality adjusted life years gained over 30 year horizon
- $110.3 million over 30 years in additional fortification costs, which would sit across the baking industry
- consumer choice limited to organic
- increased compliance and monitoring costs for government because of the number of bakeries

Which bread would likely contain folic acid

Bread is defined in the Australia New Zealand Food Standard Code as a food “made by baking a yeast-leavened dough prepared from one or more cereal flours or meals and water”.

Bread products that would **have to be fortified** under this proposal include non-organic:

- plain white, high fibre, wholemeal, multigrain and gluten free bread loaves, buns, bagels and rolls;
- flat breads containing yeast (for example, pita bread and naan bread);
- focaccia and pide (Turkish bread);
- topped breads, buns, and rolls (for example, cheese and bacon rolls);
- sweet buns (for example, raspberry buns);
- fruit breads, bagels and rolls; and
- baked English-style muffins containing yeast.

Products that would **not have to be fortified** would include dough not leavened with yeast (such as pikelets or chapati), and any bread represented as organic.

How it would work

If mandatory fortification of bread was implemented, each bread manufacturer would be responsible for adding the right amount of folic acid to all their breads.

Ongoing sustainability of the model is likely, given there would be enforceable regulatory levers that would apply equally to the whole non-organic bread-making industry.

Adding the folic acid

Under this option, folic acid would be added to bread at the bakery. However, bread is manufactured not only in large commercial bakeries, but also in smaller artisan bakeries, 'in-house' supermarket bakeries, and hot bread shops. The number of bakeries (2,500-3,500) and individual variations in baking processes and ingredients may present some challenges for bakers to achieve the level of quality control and certainty required for regulatory compliance for folic acid addition.

Folic acid concentration

Because of the increase in the range of bread being fortified, there would be more folic acid available in the food supply. This option proposes a target range of 100 to 200 micrograms folic acid per 100 grams of bread, with a target of 150 micrograms per 100 grams.

A proportion of bread may initially show variable concentrations of folic acid as bread-makers come to grips with the fortification process. Certainty of folic acid levels should improve over time and with support from government agencies (such as with the provision of user guides).

Labelling requirements

Breads fortified with folic acid need to declare folic acid (or folate) in the ingredient list in addition to all other labelling requirements (Standard 1.2.4 – Labelling of Ingredients of the Australia New Zealand Food Standards Code). All non-organic, leavened bread would be fortified under this option, which would mean labelling and packaging changes for most bakers in New Zealand (see the section on the proposed transition period, below).

Assessing option 3a against the criteria

Health impacts

Option 3a would have significantly positive health impacts, with the NTD rate likely to reduce to that seen by other countries with mandatory fortification programmes. It would be more effective than both the status quo and enhanced voluntary fortification and have similar health results as for mandatory fortification of all non-organic bread-making wheat flour (option 3b).

Science modelling demonstrates that 144 to 270 additional NTD-affected pregnancies could be prevented over 30 years compared to the status quo, which is equivalent to society gaining 840 to 1,570 quality-adjusted life years over that period.

On the available evidence, including overseas experience, the proposed level of fortification of 150 micrograms of folic acid per 100 grams of bread does not pose a risk to public health and safety. The level has been set to minimise any potential risk of excess consumption of folic acid by non-target groups, especially children.

Cost effectiveness

This option would provide the least value for money compared to any other option, with a net monetary cost of $33 to $69.1 million over 30 years. Although it would have health gains, option 3a is the only option with a net financial cost, rather than a net financial benefit.

Compliance costs are anticipated to be significantly higher than for the other mandatory options, which propose fortifying at the mill, because of the number of affected businesses (2500-3500 bakeries compared to 7-8 mills).

Equity

All bread other than organic bread would be fortified, which would help reduce the disparity in NTD rates, particularly for Māori women and younger mothers.

Consumer choice

For those wanting to opt out of consuming folic acid, choice would be limited to organic or home-made bread, but this restriction would be balanced by an increase in consumer certainty that the product they are buying is fortified.

Other impacts

Impact on industry

This option would spread the responsibility for folic acid fortification across the whole bread-making industry more equitably than either the status quo or enhanced status quo. Start up and on-going costs would vary depending on the size of the bakery, the range of breads to be fortified, and whether the bakery is already fortifying some bread. Large plant bakers would likely be able to better absorb the costs than small businesses. MPI estimate costs may include:

- purchasing a premix or dough conditioner that includes folic acid;
- training staff so the desired amount of folic acid is achieved according to the type of bread;
- compliance costs.

Impact on government

MPI would assist bakeries, especially small ones, with implementing the mandatory approach and ensure compliance.

Proposed transition period

A two-year transition period is proposed to allow bakers sufficient time to ensure all bread is fortified with folic acid within the required range. This also allows for stock-in-trade provisions affecting labelling and packaging.

A two year transition would align with the two-year transition period allowed in Australia when mandatory fortification of bread-making flour was introduced.

5. DO YOU AGREE WITH THE ASSESSMENT OF MANDATORY FOLIC ACID FORTIFICATION OF BREAD AGAINST THE CRITERIA AND LIKELY IMPACTS? WHY/WHY NOT?

(3b) Mandatory fortification of non-organic bread-making wheat flour

What this option covers

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.

The Australia New Zealand Food Standards Code would continue to permit the voluntary fortification of folic acid in other specified foods that are made of wheat (such as breakfast cereals). It would also permit the fortification of flour made of non-wheat cereals.

Organic flour would be exempt

Wheat flour for making bread that is represented as organic would be exempt from mandatory folic acid fortification.

Wheat flour imported for making bread

Wheat flour imported into New Zealand for making bread would have to comply with the mandatory fortification requirements.

Exported wheat flour

Bread-making wheat flour exported from New Zealand may contain folic acid provided it is permitted in the destination country and meets commercial requirements. This would apply to any product made from bread-making wheat flour for an export market.

OPTION 3b SUMMARY

- applies to all non-organic wheat flour for bread-making
- would result in all non-organic wheat bread being fortified
- level of fortification would be 2-3 mg folic acid/kg flour
- 162 to 240 further NTDs prevented over 30 years compared to the status quo
- $32.2 to $54.6 million in taxpayer savings over the 30 year period
- 940 to 1400 quality adjusted life years gained over 30 year horizon
- $14.1 million over 30 years in additional fortification costs, which would sit with the flour millers
- limited consumer choice
- low monitoring costs for Government because of small number of mills

Which foods would likely contain folic acid

Any food that uses non-organic bread-making wheat flour would be fortified with folic acid. The main difference between bread-making flour and any other flour (such as cake, pastry, or plain flour) is the protein content. Bread-making flour has a higher protein content than plain flour, usually 11-13%, to enhance gluten elasticity.

The following products (which are the same as for option 3a except they only apply to wheat products) are normally made from bread-making flour. Unless organic, option 3b would result in the following products being fortified with folic acid, through the fortified flour:

- plain white, high fibre, wholemeal and multigrain bread loaves, buns, bagels and rolls;
- flat breads containing yeast (for example, pita bread and naan bread);
- focaccia and pide (Turkish bread);
- topped breads, buns, and rolls (for example, cheese and bacon rolls);
- sweet buns (for example, raspberry buns);
- fruit breads, bagels and rolls;
- baked English-style muffins containing yeast; and
- wheat flour bread mixes for making bread at home.

Current industry practice indicates that bread-making wheat flour may also be used to produce other foods, such as crumpets, pizza bases, scones, pancakes, croissants and doughnuts. Based on the Australian experience, an estimated additional 4% of products such as pikelets and crumpets would also be fortified.[32]

How it would work

If mandatory fortification of bread-making wheat flour was implemented, each mill producing this type of flour would be required to add the right amount of folic acid to the flour. It would be the responsibility of the mill to decide which method is best for them to use to ensure their bread-making flour contains folic acid within the permitted concentration range.

The approach would be sustainable given it would be mandatory and government regulation would ensure continued compliance. A mandatory standard could be implemented through a domestic regulation under the Food Act 2014, or by 'opting back in' to the Australia New Zealand Food Standards Code.

Adding the folic acid

Bread-making wheat flour would need to meet the mandatory standard for folic acid fortification at the final point of production at the mill. Imported bread-making wheat flour would be required to be fortified to the same standard at the point of import into New Zealand.

Folic acid concentration

For this option, it is proposed that the level of fortification be set at 2-3 milligrams per kilogram of bread-making flour. This aligns with the current mandatory fortification standard in place for

[32] Australian Health Ministers' Advisory Council (2017). A review of compliance with, and enforcement impacts of, the mandatory fortification of bread with folic acid and iodine.

Australian bread-making flour under Australia New Zealand Food Standard 2.1.1. Folic acid would be the only permitted form of folate that could be used to meet the requirement.

Due to the small number of mills compared to the large number of bakeries, fortifying at the mill would likely result in greater certainty of consistently achieving folic acid in the required range when compared to the options where fortification is carried out by the bread makers.

Labelling requirements

Non-organic bread-making flour and products made with folic-acid fortified non-organic bread-making flour would need to declare folic acid (or folate) in the ingredient list in addition to all other labelling requirements (Standard 1.2.4 – Labelling of Ingredients of the Australia New Zealand Food Standards Code).

This would mean labelling and packaging changes for bread-making flour producers, bread makers, and manufacturers of other products that use bread-making flour as a base. There are exceptions such as if the flour is an ingredient of a food product and makes up less than 5% of the final food product.

Assessing option 3b against the criteria

Health impacts

Option 3b would have significantly positive health impacts, with the NTD rate likely to reduce to that seen by other countries with mandatory fortification programmes. It would be more effective than both the status quo and enhanced voluntary fortification and have similar health results as for mandatory fortification of all non-organic bread (option 3a).

It is estimated that this option could prevent an additional 162 to 240 NTD-affected pregnancies over 30 years compared to the current voluntary approach. This is the equivalent of society gaining 940 to 1,400 quality-adjusted life years over that period.

Science modelling indicates <1-6% of five to eight year olds may exceed the UL under this option. At a population level, a small proportion of intake above the UL is generally considered acceptable and indicative of a low likelihood of adverse health effects.

Cost effectiveness

This option would provide greater value for money compared to the status quo, option 2, and option 3a.

Although there would be initial start-up costs for millers, these are a necessary part of implementation (for example new silos and folic acid micro-dosing machines). On-going purchasing of folic acid would only add marginal operational costs for millers. Compliance costs are not anticipated to be as high as for the option to fortify non-organic bread (option 3a) because of the small number of mills affected.

The net monetary benefit from this option is estimated at $32.2 to $54.6 million over 30 years.

Equity

Option 3b would remove the element of chance inherent in a voluntary approach and help reduce the disparity in NTD rates, particularly for women with less education, younger mothers, and Māori women (who have a significantly higher prevalence of live birth NTDs than other population groups[33]).

Consumer choice

Consumer choice would be limited under this option, given it would result in all non-organic wheat bread being fortified. Consumers wanting to opt out of eating bread containing folic acid would be able to do this by choosing organic bread or bread made of other cereal flours such as rice or rye. However, this option provides a high level of consumer certainty that all non-organic wheat bread is fortified, and removes the need for women of childbearing age to:

- know about the importance of folic acid for the prevention of NTDs,
- know which breads are fortified, and
- choose a fortified bread over an unfortified product.

Other impacts

Impact on industry

In New Zealand, wheat flour is milled domestically to meet local market demands and relatively little flour is imported. A small (albeit potentially significant for some millers) quantity of bread-making wheat flour is exported (e.g. in the form of frozen doughs) by some millers. A segregation infrastructure may need to be developed if export markets demand unfortified bread-making flour and bread-making flour products.

There are likely to be some initial challenges, and some costs associated with set-up could be significant. Large plant bakers would likely be able to absorb the costs better than small businesses. Initial costs could include:

- new silos, at an approximate cost of $300,000 each to ensure no cross contamination between fortified and unfortified flour;
- one or more micro-dosing machines for adding folic acid to flour, at a cost of approximately $30,000 each (a large milling operation may require up to six such machines);
- separate tankers to transport unfortified flour without the risk of cross-contamination;
- reconfiguring milling processes and upskilling staff;
- compliance costs.

[33] Ministry for Primary Industries (2018). Voluntary Folic Acid Fortification: Monitoring and Evaluation Report. MPI technical paper no:2018/02

Impact on government

One of the benefits of fortifying at the milling stage, rather than the bread-making stage, is that the small number of mills would simplify quality control and the monitoring process. Lessons learnt from the Australian experience with introducing mandatory fortification of bread-making flour should be beneficial. MPI would assist flour mills with implementing the mandatory approach and ensure compliance.

Proposed transition period

A two-year transition period is proposed to allow flour millers sufficient time to upgrade equipment and processes to ensure all non-organic bread-making wheat flour is fortified with folic acid within the required range. It would also allow sufficient time for bread makers to adjust their food labels.

This would match the two years allowed for stock-in-trade provisions when mandatory folic acid fortification of bread-making flour was introduced in Australia.

6. DO YOU AGREE WITH THE ASSESSMENT OF MANDATORY FOLIC ACID FORTIFICATION OF BREAD-MAKING WHEAT FLOUR AGAINST THE CRITERIA AND LIKELY IMPACTS? WHY/WHY NOT?

Note: this option does not include organic bread-making flour, or flour made of cereals other than wheat (such as rye or rice), or flour used for purposes other than bread making.

(3c) Mandatory fortification of all non-organic wheat flour

What this option covers

This option considers the introduction of regulations requiring the fortification of all non-organic wheat flour, whether milled in New Zealand or imported from overseas. It proposes that compliance, monitoring and verification would be carried out on the flour itself, not end products made of flour.

This option would be sustainable, given it would be mandatory and government regulation would ensure continued compliance.

The Australia New Zealand Food Standards Code would continue to permit the voluntary fortification with folic acid of other specified foods (such as breakfast cereals) and of flour made of non-wheat cereals.

Organic flour would be exempt

Wheat flour that is represented as organic would be exempt from mandatory folic acid fortification.

Imported non-organic wheat flour

Non-organic wheat flour imported into New Zealand would have to be fortified with folic acid.

Exported wheat flour

Exported wheat flour or products made from wheat flour would not be required to be fortified. Wheat flour exported from New Zealand may contain folic acid provided it is permitted in the destination country and meets commercial requirements.

Domestic vs imported wheat products

As all non-organic wheat flour would be fortified, any flour-based product (such as bread, cakes, biscuits, or pasta) made domestically would be made with fortified flour. However, equivalent imported products would not have to be made from fortified flour (as the requirement to fortify sits with the flour, not with any end products).

OPTION 3c SUMMARY

- applies to all non-organic wheat flour
- would result in all non-organic wheat products (bread, cakes, biscuits, etc) being fortified
- level of fortification would be 2-3 mg folic acid/kg flour
- 252 to 405 further NTDs prevented over 30 years compared to the status quo
- $54 to $97.9 million in taxpayer savings over the 30 year period
- 1,470 to 2,360 quality adjusted life years gained over 30 year horizon
- $18.1 million over 30 years in additional fortification costs, which would sit with the flour millers
- limited consumer choice across a range of wheat flour-based products
- relatively low monitoring costs for Government because of the small number of mills

Which foods would likely contain folic acid

Any food that uses non-organic wheat flour would be fortified with folic acid, expanding the range of fortified food under option 3b (bread-making flour). Fortifying all non-organic wheat flour would result in all domestically-produced non-organic bread and breadcrumbs (including crumbed fish, chicken and meats), biscuits, pastries, cakes, pasta, and pizza bases being fortified. It would also include products that use wheat flour as a thickener, such as sauces, canned soups, packet gravy, and condiments.

Potential safety concern

The overall aim of any folic acid fortification programme is to ensure that intakes are maximised for the target group (women of childbearing age) while minimising the potential for exceeding the upper level of intake (UL) for all population groups. The UL for folic acid is 1000 micrograms a day for adults, but only 600 micrograms a day for 5-8 year olds, and 300 micrograms a day for the under-5s.

A small proportion of intakes above the UL is generally considered acceptable and indicative of a low likelihood of adverse health effects. Where the UL is exceeded, it is common to determine whether the proportion above the UL is acceptable on a case-by-case basis taking into account factors including the extent of exceedances and the affected population group.

Under option 3c there is the potential that up to 36% of 5-8 year olds could consume too much folic acid because of the wide range of food that would be fortified. The science modelling used to estimate this was based on a worst-case scenario that all flour-based goods that are consumed would be made of domestically-produced fortified flour and that the flour would be fortified to the maximum permitted amount rather than the mid-point of the range.

How it would work

If this option was implemented, each mill producing wheat flour would be required to add the right amount of folic acid to that flour. It would be the responsibility of the mill to decide which method is best for them to use to ensure their bread-making flour contains folic acid within the permitted concentration range.

Fortifying at the mill would likely result in greater certainty of consistently achieving folic acid in the required range when compared to the bread-making options.

Adding the folic acid

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. The flour would need to meet the mandatory standard for folic acid fortification at the final point of production at the mill. Imported non-organic wheat flour would need to meet the same standard at the point of import.

Folic acid concentration

For this option, it is proposed that the level of fortification be set at 2-3 milligrams per kilogram of flour (the same level being proposed for option 3b). This aligns with the current mandatory fortification standard in place for Australian bread-making flour and with the current voluntary permissions for cereal flours under Australia New Zealand Food Schedule 17.

It is possible that this concentration level could be revised downwards to avoid any over-consumption of folic acid by either the target group or any non-target group, but in doing so could also decrease the health impact.

Labelling requirements

Products fortified with folic acid need to declare folic acid (or folate) in the ingredient list in addition to all other labelling requirements (Standard 1.2.4 – Labelling of Ingredients of the Australia New Zealand Food Standards Code). This would mean labelling and packaging changes for producers of non-organic wheat flour and flour-based products. (There are exceptions such as if the flour is an ingredient of a food product and makes up less than 5% of the final food product).

Assessing option 3c against the criteria

Health impacts

Option 3c would likely see the NTD rate reduce to that seen by other countries with mandatory fortification programmes and it would have a greater reduction in NTD prevalence than any other option. It is estimated that this option could prevent an additional 252 to 405 NTD-affected pregnancies over 30 years compared to the current voluntary approach, the equivalent to society gaining 1,470 to 2,360 quality-adjusted life years.

However, it would introduce the risk of overconsumption of folic acid by children, because of the extra amount available in the food supply and because children have a much lower UL than adults. (Please see the section on potential safety concerns, above).

Cost effectiveness

This option would provide greater value for money compared to any other option. The largest costs for millers would be the initial costs associated with implementation. On-going purchasing of folic acid would only add marginal operational costs, and compliance costs are also anticipated to be relatively low. The net monetary benefit from this option is estimated at $54 to $97.9 million over 30 years.

Equity

Fortifying all non-organic wheat flour would further reduce the element of chance inherent in the current voluntary approach by expanding the range of food in which folic acid is available to include all wheat-based products. It is expected this would reduce the disparity in NTD rates, particularly for women with less education, younger mothers, and Māori women (who have a significantly higher prevalence of live birth NTDs than other population groups).

Consumer choice

For those wanting to opt out of consuming folic acid, option 3c is the most restrictive of all the options presented, given it would result in the fortification of a wide range of flour-containing food products (not just bread). Consumers wanting to opt out of foods that contain folic acid would need to choose organic or non-wheat options.

Impact on industry

In New Zealand, flour is milled domestically to meet local market demands and relatively little flour is imported. A small (albeit significant for some millers) quantity of flour is exported (e.g. frozen doughs) by some millers. A segregation infrastructure may need to be developed if export markets or export businesses demand unfortified flour and flour products.

Some costs associated with set-up could be significant. Large plant bakers would likely be able to absorb the costs better than small businesses. For example, initial costs could include:

- new silos, at an approximate cost of $300,000 each to ensure no cross contamination between fortified and unfortified flour. One new silo may be needed per flour milling operation;
- one or more micro-dosing machines for adding folic acid to flour, at a cost of approximately $30,000 each and noting that a large flour milling operation may require up to six such machines;
- separate tankers to transport unfortified flour without the risk of cross-contamination;
- reconfiguring milling processes and upskilling staff;
- compliance costs.

Impact on government

One of the benefits of fortifying at the milling stage, is that the small number of mills simplify quality control and the monitoring process. Lessons learnt from the Australian experience with introducing mandatory fortification of bread-making flour, or other jurisdictions who fortify wheat flour, cornmeal, and rice should be beneficial. MPI would assist flour mills with implementing the mandatory approach and ensure compliance.

Potential impact on trade and competition

This option could introduce potential trade implications if trade partners restrict fortification of flour-containing products, other than bread, such as pasta or biscuits.

Proposed transition period

A two-year transition period is proposed to allow flour millers sufficient time to upgrade equipment and processes to ensure all non-organic wheat flour is fortified with folic acid within the required range. It would also allow sufficient time for manufacturers of wheat-based goods to adjust their food labels.

This would match the two years allowed for stock-in-trade provisions when mandatory folic acid fortification of bread-making flour was introduced in Australia.

7. DO YOU AGREE WITH THE ASSESSMENT OF MANDATORY FOLIC ACID FORTIFICATION OF NON-ORGANIC WHEAT FLOUR AGAINST THE CRITERIA AND LIKELY IMPACTS? WHY/WHY NOT?

Note: this option does not include organic flour, or flour made of cereals other than wheat, such as rye or rice.

6 | Implementation

Changes to regulations

Option 1 – continuing with the status quo would require no legislative or food standard changes.

Option 2 – enhancing voluntary fortification would only require changes to the Code of Practice to reflect the agreed new fortification volumes, but no changes further to that.

Option 3 – introducing mandatory fortification would require changes to secondary legislation in order for the option to be implemented and enforced.

Implementation

Under the voluntary options, signatories to the current Code of Practice would continue to implement folic acid fortification with the assistance of the Baking Industry Research Trust.

Proposed guidance for mandatory folic acid fortification would comprise:

- working with industry to develop guidance (written, video and potentially on-line tools) to assist businesses to understand and meet their requirements;
- MPI workshops for verifiers and businesses at the time of introduction of a mandatory requirement; and
- advisers for one to two years to assist with ensuring compliance.

Compliance

Compliance activities will include being able to answer some common questions:

- Are relevant industry groups well informed of regulations for mandatory fortification or the Code of Practice for voluntary fortification?
- Are relevant industry groups complying with regulations/the Code of Practice?
- Have sufficient monitoring strategies been implemented?
- For mandatory fortification, is the enforcement agency working with relevant industry groups to enable and ensure compliance?
- For mandatory fortification, have enforcement activities been undertaken where continued non-compliance has been identified?

Compliance under voluntary fortification

Under option 1 (status quo) compliance would continue to be achieved by each of the signatories to the Code of Practice internally auditing their practices to fortify bread with folic acid. Additionally, the Baking Industry Research Trust (BIRT) would sample products six monthly from supermarkets and other outlets, and test them to check the levels of folic acid are in the target range, as set out in the Code of Practice.

Where products are not within the target range, BIRT would continue to work with the affected business to modify processes and then repeat the sampling and testing regime. Sometimes several rounds of tests may be required before improvements are made.

BIRT would continue to publish an annual report showing the audit results. Included in the report would be the percentage of packaged sliced bread fortified, by volume, and a list of fortified breads and their costs.

Under option 2 (enhanced voluntary fortification) the same compliance regime would apply as for the status quo.

Compliance under mandatory fortification

Under the mandatory fortification options, businesses would be required to implement a document system that is capable of being audited and is designed to control compliance. In particular, records would need to be kept to demonstrate that folic acid has been purchased and in an appropriate form, and is added to the food in such a way as to ensure the level of folic acid falls within the required range.

Testing by industry would be carried out on a regular basis at least six monthly.

The Food Act ensures food businesses are independently checked at regular intervals by verifiers, such as Territorial Authorities. The intervals vary according to the type of business, its food safety risks, and its performance (i.e. it would be checked more if needed).

Bread making is under a risk management programme called a National Programme 2 (NP2). The maximum period for verification (checking) of a NP2 business is three years. Some bread makers, however, operate under a higher risk programme (a Food Control Plan) because of other products made on the premises such as pies. In these cases the maximum verification period is 18 months.

Flour milling is under a National Programme 3 with a two year maximum period for verification. Like bread makers, some flour millers elect to be regulated under a higher risk programme and are therefore checked more frequently.

To minimise costs to industry, it would seem more efficient that the documentation system for folic acid would be verified when the entire operation of a food business is verified. MPI would consider a business has demonstrated compliance by adherence to the documented system (as assessed in the verification report).

Monitoring

Monitoring folic acid levels

MPI sampled and tested the folic acid levels in packaged sliced bread in 2011/12 and 2016. Under the status quo and option 2 (enhanced voluntary fortification), MPI would continue to monitor products in this way once every five years.

For mandatory fortification, MPI would likely increase its monitoring in the first instance to make sure bread makers or flour millers are achieving folic acid levels within the permitted range.

A plan would be developed that might include sampling and testing at regular intervals once the mandatory regime was in full force (for example, in years one, three and five), and then less frequently after that if results indicated products were within the required range.

MPI would also consider undertaking onsite checks six months after implementation.

Monitoring health impacts

The impact of any fortification approach taken as a result of this review will be assessed as part of the regular on-going monitoring work carried out by MPI and the Ministry of Health.

This work measures the level of folic acid in the food supply, blood folate levels in the target and non-target groups, and the prevalence of total NTDs, and has been carried out since 2012 to look at the health impacts of the current voluntary fortification approach.

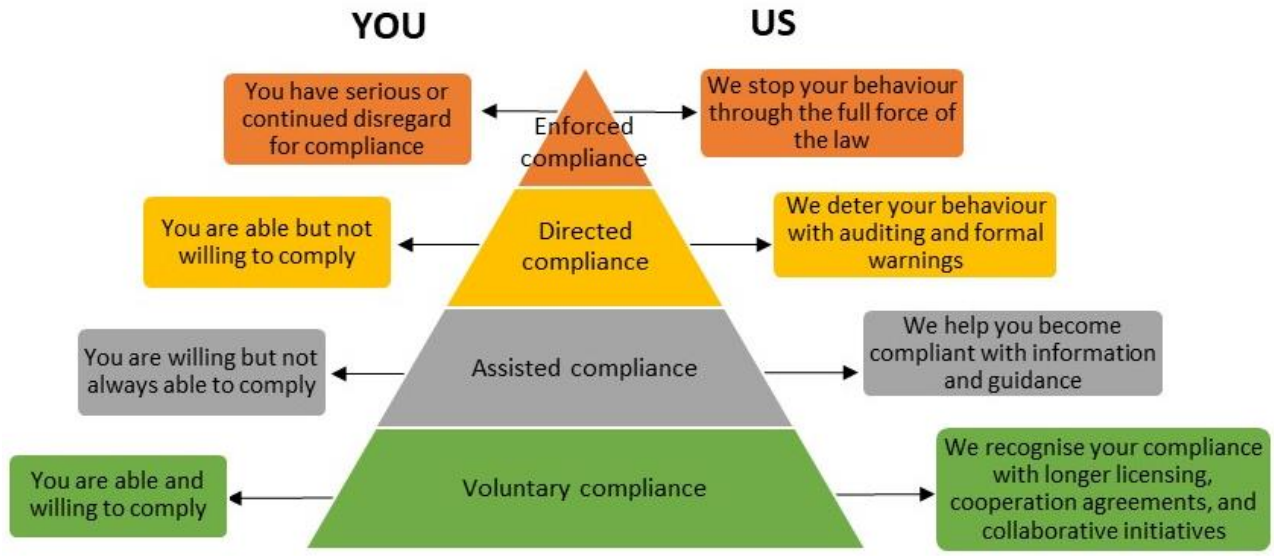
Enforcement requirements

Dealing with non-compliance

One of the key differences between a voluntary and mandatory standard is enforcement provisions:

- MPI would have no enforcement powers for dealing with non-compliance under either status quo or enhanced voluntary.
- For the mandatory options, every affected business would need to fortify. Clear consequences through infringement fees would apply to businesses for continued non-compliance.

Graduated approach to enforcement for mandatory options



MPI recognises that compliance and enforcement is critical to the integrity of any regulatory system.

Our enforcement approach is graduated and steps through voluntary compliance, assisted compliance, directed compliance and enforced compliance, with a focus on information and assistance where this is a better intervention but strong enforcement where needed.

Enforcement activities cover a range of actions including working with businesses to ensure they understand the requirements they must meet, warning notices, infringement fees where test results continued to be non-compliant (and there is no information to demonstrate compliance and due diligence), or a formal prosecution for an offence.

8. DO YOU AGREE WITH THE APPROACH TO IMPLEMENTATION? WHY/WHY NOT?

Note: if you are one of the business that could be affected, what do you estimate the increased costs would be? Please provide any evidence you may have.

7 | Conclusion and next steps

Conclusion

This discussion document sets out the reasons we are undertaking a review of our approach to folic acid fortification, what we want to achieve, and the estimated impact each of the options could have on New Zealand's NTD rate, equity, consumer choice, and industry.

We have aimed to provide you with enough information so you can make an informed submission, including information about:

- the nature and severity of the problem we are trying to solve (i.e. reducing the number of NTDs);
- the link between increased folic acid in the food supply, improved blood folate status in women of childbearing age and a reduction in the prevalence of NTD-affected pregnancies; and
- the feasible options available to reduce NTD-affected pregnancies by increasing the amount of folic acid available in food while considering consumer choice, increasing equity of health outcomes, and minimising costs to business.

Based on the information provided, we welcome your views in response to the questions we have asked throughout this document. Please feel free to submit other relevant information.

Next steps

We are interested to hear your thoughts about whether or not New Zealand's approach to folic acid fortification should change, and if so, how?

Once we have received submissions from interested parties, we will consider all of the new information and perspectives that have been provided. We will use this to further inform our policy analysis (including a cost benefit analysis) and further science work on estimating the NTD rates under each option. A summary of the information we have received through consultation will be made available.

8 | Appendices

Appendix 1 – key terms and abbreviations

Code of Practice	The New Zealand Association of Bakers and Private Label Partners Code of Practice for Voluntary Folic Acid Fortification of Bread (the Code of Practice).
Folate	Folate is a water-soluble B-group vitamin found in a wide variety of foods including leafy green vegetables, cereals, fruits, grains, legumes, yeast extract, and liver.
Folic acid	Folic acid is the most common synthetic form of folate and is the form used in food fortification and in the majority of supplements.
Food Standards Australia New Zealand (FSANZ)	In New Zealand, FSANZ is responsible for developing food standards relating to labelling, composition and contaminants.
The PMCSA report	'The PMCSA report' is used in this document as a shorthand reference to: *The Health Benefits and Risks of Folic Acid Fortification of Food*: A report by the Prime Minister's Chief Science Advisor and the Royal Society Te Apārangi (June 2018), commissioned by the Ministry of Health in 2017.
MPI	Ministry for Primary Industries.
NTD	Neural tube defect. The neural tube is a hollow structure from which the brain and spinal cord form in a developing baby. This tube closes and fuses very early in pregnancy (15-28 days after conception). If it fails to close, NTDs, such as spina bifida and anencephaly, can occur.
QALY	Quality-adjusted life year (QALY).
Upper Level of Intake (UL)	The UL is referred to in this document in relation to folic acid. The UL is the highest daily nutrient intake level likely to pose no adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects increases.
Women of childbearing age (WCBA)	For the purposes of this document, women of childbearing age refers to women aged 15-49 years.
WHO	World Health Organisation.

Appendix 2 – Fortifying a food other than bread or flour

MPI undertook initial, high-level analysis on a further possible proposal, which looked at whether a food other than bread or flour could be fortified. Detailed analysis determined it would not be viable and is not seeking feedback on it. Further detail can be found in the Folic acid fortification technical supporting document[34].

This option looked at whether a food other than bread or flour could be fortified. Analysis comparing what people eat has identified there is no better food for fortification than bread or flour (see Summary table of food suitable to fortify).

Background

In Australia and New Zealand, the vehicle for mandatory folic acid fortification was previously considered under Food Standards Australia New Zealand's proposal P295 – Consideration of mandatory fortification with folic acid.

In determining appropriate food vehicles for the purpose of fortification it is important to ensure that it is efficacious and effective for the target group, and safe for target and non-target groups. In general, basic commodities are more suited to mandatory fortification due to their widespread and regular consumption.

In undertaking the assessment of which food/s would be most suitable for mandatory fortification, Food Standards Australia New Zealand considered whether the food:

- is regularly consumed by the population at risk in stable, predictable amounts;
- is available to the target population regardless of socio-economic status;
- supplies optimal amounts of micronutrient without risk of excessive consumption or toxic effects;
- retains high level stability and bioavailability of the added micronutrient under standard local conditions of storage and use;
- is economically feasible;
- is centrally processed so that quality control can be effectively implemented; and
- does not interact with the fortificant or undergo changes to taste, colour or appearance as a result of fortification.

Foods initially considered as potential food vehicles included milks (full fat and reduced fat), fruit juices, breakfast cereals, yoghurts, soy beverages, and bread and bread products.

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[34] *Folic acid fortification: technical supporting document*. MPI New Zealand Food Safety. October 2019.

Updated food consumption data

Since the original FSANZ proposal, more up-to-date adult population intake data is available (2008/09 Adult Nutrition Survey) in New Zealand. MPI has replicated some of the original work conducted by FSANZ to ensure that bread/bread-making flour is still the most suitable fortification vehicle. Further, it was considered that fortification of flour and foods made from flour is consistent with overseas implementation of mandatory fortification.

Although over a decade old, the nutrition survey provides the most comprehensive data on food consumption patterns of New Zealand adults.

Milk, bread, fruit, and vegetables were the foods reported to be consumed by the largest proportion of women (more than 50% reported eating each of these foods on a regular basis)[35].

Although bread consumption was found to decrease between the two surveys, bread remains the largest source of energy for WCBA[36]. Of the foods reported to be consumed, bread remains the most suitable for mandatory fortification:

- bread was most commonly consumed by the target population; it is consumed in consistent amounts across age, ethnicity and neighbourhood deprivation index; it is technically and economically feasible to fortify and does not pose a significant risk to overconsumption
- breakfast cereals, fruit juice, and soy products (which are all currently permitted to be voluntarily fortified) are not consumed by a sufficient number of women of childbearing age;[37]
- fruit and vegetables are all consumed regularly by sufficient women, but are not feasible to fortify; and
- milk, which is consumed regularly and is technically able to be fortified, is not currently permitted to be fortified in Australia or New Zealand under the Australia New Zealand Food Standards Code. Young children have a high consumption of milk compared to adults and there remains the risk of overconsumption of folic acid if milk was selected as the food vehicle.

To verify that bread is still widely consumed by women of childbearing age, MPI commissioned a survey in 2017. The survey found that 87% of women of childbearing age eat bread,[38] consuming an average of approximately two slices of bread a day.

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[35] Smith, C; Gray A; Mainvil, L.A., Fleming, E.A. 2015 Secular changes in intakes of foods among New Zealand adults from 1997 to 2008/09. Public Health Nutrition 18(18):3249-3259.

[36] Ministry of health. A Focus on Nutrition: key findings from the 2008/09 NZ adult nutrition survey. https://www.health.govt.nz/publication/focus-nutrition-key-findings-2008-09-nz-adult-nutrition-survey

[37] Approximately 30% for breakfast cereals, 20% for pasta, and 16-19% for juice

[38] Folic acid fortification: consumers' attitudes and behaviours. September 2017. Ministry for Primary Industries.

Summary table of food suitable to fortify

Food vehicle	Regularly consumed?	Technically feasible to fortify?	Permitted to be fortified?	Limited risk of over consumption?
Bread	✓	✓	✓	✓
Milk	✓	✓	✗	✗
Fruit juices	✗	✓	✓	N/A
Breakfast cereals	✗	✓	✓	N/A
Soy beverages	✗	✓	✓	N/A
Fruit	✓	✗	✗	N/A
Vegetables	✓	✗	✗	N/A
Meat	✓	✗	✗	N/A

Potential trade issues

Fortifying a food other than bread or flour may raise possible trade restrictions depending on the alternative food vehicle selected for fortification (e.g. restrictions by trade partners on imports of milk or milk powder fortified with folic acid). It could be particularly difficult with regard to trading with Australia, given their recent monitoring work on folic acid fortification revealed an effective strategy. Any alterations through further fortification of New Zealand-imported food could be problematic.

Appendix 3 – Outcome of previous consultations

Outcome of consultation in 2009

In 2009 the New Zealand Food Safety Authority released a public discussion paper on the proposed amendment to the New Zealand folic acid standard.

There were 124 submissions received including some strong support from health and science groups for mandatory fortification and some strong objections from consumers and industry.

Issues raised by submitters included concerns that mandatory fortification might:

- limit consumer choice;
- increase costs to industry and consumers;
- have adverse health effects;
- give women a false sense of security about their folic acid levels;
- not be effective at proposed levels, or benefit only a small number of people;
- cause issues for bakeries that do not have the technical capacity to comply with the Standard.

However, there were also many submissions received in support of mandatory fortification. Reasons for support include:

- it decreases the number of NTDs and reduces the burden on public health care;
- it is much more effective than voluntary fortification;
- there is no evidence of harmful side effects at the levels proposed;
- folate deficiency is common in women of childbearing age and the Government needs to protect vulnerable people; and
- it is inexpensive and efficient.

Outcome of consultation in 2012

The 2012 consultation document is available from the MPI Food Safety website at: https://www.mpi.govt.nz/dmsdocument/3450-the-future-of-folic-acid-fortification-of-bread-in-new-zealand

A summary of submissions received is available at: https://www.mpi.govt.nz/dmsdocument/3984-fortification-of-bread-with-folic-acid-summary-of-submissions

There were 134 submissions received on the consultation document: The Future of Folic Acid Fortification of Bread in New Zealand. The views expressed were similar to 2009.

Submissions opposed to mandatory fortification (or who supported voluntary fortification) were mainly from individual consumers, industry associations, and individual bakery firms. They did not support mandatory fortification because they:

- were concerned about the risks associated with adding folic acid to bread;
- questioned the proportionality of fortifying all bread when only a very small subset of the population would benefit;
- objected to the lack of choice that mandatory fortification would impose on consumers.

Submissions favouring mandatory fortification were mainly from professional medical associations, doctors, and families and whānau affected by an NTD pregnancy. They supported mandatory fortification because they said it:

- would prevent/reduce the number of NTD-affected pregnancies;
- was safe (or low risk);
- was the most effective approach; and
- would reduce the costs to health and education sectors, as well as those families and whānau affected by NTD pregnancies.

Appendix 4 – Commonly asked questions

What is folate/folic acid?

Folate/folic acid is a B group vitamin that is needed for healthy growth and development. This vitamin is known as folate (B9) when it is found naturally in food, and folic acid when it is synthesised and added to food, such as bread or breakfast cereals, or when it is used in dietary supplements. Natural food sources include leafy green vegetables, citrus fruit, animal liver, and cereal grains, although folate is lost during food processing (e.g. milling), storage, and handling.

Who needs folate and why?

Folate is essential for healthy growth and development for everyone, but is especially important for women planning a pregnancy. Folic acid, the synthetic form of folate, is crucial to the healthy development of babies in early pregnancy. A baby's growth is the most rapid in the first weeks of life, often before a woman even knows that she is pregnant. Folic acid taken at least one month before conception and for the first three months of pregnancy will substantially reduce the risk of birth abnormalities called neural tube defects (NTDs) in babies.

What are neural tube defects?

Neural tube defects (NTDs) are severe congenital malformations of the central nervous system which may occur during early development of the baby in the womb. The two major types of NTDs are anencephaly and spina bifida. In New Zealand, women are recommended to consume a tablet containing 800 micrograms of folic acid a day for the four weeks before and 12 weeks following conception. These recommendations are in addition to maintaining a normal, healthy diet which contains naturally-occurring folate in fruit and leafy greens.

Why can't women get enough folate in their diet?

A woman needs to consume large quantities of food with high levels of naturally-occurring folate to obtain the recommended daily dose. Foods naturally high in folate include leafy green vegetables, legumes, citrus fruit and bananas, nuts, and animal liver. Although the naturally-occurring folate in these foods also contributes to protecting against NTDs, naturally-occurring folate is not as easily absorbed by the body as folic acid, found in supplements and fortified foods. For example, to obtain the equivalent of 400 micrograms of folic acid, a woman would need to eat nearly half a kilogram of cooked spinach or raw broccoli every day.

Why can't women just take folic acid supplementation tablets?

The Ministry of Health recommends women who are planning a pregnancy should take folic acid supplementation tablets for at least a month before and for the three months after conception. These tablets work really well for women who plan their pregnancy and know about the importance of folic acid during the critical period. However, 53% of pregnancies in New Zealand are not planned, with an uneven spread across population groups. Māori and Pacifica women have the highest unplanned pregnancy rates (75% and 71% respectively)

while Europeans have the lowest (40%). For women aged 24 and younger, 83% of pregnancies are unplanned compared to an average of 41% for women who are 25 or older. [39]

How does New Zealand compare with overseas countries?

Rates of NTDs in New Zealand are much higher than in similar overseas countries that have introduced mandatory fortification such as Australia, Canada, and the United States.

Do women still eat enough bread for fortification to make a difference?

Bread remains a suitable food vehicle for fortification as it is commonly consumed by women of childbearing. On average, women of childbearing age eat two slices of bread most, if not every, day. Importantly, women from less socio-economically advantaged groups – those who bear more of the burden of NTD-affected pregnancies – eat, on average, three slices a day. Mandatory fortification should address some of the inequities seen, for example, in the rate of NTD live births between Māori women and other population groups.

If we do change our approach, how will we know it is working?

The impact of any fortification approach taken as a result of this review will be assessed as part of the regular on-going monitoring work carried out by MPI and the Ministry of Health. This work measures the level of folic acid in the food supply, blood folate levels in the target and non-target groups, and the prevalence of total NTDs.

Are there any foods in New Zealand for which fortification is mandatory now?

Yes. The Australia New Zealand Food Standards Code mandates that any salt used in making bread must be iodised salt (organic bread is exempt). This requirement is a response to the re-emergence of iodine-deficiency in some areas of Australia and New Zealand. Adequate intakes of dietary iodine, particularly for women of childbearing age and breast-feeding mothers, is important for health and to reduce possible iodine-deficiency health problems such as impaired neurological function in babies and young children.

[39] Bryndl E. Hohmann-Marriott. *Unplanned pregnancies in New Zealand*. Aust NZ J Obstet Gynacol 2018: 247-250.