



The Future of Folic Acid Fortification of Bread in New Zealand

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Prepared by the Biosecurity, Food and Animal Welfare Directorate
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Introducing the Ministry for Primary Industries

The Ministry of Agriculture and Forestry (MAF) has changed its name to reflect the new functions of the organisation following its merger with the New Zealand Food Safety Authority and Ministry of Fisheries.

The new name is the Ministry for Primary Industries – Manatū Ahu Matua (MPI). It came into effect on 30 April 2012.

The name was chosen because it covers all of the Ministry's work across the agricultural, horticultural, aquaculture, fisheries, forestry and food sectors, and the protection of our primary industries from biological risk.

It reflects that we continue to be the gateway to government for all of New Zealand's primary industries.

Throughout this document MPI is referred to, including where the agency may have been either MAF or the New Zealand Food Safety Authority.

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Abbreviations

µg	Micrograms – also written elsewhere as mcg
BIANZ	Baking Industry Association of New Zealand
DoHA	Department of Health and Ageing (Australia)
EFSA	European Food Safety Authority
FSANZ	Food Standards Australia New Zealand
MoH	Ministry of Health
MPI	Ministry for Primary Industries
nmol/L	Nanomoles per litre
NTD	Neural tube defect
OIA	Official Information Act 1982
RIA	Regulatory Impact Analysis
The Standard	The New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007
UK	United Kingdom
US	United States of America

1 Executive summary

1.1 PURPOSE AND SCOPE OF REVIEW

Purpose of review

This document provides information and invites submissions on the future of the New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007 (the Standard).

Fortification is the process of adding nutrients such as vitamins or minerals to food. It is one way for people to gain some of the nutrients they need from their diet. The Standard allows folic acid to be voluntarily added to most breads up until 30 September 2012, after which those breads will have to contain folic acid.

Bread products covered by the Standard include:

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

Bread that does not have to be fortified includes bread not leavened with yeast, unbaked bread products like pizza bases, bread represented as “organic”, breadcrumbs, cakes, and biscuits.

The Minister for Food Safety, the Hon Kate Wilkinson, amended the Standard in 2009 to extend the commencement date of mandatory fortification due to concerns expressed by the baking industry and consumers. She advised that government would consider the impact of voluntary fortification and other research before making a final decision on mandatory fortification. To allow time for the review, on 23 April 2012, the Minister extended the commencement date of mandatory fortification to 30 September.

The Ministry for Primary Industries (MPI) has released this discussion document as part of the review of the Standard. It summarises relevant research and information, and considers options for the future. A review of scientific studies is available on MPI’s website as *Voluntary folic acid fortification monitoring and evaluation report* – MPI Technical Paper No: 2012/03 (referred to later as the *Monitoring* report) <http://www.foodsafety.govt.nz/consultation/>.

MPI welcomes submissions with consultation closing on **Monday 16 July 2012**. Submissions will help inform a decision on the future of the Standard.

Scope of review

This review will consider whether addition of folic acid to bread should be voluntary or mandatory. It will not reconsider what foods should be fortified with folic acid or at what stage of production folic acid should be added to bread. Food Standards Australia New Zealand (FSANZ) considered those matters prior to the Standard being issued in 2007. This

included public consultation on options for fortification. MPI does not intend that the Standard will apply to home bakers and other non-commercial bakers.

1.2 BACKGROUND

Why women need to consume folic acid

Folic acid is a synthetic form of folate, which is part of the B vitamin group. Many foods, such as leafy green vegetables, contain folate. Folic acid is also added to some foods and supplements. When women consume adequate folic acid before and during pregnancy, they reduce the risk of having a baby with a neural tube defect (NTD).¹ NTDs affect the brain and spinal cord and are one of the most common and serious birth defects. They include anencephaly² and spina bifida³ and can result in death or lifelong disabilities.

Women who are planning to become, or are pregnant need more folate than the general population and it is difficult to get this level from a natural diet alone. As a result, the Ministry of Health (MoH) recommends women take a folic acid tablet containing 800 micrograms (µg)⁴ daily for at least 4 weeks before conceiving and during the first 12 weeks of pregnancy⁵. MoH recommends tablets with higher levels of folic acid for women who are at high risk of having an NTD-affected pregnancy including those who have already had an NTD-affected pregnancy. These subsidised folic acid tablets are available over-the-counter from pharmacies but the lowest cost is on prescription.

A recent consumer survey of women of childbearing age showed that their unprompted awareness of the need for periconceptional (before pregnancy) use of folic acid is high where there is pre-existing knowledge of folate or folic acid, but it is low overall.⁶ New Zealand has permitted the addition of folic acid to a variety of foods since 1996 but most women in the survey reported not knowing why or how to identify folic acid fortified foods.

Consuming fortified foods can help increase the folate status of all women, including those who do not understand folate's importance, do not know the best time to take a folic acid supplement, or have an unplanned pregnancy. A recent survey of women in New Zealand⁷ found that about 40% of pregnancies they studied were unplanned but older studies⁸ found higher rates.

Why bread is fortified with folic acid

Fortified bread is intended to complement educational efforts to improve women's knowledge of the importance of adequate folate consumption and their use of folic acid tablets to support a successful pregnancy. Because most women of childbearing age eat bread regularly, it was chosen as the vehicle for fortification. Providing a base level of folic acid for women who eat

¹ See for example: De-Regil L M, Fernandez-Gaxiola A C, Dowswell T, Pena-Rosas J P. *Effects and safety of periconceptional folate supplementation for preventing birth defects*. Cochrane Database Syst Rev 2010 Oct 6;(10)(10):CD007950. Other resources are listed in Appendix 5.

² Anencephaly is the absence of a large part of the brain and the skull. <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0002547/>

³ Spina bifida is caused by the failure of the foetus' spine to close properly during the first month of pregnancy. http://www.ninds.nih.gov/disorders/spina_bifida/spina_bifida.htm

⁴ In this paper, we refer to measures of folic acid in micrograms and use the scientific symbol µg for that measure. However, on some vitamin tablets, it is written as "mcg". So 800 µg = 800 mcg. 100 micrograms is the same as 0.1 milligram. So it is also possible that 800 µg may be referred to elsewhere as 0.8 mg or 0.8 milligrams.

⁵ See the MoH recommendation at <http://www.health.govt.nz/our-work/life-stages/maternity-and-breastfeeding/supplement-tablet-take-when-pregnant-or-breastfeeding>

⁶ *Awareness and knowledge of folate and folic acid in women of child-bearing age* is available on MPI's food safety website: www.foodsafety.govt.nz/elibrary/industry/folate-NZ-women.pdf. A summary is included in Appendix 3 and in more detail in the *Monitoring* report.

⁷ *Growing up in New Zealand*. <http://www.growingup.co.nz/>

⁸ Studies from before the introduction of the Standard can be found at the FSANZ website. <http://www.foodstandards.gov.au/>

bread regularly should improve their blood folate status and reduce their risk of having an NTD-affected pregnancy.

There are currently 59 countries that have mandatory fortification of bread (or flour) with folic acid, as well as many countries that allow voluntary fortification.⁹ However, the precise meaning of “mandatory” varies. For example, in Australia, all wheat flour for making bread but not pasta is fortified. In the United States (US) “enriched” flour (actually, enriched grain products generally including rice, barley and others) must be fortified including enriched flour used for pasta, but wholegrain¹⁰ flour and corn masa flour for tortillas in the US are generally not fortified.¹¹

History of New Zealand folic acid fortification standards

New Zealand has permitted voluntary fortification of certain foods with folic acid (bread, breakfast cereals, fruit juices, and others) since 1996. Later, New Zealand and Australia agreed to a joint mandatory folic acid fortification standard under the joint Australia New Zealand Food Standards Code. The original proposal was for the fortification of bread-making flour but this “was considered particularly problematic for New Zealand, who did not have any fortification infrastructure in place”.¹²

In September 2007, New Zealand issued a New Zealand-only standard under the Food Act 1981 (the New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007). The Standard simply requires bread to contain a certain amount of folic acid so permits fortification during the baking process or the use of fortified flour to achieve the desired results in bread.

In 2009, a few months before the Standard was to take effect, industry and consumers raised concerns about mandatory fortification.¹³ In response to the level of public interest and the concerns raised, the Minister for Food Safety asked now MPI to consult on a range of options for the Standard including delaying its commencement. As a result, in 2009 the Standard was amended to delay the start of mandatory fortification until 31 May 2012 and to provide for the continuation of voluntary fortification. The Minister committed to a review of the Standard before mandatory fortification commenced. To allow time for a full and robust review incorporating the results of commissioned research, an amendment further extending the commencement date of mandatory fortification to 30 September was notified in the Gazette on 26 April 2012.

1.3 NEW RESEARCH INFORMING THE REVIEW

The Minister for Food Safety created a Folic Acid Working Group in 2009 to encourage voluntary fortification initiatives and to contribute to the development and assessment of information relating to folic acid fortification. The Working Group includes representatives from the baking industry, government departments, health professionals, academics and groups who represent families affected by NTD pregnancies.

⁹ See: Flour Fortification Initiative: <http://www.sph.emory.edu/wheatflour/index.php>

¹⁰ “Wholegrain” refers to any grain including rice, barley, oats and others. “Wholemeal” refers to products where the particles have been refined into finer particles. See the Food Standards Code information here:

<http://www.foodstandards.gov.au/scienceandeducation/factsheets/factsheets/wholegrainfoodnovemb5372.cfm>

¹¹ Wholegrain wheat flour makes up less than 5% of the market in the USA. *Consumer preferences change wheat flour use - amber waves* September 2008: <http://www.ers.usda.gov/amberwaves/september08/findings/wheatflour.htm>

¹² Section 5.4.1.4 of *First Review Report – Proposal P295 – Consideration of mandatory fortification with folic acid*. FSANZ, 23 May 2007: <http://www.foodstandards.gov.au/foodstandards/proposals/proposalp295considerationofmandatoryfortificationwithfolicacid/>

¹³ Examples of the for and against arguments from the time can be found at <http://www.bpac.org.nz/magazine/2008/august/upfront.asp>

Following the amendment of the mandatory fortification standard, MPI commissioned the following two studies to review voluntary initiatives and help inform any future decision on the Standard.

Major findings of the consumer awareness survey

This 2010 telephone interview survey of 1000 women, conducted by Research New Zealand, found that over half of women knew of the need for folic acid before or during pregnancy. Of women who had been (or were) pregnant, 80% took a vitamin or supplement with folic acid but only 41% of these women started taking it at the most effective time (before conception). Most women (88%) knew that folic acid was available through supplements but many could not identify other sources of folate such as naturally occurring sources like green vegetables or fortified foods like breakfast cereals.

Major findings of blood folate status research

This 2011 study of 288 women in Dunedin and Wellington, conducted by the University of Otago, looked at women's consumption of folic acid fortified foods, their blood folate status, and the amount of folic acid in fortified breads.¹⁴ More than half of women in the study had a blood folate status¹⁵ that was similar to that found in women taking a daily 400 µg supplement and associated with a very low risk of NTDs. Women in this survey had higher serum and red blood cell folate than women in a national survey in 2008/2009. There was a non-significant trend for average red blood cell folate levels to be higher in those women who consumed folic acid fortified breads.

The study of folic acid in bread found inconsistent results. The target goal agreed to by industry in 2009 was 200 micrograms per 100 grams of bread. Of the 17 breads tested, 5 were found to have less than 50 micrograms per 100 grams of bread and the other 12 had levels between 105 and 452 micrograms per 100 grams of bread. During the 2009 consultation, industry reported that fortification of bread was more difficult than first thought but believed that over a number of slices of bread, the level of folic acid would meet the Standard. The recent results suggest that not all the technical challenges have been met. MPI is working with industry to find solutions to these challenges.

1.4 CURRENT VOLUNTARY FORTIFICATION INITIATIVE

There are now 34 packaged breads from major bakeries listed on the Baking Industry Research Trust (the Trust) website as containing folic acid.¹⁶ Some takeaway stores are also fortifying some breads. The Trust sent a publication encouraging small bakeries to fortify their bread and a small number have started (3 of 51 bakeries). The cost of fortifying is estimated by industry as one half a cent per loaf (or close to \$1.5 million/annum on the total cost of packaged bread in New Zealand ≈249 million loaves¹⁷).

MPI-commissioned research shows blood folate levels were higher in 2011 than in 2008/2009, which may have been helped by the voluntary bread fortification initiative. There is no data available yet on whether the number of NTD-affected pregnancies has decreased since voluntary fortification began in New Zealand, as it will take a number of years before that can be reliably measured.

¹⁴ Section 5 and Appendix 4 contain more information on this research. It is also included in the *Monitoring* report and the full results are available at <http://www.foodsafety.govt.nz/science-risk/project-reports/food-composition/nutrients/folic-acid.htm>

¹⁵ Red blood cell folate measurement of 906 nanomoles per litre or higher = red blood cell folate level of ≥ 906 nmol/L.

¹⁶ <http://www.bakeinfo.co.nz/Hot-Topics/News/Companies-Respon-To-Voluntary-Fortification-of-Folic-Acid>

¹⁷ Submission from the New Zealand Association of Bakers.

1.5 HOW MANDATORY FORTIFICATION WOULD WORK

If mandatory fortification takes effect, each bread manufacturer will be responsible for adding the right amount of folic acid to all their breads. Folic acid would be required to be in most bread (see the list in Section 1.1). Fortifying these breads would have start-up and ongoing costs for bread-makers that will vary depending on the size of the baker and whether they are already fortifying some bread. MPI would be responsible for assessing compliance while bread-makers/retailers would need to document their compliance.

FSANZ estimated that mandatory fortification would result in an additional reduction of 4 to 14 pregnancies affected by NTDs every year (an up-to-20% reduction of total NTD-affected pregnancies of 70–75/year) compared to what was being achieved through voluntary fortification of food in 2007.¹⁸

1.6 MPI'S PROPOSED OPTIONS

MPI has proposed four options with some possible variations within each option. The options are:

1. Mandatory fortification as defined in the current Standard with the possibility of delayed or phased-in commencement
2. Limited mandatory fortification where a threshold is set before mandatory fortification applies
3. Mandatory reporting where all bakeries must report on whether they fortify their bread with folic acid and how much of their bread is fortified
4. Voluntary fortification with a mandated review starting in 2015

MPI welcomes submissions on the options and variations as presented in the document. MPI also welcomes suggestions for variations not addressed in the document.

MPI will not reconsider what foods should be required to be fortified with folic acid or at what stage of production folic acid should be added to bread. These issues were addressed in the original consultations with FSANZ. MPI does not intend that the Standard will apply to home bakers and other non-commercial bakers.

Option 1: Mandatory fortification from 30 September 2012 as defined in the current Standard with the possibility of delayed or phased-in commencement
<ul style="list-style-type: none">• The current New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007 (as amended in 2009) could be left unchanged.• All bread (except for “organic” bread and bread not leavened with yeast) would be required to have folic acid added to it from 30 September 2012. Bread that does not have to be fortified includes bread not leavened with yeast, unbaked bread products like pizza bases, bread represented as “organic”, breadcrumbs, cakes, and biscuits.• The current Standard could be amended to have a commencement date of 30 September 2013 to give industry more time to prepare.

¹⁸ Proposal P295 – Consideration of mandatory fortification with folic acid. First review report – 23 May 2007. Page 5. This was a conservative estimate. This estimate is based on predictions for if flour is fortified at a level of 2 mg per kg.

Option 2: Limited mandatory fortification where a threshold is set before mandatory fortification applies

- The current Standard could be amended to stipulate that all bakeries must fortify a minimum percentage (but less than 100%) of their breads.
- The current Standard could be amended to require that bakeries producing over a minimum amount of bread in any year must fortify a minimum proportion of their production.

Option 3: Mandatory reporting where all bakeries must report on whether they fortify their bread with folic acid and how much of their bread is fortified

- A new standard could be issued that requires reporting by all bakeries on whether they fortify their bread with folic acid and how much of their bread is fortified.
- A new standard would also need to explicitly permit voluntary fortification with folic acid to continue. This is because the ANZ Food Standards Code Standard 1.3.2 that permits fortification of food with vitamins and minerals excludes breads, except for bread that contains no wheat flour.
- A new standard could also specify record-keeping that would allow independent audits of whether and to what extent bakeries add folic acid to their bread.

Option 4: Voluntary fortification with or without a review to start in 2015

- Bakers would continue to be allowed to add folic acid to their bread but would not be legally required to fortify bread with folic acid.
- The New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007 (as amended in 2009) would be revoked and replaced with a new standard that permits voluntary fortification. The new voluntary standard could include a clause requiring a review of the standard to start in 2015. Such a review would provide an opportunity to reconsider mandatory fortification if the voluntary regime was not proving effective.
- A new voluntary standard could permit the development of an approved Code of Practice or Guidelines that would apply to breads fortified with folic acid.

2 Consultation

Written submissions on the issues raised and options presented in the consultation paper are invited from all interested parties.

The closing date for submissions is **Monday 16 July 2012**.

Submissions should be sent to:

Food Policy Team
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Ministry for Primary Industries
PO Box 2526
Wellington 6104
New Zealand

Delivery address: Level 10, Pastoral House, 25 The Terrace, Wellington

Fax: (04) 894 2530
Email: folicacid@mpi.govt.nz

Please include your name and address on your submission. If you are making comments on behalf of an organisation, also include your title and the name of the organisation.

Please make sure your comments can be clearly read as a number of copies may be made of your submission.

Submissions backed by evidence and argument will carry more weight than statements of opinion.

2.1 OFFICIAL INFORMATION ACT

The Official Information Act 1982 (OIA) states that information is to be made available unless there are grounds for withholding it. The grounds for withholding information are outlined in the OIA. Submitters may wish to indicate any grounds for withholding information contained in their submission. Reasons for withholding information could include that information is commercially sensitive or that the submitters wish personal information such as names or contact details to be withheld. MPI will take such indications into account when determining whether or not to release information. Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman.

2.2 PROCESS AFTER SUBMISSIONS

Once the consultation period has closed, MPI will analyse submissions and make recommendations to the Minister for Food Safety. A summary of submissions and analysis will be sent to all submitters and posted on MPI's website.

Information on the timing of this consultation will be posted on MPI's website and sent to interested parties.

3 Introduction

Fifty-nine countries require the fortification of bread with folic acid as a public health measure.¹⁹ They include most of North, Central, and Latin America, Australia, and a number of countries in Africa, Asia and the Middle East. Many other countries provide for voluntary fortification.

Folic acid is a synthetic form of folate, a member of the B vitamin group. Natural sources of folate include whole grains and green vegetables. Folate helps the body build and maintain DNA and is important in helping the body make new cells, especially red blood cells. Women who are planning to become, or are, pregnant need more folate than the general population but it is difficult to get this level from diet alone.

Research shows that adequate intakes of folate prior to and in the early stages of pregnancy reduce the risk of the baby having a neural tube defect (NTD). NTDs are major birth defects of the baby's brain and spine, such as anencephaly (the absence of a large part of the brain and skull) and spina bifida (incomplete closure of the foetus' spine).²⁰ NTDs can result in the baby dying before birth or in infancy, or having a lifelong disability including paralysis or bowel and bladder issues.²¹ To help prevent NTDs, the Ministry of Health (MoH) recommends women take an 800 micrograms (µg) folic acid tablet for at least 4 weeks before conceiving and during the first 12 weeks of pregnancy.²²

Folic acid is also added to a number of vitamin supplements and to certain foods that are allowed to be fortified with folic acid. These include juice, breakfast cereals, yeast and meat spreads, and some bread. Many women do not take folic acid tablets at the right time. This may be because they do not know of the risks or because their pregnancy is unplanned. Fortification of bread with folic acid is one way to reduce NTDs as part of a holistic approach that includes education campaigns about NTDs and the advantages of taking folic acid tablets before conception and during the first 12 weeks of pregnancy to reduce the risk.

The New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007 (the Standard) requires the fortification of most bread from 30 September 2012. Bakers can already voluntarily add folic acid to bread until it becomes mandatory; currently more than 30 packaged breads are voluntarily fortified.

Bread that does not have to be fortified includes bread not leavened with yeast, unbaked bread products like pizza bases, bread represented as “organic”, breadcrumbs, cakes, and biscuits.

Bread products that have to be fortified include:

- plain white, white high fibre, wholemeal and multigrain bread loaves, buns and rolls;
- yeast-containing flat breads (for example, pita bread, naan bread);
- focaccia and pide (Turkish bread);
- bagels (white, wholemeal, sweet);
- topped breads, buns and rolls (for example, cheese and bacon rolls);
- sweet buns (for example, raspberry buns, Boston buns);

¹⁹ See: Flour Fortification Initiative: <http://www.sph.emory.edu/wheatflour/index.php>

²⁰ Anencephaly is the absence of a large part of the brain and the skull. Spina bifida is caused by the failure of the foetus' spine to close properly during the first month of pregnancy.

²¹ See the Ministry of Health site dealing with folic acid and NTDs: <http://www.health.govt.nz/our-work/preventative-health-wellness/nutrition/folate-folic-acid>

²² See the MoH recommendation at <http://www.health.govt.nz/our-work/life-stages/maternity-and-breastfeeding/supplement-tablet-take-when-pregnant-or-breastfeeding>

- fruit breads and rolls;
- yeast-containing baked English-style muffins.

This discussion document reviews how voluntary fortification has worked, looks at how mandatory fortification might work, and considers recent research. It also describes some options for fortification in the future. The Ministry for Primary Industries (MPI) welcomes submissions on the future of the Standard.

MPI will analyse the submissions received, finalise the regulatory impact analysis, and will make recommendations to the Minister for Food Safety who will make a final decision on the Standard. Any changes to the Standard would occur before it comes into effect on 30 September 2012.

4 Background

4.1 WHAT IS FOLIC ACID AND WHY IS IT IMPORTANT?

What are folate and folic acid?

Folate is an essential member of the B vitamin group. Many foods naturally contain folate, including whole grains, green vegetables like spinach and asparagus, beans, liver, eggs and citrus fruit. Folic acid is a synthetic form of folate. Folic acid can be taken as a tablet and is added to some foods and multi-vitamin preparations where permitted. New Zealand has permitted folic acid addition to breads, breakfast cereals, fruit drinks and some other foods since 1996.

Folate is necessary to synthesise and repair DNA, it aids in cell division and growth, and a deficiency can cause a form of anaemia. At times of fast growth, such as when a baby is developing in the womb, it is especially important.

Folic acid and healthy babies

Folate and folic acid play a major role in reducing a woman's risk of having a baby with an NTD. Women who have adequate levels of folate in their blood prior to and during pregnancy have a reduced risk of having their baby affected by an NTD. NTDs are some of the most common and serious birth defects: they affect the baby's brain and spinal cord and include spina bifida and anencephaly. Anencephaly results in most of the brain and skull not forming due to the neural tube not closing. All babies with this condition die before or shortly after birth. Spina bifida occurs when the neural tube closes incompletely and can result in paralysis, bowel and bladder control issues, and other serious complications. People who have NTDs may require many operations and healthcare support throughout their lives. A recent report based on six patients suggests that at least some patients may require more extensive (and expensive) medical care than previously estimated.²³ Data from the New Zealand Birth Defects Register indicates 142 babies were born alive with NTDs between 2001 and 2008.

How much folic acid do we need?

Health professionals recommend that both men and women should consume 400 µg of folate every day. Women who are planning to become, or are, pregnant need more folate, which is difficult to get from diet alone.²⁴ The Ministry of Health recommends women take subsidised folic acid tablets for at least 4 weeks before conceiving and during the first 12 weeks of a pregnancy. Folic acid tablets are available in an 800 µg daily dose or 5000 µg daily dose (for women at high risk of an NTD-affected pregnancy) from pharmacies. Doctors can prescribe the folic acid tablets (at a lower price) but they are also available (over the counter) without a prescription.

However, a recent study²⁵ found that only 58% of women who were planning their pregnancy began taking a folic acid supplement at the recommended time, which is before conception. These results highlight the fact that many pregnancies are unplanned and many women do not

²³ *The costs of paediatric spina bifida inpatient treatment at Wellington Regional Hospital: A cost analysis of sequential patients.* Bowkett & Deverall, NZMJ 2012;125;1351.

²⁴ The Ministry of Health explains this on their website at <http://www.health.govt.nz/our-work/preventative-health-wellness/nutrition/folate-folic-acid>

²⁵ The University of Auckland is conducting research on over 7000 babies and will follow them for the next 21 years. As part of this study, the University of Auckland published a survey conducted in 2010 that included questions on whether the women took a folic acid supplement before or during their pregnancy. *Growing up in New Zealand: A longitudinal study of New Zealand children and their families. Report 1: Before we are born.* Auckland: Growing up in New Zealand. 2010. Morton, S M B; Atatoa Carr, P E; Bandara, D K; Grant, C C; Ivory, V C; Kingi, T R; Liang, R; Perese, L M; Peterson, E; Pryor, J E; Reese, E; Robinson, E M; Schmidt, J M; and Waldie, K E. <http://www.growingup.co.nz/>

start taking folic acid at the recommended time to minimise (but not eliminate) the risk of having a baby with an NTD. However, the Ministry of Health recommends taking a folic acid tablet for the first 12 weeks even if the mother did not start before getting pregnant.

4.2 FORTIFICATION OF FOOD WITH FOLIC ACID IN NEW ZEALAND

Fortified foods

Fortification is the process of adding nutrients such as vitamins or minerals to food. It is one way for people to gain some of the nutrients they need from their diet.

In some countries, there are nutrients that must be added to certain foods. Governments consider the use of mandatory fortification when a widespread public health problem is the result of a lack of a vitamin or mineral. Fortification is usually not the first response to a public health problem but is used when there is a population-wide issue and there are no other feasible options.

Fortified foods in New Zealand

New Zealand permits the following foods to be fortified:

- Milk may have added calcium, vitamin A and vitamin D.
- Fruit juices may have added calcium, folic acid, or vitamins A or C.
- Cereals may have iron, zinc, and B vitamins added including folic acid and thiamin. (Folate is the naturally occurring vitamin found in food and folic acid is the synthetic form usually added to food.)

Manufacturers may only fortify foods with approved nutrients. The Australia New Zealand Joint Food Standards Code sets out what vitamins and minerals may be added to food in New Zealand.²⁶

In New Zealand, all salt added to bread (except “organic” bread) must now be iodised.²⁷ This measure is to help reduce levels of iodine deficiency disorders in New Zealand. The addition of iodine to food in New Zealand is not new; iodine has been a permitted addition to salt since the 1920s.

New Zealand folic acid fortification standard

New Zealand and Australia both have standards setting out requirements for mandatory folic acid fortification of bread. The standards were the result of work that began in 2004, when the Ministerial Council (which included New Zealand’s then Minister for Food Safety, Hon. Annette King) asked Food Standards Australia New Zealand (FSANZ) to give high priority to investigating mandatory folic acid fortification as a means of reducing NTDs in Australia and New Zealand. In developing the folic acid standard, FSANZ prepared several assessment reports including cost benefit assessments covering both New Zealand and Australia.²⁸

Why fortify bread?

Bread was chosen as the food to be fortified because most women consume it and it is not traded internationally. Internationally traded foods need to meet the requirements of the countries to which they are exported. Fortifying foods that need to meet many different

²⁶ Vitamins and minerals that can be added to food in New Zealand and any limits on quantities are outlined in Standard 1.3.2 (Vitamins and Minerals).

²⁷ This requirement is also found in New Zealand and Australia’s joint food code in Standard 2.1.1 (Cereals and Cereal Products).

²⁸ All the assessment reports can be found on the FSANZ website:

<http://www.foodstandards.gov.au/foodstandards/proposals/proposalp295considerationofmandatoryfortificationwithfolicacid/>

standards is difficult and expensive. Mandatory fortification of a food produced in New Zealand and then exported could have adversely affected New Zealand exporters.²⁹

Australian standard

Australia's standard is set out under New Zealand and Australia's joint food code.³⁰ This standard has required, since 2009, the addition of folic acid to wheat flour used for making bread (except "organic" bread). This standard does not apply in New Zealand.

New Zealand standard: the New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007

New Zealand developed and issued in 2007 under the Food Act 1981 its own standard requiring bread to contain folic acid.³¹ The Standard, issued under the Food Act 1981, does not state when folic acid should be added but makes it necessary that bread contains it. Compared to Australia, the New Zealand grain milling industry is very small. That meant that if folic acid was added at the milling stage in New Zealand, there would be limited access to unfortified flour for making other foods like cakes or biscuits. The New Zealand Standard was due to come into effect in 2009 but the Minister delayed commencement of the mandatory requirement until 30 September 2012. Until then the Standard allows for voluntary fortification of bread with folic acid.

Other countries

Fifty-nine countries require mandatory fortification of wheat or maize flour for bread-making with folic acid. Many other countries such as the United Kingdom (UK), Ireland and some European Union countries have voluntary fortification regimes.

However, the precise meaning of "mandatory" varies. For example, in Australia, all wheat flour used for making bread is fortified but in the United States (US) only "enriched" flour must be fortified, meaning that wholegrain flour in the US is generally not fortified.³² Pasta may be made in the US from enriched flour and then it will contain folic acid. The ways in which Australia, the US, Canada, the UK, and Ireland approach folic acid fortification are described in Appendix 1.

4.3 WHY WAS THE MANDATORY FORTIFICATION STANDARD DELAYED IN NEW ZEALAND?

Review and amendment of the fortification standard in 2009

In 2009, in response to concerns raised by industry and consumers,³³ the Minister for Food Safety, Hon. Kate Wilkinson, publicly consulted on options for the future of the Standard.

The public consultation document proposed three options: allow the Standard to commence on 29 September 2009, amend the commencement date of the Standard to 31 May 2012, or revoke the Standard. It recommended amendment of the commencement date and invited submissions.

Issues raised by consumers in their submissions included limiting the choice of New Zealanders over folic acid in their food and concerns that there might be negative health

²⁹ In 2008, Yarrows was exporting frozen dough rolls to Subway outlets in Australia, Taiwan, Korea, Singapore and Japan.

³⁰ <http://www.yarrows.co.nz/news.php?type=news&cat=general&id=1>

³¹ Standard 2.1.1 (Cereal and Cereal Products) requires between 2 and 3 mg of folic acid to be added per kg of bread-making wheat flour.

³² The New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007.

³³ Wholegrain wheat flour makes up less than 5% of the market in the USA. *Consumer preferences change wheat flour use – amber waves* September 2008: <http://www.ers.usda.gov/amberwaves/september08/findings/wheatflour.htm>

Examples of the for and against arguments from the time can be found at <http://www.bpac.org.nz/magazine/2008/august/upfront.asp>

consequences from consuming folic acid fortified bread. Many health professionals and academic submitters supported mandatory fortification because of its potential to reduce NTD risk. A summary of these submissions is available in Appendix 2.

The Minister introduced an amended standard that delayed commencement of mandatory fortification until 31 May 2012 and provided for the ongoing voluntary fortification of bread. She committed to a full review of the Standard before it became mandatory to fortify bread with folic acid. That New Zealand review was expected to incorporate the outcome of the planned review by FSANZ of mandatory fortification of bread-making flour in Australia (scheduled to start in 2011) as well as the impact in New Zealand of voluntary fortification initiatives. The Minister also committed to government working with the baking industry to develop and progress voluntary folic acid fortification initiatives.

In order to permit that review of the Standard, the commencement date was extended by four months to 30 September 2012.

4.4 WHY NEW ZEALAND IS REVIEWING THE STANDARD

Today, New Zealand has voluntary fortification of bread with folic acid under the Standard and some bread is fortified. The Standard requires that from 30 September 2012, there will be mandatory fortification of bread with folic acid.

This public consultation process is part of the review that the Minister committed to in 2009. The planned FSANZ review of the impact of mandatory fortification of bread flour in Australia is not complete and will not be for some time. At this stage only the baseline data collection is complete so the research cannot be taken into account with this review.

5 Research undertaken to inform this review

In 2010, MPI commissioned two studies to provide current data to help inform this review. Research New Zealand conducted the first study, which looked at New Zealand women's awareness of folic acid. The second study, carried out by the University of Otago, looked at the impact the voluntary fortification of bread with folic acid on New Zealand women.

5.1 NEW ZEALAND WOMEN'S AWARENESS OF FOLIC ACID

The survey carried out by Research New Zealand looked at how aware women in New Zealand are of folic acid and how they feel about the fortification of bread.³⁴ Key findings of the study of 1000 women were:

- Most women had heard of folic acid and folate, with most of their knowledge coming from the media or health providers during pregnancy. More than half of women knew that folic acid is needed before or during pregnancy.
- While most women knew folic acid was available through supplements, there was much lower awareness of natural food sources or fortified food sources of folate and folic acid.
- Most women who had been, or were, pregnant took additional folic acid during pregnancy but only 41% of these women began taking it before conceiving (the recommended time).
- The vast majority of women did not consider folate or folic acid content when choosing what food they bought, whether to select it for preference or to avoid it.
- Women had mixed views on mandatory fortification with as many agreeing as disagreeing with it. Reasons for supporting mandatory fortification included making folic acid more accessible. Reasons for disagreeing included the reduction in consumer choice and concerns about potentially adverse health effects.

More information about these key points is available in Appendix 3 and the full document is available at <http://www.foodsafety.govt.nz/elibrary/industry/folate-NZ-women.pdf>.

5.2 IMPACT OF VOLUNTARY FORTIFICATION ON NEW ZEALAND WOMEN

The University of Otago study looked at the consumption of folic acid fortified foods and the blood folate status of 288 women in Wellington and Dunedin. They also studied the folic acid content of breads listed on the Baking Industry Research Trust's website as fortified with folic acid. Key findings of this study were:

- More than half of women surveyed (59%) had a red blood cell folate level ≥ 906 nmol/L which is the level associated with the maximum protection against NTDs.
- The study quotes the 2008/09 New Zealand Adult Nutrition Survey as finding that only 27% of women had a red blood cell folate level ≥ 906 nmol/L. The report states in its conclusions that while the improvement cannot be statistically attributed to the wider availability of folic acid fortified breads, it does appear to have made a contribution.
- Eating fortified breakfast cereal was also related to higher blood folate levels (and a reduced NTD risk).
- Seventeen fortified breads were tested for folic acid content. Ten had an amount within the expected range, two had more than expected, and five did not appear to contain any folic acid.

³⁴ Dr Lisa Houghton of Otago University has conducted several studies in this area. Her research can be found at <http://nutrition.otago.ac.nz/staff/lisahoughton>

- The amount of folic acid in bread stayed fairly stable over its shelf life.

More information about these key points is available in Appendix 4 and online at <http://www.foodsafety.govt.nz/elibrary/industry/monitoring-fortification-of-bread-folic-acid.pdf>.

5.3 REVIEW OF THE SCIENTIFIC LITERATURE

A companion document to this discussion paper is *Voluntary Folic Acid Fortification: Monitoring and evaluation report* (the *Monitoring report*) prepared by MPI. The *Monitoring report* and a *Scientific Interpretive Summary* are available on the MPI website www.foodsafety.govt.nz.

The *Monitoring report* summarises technical information on six areas:

- folic acid fortified food composition and food industry compliance;
- consumer knowledge of folate and folic acid;
- folic acid intake and folic acid supplement use;
- folate status;
- health benefits;
- potential adverse health effects.

It reports that there are no new data on New Zealanders' dietary folic acid intakes nor are there complete data on the number and/or rate of NTDs in New Zealand since 2009 when the initiative to increase voluntary fortification of bread started. This is partly because it can take some years after birth before a child receives a diagnosis of an NTD. The mean rate for live births and stillbirths (foetal deaths) from 2001–2008 was 5.4 cases per 10 000 total births. In 2009, there was concern about possible effects of folic acid on cancer but there are no updated data on cancer numbers in the New Zealand population since 2008.

It discusses the 2008/09 New Zealand Adult Nutrition Survey that examined folic acid supplement usage by type. The survey found that multivitamin or multivitamin-plus-mineral supplements had lower median levels of folic acid than folic acid only tablets. It also looks at the results of some large randomised controlled folic acid supplementation trials and their meta-analyses. Details of those results are in the *Monitoring report*.

The *Monitoring report* includes a review of the published scientific literature since 1 January 2007 on the possible association of folic acid and cancer. The *Monitoring report* concludes that the evidence that had accumulated since the last review suggests that folic acid does not have an adverse effect on overall cancer incidence. It recommends that research in this area should continue to be monitored.

Research on site-specific cancers was reviewed (colorectal, breast, and prostate cancer) and the *Monitoring report* concluded that there is no indication of an increased risk of colorectal cancer, nor an association between folic acid and breast cancer. The *Monitoring report* also concludes that evidence to date suggests there is no effect of folic acid supplementation on the recurrence of colorectal adenomas. However, it is uncertain whether supplementing with folic acid for longer than three years has any adverse effect. Prostate cancer data were inconclusive but the limited data “is suggestive of a small increase in risk, of borderline significance.” The overall conclusion is that given the long latency period for the development of some cancers and that the association between folic acid and cancer is an emerging area of research, it is too early to draw unequivocal conclusions.

In December 2011, the Australian Institute of Health and Welfare released the final report in their baseline study of NTDs before the introduction of mandatory fortification of bread flour in 2009. The study – *Neural tube defects in Australia: prevalence before mandatory folic acid fortification* – is available at <http://www.aihw.gov.au/publication-detail/?id=10737420864>. The authors report a continued downward trend in the overall prevalence of all NTDs but advised that such a reduction does not necessarily reduce birth prevalence of NTDs. The results in this report will inform the next stage of research into the impact of mandatory folic acid fortification on the prevalence of NTDs in Australia. That research is expected to take several years.

6 New Zealand's current voluntary fortification initiative

New Zealand has allowed the addition of folic acid to bread since 1996. In 2009, the baking industry agreed with Government to an initiative to increase the voluntary fortification of breads.

This initiative gives New Zealand an opportunity to see how increased voluntary fortification has worked in practice and what impacts it has had on blood folate status. Any data on the impact of changes in blood folate status on NTD incidence will not be available for some time.

6.1 HOW IS VOLUNTARY FORTIFICATION WORKING – IMPACT ON BREAD

Actions taken to promote fortification

The New Zealand Association of Bakers represents large plant bakeries that produce an estimated 90% of all bread in New Zealand. Their members produce the packaged breads described below as being voluntarily fortified.

The Baking Industry Association New Zealand (BIANZ) represents many of the smaller bakers. BIANZ promoted the voluntary fortification initiative by sending a magazine to around 2000 bakeries with information on folic acid and recipes. BIANZ conducted a survey of 51 smaller bakeries in 2010 which found only three bakeries (6%) fortifying any bread with folic acid.³⁵

MPI also developed a user guide to help bakers, retailers, and Food Act officers understand the Standard, including how to add folic acid to bread. This user guide is available through MPI's Food Safety website: <http://foodsafety.govt.nz/industry/sectors/manufacturers-food-beverages/bakery-products/bread-with-folic-acid.htm>.

Breads being fortified

There are currently 34 packaged breads reporting they contain added folic acid. The list of these breads is on the Baking Industry Research Trust website: <http://www.bakeinfo.co.nz/Hot-Topics/News/Companies-Respos-To-Voluntary-Fortification-of-Folic-Acid> as well as on the Food Safety website: <http://foodsmart.govt.nz/whats-in-our-food/chemicals-nutrients-additives-toxins/food-additives/folate/>. The number of fortified breads has more than doubled since the voluntary initiative began in 2010 (see Figure 6.1 below). Information from industry suggests this amounts to about 12.5% of production (see Appendix 6).

The 34 fortified breads are predominantly multigrain and wholemeal breads as they are the types the bread industry believe that women are most likely to buy.³⁶ There are also four types of garlic bread and one type of white bread with folic acid added.

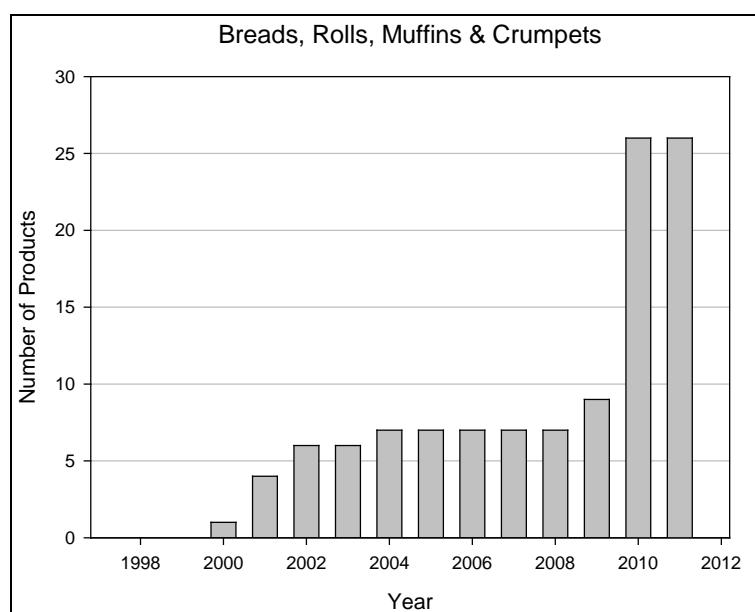
MPI is aware of at least one takeaway chain that is fortifying their breads and it is likely that some supermarket bakeries are also fortifying some of their products.³⁷

³⁵ Of these three, one was adding it to all their breads (except gluten free), one to 30% of their breads, and the last to only 1% of their breads.

³⁶ This was the reasoning industry gave. The MPI commissioned survey of women found that the most common types of bread consumed by the respondents were multigrain (41%), brown or wholemeal (31%), and white bread (22%). While women eat more multigrain or wholemeal breads, white bread holds 40% of the total market share.

³⁷ If they get their bread mixes from Australia where flour for making bread is fortified with folic acid.

Figure 6.1: Number of breads, rolls, muffins and crumpets fortified with folic acid in New Zealand since 1996.



Level of fortification occurring

The industry-agreed level for voluntary fortification is 200 µg per 100 g of bread. This level is slightly higher than it would be if fortification was mandatory because fewer products are voluntarily fortified.

The stated level of folic acid did not match the actual level of folic acid in some products, as MPI-commissioned research found that 5 out of 17 fortified breads had less than 50 µg of folic acid per 100 g of bread. MPI is working with the industry to identify and resolve the reasons behind these apparent inconsistencies.

Fortifying bread with folic acid is recognised as technically challenging. An August 2006 study by Access Economics for FSANZ noted that “controlling the accuracy of the dose of folic acid will be difficult, particularly for smaller bakeries...”. It also noted the experience of a bakery already adding folic acid to bread that found only 40% of samples had folic acid in the range of 70 µg to 280 µg per 100 g of bread.³⁸

Reasons that some bakers have not fortified any breads

As noted above, while there has been great participation by some bakers, there has been less enthusiastic uptake by others.

A number of reasons have been identified to explain the low participation by smaller bakeries in the voluntary scheme:

- It is too difficult to fortify or bakeries do not know how to add folic acid in the right amount.
- Bakeries are worried that it will have a negative health effect and on their sales..
- Bakeries are worried that it is not what consumers want in their bread and will adversely impact sales.
- It costs more in time and money to fortify bread and there is no incentive to do it, such as consumer demand for fortified products.

³⁸ *Fortification of bread with folic acid*. Access Economics, 2006, p. 10.

6.2 CONSUMER REACTION AND HEALTH IMPACTS

There are now indications that voluntary fortification of bread may be having a positive effect on blood folate status and that consumers are not deliberately avoiding bread with folic acid in any significant numbers (see Sections 5.1 and 5.2 above). However, that may be because the consumers who would otherwise avoid bread with folic acid have a wide number of non-fortified breads to choose from. It is still too early to measure longer-term effects such as a demonstrable reduction in NTDs that can be linked to the improved folate status.

Consumer reaction and consumption patterns

The research carried out by the University of Otago indicates that currently more than a quarter of women who eat bread are eating bread that bakeries claim is fortified (27%).

The study carried out by Research New Zealand highlighted the fact that almost all women in the study (97%) did not discriminate based on folic acid in food. Only 1% specifically avoided some products because of folic acid content (Appendix 3).

Health impacts

The University of Otago study results also suggest that accounting for other factors, the increase in availability of fortified bread has likely contributed to the improved blood folate levels, although the improvement cannot be statistically attributed to that increased availability. Results of the research are available in Appendix 4 and in the *Monitoring* report. The full report is available at <http://www.foodsafety.govt.nz/elibrary/industry/monitoring-fortification-of-bread-folic-acid.pdf>.

Data is not currently available to assess whether this change in blood folate levels has corresponded with a decrease in the number of NTDs.

6.3 COST OF VOLUNTARY FORTIFICATION TO INDUSTRY AND CONSUMERS

Information from the New Zealand Association of Bakers indicates that adding folic acid to bread (using a premix) adds 0.5 of a cent to the cost of a loaf of bread. Information from industry suggests that the voluntarily fortified loaves are about 12.5% of the 249 million loaves produced annually (source: New Zealand Association of Bakers).

The main costs of voluntarily fortifying are the ongoing cost of folic acid (either in the premix or added by the baker), staff training, equipment, labelling changes, and testing. In a 2006 study conducted by Access Economics these costs were estimated to be about \$4 million per year. Costs to government for monitoring and testing were estimated at around \$2 million per year. More information about these costs is available in the Interim Regulatory Impact Analysis (Appendix 6).

7 Mandatory fortification

7.1 HOW IT WOULD WORK – THE CURRENT STANDARD

If mandatory fortification goes ahead as required in the current Standard, it would work as described in this section.

Adding folic acid to bread

It would be the responsibility of each bread manufacturer to ensure that they add folic acid to bread at the correct levels. This would include everyone from small bakers to big factories. MPI does not intend that the Standard will apply to home bakers and other non-commercial bakers.

The Standard would impose start-up and ongoing costs for bread manufacturers.³⁹ Costs would be similar to those already incurred by some bakers under the voluntary initiative. Those costs include maintaining equipment, buying folic acid or premix, testing to ensure compliance, and administration.

Most packaged breads would need to have folic acid included on the label list of ingredients. While folic acid would be in most bread, ingredient labelling lets consumers know what is in their food so they can make an informed choice.

How it would be enforced

MPI would be responsible for assessing compliance with the mandatory Standard. Assessment of compliance would occur through sampling and testing bread or audits of manufacturers and/or suppliers. Testing bread would be very similar to the way Otago University checked levels of folic acid in voluntarily fortified breads. The cost of the analysis of bread in that study was about \$52 000. However, those breads were readily available packaged breads. If breads from smaller bakeries (BIANZ estimates there are 2000–3000 small bakeries) needed to be sampled and tested, the cost could be expected to be higher simply because collection of samples would be more difficult.

Bakers or retailers would need to make sure they comply with the Standard and to supply documentation that demonstrates this. Compliance checks would occur at the same time as checks on other aspects of the bakeries compliance with food regulation. Documentation might include recipes, evidence that recipes are used and staff trained, receipts proving purchase of premix or improvers with folic acid, test results, and the use of food control plans or food safety programmes.

More information on compliance and enforcement of folic acid fortification is available in a user guide on MPI's Food Safety website:

<http://foodsafety.govt.nz/industry/sectors/manufacturers-food-beverages/bakery-products/bread-with-folic-acid.htm>.

7.2 CONSUMER AND HEALTH IMPACTS

Health

The FSANZ final report contained an estimate of the effect of mandatory fortification in New Zealand. That estimate suggested there would be a reduction each year of between 4 and 14

³⁹ Ongoing costs for industry when mandatory folic acid is added at bread-making stage is estimated to be \$4 149 593 per year.

pregnancies out of 70 to 75 pregnancies affected by NTDs (that is, up to 20%).⁴⁰ The New Zealand Birth Defects Register (www.nzbdmp.ac.nz) provides recent data on the incidence of NTD affected pregnancies. Data available for 2001–2008 shows a range of 21–41 NTD-affected births per year and a simple mean of 32/year.

Table 7.1: Incidence of NTD affected pregnancies in New Zealand

Year	NTD stillbirths ⁴¹	NTD live births	Total NTD births	Rate/10 000 total births
2001	7	14	21	3.74
2002	9	16	25	4.60
2003	13	14	27	4.78
2004	20	18	38	6.49
2005	19	22	41	7.06
2006	18	20	38	6.38
2007	15	15	30	4.65
2008	11	23	34	5.24
Total	112	142	254	5.4

Note: The Registry has continuous ascertainment of cases. Data on children initially considered to have an NTD may be later removed from the database if an alternate diagnosis is made, and similarly children diagnosed with an NTD some time after birth may be added to the database. Data are accrued according to the year the child was born, whether as a live birth or foetal death. Therefore, changes to diagnoses in the present may affect NTD data recorded against preceding years. This means that if a child is born in 2006, but treated/diagnosed and reported to the New Zealand Birth Defects Register in 2010, that case is included in the 2006 birth cohort. The data above was extracted from the database in February 2012.

The benefits of reducing NTD rates include fewer people affected by pain, disability or early death; fewer terminations, miscarriages and stillbirths; lower healthcare spending, and reduction in the cost to families who may not be able to work in order to care for the person with an NTD. Other benefits would include the reduced social cost of the impact on the affected person and their family.

The next section summarises costing for these benefits and the details are available in Appendix 6.

Choice

If under the current Standard, consumers wish to eat bread that does not contain folic acid then they may be limited to buying organic bread and/or buying bread not leavened with yeast, making their own bread, or choosing types of bread that do not need to contain folic acid (pikelets, pizza bases).

Of women in the MPI-commissioned survey, 19% objected to the fact it would reduce the element of choice and 7% were concerned about unknown health impacts. Fifteen percent of women strongly agreed with mandatory fortification, 15% strongly disagreed, and 37% were neutral. However, while over half of respondents knew that folate/folic acid was needed before or during pregnancy, few understood its specific benefits.

Submissions from the consultation in 2009 (Appendix 2) indicate that consumers were worried then about mandatory fortification limiting choice.

⁴⁰ FSANZ report. This was a conservative estimate. This estimate is based on predictions for if flour is fortified at a level of 2 mg per kg.

⁴¹ We use the term “stillbirths” to aid understanding by non-medical professionals. The technically correct term is “foetal deaths”. As defined by the Births, Deaths, Marriages and Relationships Registration Act 1995, a stillborn child or foetal death is a dead foetus that weighed 400 g or more when issued from its mother, or issued from its mother after the 20th week of pregnancy.

7.3 COSTS AND BENEFITS OF FORTIFICATION TO INDUSTRY AND CONSUMERS

The Interim Regulatory Impact Analysis⁴² (RIA) provides a summary of the costs and benefits of fortification with references to the source data.

The RIA references FSANZ-commissioned research conducted by Access Economics in 2006 that established a total annual cost to industry of over \$4 million per year.⁴³ It states the cost to government of a full monitoring programme of about \$2 million over 5 years. Additional costs to government were estimated at around \$90 000/year.

The benefits are presented as the reduced economic burden per case based on data from the Access Economics report. That figure is around \$5.5 million per case “present value” over the lifetime regardless of whether the case results in a live birth, a stillbirth, or termination of pregnancy. The bulk of the economic burden of each case (\$4.2–\$4.8 million) is attributed to the value of life and suffering. The present value is calculated by discounting the costs to the year of birth. A recent report based on six patients suggests that at least some patients may require more extensive (and expensive) medical care than previously estimated and more than the average cost used by Access Economics.⁴⁴

⁴² Attached as Appendix 6.

⁴³ *Cost benefit analysis of fortifying the food supply with folic acid*. Report by Access Economics Pty Limited for Food Standards Australia New Zealand June 2006: http://www.foodstandards.gov.au/_srcfiles/FAR_P295_Folic_Acid_Fortification_Attach_11b.pdf

⁴⁴ *The costs of paediatric spina bifida inpatient treatment at Wellington Regional Hospital: A cost analysis of sequential patients*. Bowkett & Deverall, NZMJ 2012;125:1351.

8 Options for the future

8.1 OPTIONS

This section outlines options that MPI is considering as part of this consultation.

MPI has proposed four options with some possible variations within each option. MPI does not intend that the Standard will apply to home bakers and other non-commercial bakers. The options are:

1. Mandatory fortification as defined in the current Standard with the possibility of delayed or phased-in commencement
2. Limited mandatory fortification where a threshold is set before mandatory fortification applies
3. Mandatory reporting where all bakeries must report on whether they fortify their bread with folic acid and how much of their bread is fortified
4. Voluntary fortification with a mandated review in 2015

Option 1: Mandatory fortification from 30 September 2012 with or without a one-year transition period or some other modifications

- The current New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007 (as amended in 2009) could be left unchanged. All bread (except for “organic” bread and bread not leavened with yeast) would be required to have folic acid added to it from 30 September 2012.
- The current Standard could be amended to have a commencement date of 30 September 2013 to give industry more time to prepare.
- The current Standard could be amended to introduce mandatory fortification as a staged process, possibly extending over several years.

Leaving the Standard unchanged is likely to be the most effective in supporting optimal folate blood status levels in New Zealand women of childbearing age. To the extent that it succeeds in improving those levels, it is expected to make the most impact in reducing the incidence of NTDs. That reduction in NTD incidence should result in savings to the country from direct health costs and from improved contributions to the economy by children who might otherwise have been more severely handicapped.

The unchanged Standard is also likely to be the most expensive for the baking industry, which will likely pass on those costs to consumers. It will also result in the most reduction of choice for consumers. If consumers dislike the increased cost or lack of choice, they may reduce their consumption of bread. That would adversely affect the baking industry and reduce the potential positive impact of fortification. Monitoring of compliance with the Standard would be the most expensive for this option because of the number of small bakeries (2000–3000) that would be required to fortify their products.

It would make New Zealand fortification requirements different from those in either Australia or the US. This is because the New Zealand Standard applies to bread made from any cereal flour, not simply wheat flour (for bread making) as is the case in Australia. In the US, fortification of flour with folic acid is required of “enriched” (refined) flour, which includes flour for regular pasta and cornmeal (for grits) as well as flour for making bread but not wholegrain flour⁴⁵ or corn masa flour for tortillas.

⁴⁵ “Almost all refined grains are enriched ...” <http://www.ers.usda.gov/AmberWaves/June05/Features/Will2005WholeGrain.htm>
Wholegrain wheat flour constitutes less than 5% of total flour production in 2006–07 in the US.
<http://www.ers.usda.gov/amberwaves/september08/findings/wheatflour.htm>

The option to have a one-year phase-in period would permit the industry, particularly the small bakeries, to prepare for mandatory fortification. If mandatory fortification is introduced with a staged commencement over more than one year, industry and consumers would have more time to adjust and the up-front costs could be spread over a longer period. Both of these options would likely reduce the positive impacts on NTD incidence during the phase-in periods.

MPI is interested in receiving comments on the current Standard and the possible modifications we have identified.

MPI also welcomes suggestions for alternative approaches to implementing mandatory fortification that we have not identified.

Option 2: Limited mandatory fortification from 30 September 2012

- The current Standard could be amended to stipulate that all bakeries must fortify a minimum percentage (less than 100%) of their breads.
- The current Standard could be amended to require that bakeries producing over a minimum amount of bread in any year must fortify a minimum proportion of their production.

If mandatory fortification is set at a minimum of less than 100% of the current Standard – by weight or number of loaves or some other measure – consumer choice and possibly the costs to industry would be less adversely affected but again, the positive impact on the incidence of NTDs would be reduced.

If mandatory fortification is required of bakeries that produce over a certain amount of bread each year, the very small bakeries that make up possibly 5% of the industry could be excluded from the requirement. That would reduce the hardship on very small bakeries and remove the need to monitor and test many small producers.

MPI is interested in receiving comments on the current Standard and the possible modifications we have identified.

MPI also welcomes suggestions for alternative approaches to implementing limited mandatory fortification that we have not identified.

Option 3: Mandatory reporting where all bakeries must report on whether they fortify their bread with folic acid and how much of their bread is fortified

- A new standard could be issued that requires reporting by all bakeries on whether they fortify their bread and how much of their bread is fortified.
- A new standard would also need to explicitly permit voluntary fortification with folic acid to continue. This is because the ANZ Food Standards Code Standard 1.3.2 that permits fortification of food with vitamins and minerals excludes breads, except for bread that contains no wheat flour.
- A new standard could also specify record-keeping that would allow independent audits of whether and to what extent bakeries add folic acid to their bread.

Mandatory reporting would allow the public to know to what extent bakeries are contributing to the effort to reduce the incidence of NTDs. The nature of the reporting might vary depending on the impact the bakery has on the public.

Small bakeries might be required to post a notice in their retail premises informing the public of what bread they are or are not fortifying. Larger bakeries where the product is widely distributed might be required to report to a publicly accessible website so that the information is available to all their possible customers. Another constraint could be for the new standard to require mandatory record-keeping allowing for independent audits on whether and to what extent bakeries add folic acid to their bread.

It is unlikely that voluntary fortification would be as effective as 100% mandatory fortification at improving the blood folate status of women of childbearing age. However, it would preserve consumer choice and reduce the potential costs to industry and consumers.

MPI is interested in receiving comments on a possible new standard that would require mandatory reporting on folic acid fortification of bread and continue the current voluntary permissions. It might also specify record-keeping requirements and permit independent audits.

MPI also welcomes suggestions for alternative approaches to implementing voluntary fortification that we have not identified.

Option 4: Voluntary fortification (with or without a review to start in 2015)

- Bakers would continue to be allowed to add folic acid to their bread but would not be legally required to fortify bread with folic acid.
- The New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007 (as amended in 2009) would be revoked and replaced with a new standard that permits voluntary fortification. The new voluntary standard could include a clause requiring a review of the standard to start in 2015. Such a review would provide an opportunity to reconsider mandatory fortification if the voluntary regime was not proving effective.
- A new voluntary standard could permit the development of an approved Code of Practice or Guidelines that would apply to breads fortified with folic acid.

The basic voluntary option does not provide assurance that any bread will be fortified with folic acid or any assurance that breads currently voluntarily fortified will continue to be fortified with folic acid. That is unlikely to be acceptable given the known impact of NTDs on New Zealand families and our health system.

Hence the likelihood is that if a new standard is introduced making fortification with folic acid voluntary, it will need to have constraints that ensure that some minimum level of fortified breads are available. One such constraint could be a full review to start in 2015 to assess the effectiveness of the voluntary standard compared to what could be expected from mandatory fortification. It would provide an opportunity to reconsider mandatory fortification.

It is unlikely that voluntary fortification would be as effective as 100% mandatory fortification at improving the blood folate status of women of childbearing age. However, it would preserve consumer choice and reduce the potential costs to industry and consumers.

MPI is interested in receiving comments on a possible new standard that would continue the current voluntary permissions and the possible constraints we have identified to improve accountability.

MPI also welcomes suggestions for alternative approaches to implementing voluntary fortification that we have not identified.

8.2 OPTIONS NOT CONSIDERED AS PART OF THIS REVIEW

No fortification with folic acid

This review does not consider the option to revoke the permission to fortify bread with folic acid. To do that there would need to be strong evidence of adverse health effects from the consumption of folic acid. The *Monitoring* report does not indicate any demonstrable adverse effects at this time.

Such evidence would also mean reviewing the Standard that allows the fortification of many other foods with folic acid, including breakfast cereals and fruit juices.

MPI does not intend that the Standard will apply to home bakers and other non-commercial bakers.

8.3 ANALYSIS OF OPTIONS

Options were analysed based on their expected impact on blood folate status and reduction of NTDs, health effects and costs to consumers and industry.

Option 1: Mandatory fortification from 30 September 2012 as defined in the current Standard with the possibility of delayed or phased-in commencement

Advantages	Disadvantages
<ul style="list-style-type: none">• Mandatory fortification in accordance with the existing Standard is expected to result in the greatest reduction in NTDs• The current Standard is expected to result in the greatest reduction in healthcare costs• It benefits women with unplanned pregnancies or who do not know about the importance of folic acid• It provides an additional food option for people trying to get more folic acid from diet• A phased-in approach could assist industry with achieving compliance with the Standard	<ul style="list-style-type: none">• Without a transition period, there will be an immediate cost to industry• The industry, especially small bakers, is unlikely to be prepared for 30 September 2012• Any phased-in introduction would adversely affect the expected reduction in NTDs and associated healthcare costs• Reduction in consumer choice• Small increase in the price (0.5 cents/loaf) of most breads to consumers• Total cost to industry of \$1.49 million/year (249 million loaves)• Consumer concerns about the possibility of unknown adverse health effects• Mandatory fortification may be difficult and expensive to enforce

Option 2: Limited mandatory fortification where a threshold is set before mandatory fortification applies

Advantages	Disadvantages
<ul style="list-style-type: none"> • Some expected reduction in NTDs • Some expected reduction in healthcare costs • Additional food option for people trying to get more folic acid from their diet • Maintains consumer choice • Less pressure and costs for industry • Less costs passed on to consumers 	<ul style="list-style-type: none"> • Expected to be less effective than full mandatory fortification at preventing NTDs • Many smaller bakeries may not fortify any of their breads • Women most at risk may not choose to buy bread fortified with folic acid • Possible difficulty or expense in monitoring compliance with folic acid claims

Option 3: Mandatory reporting where all bakeries must report on whether they fortify their bread with folic acid and how much of their bread is fortified

Advantages	Disadvantages
<ul style="list-style-type: none"> • Some expected reduction in NTDs • Some expected reduction in healthcare costs • Additional food option for people trying to get more folic acid from their diet • Maintains consumer choice • Less pressure and costs for industry • Less costs passed on to consumers • Would permit the public to know exactly what breads are being fortified and by how much 	<ul style="list-style-type: none"> • Expected to be less effective than mandatory fortification at preventing NTDs • Many bakeries may not fortify any of their breads • Women most at risk may not choose to buy bread fortified with folic acid • Possible difficulty or expense in monitoring compliance with folic acid claims • Bakeries that voluntarily fortify their products may be disadvantaged because of higher costs compared to their competitors

Option 4: Voluntary fortification (with or without a review to start in 2015)

Advantages	Disadvantages
<ul style="list-style-type: none">• Some expected reduction in NTDs• Some expected reduction in healthcare costs• Additional food option for people trying to get more folic acid from their diet• Maintains consumer choice• Less pressure and costs for industry• Less costs passed on to consumers• More time for research and consideration• Will be able to take FSANZ review of Australian standard into account• Possibility for mandatory fortification to occur in the future	<ul style="list-style-type: none">• Many or even all bakeries may not fortify any of their breads• Expected to be less effective than mandatory fortification at preventing NTDs• If a mandatory review is not stipulated, it may not happen• Women most at risk may not choose to buy bread fortified with folic acid• Possible difficulty or expense in monitoring compliance with folic acid claims• Bakeries that voluntarily fortify their products may be disadvantaged because of higher costs compared to their competitors

Appendix 1 Folic acid fortification in other countries

Australia

Standard

Australia has had mandatory folic acid fortification of bread made with wheat flour (excluding organic bread) since 2009. Addition of folic acid occurs at the milling stage at a rate of 200–300 µg per 100 g. Australia will review the amount of folic acid added once there is monitoring data to assess the impact the standard has had.

Review of standard

The Department of Health and Ageing (DoHA) in Australia has commenced a review of how folic acid fortification has worked in practice. New Zealand hoped to use the outcome of this review to help inform decisions on fortification but the review will not be completed before a decision on the New Zealand Standard is made later this year.

This review of the Australian standard will occur in two phases. Phase one will include the impact on the Australian industry, enforcement agencies, and a literature review of the overseas experiences of other countries seeking to achieve the same public health outcomes. The final report for phase one has a proposed delivery of mid-2012.

Phase two will include an assessment of the health impacts of mandatory fortification and effectiveness of this initiative compared to non-regulatory strategies such as voluntary fortification. Phase two is proposed to be released after April 2013.

A report released in December 2011 by the Australian Institute of Health and Welfare showed the overall prevalence of NTDs decreased during the period when fortification of bread with folic acid was voluntary (1998 to 2008).⁴⁶

Early outcomes of standard

While the review has not been completed, there have been other studies that indicate that fortification in Australia may have had a positive effect on blood folate levels. One study found that in the year following the introduction of the mandatory standard there was a 77% reduction in the number of people with low serum folate levels and 85% reduction in people with low red blood cell folate levels.⁴⁷

This reduction indicates that mandatory fortification in Australia has significantly reduced the folate deficiency in women of childbearing age and across the general population. This reduction in folate deficiency should correspond with a decrease in the number of NTD-affected pregnancies. While this study indicates promising results, no strong conclusions can be drawn about the benefits of Australia's mandatory fortification until the DoHA review is completed.

⁴⁶ The full report (*Neural tube defects in Australia: prevalence before mandatory folic acid fortification*) is available at: <http://www.aihw.gov.au/publication-detail/?id=10737420864&tab=2>

⁴⁷ This study (*The impact of mandatory fortification of flour with folic acid on the blood folate levels of an Australian population*) can be found at: http://www.mja.com.au/public/issues/194_02_170111/bro10844_fm.html

United States and Canada

United States

In the US, mandatory fortification of “enriched” refined cereal grain products with folic acid began in 1998.⁴⁸ That includes pasta made with enriched (white) flour and cornmeal (for grits) but does not include wholegrain flour or corn masa flour. That latter omission is why there is now some interest in the US in fortifying corn masa flour.⁴⁹

The original decision to fortify enriched refined flour was sparked by a large study conducted by the Medical Research Council in 1991 of women who had previously had a pregnancy with an NTD. The study found that taking folic acid before and during pregnancy resulted in a 71% reduction in subsequent NTD-affected pregnancies in these women. This study, and several others conducted shortly after, convinced the Public Health Service that this was a significant health issue and they suggested food fortification as one way to approach the issue.

Outcome of US standard

Enriched flour in the US is required to be fortified with 140 µg per 100 g. Folic acid fortification in the US has helped contribute to a 36% reduction in NTDs between 1996 and 2006. The US Centers for Disease Control and Prevention estimate that this reduction in NTD pregnancies has resulted in direct savings of \$4.7 billion⁵⁰.

Canada

Following mandatory fortification with folic acid in the US, Canada also began mandatory fortification of some cereal-based foods in 1998, including the fortification of enriched white flour.⁵¹ Canada fortifies white flour at a level of 150 µg per 100 g. There is also mandatory fortification of enriched pasta and enriched cornmeal that parallels the fortification regime in the US.

Outcome of Canadian standard

Mandatory fortification in Canada has also corresponded with a reduction in the rate of NTDs. This reduction has been greatest in areas where the rates of NTDs had been the highest before mandatory fortification.

United Kingdom and Ireland

United Kingdom

The UK currently allows voluntary fortification of foods with folic acid. In 2007, the UK Food Standards Agency recommended that there should be mandatory fortification of bread or flour with folic acid. The recommendation was based on an extensive review, which considered links between folic acid and cancer and cardiovascular disease.

These recommendations are under consideration before Health Ministers are advised, in order to make sure that recommendations are based on thorough scientific evidence and there is a satisfactory balance between the benefits of mandatory fortification with folic acid and any potential risks.

⁴⁸ See: US Code of Federal Regulations Title 21 – Food and drugs: http://law.justia.com/cfr/title21/21cfr137_main_02.html

⁴⁹ Fortification of corn masa flour with folic acid in the US. Fleischman, A R; Oinuma, M; *Am J Public Health*, 2011 Aug, 101(8): 1360–4. Epub 2011 Jun 16. Available at <http://www.ncbi.nlm.nih.gov/pubmed/21680940>

⁵⁰ See <http://www.cdc.gov/ncbddd/folicacid/global.html>

⁵¹ <http://www.inspection.gc.ca/english/fssa/labeti/inform/flofare.shtml>

The UK already has mandatory fortification of flour with thiamin, calcium, iron and niacin. The latest update from the UK Food Standards Agency on the proposal to require mandatory fortification may be viewed at <http://www.food.gov.uk/news/newsarchive/2008/mar/folic>.

Ireland

Ireland decided in 2009 that mandatory fortification was not necessary due to the improved blood folate status of women of childbearing age because of their voluntary fortification initiatives. Food fortified voluntarily in Ireland includes breakfast cereals and cereal bars, fruit juice, dairy products and soups. Since 2005, there has been an increasing trend in adding folic acid to food products.

Women in Ireland now receive 30% more folic acid from their diets. This correlates with a reduction in the incidence of NTDs from between 1.0 and 1.5 per 1000 births to 0.93 per 1000 births.

This improvement meant that Ireland's Implementation Group on Folic Acid Fortification decided there would be very little further improvement made by introducing mandatory fortification. The possibility that high levels of folic acid could have adverse health effects was also a factor in this decision.⁵²

The European Union

In 2008, the European Food Safety Authority (EFSA) established an EFSA Scientific Cooperation Working Group (ESCO WG) on the "Analysis of risks and benefits of fortification of food with folic acid", with the aim of sharing experiences and concerns regarding folic acid food fortification amongst member states. The minutes of the WG meetings are available on the EFSA website.

The group held a meeting in 2008 on the subject and the report is available at <http://www.efsa.europa.eu/en/supporting/pub/2e.htm>.

In 2009, EFSA published a report by the ESCO WG. The summary of that report stated: "A range of foods are voluntarily fortified with folic acid at variable levels in most European countries. Mandatory fortification has not been introduced in any European country." The report is available at <http://www.efsa.europa.eu/en/supporting/pub/3e.htm>.

⁵² <http://www.folicacid.ie/>

Appendix 2 Outcome of consultation in 2009

The consultation documents are available from the MPI Food Safety website at <http://www.foodsafety.govt.nz/elibrary/industry/proposed-amendment-nz-folic-acid-standard/index.htm> and a summary of submissions received is available at <http://www.foodsafety.govt.nz/elibrary/industry/proposed-amendment-nz-folic-acid-standard/folic-acid-key-issues-nzfsa-response.pdf>.

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 would decrease the number of NTDs and reduce the burden on public healthcare.
- 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.
- It is inexpensive and efficient.

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.

Appendix 3 Women's knowledge and awareness of folic acid in New Zealand

Consumer awareness survey (commissioned by MPI)

MPI commissioned a survey to find out how aware women of childbearing age in New Zealand are of folic acid and its importance, and how they feel about the fortification of bread. (Note: The survey is not an indication of the knowledge or opinions of New Zealanders generally, merely those of the target group.) Research New Zealand carried out this survey in 2010 of 1000 women between the ages of 16 and 44. The full report of findings (*Awareness and knowledge of folate and folic acid in women of child-bearing age*) is available on the MPI Food Safety website: www.foodsafety.govt.nz/elibrary/industry/folate-NZ-women.pdf.

Knowledge of folate and folic acid

While 95% of women had heard of folic acid and 68% of folate, most rated their knowledge of folic acid and folate as low. Most of what women knew about folic acid and folate came from the media or through health providers during pregnancy. Just over half (54%) of respondents knew that folic acid was needed before or during pregnancy, though only 21% of respondents knew it was recommended specifically to minimise the risk of NTDs in babies.

Knowledge of sources of folate and folic acid

Most respondents (88%) knew that folic acid was available through supplements, although one third (30%) believed pregnant women could get enough folic acid or folate through food and drink alone. However, 39% of respondents could not identify any foods or drinks that contained folic acid and 25% could not identify any foods that were naturally good sources of folate.

Numbers of women who have taken folic supplements

Most women (80%) who had been, or were, pregnant took a vitamin or supplement with folic acid during pregnancy. Of these women, 41% had started taking it before they became pregnant. The vast majority (97%) of respondents were not buying or avoiding food based on its folic content.

Views on folic acid fortification

Almost as many women agreed with mandatory fortification as those that disagreed, while 36% had a neutral view. The most common reasons for agreeing with mandatory fortification were that it would make folic acid more accessible to those who need it and that women who will become, or are, pregnant would get the folic acid they need regardless of their knowledge. The most common reasons for disagreeing with mandatory fortification is that it removed the element of choice for consumers and there was concern about potentially adverse health effects.

Appendix 4 Blood folate status of women in New Zealand

This research was commissioned by MPI and carried out by the University of Otago. The full research paper (*Monitoring voluntary fortification of bread with folic acid*) is available on the MPI Food Safety website: <http://www.foodsafety.govt.nz/science-risk/project-reports/food-composition/nutrients/folic-acid.htm>. The study looked at the consumption of folic acid fortified foods and the blood folate status of 288 women in Wellington and Dunedin.

Folic acid concentration in a range of fortified breads available in the New Zealand market

A total of 17 breads fortified with folic acid were tested to see what their actual folic acid levels were (compared to the expected value of 200 µg per 100 g).

Of the 17 breads surveyed, 10 had between 100 µg and 300 µg of folic acid per 100 g portion while another two had more than 400 µg per 100 g (the highest had 452 µg). Five breads had less than 50 µg folic acid per 100 g of bread. The mean folic acid content of fortified bread was 151 µg per 100 g of bread.

Folic acid shelf life stability

Over the five- to six-day shelf life of bread, the folic acid content remains generally stable. By the end of its shelf life, white bread folic acid content has decreased by 0.4% and wholemeal bread by 9.1%.

Consumption of fortified foods

The vast majority (83%) of participants ate bread of some type. Of the women who ate bread, 73% ate bread that was not fortified. The actual number of women who ate fortified bread may be higher as many women could not recall the brand of bread they ate.

Half of women consumed a folic acid fortified table spread and 41% of women ate folic acid fortified breakfast cereal. Consumption patterns were similar in Wellington and Dunedin.

Blood folate status of women of childbearing age

More than half of women (59%) had a blood folate status that was associated with an NTD risk similar to women taking a 400 µg daily folic supplement (≥ 906 nmol/L). Blood folate concentration was lower in women in Wellington compared to those living in Dunedin.

Relation between consumption of fortified foods and blood folate

Those who ate fortified bread had higher serum folate concentration, but similar red blood cell folate. The similar red blood cell folate may be due to the group being too small to be statistically significant, as well as because some of the breads (5/17) that were thought to be fortified did not contain significant amounts of folic acid.

Those who ate fortified breakfast cereals had higher serum and red blood cell folate. There was a stronger association between eating folic acid fortified breakfast cereal and improved blood folate than there was with eating fortified bread.

Comparison with levels found before voluntary folic acid fortification of bread

Women in this survey had higher serum and red blood cell folate than women in 2008/2009 when only 26% met the ≥ 906 nmol/L level. Women also had higher blood folate levels in this survey compared to women in 1999.

Appendix 5 Resources for more information

Government organisations

- **Ministry of Health New Zealand:** <http://www.health.govt.nz/our-work/preventative-health-wellness/nutrition/folate-folic-acid>
- **Ministry for Primary Industries:** Research reports and links to other information: <http://www.foodsafety.govt.nz/science-risk/project-reports/food-composition/nutrients/folic-acid.htm>
- **Food Standards Australia New Zealand (FSANZ):**
<http://www.foodstandards.gov.au/consumerinformation/fortification/>
 - **Proposal P295 – Consideration of mandatory fortification with folic acid:**
Material relating to the FSANZ study of folic acid fortification is available at <http://www.foodstandards.gov.au/foodstandards/proposals/proposalp295considerationofmandatoryfortificationwithfolicacid/index.cfm>
- **Australian Institute of Health and Welfare** (*Neural tube defects in Australia: prevalence before mandatory folic acid fortification*): <http://www.aihw.gov.au/publication-detail/?id=10737420864&tab=2>
- **(United Kingdom) National Health Service:** <http://www.nhs.uk/Conditions/vitamins-minerals/Pages/Vitamin-B.aspx>
- **(United States) Centers for Disease Control and Prevention:** <http://www.cdc.gov/ncbddd/folicacid/index.html>

Non-governmental organisations

- **Flour Fortification Initiative:** <http://www.sph.emory.edu/wheatflour/index.php>
- **New Zealand Organisation for Rare Disorders:** <http://www.nzord.org.nz/>
- **Medical Research Council (UK):** <http://www.mrc.ac.uk/Achievementsimpact/Storiesofimpact/Folicacid/index.htm>
- **The Journal of Primary Health Care (NZ)** published two opinion pieces on the topic in their March 2010 issue – see *Back to Back*: <https://www.rnzcgp.org.nz/march-2010/>
- **The Medical Research Council (UK):** <http://www.mrc.ac.uk/Achievementsimpact/Storiesofimpact/Folicacid/index.htm>

Industry

- **New Zealand Baking Industry Research Trust:** <http://www.bakeinfo.co.nz/Facts/Nutrition/Vitamins/Folic-Acid>
- **Baking Industry Association of New Zealand:** <http://www.bianz.co.nz/industry-news/folic-acid-fortified-breads-list.html>

Appendix 6 Interim regulatory impact analysis

STATUS QUO⁵³ AND PROBLEM DEFINITION

Neural tube defects (NTDs)

NTDs affect the formation of the brain and spinal cord resulting in some of the most serious birth defects, including the conditions *anencephaly* and *spina bifida*. Anencephaly always results in death, shortly before or after birth. Spina bifida can result in paralysis, bowel and bladder control issues, and other serious complications, typically requiring many operations and ongoing healthcare support throughout life.

In 2008 (the latest year for which complete data is available) New Zealand had 64 NTD-affected pregnancies, made up of 23 live births, 11 stillbirths and 30 terminations. This was an overall rate of 9.87 cases per 10 000 total births.⁵⁴

The lifetime economic cost of a single NTD-affected pregnancy has been estimated at around \$5.5 million (see ‘Cost Benefit Analysis’ below). This includes:

- direct healthcare costs;
- disability aids and building modifications;
- lost productivity of the disabled and their carers;
- value of premature mortality and suffering;
- tax efficiency losses.

The role of folate

Consumption of folate prior to and during the first 28 days of pregnancy is known to reduce the risk of having a baby with an NTD. The Ministry of Health recommends that women planning to become pregnant take a daily supplement of folic acid (a synthetic form of folate), as it is difficult to attain an adequate level of folate from natural diet alone.

However, around 40% of pregnancies in New Zealand are unplanned⁵⁵ and some women do not know the right time to take a folic acid supplement or do not know the right amount to take. A recent survey found that about two thirds of current or expecting mothers either had not taken folic acid supplements or did not start them prior to conception.⁵⁶ This implies the need for an alternative means of boosting the folate consumption of women of childbearing age, regardless of whether or not they are planning a pregnancy.

Not all cases of NTDs are amenable to increased consumption of folate and a survey of intervention studies of mandatory fortification policies has identified evidence of a “floor effect” which may limit the impact of interventions.⁵⁷

⁵³ For the purpose of this analysis, *the status quo* refers to what has currently been implemented by industry; that is, voluntary fortification.

⁵⁴ New Zealand Birth Defects Register, data compiled by Barry Borman, Massey University.

⁵⁵ *Growing up in New Zealand – Before we are born*, University of Auckland, 2010.

⁵⁶ MPI calculation, based on Research New Zealand survey, 2010 (see Appendix 3).

⁵⁷ Heseker, H B; Mason, J B; Rosenberg, I H; Jacques, P F. Not all cases of neural-tube defect can be prevented by increasing the intake of folic acid. *British Journal of Nutrition* (2009), 102, 173–180.

Voluntary fortification

Fortification of food staples with folic acid provides a means of reducing risk for women who have not taken a course of supplementation prior to pregnancy. New Zealand therefore introduced a voluntary regime in 1996, permitting the fortification of bread, breakfast cereals, fruit juices, and other food items.

The Minister for Food Safety created a Folic Acid Working Group in 2009 to contribute to the development and assessment of information relating to fortification and to encourage the bread-making industry, in particular, to fortify more of their products.

Information provided by industry suggests that around 12.5% of current bread production is fortified and University of Otago research⁵⁸ has found that 27% of bread eaten by women had been fortified. The research also showed that blood folate levels of women were higher in 2011 than in 2008/2009, which is likely to be at least due in part to this voluntary fortification initiative.

There is no data available yet on whether the number of NTD-affected pregnancies has decreased as it will take more time before that can be reliably measured.

Problem definition

In terms of economic principles, the level of folate consumed by women of childbearing age is a free choice made by consumers, and industry responds with the supply of fortified food that consumers demand. These choices do impose some costs on other parties (an “externality”), as taxpayers will fund the majority of the direct healthcare costs for cases of NTDs. The remaining costs fall on families themselves. In theory, families should be incentivised to manage this risk by consuming an appropriate level of folate but do not appear to be doing so for a variety of informational or behavioural reasons.

Further public health intervention may be effective in reducing NTDs but this will need to be balanced against the costs and the possibility of a “floor effect” limiting the scale of impact.

OBJECTIVES

The overarching policy objective is to promote the outcome of healthier New Zealanders through a reduction in the number of pregnancies affected by NTDs. This is to be achieved through an increase in the consumption of folate by women prior to and during pregnancy.

Any standard developed under this policy should be consistent with the principles agreed by the Australia and New Zealand Food Regulation Ministerial Council. These are that mandatory fortification of the food supply should only be introduced in response to a demonstrated significant health need, and where:

- it is the most effective public health strategy to address the problem;
- it is consistent with the nutrition policies of Australia and New Zealand;
- it will not result in detrimental excesses or imbalances;
- it will deliver effective vitamins to the target population to meet the health objectives.

The standard should also be consistent with the Government Statement on Regulation.⁵⁹

⁵⁸ See Appendix 4.

⁵⁹ <http://www.treasury.govt.nz/economy/regulation/statement>

OPTIONS

There are a range of interventions that could help to decrease the prevalence of NTDs in New Zealand, although some approaches, such as promoting the use of folic acid supplements in family planning, would not address the large number of pregnancies that are unplanned. Other possible approaches include various kinds of campaigns to promote a higher consumption of natural folate in the diet and various approaches to food fortification.

The scope of the current policy review is limited to the fortification of bread. Four options for implementing fortification of bread are set out in Section 8 of this discussion paper.

Option 1: Mandatory fortification

In this option all yeast-leavened bread, except for that sold as “organic”, must be fortified at a level of between 0.8 mg and 1.8 mg folic acid per kg of bread. Within this option is the possibility of having it with or without a one-year transition period.

Option 2: Limited mandatory fortification

In this option, bakeries would only have to fortify at least a specified proportion of their output. Within this option there is the possibility that it would only apply to bakeries producing over a certain level of output.

Option 3: Mandatory reporting

In this option, fortification would be voluntary, but there would be a reporting regime making publicly transparent the extent to which a bakery has fortified their bread.

Option 4: Voluntary fortification

This option is a continuation of the effective status quo.

IMPACTS

Industry

There are three main elements of compliance cost involved. The first is a “switchover” cost – each additional product line fortified that has ingredients listed on its packaging will require a change to the labelling involving new artwork and printing plates. If sufficient transition time is not allowed for the new regulations, then some existing stocks of packaging materials would also have to be dumped. This transition time has been estimated at up to 12 months. It is our understanding that most small bakeries do not list ingredients on their packaging and so would not incur these switchover costs.

The second is the ongoing ingredient cost of the folic acid itself. This is likely to be added at the premix stage at a cost of 0.5 cents per loaf.

The third main compliance cost will be the additional quality assurance processes required to ensure that bread is being fortified to prescribed levels. Research has highlighted some

difficulties with achieving consistency. This should become less of a problem with greater experience, although may still remain a challenge for bakeries with smaller production batches. The reasonably wide range of fortification levels provided for by the Standard provides a degree of flexibility, but some batch testing will still be required on an ongoing basis.

A possible issue for the industry would be a decrease in the demand for bread by consumers who object to folic acid. While this would not affect consumer spending overall, it creates a disadvantage for the bread-making industry *vis à vis* other industries. Research on consumer awareness among women⁶⁰ found that around 1% specifically avoided food containing folic acid.

Consumers

Consumers are likely to bear the economic incidence of any costs incurred by industry. Mandatory fortification will also mean a loss of choice by those consumers who object to folic acid. Under Option 1 there will still be some non-fortified choices available (for example, organic); nevertheless, these will be significantly fewer than what was previously enjoyed. Option 2 provides a way of mitigating this problem.

Consumers also bear most of the health impacts of fortification; that is, the reduction in the prevalence of NTD-affected pregnancies; although the possibility of a “floor effect” potentially limits these benefits.

As an essential B vitamin, folate provides health benefits to the general population. There is some research quantifying some of the risk reductions associated with folate (for example, cardiovascular), but none of it is considered conclusive at this stage.⁶¹

The weight of research evidence also does not indicate an increased risk of total cancer incidence.⁶² Folic acid can also mask vitamin B12 deficiency, but it is not thought to be a risk at the level of fortification proposed.⁶³

Government

MPI will incur some costs to administer and enforce mandatory fortification. Government agencies may also undertake research to monitor the impacts of the policy.

Government health-funding agencies will benefit from a reduction in taxpayer-funded healthcare associated with NTDs.

COST BENEFIT ANALYSIS

FSANZ commissioned Access Economics in 2006 to undertake a cost benefit analysis of folic acid fortification.⁶⁴ A second report was commissioned, making a further study of industry

⁶⁰ See Appendix 3.

⁶¹ *Proposal 295 Final Assessment Report, Attachment 6 – Potential health benefits and risks of increased folic acid intake*, Food Standards Australia New Zealand (FSANZ), 2006.

⁶² *Voluntary folic acid fortification – monitoring and evaluation report*, MPI Technical Paper No: 2012/03.

⁶³ FSANZ, *op cit*.

⁶⁴ This can be downloaded as Attachment 11b from:

<http://www.foodstandards.gov.au/foodstandards/proposals/proposalp295considerationofmandatoryfortificationwithfolicacid/p295finalassessment3568.cfm>

and government costs.⁶⁵ This section summarises their methodology, assumptions and key findings. The Ministry for Primary Industries is currently working on a review and update of this analysis which will also take into account feedback from the consultation process.

Industry costs

Table A1: Industry costs	
Assumptions:	
Annual production	265 million kg
Share of production	61% plant bakeries, 39% retail bakeries
Folic acid	0.14–1.02 cents per kg
Label redesign	\$500 per retail stock keeping unit
Liability insurance	Unchanged
Switchover costs:	
Labelling	\$436 063
Packaging written off	\$500 000
Total switchover costs	\$936 000
Annual costs:	
Folic acid premix	\$1 786 818
Analytical testing	\$2 253 497
Administration	\$109 278
Total annual costs	\$4 149 593

Source: Access Economics

Government costs

This information is based on information provided to Access Economics by the former New Zealand Food Safety Authority. It does not include the full monitoring programme proposed by FSANZ, which was estimated at around \$2 million over 5 years.

Table A2: Government costs		
	Upfront	Annual
Set-up costs	\$2520	
Industry training	\$4800	\$2400
Administration		\$1320
Auditing	\$600	\$80 000
Enforcement		\$4780
Total	\$7920	\$88 500

Source: Access Economics

⁶⁵ Attachment 11a from:
<http://www.foodstandards.gov.au/foodstandards/proposals/proposalp295considerationofmandatoryfortificationwithfolicacid/p295finalassessment3568.cfm>

Benefits

The basis for calculating benefits is avoiding the economic costs associated with NTDs. Therefore, total benefits will be the number of cases prevented by the intervention multiplied by the economic burden per case. In Table A3 we have calculated the economic burden per case from data in the Access Economics report. The data is in “present value” terms, which means it is the lifetime cost of each case, discounted to the year of birth.

Table A3: Economic costs per NTD case (present value, \$2005)				
	Live births	Share of total	Stillbirths and terminations	Share of total
Healthcare	\$115 484	2%	-	0%
Aids and modifications	\$155 840	3%	-	0%
Productivity losses	\$849 495	16%	\$738 817	13%
Tax efficiency losses	\$71 460	1%	\$29 257	1%
Value of life and suffering	\$4 241 948	78%	\$4 789 602	86%
Total per case	\$5 434 227		\$5 557 677	

Source: MPI calculations based on analysis by Access Economics

As can be seen from the table, the Access Economics model values the economic costs at around \$5.5 million per case, regardless of whether or not it is a live birth. This is because most of the burden does not come from direct costs, such as healthcare and disability aids; rather, it comes from the value of life and suffering.⁶⁶ To calculate this value, a metric known as *Disability Adjusted Life Years* (DALYs) is used to combine mortality and morbidity losses of the various kinds of NTD conditions into a single index. The DALYs are then multiplied by the *Value of Statistical Life* (VSL) to produce a figure expressed in dollar terms.

The calibration of the VSL is, therefore, one of the most critical assumptions in the model. The model assumes a VSL of \$3.9 million, which is based on a survey of international literature. Access Economics describes this as a “conservative” estimate and it is comparable to values commonly used in New Zealand policy settings.⁶⁷

MPI is interested in receiving comments on the Access Economics model and any current data that would assist with updating it.

⁶⁶ This is called the “net burden of disease” in the Access Economics report.

⁶⁷ For example, *Understanding transport costs and charges phase 2 – value of statistical life: a meta analysis*, Ministry of Transport, 2009.