



Fortification of Bread with Folic Acid

Regulatory Impact Statement

ISBN No: 978-0-478-40075-5 (online)

August 2012

Contents

Page

Background	3
Problem Definition	5
Incidence of NTDs in New Zealand:	5
Cost of NTDs	6
Current blood folate status	6
Expected outcomes in the absence of any further government action	6
Objectives	7
Regulatory impact analysis	7
Options for increasing blood folate levels	7
Options for fortification of bread	8
Impacts	9
Benefits	9
Effect of Fortification on NTD cases	9
Economic burden per NTD case	10
Option 1: Mandatory fortification	10
Benefits	11
Achievement of objectives	11
Industry	11
Individuals	11
Government	11
Costs/Risks	12
Achievement of objectives	12
Industry	12
Consumers	13
Government	14
Cost Benefit Analysis	16
Consultation	17
Conclusions	18
Recommendations	20
Options 1 & 2: Mandatory	20
Option 3: Mandatory reporting	20
Option 4: Voluntary	20
Implementation	21
Monitoring, evaluation and review	21
Appendix – Cost-Benefit Analysis	23
Introduction	23

Costs of fortification	23
Benefits of fortification	24
Net Benefits	25
Sensitivity Testing	25

Regulatory Impact Statement

Fortification of Bread with Folic Acid

Agency Disclosure Statement

This Regulatory Impact Statement has been prepared by the Ministry for Primary Industries.

It provides an analysis of options for increasing the fortification of bread with folic acid in order to reduce the incidence of neural tube defect (NTD) affected pregnancies in New Zealand, and their associated economic and social costs.

The analysis is based on quantitative and qualitative cost-benefit analyses of the impact of the options on the blood folate status of the target population group and reduction of NTDs; benefits and costs to consumers, the baking industry, and government. The analysis is informed by scientific studies and modelling, and takes into account information received in submissions during consultation.

Key gaps

- Information on the incidence of NTD affected pregnancies in New Zealand since 2009, a period during which there has been increasing voluntary folic acid fortification of food products in New Zealand. Therefore it is not possible to know to what extent current interventions and strategies are addressing the problem.
- Based on the current NTD data it is impossible to answer the monitoring question for the pre- and post- fortification periods. Rates of NTD prevalence are variable year-to-year, with little discernable trend before the fortification of bread with folic acid was permitted.
- New Zealand data on terminations due to NTDs; the numbers are therefore based on extrapolation from Australian data. This data will be important to capture the breadth of NTD outcomes, but due to the nature of reporting may not be available for several years.

Key assumptions

For quantitative cost-benefit analysis – value of *Disability Adjusted Life years* (DALYs), value of a statistical life (VSL), and discount rate for calculating net present values.

Key uncertainties

- The current “size” of the NTD problem that is the target of government intervention.
- The number of NTDs that will be prevented by consumption of fortified bread.
- The extent to which mandatory fortification will result in a decrease in demand for bread (estimates range from 1% to 30%).

A particularly strong case is required before mandatory fortification is considered because it:

- must be the most effective public health strategy to address a significant public health need; and
- must not result in detrimental excesses or imbalances;
- must deliver effective vitamins to the target population to meet the health objectives
- would impose additional costs on the baking industry; and

- could affect market competition by changing the relative competitive position of bread products *vis a vis* competing products.

Julie Collins, Director of Biosecurity, Food and Animal Welfare Policy

A handwritten signature in black ink, appearing to read 'Julie Collins', with a stylized flourish at the end.

13 August, 2012

Background

The New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007 (the Standard) requires all bread baked in New Zealand (with the exception of organic and unleavened bread) to have folic acid added to it from 30 September 2012. Until then fortification is permitted, but not required (i.e. addition of folic acid is voluntary).

Consumption of adequate levels of folic acid before conception and during early pregnancy is proven to reduce the incidence of NTDs such as spina bifida. Folic acid is the synthetic form of folate, an essential B vitamin.

New Zealand and Australia agreed to a joint mandatory folic acid fortification standard under the joint Australia New Zealand Food Standards Code in 2007, as part of a strategy to reduce the incidence of neural tube defect (NTD) affected pregnancies in both countries.

Australia's mandatory standard requires the addition of folic acid to wheat flour used for making bread (except "organic" bread) and has been in place since 2009.

The New Zealand Standard, requiring fortification of bread rather than flour, was originally to due come into force in 2009, but in light of concerns expressed by consumer and industry groups, the Minister for Food Safety deferred implementation until May 2012, and committed to a review before that date of the impact of voluntary fortification and other research before making a decision on mandatory fortification.

In May 2012 the implementation of the Standard was further deferred, to 30 September 2012, to provide for a full review of recent evidence and public consultation.

Decisions must be taken before September 2012. The bread manufacturing industry is not in a position to comply with the current requirement by that date. There is insufficient lead time for making the necessary changes to processes, equipment, recipes, labels and packaging.

Unless the current Standard is changed, the majority of bread manufactured in New Zealand after 30 September 2012 will be legally non-compliant.

Policy decisions that have already been taken.

1. The addition of folic acid to a range of food products has been allowed in New Zealand since 1996.
2. The addition of folic acid to bread has been permitted since 2009.
3. Any regulatory intervention needs to be consistent with:
 - (a) Australia New Zealand Food Safety Council (ANZFSC – now the Legislative and Governance Forum on Food Regulation) Agreement.

ANZFSC has agreed principles on the mandatory fortification of the food supply, viz that it 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.

(b) Government Statement on Regulation

The Government Statement on Regulation requires that new regulation should only be introduced when it is required, reasonable, and robust. Specifically that:

- the problem cannot be adequately addressed through private arrangements and a regulatory solution is required in the public interest;
- all practical options for addressing the problem have been considered;
- the benefits of the preferred option not only exceed the costs (taking account of all relevant considerations) but will deliver the highest level of net benefit of the practical regulatory options available;
- the proposed obligations or entitlements are clear, easily understood and conform as far as possible to established legislative principles and best practice formulations; and
- implementation issues, costs and risks have been fully assessed and addressed.

The Statement also requires there to be a particularly strong case made for any regulatory proposals that are likely to:

- impose additional costs on business during the current economic recession;
- impair private property rights, market competition, or the incentives on businesses to innovate and invest; or
- override fundamental common law principles (as referenced in Chapter 3 of the Legislation Advisory Committee guidelines).

Problem Definition

INCIDENCE OF NTDS IN NEW ZEALAND:

The most recent year for which data is available on the rate of live and still births affected by neural tube defects (NTD) in New Zealand is 2009.

The incidence of NTD-affected pregnancies fluctuates from year to year. For instance, in 2008 there were 34 NTD-affected live and still births compared to 22 in 2009. Because of this fluctuation, an average of five years is used to determine the underlying rate. The average rate of live and still births affected by an NTD for the period 2005-09 was 5.3 per 10,000 births.

For the purposes of this analysis, the total number of NTD-affected pregnancies in New Zealand i.e. including the number that result in a therapeutic termination of pregnancy (TOP), needs to be considered. New Zealand does not collect reliable data on NTD-affected pregnancies that result in a termination, so it has been assumed that New Zealand has a similar rate as Australia.

Table 1: Neural Tube defects, New Zealand, 2001-2009

Year	Live births	Foetal deaths* (stillbirths)	Terminations [‡]	Total live and stillbirths	Total live births and stillbirths	Rate [†]	Total live births, stillbirths and terminations [‡]	Rate [†]
	<i>Number</i>	<i>Number</i>	<i>Number</i>	<i>Number</i>	<i>Number</i>		<i>Number</i>	
2001	14	7	30	56124	21	3.7	51	9.1
2002	16	9	36	54375	25	4.6	61	11.2
2003	14	13	39	56480	27	4.8	66	11.7
2004	18	20	55	58556	38	6.5	93	15.9
2005	22	19	59 [‡]	58105	41	7.1	100 [‡]	17.2
2006	20	18	55 [‡]	59563	38	6.4	93 [‡]	15.6
2007	15	15	43 [‡]	64503	30	4.7	73 [‡]	11.3
2008	23	11	49 [‡]	64850	34	5.2	83 [‡]	12.8
2009	13	9	32 [‡]	62907	22	3.5	54 [‡]	8.6
2005 - 2009	93	72	238[‡]	309928	165	5.3	403[‡]	12.9

Notes:

* Defined as foetal deaths of 20 weeks' or more gestation, or 400g or more birth weight

† Prevalence rates are per 10000 live births and foetal deaths

‡ Estimated number of terminations calculated based on the NTD outcome proportion published in the AIHW 2009 report "Mandatory folic acid and iodine fortification in Australia and New Zealand: Baseline report for monitoring."

Source: New Zealand Birth Defects Registry. Data extracted on 13 February 2012 by Associate Professor Barry Borman, Centre for Public Health Research (Massey University, Wellington, NZ). Data presented at Folic Acid Working Group meeting 16 February 2012.

For the period 2005-2009 the average number of **total** NTD-affected pregnancies per year was 80. This comprised 16 live births, 13 still births and an estimated 41 terminations, giving an average rate of 12.9 per 10,000 births.

COST OF NTDS

The lifetime economic cost of a single NTD-affected pregnancy is significant, estimated at around \$4.8 million (see 'Cost Benefit Analysis' Table 3 below; weighted average of live/still births and terminations). This includes:

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

CURRENT BLOOD FOLATE STATUS

A survey of the folate status of women of childbearing age throughout New Zealand was conducted in 2008/09. The survey found that 26% of women had a red blood cell folate concentration associated with a very low risk of neural tube defect.

A survey of women of childbearing age in Wellington and Dunedin was conducted in 2011. This survey found that nearly 60% of women had a red blood cell folate concentration associated with a very low risk of having an NTD-affected pregnancy. Conversely, around 40% of the women surveyed had a red blood cell folate level that does **not** confer the maximum protection against NTDs.

EXPECTED OUTCOMES IN THE ABSENCE OF ANY FURTHER GOVERNMENT ACTION

Under the existing permissions, an increasing number of food products are being (voluntarily) fortified with folic acid. In respect of bread in particular, current government policy is to work with the baking industry to encourage uptake of the permission to fortify. Current estimates are that around 17% of packaged breads are now fortified.

The results of the 2011 survey suggest that this voluntary fortification has contributed to an improvement in the serum folate status of women since 2008. It is not possible to attribute the effect to any particular food product from within the fortified group.

It is likely that the number of fortified products will continue to increase if the status quo (voluntary fortification with government/industry co-operation) is maintained.

Objectives

The policy objectives are to:

- Reduce the incidence of NTDs in New Zealand, and their associated economic and social costs, by increasing the folic acid intake of woman of childbearing age; and
- Minimise the costs of folic acid fortification, including administration and compliance costs.

Not all cases of NTDs are amenable to increased consumption of folate. It is estimated that about 30% of NTD-affected pregnancies will not be affected by any folic acid initiatives. Therefore the target rate is not zero.

Regulatory impact analysis

OPTIONS FOR INCREASING BLOOD FOLATE LEVELS

There are several options (not mutually exclusive) for increasing the folate/folic acid consumption of the target population group (women of child-bearing age):

- voluntary changes to diet to increase intake of naturally folate-rich foods;
- taking folic acid supplements;
- public education campaigns aimed at the target population, and at health professionals, to increase awareness of the need to take the above actions;
- addition of folic acid to foods likely to be consumed by the target group e.g. breakfast cereals, bread, yeast extracts, non-alcoholic beverages.

The last can be either:

- voluntarily added by food manufacturers, increasing the choice for the at-risk population of food that will meet their needs; or
- mandated by government i.e. compulsorily added to specified food products.

The most effective way to increase folic acid intake among women of child bearing age to the level required to prevent NTDs is via supplements. However, there are issues associated with relying on this approach alone:

- the optimal time to increase folic acid intake is in the three months before conception, and around 40% of pregnancies in New Zealand are unplanned.
- information/knowledge – lack of awareness about the need to increase folate intake, the right time to take a folic acid supplement, or 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 at the appropriate dose or did not start them prior to conception.

The current policy review is focussed on the option of fortifying bread with folic acid.

OPTIONS FOR FORTIFICATION OF BREAD

Four options for implementing fortification of bread with folic acid were analysed:

Option 1 Mandatory fortification of all bread.

Option 2 Limited mandatory fortification - requiring bakers to add a specified amount of folic acid to a minimum proportion of their production.

Option 3 Voluntary fortification but with mandatory reporting of what products have been fortified and to what level.

Option 4 Voluntary fortification; allowing the baking industry to decide what products to fortify and to what level (the effective status quo).

Options were analysed based on their expected impact on the blood folate status of the target population group and consequent reduction of NTDs; benefits and costs to consumers, industry, and government.

Impacts

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.

Most of the burden of NTDs falls on households through lost productivity and the value put on the avoidance of deaths or experiencing a disability. The remainder of the burden, including the majority share of the healthcare costs, falls on the government.

EFFECT OF FORTIFICATION ON NTD CASES

MPI has modelled the effect on NTD cases of fortifying bread at different levels; this is shown in the tables below. The results of the model demonstrate that the effectiveness of various proportions of fortification are non-linear and that with greater proportions of bread fortified the intervention reaches a greater proportion of the population and is more effective.

Table 2: Estimated Reduction in NTDs at various levels of fortification

Table 2a: At folic acid concentration of 135mcg/100gm						
Proportion of bread fortified		12.5%	30%	50%	70%	100%
NTDs prevented	Average	1	2	5	9	17
	Range	0 - 2	0 - 5	3 - 8	7 - 11	14 - 20
	Rate (per 10,000 births)	12.7	12.6	12.1	11.5	10.2

Table 2b: At folic acid concentration of 200 mcg/100gm						
Proportion of bread fortified		12.5%	30%	50%	70%	100%
NTDs prevented	Average	3	7	11	15	21
	Range	0 - 7	4-9	9-13	13-17	18-24
	Rate (per 10,000 births)	12.4	11.8	11.1	10.5	9.5

ECONOMIC BURDEN PER NTD CASE

The table below shows the economic burden per case. The data is in “present value” terms, which means it is the lifetime cost of each case, discounted to the year of birth.

Table 3: Economic burden per NTD case

Economic burden per NTD case				
	Live Births		Still Births/TOPs	
Value of life and suffering	1,830,000	49%	4,100,000	82%
Healthcare	150,000	4%	-	0%
Aids and Modifications	270,000	7%	-	0%
Productivity	1,330,000	36%	870,000	17%
Tax Efficiency	130,000	4%	60,000	1%
Total	\$ 3,710,000	100%	\$ 5,030,000	100%

As can be seen from the table, most of the burden does not come from direct costs, such as healthcare and disability aids; but from the value of life and suffering.

The values assumed for these factors are therefore the most critical in the model. The model assumes a “Value of Statistical Life” of \$3.7 million, which is based on a on the value calculated by the Ministry of Transport for road safety purposes¹. This value is commonly used in New Zealand policy analysis and is consistent with surveys of international literature.

OPTION 1: MANDATORY FORTIFICATION

Continue with the current Standard, which requires all yeast-leavened bread (except for that sold as “organic”) produced after 30 September 2012 to be fortified at a level of between 0.8 mg and 1.8 mg folic acid per kg of bread.

¹ For example, The Social Cost of Road Crashes and Injuries, June 2011 Update, Ministry of Transport

Benefits

ACHIEVEMENT OF OBJECTIVES

Since over 90% of all women consume bread on a regular basis, mandatory fortification of bread with folic acid would increase the consumption of folate by almost all women of childbearing age. Folic acid intake of the target group will be higher than under a voluntary regime, since:

- women of childbearing age do not always know the potential costs of under-consumption of folate (in terms of the increased risk of NTDs), so may not alter their dietary habits when planning a pregnancy; and
- pregnancies are not always planned.

This option is thus likely to achieve the greatest reduction in the risk of NTD-affected pregnancies via this medium (bread fortification).

INDUSTRY

No quantifiable benefits.

INDIVIDUALS

For the target group (women of child-bearing age), there will be a reduced risk of NTD-affected pregnancies, with a resultant reduction in the personal costs associated with such occurrences. This benefit will also accrue to a wider population group of those affected by NTD pregnancies (family members, carers).

There may also be health benefits to the general population. Some research shows possible health risk reductions associated with folate (for example, stroke, childhood cancer, breast cancer), but the results are inconclusive at this stage.

GOVERNMENT

To the extent that NTDs are reduced, there will be a reduction in the costs associated with managing the ongoing health problems of affected individuals.

Costs/Risks

ACHIEVEMENT OF OBJECTIVES

Folic acid intake via bread consumption alone is unlikely to reach the level required to prevent NTDs in all possible cases.

Some women may think that because all bread is fortified, they do not need to take any other measures to increase folic acid intake. This potential perverse incentive may affect the achievement of objectives. However, the probability of this risk is assessed to be low.

INDUSTRY

Mandatory fortification will impose costs on New Zealand bread manufacturers. The Baking Industry Research Trust² has provided estimates of the cost of adding folic acid and making necessary changes to labelling.

There are an estimated 1,165 bakery operations (92 factory based & 1,073 non-factory based) in New Zealand. Around ten large firms account for 95% of production, while the remainder is produced by 2,000-3,000 small bakeries.

1. *Manufacturing costs*

a) *Set-up costs – labelling changes*

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, with associated costs.

Industry has estimated that the cost of changing bread labels is approximately \$500 per sales unit (product line/SKU). This will affect around 700 sales units for the major manufacturers.

Each line of fortified product packaged with a nutrition information panel (large bakers only) will have to undergo initial assessment by a nutritional analyst, at a cost of \$100-600 depending on whether laboratory testing is required.

The total one-off cost to industry is estimated at \$1.0m.

If “old” packaging stock is unable to be used, for example during a phase-in period, so has to be dumped, this would increase the cost of the changeover by \$500,000.

b) *Operational costs.*

The ingredient cost of the folic acid itself. This is likely to be added at the premix stage. Industry has estimated that the cost of fortifying an individual loaf of bread is approximately 0.5c (\$0.005). Folic acid will have to be added to approximately 173,000,000 units for the major manufacturers, plus an estimated 5% to account for

² A sub-committee of the New Zealand Association of Bakers, comprising representatives of the various levy-paying sectors, including plant bakers, small bakeries, biscuit manufacturers and the flour milling industry; responsible for undertaking research projects using industry levies.

hot bread shops and other producers; a total of 180,000,000 units. At 0.5c per loaf this equates to \$900,000 per year.

2. *Compliance costs*

Bread producers would need to be able to demonstrate that they comply with the Standard. This will involve additional documentation such as recipes, evidence that recipes are used, evidence that staff have been trained in the required processes, receipts proving purchase of premix or improvers with folic acid, and the alteration of food control plans or food safety programmes.

There will be additional quality assurance processes required to ensure that bread is being fortified to prescribed levels. Research has highlighted some difficulties with achieving consistency. The reasonably wide range of fortification levels provided for by the Standard provides a degree of flexibility, but some batch testing will be required on an ongoing basis.

Compliance costs are estimated at around \$1million a year.

3. *Decrease in demand*

Mandatory fortification of all bread may result in a decrease in the demand for bread by consumers who object to folic acid. An MPI study of consumer awareness among women found that around 1% specifically avoided food containing folic acid. On current sales levels this would equate to \$5m per year. A baking industry market research survey found that 30% of respondents would move away from fortified products³. The baking industry considers that a conservative estimate of the drop in demand would be 5%, or \$25m per year.

The increased costs would also alter the competitive position of the baking industry *vis à vis* competing foods not required to be fortified (for example, to the extent that bread competes with cereals in the breakfast market).

CONSUMERS

1. *Price*

Increased manufacturing costs will be passed on to consumers through an increase in the price of bread. Since all bread manufacturers have to comply, relative competitive positions within the industry will remain unchanged and there will be no incentive not to pass on costs. It is estimated that industry is likely to pass on additional costs to consumers of \$1.8million per year, approximately 1c per loaf.

2. *Lack of choice*

Mandatory fortification will mean a loss of purchasing choice for consumers. There will still be some non-fortified choices available (for example, organic), but there will be significantly fewer choices than currently available.

3. *Health impacts*

There are some concerns about the risk of over-exposure to folic acid in young children, who have a lower upper tolerable level (UL) of folic acid (300 mcg/day for 1-3 year olds).

³ Consumer Link CATI Omnibus Survey Dec 2011/Jan 2012.

The UL in young children was derived from the impact on masking of B12 in the elderly and it is uncertain how relevant these extrapolated values are to this age group. A review is planned to update these values.

Consumer concerns include the possibility of folic acid masking vitamin B12 deficiency in older people, and that folic acid might encourage the growth of existing cancer cells. The weight of research evidence does not indicate an increased risk of total cancer incidence. Under current medical practice in New Zealand, the masking of B12 insufficiency in the elderly is considered negligible as diagnostic testing of B12 is routine practice.

GOVERNMENT

1. Additional resources required for administering legislation, monitoring and enforcing compliance, estimated at around \$100,000p.a. The latter cost may be recovered from industry, but it could be considered inequitable to do so, because industry is not the source of risk, and does not get any benefit.
2. Government agencies may also incur costs to undertake research to monitor the impacts of the policy.

Option 1a Amend the Standard to allow a one-year transition period (i.e. come into force on 1 October 2013).

Impacts:

- The benefits from expected reduction in NTDs and associated healthcare costs would be deferred by one year.
- some costs to industry would be avoided, such as dumping of packaging and inability to comply with labelling requirements due to inability of packaging industry to supply new packaging.

Option 1b Amend the Standard to allow a one-year transition period and exempt small bakers i.e. regulation would apply only to those producing over a certain level of output.

Impacts

- This would remove the cost impact on small bakers. The compliance costs of record-keeping and monitoring the addition of folic acid would be particularly onerous for this group. Also, the Commerce Commission has advised that if folic acid is added, it may be misleading to consumers to state that bread containing folic acid is “natural”, significantly affecting the selling point for many small and artisan bakers.
- It is assessed to have little effect on the achievement of objectives, as small bakers account for only a small proportion (around 5%) of the bread market, and likely an even smaller proportion of the target population group.

Option 2: Limited mandatory fortification

Bread producers would only have to fortify a specified minimum proportion of their output. The requirement would apply to large bakeries only and come into force on 1 October 2013. The base case is mandatory fortification of 50% of production.

Benefits

- Between 3 and 8 NTD cases prevented at 50% fortification.

- Maintains some consumer choice.
- Lower increase in manufacturing costs for industry.
- Lower price increase for consumers (and consumers may be able to avoid higher prices if only the price of fortified bread is increased).

Costs/Risks

- Likely to be less effective than full mandatory fortification at preventing NTDs.
- Women at risk may not choose to buy bread fortified with folic acid.
- Would be difficult and costly to enforce and monitor compliance with regulations.

Option 3 – Voluntary fortification with mandatory reporting

All bakeries must report on whether they fortify their bread with folic acid and how much of their bread is fortified.

Benefits

- Government and potentially the public would have information on what bread products are being fortified and to what level.

Costs

- Industry compliance costs associated with recording and reporting fortification.

Option 4: Voluntary fortification

Revoke the 2007 Standard and issue a new Standard, to allow folic acid fortification to continue to be voluntary. This is a continuation of the effective current situation.

Option 4a – Industry voluntary commitment to fortify at least 25% and up to 50% of bread production.

Benefits

- Between 1 and 2 NTD cases prevented per annum, if current levels of fortification are maintained.
- Option 4a – between 4 and 9 NTD cases prevented per annum, if the lower target level of fortification is met, and up to 13 if the higher level is achieved.
- Maintains consumer choice.
- Lower costs for industry; incurrence of costs is voluntary business decision.
- Lower price increase for consumers.
- Retains possibility for mandatory fortification to occur in the future.

Costs/risks

- Less effective than mandatory fortification at preventing NTDs.
- Some bakeries may not fortify any of their breads.
- Women most at risk may not choose to buy bread fortified with folic acid.

Cost Benefit Analysis

A summary of the costs and benefits of options for mandatory fortification (as compared with what has currently been achieved under voluntary fortification) is presented in the table below. A more detailed analysis is in the Appendix.

It has been assumed that the fortification achieved under Option 3 will not be materially different from the current voluntary regime, and so it has been excluded from further economic analysis.

There is a high degree of uncertainty associated with this type of analysis, particularly as most of the benefits are an intangible willingness to pay to avoid the deaths and suffering associated with disease. Therefore the numerical estimates should only be taken as broad indicators to help establish

- (a) which options have the highest net benefits; and
- (b) whether the net benefits are actually positive.

Table 4: Cost-benefit analysis

Cost-benefit analysis (\$ millions)					
	Option 1 Immediate Mandatory	Option 1a 1 year transition	Option 1b Exclude small bakers	Option 2 Limited mandatory @50%	Option 4a Industry Voluntary Target
COSTS	\$m	\$m	\$m	\$m	\$m
Incremental Upfront Costs	1.5	1.0	0.5	0.2	0.1-0.2
Incremental Costs p.a.	1.9	1.9	1.5	0.6	0.3-0.8
BENEFITS					
Incremental Benefits p.a.	79	79	71	18	21-44
NET BENEFITS					
20 years Net Present Value	1,090	1,010	920	230	270-560

All the options have positive net benefits and these increase in line with the overall volume of industry output fortified.

Option 1 has the highest net benefits because all bread output is fortified. The net benefits (NPV) of Option 1 are higher than 1a because there is no transition period, so the benefits (and ongoing costs) from fortification begin immediately.

Option 4a shows what could be achieved under the industry’s proposed voluntary target. The lower estimate indicates what industry would achieve if 25% of bread is fortified at 200 micrograms, the upper estimate is for 50% fortified at 200 micrograms.

Consultation

The issue of mandatory fortification of bread with folic acid was considered by Government in 2006 and again in 2008/09. In both these considerations there was extensive consultation with stakeholders, including industry, health professionals, and consumers.

The latest round of consultation as to whether the addition of folic acid to bread should be voluntary or mandatory was undertaken in May 2012. A Discussion Paper⁴ was released and posted on MPI website. The consultation was advertised in the 4 major daily newspapers, and more than 200 stakeholders and/or their representative groups were advised directly, including consumers, baking industry participants, government departments, health professionals, academics, groups who represent families affected by NTD pregnancies and other interested individuals.

In the 8 week consultation period, 134 submissions were received. Of those, 132 indicated a preference for an option:

- 39 supported Option 1 (mandatory fortification of all bread);
- 3 supported Option 2 (limited mandatory fortification),
- 2 supported Option 3 (mandatory reporting); and
- 88 supported Option 4 (voluntary fortification).

Overall, the submissions generally fell into two camps – those supporting mandatory fortification (health professionals and health sector groups), and those opposing it (individuals and consumer groups, baking industry firms and associations).

Reasons mentioned for supporting mandatory fortification were:

- It will achieve the maximum reduction in the number of neural tube defect affected pregnancies.
- The high percentage of unplanned pregnancies.
- The cost to the health and education systems of neural tube defects.
- The high emotional and financial costs to the affected families.
- Widespread lack of awareness of the importance of adequate folate consumption before and in the early stages of pregnancy.
- Risks to the general population are minimal.

Reasons for opposing mandatory fortification were:

- Removal of consumer choice.
- Organic and non-yeast leavened bread (those not required to be fortified) are either hard to find or more expensive.
- Objection to “mass medication” of the whole population.
- It is a disproportionate response to the problems of the few.
- Possible risks to the health of the general population.

These issues have been taken into account in the analysis of options.

⁴ The Future of Folic Acid Fortification of Bread in New Zealand. MPI Public Discussion Paper 2012/02 May 2012.

Conclusions

The option that results in the greatest reduction in the incidence of NTDs (Option 1 - mandatory fortification of all bread) produces the greatest net benefit against quantifiable costs. It is estimated that this option would result in a reduction in NTDs of between 14 and 20 cases.

When mandatory fortification of bread with folic acid was first considered, the Australian Health Minister's Advisory Council (AHMAC) determined that mandatory fortification was the most effective public health strategy and that it was consistent with the ANZFSC principles for the mandatory addition of vitamins to food.

However, there are qualitative factors to take into account in assessing whether this option should be implemented:

1. Requiring all bread to be fortified:
 - a) effectively removes consumer choice as to whether additional folic acid is consumed. Evidence from the consultation process is that there is a very strong aversion amongst the general public to "mass medication" via a basic food staple.
 - b) imposes costs on the baking industry that may be considered inequitable, since it is neither a risk exacerbator nor a beneficiary of the intervention. The imposition of costs on an industry that is already experiencing falling demand is a particular concern.⁵
2. Within the existing permissions, an increasing number of both bread and other food products are voluntarily fortified and contributing to an improvement in folate levels:
 - a) Since 2008 there has been an increase in the number of fortified products available for consumers to choose from - bread products (+19), breakfast cereal products (+37), and snack foods (+2).
 - b) Current data suggests that the folate status of women of childbearing age has increased significantly between 2008 and 2011.
3. The Government Statement on Regulation requires that regulation should not be imposed when the problem can be adequately addressed by voluntary arrangements.

The New Zealand Association of Bakers (NZAB), whose members produce around 95% of bread in New Zealand (either on their own account or under contract), has proposed that if the voluntary regime continues, they will undertake to participate in a Code of Practice (CoP) developed in conjunction with MPI to guarantee that a minimum of 25% of bread will be fortified with folic acid. Under the proposed CoP:

⁵ - The Coriolis study (*Food & Beverage Information Project 2011: Sector Stream – Processed Foods: Final Report*, October 2011) showed a 10% decrease in firms in bread manufacturing in 2010 and a loss of 480 persons employed since 2007.

- The NZ Association of Bakers July 2012 submission noted that "the bread market is in a state of decline with bread sales now lower than they have ever been despite an increase in population."

- a) each NZAB member company will fortify a minimum of 25%, by volume of their own branded breads with folic acid, at an indicative level of 200mcg/100g.
- b) NZAB will continue to work towards having a significant percentage of the packaged bread manufactured under contract to private labels fortified, at the same level. These labels account for around 25% of the NZ bread market by volume, and would bring the total volume of packaged bread fortified towards 50%.

With the higher level of fortification, the effect on NTDs of 50% voluntary fortification is greater than under the option of mandatory fortification of 70% (see table 2). Even if only 25% of bread is fortified under the voluntary initiative, net benefits are higher than those for 50% mandatory fortification (see table 4).

- 4. Evidence suggests that up to 70% of NTDs are responsive to folic acid supplementation and that there may be a limit to the number of NTDs that can be prevented through mandatory fortification. Examples from other countries with mandatory fortification of flour show that the rates of NTD-affected pregnancies have reduced to between seven and nine cases per 10,000 births.
 - a) The rate of NTD-affected pregnancies in New Zealand in 2005-09 was 12.9 per 10,000. This is likely to have declined further in the following three years, with the increase in fortified products available.
 - b) In Canada, the rate of NTDs dropped by 46% after mandatory fortification of white flour was introduced. The rate prior to fortification was 15.8 per 10,000, 10.8 during partial fortification, and 8.6 after implementation of mandatory. In Canada, because it is the flour that is fortified, there is a much wider range of fortified food products than would be the case in New Zealand.

Recommendations

Given the above considerations, on balance MPI's preferred option is to continue with voluntary fortification for the time being, with a view to re-assessing the situation when more information is available on the effectiveness of the current regime, particularly the blood folate levels of target population group; and NTD incidence.

Under this option, MPI would continue to work with the baking industry to encourage the addition of folic acid to an increased volume and range of bread and bread products, assisting in the development and implementation of an industry-agreed code of practice for folic acid fortification as proposed by NZAB.

This option would also enable the outcome of the Australian mandatory regime to be taken into account. This has only been in place since 2009 and no outcomes have yet been assessed. A FSANZ review assessing the health impacts of mandatory fortification of wheat flour in Australia and the effectiveness of this initiative compared to non-regulatory strategies such as voluntary fortification is due to be released after mid-2013.

OPTIONS 1 & 2: MANDATORY

If mandatory fortification was the preferred option:

- (a) there should be a lead-in time of one year, to allow time for the baking and packaging industries to comply. 30 Sept 2012 is not a viable or practicable implementation date; the bread manufacturing industry is not in a position to comply with the current requirement by that date. There is insufficient lead time for making the necessary changes to processes, equipment, recipes, labels and packaging. Unless the current Standard is changed, the majority of bread manufactured in New Zealand after 30 September 2012 will be legally non-compliant.
- (b) Small bakers should be exempt, as the cost of compliance for this sector would be high, compared to the benefits from "capturing" the small amount of output.

Making these adjustments does not alter the total net benefits significantly.

OPTION 3: MANDATORY REPORTING

This option is not recommended, as it does not meet the objectives. It would add costs without contributing to the achievement of the objective of reducing NTDs. There would be no incentive for the baking industry to increase the fortification of bread.

OPTION 4: VOLUNTARY

If it is decided to continue to allow the fortification of bread with folic acid on a voluntary basis, there should be a commitment by Government to monitor and review the effectiveness of this option. If industry targets in the proposed CoP are not reached, and data indicates that there is still scope for a reduction in NTDs via folic acid fortification of bread (i.e. the "floor" has not been reached), mandatory fortification could be re-considered.

Implementation

The mandatory options would be implemented by amending the current standard to

- come into effect on 1 October 2013;
- exempt small bakers from the mandatory requirement; and
- (for option 2) specify the proportion of baking industry output that must be fortified.

The voluntary option would be implemented by revoking the current Standard and issuing a new standard allowing for indefinite voluntary fortification of bread with folic acid.

Monitoring, evaluation and review

These factors will depend on the chosen option.

Under a voluntary regime, the Government may wish to monitor the level and extent of folic acid fortification being achieved by the baking industry and across other food categories.

The effectiveness of the chosen regime would also need to be reviewed, i.e.:

- blood folate status of target population group; and
- NTD incidence.

NTD data would be monitored through the Birth & Deaths register. Blood folate status would require a specific survey, similar to the one conducted in 2011.

However, it should be noted that even given new information on these factors, a review will not be able to attribute an increase in blood folate status or reduction in NTDs to bread fortification alone, since there are other factors at work – fortification is part of wider strategy that includes raising public awareness of the benefits of folic acid, health professionals getting the message across to target population group, and the increasing volume and range of other foods being fortified.

Table 5: Summary of Benefits and Costs of Options

Option1 – Full mandatory		Option 2 – Limited mandatory		Option 3 – Mandatory reporting only		Option 4 - Voluntary	
Benefits	Costs	Benefits	Costs	Benefits	Costs	Benefits	Costs
<ul style="list-style-type: none"> Between 14 and 20 NTD cases prevented per annum. Better reach to target population - will increase folic acid intake of women with unplanned pregnancies or who do not know about the importance of folic acid. 	<p>Industry</p> <ul style="list-style-type: none"> Increased costs of production: <ul style="list-style-type: none"> - One-off \$1.5m; - On-going \$1.9m p.a. Increased compliance costs \$50 -100,000 p.a. Possible decrease in demand for products: <ul style="list-style-type: none"> @1% = \$5m p.a. @5% = \$25m p.a. Reduced competitiveness <p>Consumers</p> <ul style="list-style-type: none"> Increased price @ 1c/loaf = \$1.8m p.a. Lack of choice <p>Government</p> <ul style="list-style-type: none"> Additional administration and enforcement (\$100,000/year) Adverse reaction from consumers to idea of “mass medication” of food supply. 	<p>Between 3 and 11 NTD cases prevented per annum</p>	<p>Industry</p> <ul style="list-style-type: none"> Increased costs of production. <ul style="list-style-type: none"> - One-off \$0.2m -0.4m - Ongoing \$0.6m-\$1.1m p.a. Increased compliance costs – higher than mandatory due to more complex record keeping and testing regimes. <p>Consumers</p> <ul style="list-style-type: none"> Increased price – but may be able to avoid this depending on industry pricing policies. Reduced choice (but more than under option1) <p>Government</p> <ul style="list-style-type: none"> Additional administration and enforcement – likely to be around the same as for full mandatory. 	<p>Between 1 and 2 NTD cases prevented per annum.</p> <p>Consumers Choice preserved</p>	<p>Industry Increased compliance costs</p> <p>Government Monitoring costs to ensure reporting requirements complied with.</p>	<p>Between 1 and 2 NTD cases prevented per annum.</p> <p>Industry Any increased costs will be a business decision (retain control of marketing and pricing strategies)</p> <p>Consumers Choice preserved</p>	<p>Industry -</p> <p>Consumers -</p> <p>Government Adverse reaction from health professionals and disability groups.</p>

Appendix – Cost-Benefit Analysis

INTRODUCTION

MPI has undertaken a cost-benefit analysis based on a similar analysis commissioned by Food Standards Australia New Zealand (FSANZ) in 2006 for its proposed Trans-Tasman standard to fortify breadmaking flour with folic acid. A detailed explanation of the methodology can be found in the report by Access Economics that is published on the FSANZ website.⁶

In broad terms, the net benefits of the regulatory proposal are –

Costs avoided through decreased occurrence of NTDs (the benefits) minus Costs to industry and government of mandatory fortification.

The cost-benefit analysis serves two main purposes –

1. To establish whether the options have positive net benefits, and
2. To provide a rank ordering of the options from an economic efficiency perspective.

The modelling undertaken for the analysis is considered fit for these purposes. There is a great deal of uncertainty involved in such modelling, particularly as most of the benefits are an intangible willingness to pay to avoid the deaths and suffering associated with disease. Therefore the numerical estimates should only be taken as broad indicators that help decision makers establish which options have the highest net benefits and the degree of confidence as to whether the net benefits are actually positive. It should also be noted that economic net benefits are not the sole criteria that will be used in the regulatory impact analysis.

The analysis is concerned with *incremental* (or marginal) costs and benefits. Therefore the outcomes of each policy option are compared against what has currently been achieved under voluntary fortification. It has also been assumed that the fortification achieved under Option 3 will not be materially different from the voluntary regime, and so it has been excluded from further economic analysis.

COSTS OF FORTIFICATION

Both industry and government will face costs implementing fortification, some of which will be one off costs incurred initially to set up the regime, while others will be an ongoing cost. Based on information from industry sources, the economy's annual output of bread is estimated to be 180 million loaves, of which 95% is produced by fewer than ten large firms, while the remainder is produced by 2,000-3,000 small bakeries. Around 17% of output is being fortified under the current voluntary regime.

The analysis includes the following economic costs:

Folic acid. This is the ongoing cost of the additional ingredient, which has been estimated at 0.5c per loaf.

Packaging. There will be an up front cost to changing labels for each additional product line fortified. Stocks of existing packaging will also have to be dumped if an insufficient transition period is not allowed for.

⁶ The report is Attachment 11b from the *Proposal 295 Final Assessment Report*
<http://www.foodstandards.gov.au/foodstandards/proposals/proposalp295considerationofmandatoryfortificationwithfolicacid/p295finalassessmenttr3568.cfm>

Quality Assurance. Each additional product line fortified will need to undergo some form of nutritional analysis and testing, depending on the nutritional claim made (if any) on the packaging. While MPI does not intend mandating a standard for ongoing testing, there will be some additional quality assurance measures undertaken by industry.

Administration. Most of the larger bakers are already involved in the voluntary regime and probably will not incur additional administrative costs in a mandatory regime that are material to the analysis. However if up to 3,000 small bakers are included in a mandatory regime, then this may add significant compliance costs.

Government. MPI will incur costs in administering the regime, particularly in auditing compliance. MPI will also be undertaking a monitoring programme similar to the 2011 study it commissioned from the University of Otago. MPI’s intention is to undertake this monitoring, regardless of which option is chosen, so it is not an incremental cost of mandatory fortification.

Note that a potential reduction in the demand for bread is not included in a cost-benefit analysis as it is offset by the increase in demand for other goods.

Table A1 summarises MPI’s estimates of the incremental costs of each option:

Table A1: Incremental Fortification Costs

	Option 1	Option 1a	Option 1b	Option 2	Option 4a
Incremental Upfront Costs	\$1.5m	\$1.0m	\$0.5m	\$0.2m	\$0.1-0.2m
Incremental Ongoing Costs	\$1.9m	\$1.9m	\$1.5m	\$0.6m	\$0.3-0.8m

BENEFITS OF FORTIFICATION

The basis for calculating economic benefits is that by decreasing the occurrence of NTDs, the economy avoids the costs associated with the disease. For each option analysed, this will be the number of cases prevented by the regulatory intervention multiplied by the economic burden per NTD case.

The analysis of the economic burden of NTDs includes:

Value of life and suffering. A metric known as *Disability Adjusted Life years (DALYs)* is used to calculate this value by combining mortality and morbidity losses caused by NTDs into an index number. The DALYs are then multiplied by the *Value of Statistical Life (VSL)* to express this cost in dollar terms.

Healthcare. People with spina bifida often require a number of complex surgical procedures and other health care resources during their lifetime.

Aids and modifications. These are costs associated with personal aids (mobility, continence related, orthotics) and modifications to homes and cars.

Productivity Costs. It is estimated that people with spina bifida have a 60 per cent reduced chance of employment compared to the rest of the population. In addition, the labour force participation of their carers is also affected, causing additional productivity losses.

Tax efficiency losses. The productivity losses result in lower tax receipts for the government which must be raised elsewhere. There are also additional welfare benefits paid

out because of spina bifida, which also need to be covered by additional taxation. These are both examples of ‘transfer payments’ which are not directly a net cost to the economy as they simply shift spending power from group to another. However, indirectly, taxation generates an efficiency cost because of distortions to work and other incentives.

Table A2 summarises MPI’s estimates of the average economic burden of NTD cases. These are based on Access Economics report for FSANZ.⁷ The data is in ‘present value’ terms, which means it is the lifetime cost of each case discounted to the year of birth.

Table A2: Economic burden per NTD case

	Live Births		Still Births/TOPs	
Value of life and suffering	1,830,000	49%	4,100,000	82%
Healthcare	150,000	4%	-	0%
Aids and Modifications	270,000	7%	-	0%
Productivity	1,330,000	36%	870,000	17%
Tax Efficiency	130,000	4%	60,000	1%
Total	\$ 3,710,000	100%	\$ 5,030,000	100%

MPI’s scientific modelling provides estimates of NTD reductions achieved by different levels of fortification. Table A3 summarises estimates of incremental benefits, for each year the policy is implemented:

Table A3: Incremental Fortification Benefits (per annum)

Option 1	Option 1a	Option 1b	Option 2	Option 4a
\$79 million	\$79 million	\$71 million	\$18 million	\$21-44 million

NET BENEFITS

Tables A2 and A3 clearly illustrate that costs and benefits are proportional to the level of fortification and that benefits are much higher than costs. Therefore estimates of net benefits, show substantial positive net benefits which increase with the level of fortification. This is summarised in Table A4:

Table A4: Net Benefits (\$ millions, NPV over 20 years)

Option 1	Option 1a	Option 1b	Option 2	Option 4a
1,090	1,010	920	230	270-560

SENSITIVITY TESTING

Reasonably conservative assumptions have been incorporated into all aspects of the modelling and it is quite possible that the actual level of net benefits could be substantially higher (or lower) than what has been estimated. However the purpose of the cost-benefit analysis is to rank order the options and establishing a degree of confidence that a chosen option has positive net benefits.

In this case, the rank ordering is not an issue, as the costs and benefits are clearly proportional to the level of fortification. Therefore sensitivity testing has focussed on whether reliance can be placed on the findings that the options have positive net benefits.

⁷ Cost Benefit Analysis of Fortifying the Food Supply with Folic Acid; Access Economics Pty Ltd, June 2006

The assumed value of the discount rate has a material impact on the analysis, as the benefits of avoiding an NTD extend over an entire lifetime. High discount rates imply that the burden of costs imposed on future generations can essentially be ignored. In the base case, a value of 3.5% has been used, which is the same as that used by the ACC to value their future liabilities and is also used in other health policy analysis.

The majority of the benefits derive from the willingness to pay to avoid death and suffering. There is some methodological debate over whether the same value of life can be attributed to those who do not survive pregnancy and childbirth. These are the majority of NTD cases.

Therefore a highly conservative scenario has been modelled that

1. Uses a discount rate of 8%, and
2. Excludes the value of life and suffering for still birth and TOP cases.

While this reduced benefits by more than 90% compared to the base scenario, each option still had positive net benefits. This implies that the key findings are reasonably robust to a range of assumptions.