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FIRST REVIEW REPORT

PROPOSAL P295

CONSIDERATION OF MANDATORY FORTIFICATION WITH FOLIC ACID

For Information on matters relating to this Assessment Report or the assessment process generally, please refer to http://www.foodstandards.gov.au/standardsdevelopment/

CONTENTS

SEPARATE DOCUMENT

ATTACHMENT 2 – *INFORMING A STRATEGY FOR INCREASING FOLATE LEVELS TO PREVENT NEURAL TUBE DEFECTS: A COST-EFFECTIVENESS ANALYSIS OF OPTIONS*; L SEGAL, K DALZIEL AND R KATZ, APRIL 2007

SEPARATE DOCUMENT

ATTACHMENT 3 – *MANDATORY FOLIC ACID FORTIFICATION OF BREAD-MAKING FLOUR IN AUSTRALIA*; GERARD MCMULLEN, MARCH 2007

SEPARATE DOCUMENT

ATTACHMENT 4 – MINISTERIAL COUNCIL'S POLICY GUIDELINE ON FORTIFICATION OF FOOD WITH VITAMINS AND MINERALS

ATTACHMENT 5 – ADDITIONAL INFORMATION ON THE EFFECTIVENESS AND POTENTIAL HEALTH BENEFITS AND RISKS OF INCREASING FOLIC ACID INTAKES IN THE POPULATION

ATTACHMENT 6 – IMPACT OF MANDATORY FORTIFICATION IN THE UNITED STATES OF AMERICA

ATTACHMENT 7 – DIETARY INTAKE ASSESSMENT REPORT

ATTACHMENT 8 – COMMUNICATION AND EDUCATION STRATEGY

EXECUTIVE SUMMARY

Following Ministerial advice in October 2005 that mandatory folic acid fortification is an effective public health strategy for addressing neural tube defects (NTDs), subject to clinically safety and cost effectiveness, Food Standards Australia New Zealand (FSANZ) was asked to progress mandatory fortification with folic acid as a matter of priority taking into account safety and cost effectiveness.

At Final Assessment, FSANZ proposed a variation to the *Australia New Zealand Food Standards Code* (the Code) to give effect to the direction set by the Ministerial Council.

In November 2006, the Ministerial Council requested a First Review of FSANZ's proposed variation to the Code. As part of this Review Request, FSANZ was asked to:

- review its decision on mandatory fortification due to technical and compliance issues related to the proposed food vehicle; and
- consider, and provide advice on, a range of issues including matters which fall outside FSANZ's legislative responsibilities.

In particular, FSANZ was asked to undertake a review of options for addressing NTDs to identify the most cost effective approach. While FSANZ presents the outcomes of the review of options in this First Review Report, FSANZ does not intend to comment on which option is the preferred option. This is a matter for consideration by Ministers under the terms of the policy guideline on fortification and therefore any decision to pursue mandatory fortification or an alternative strategy as the most effective strategy is one for Ministers and outside FSANZ's remit. FSANZ has however sought to provide the evidence requested in the Review Request to support any such consideration.

This Review Report addresses each issue raised in the Review Request. A summary of FSANZ's response is provided in the table that follows this Section.

In accordance with the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act), after completing a review request, the FSANZ Board is restricted to a decision to reaffirm; reaffirm with amendments; or withdraw its approval of the draft standard or variation, in this case a mandatory fortification standard. Any alternative proposed regulatory action would require FSANZ to undertake a new process. Additionally, the Board is unable to make decisions on alternative approaches unrelated to food regulation

In relation to the best means for implementing mandatory fortification, FSANZ has undertaken a comprehensive investigation of all issues raised in the Review Request and has concluded that changes should be made to the draft variation to the Code to ensure that mandatory fortification is implemented in a safe and cost effective way.

The proposed changes to the draft variations to the Code (as at Attachment 1) are as follows:

- require the mandatory addition of folic acid to wheat flour for bread-making within the prescribed range of 200 - 300 micrograms folic acid per 100 grams of flour;
- exempt wheat flour for bread-making represented as 'organic' from this requirement;
- retain the voluntary permissions for addition of folic acid to bread and cereals flours to allow for the voluntary fortification of non-wheat breads and flours; and

- consequential amendments to the mandatory thiamin standard (so to clarify that it also applies to wheat flour for bread-making); and
- a transition time of two years for implementation.

The reasons for this decision are:

- The proposed level of mandatory folic acid fortification is expected to increase average daily folic acid intakes among women aged 16-44 years by 100 µg per day and 140 µg per day, in Australia and New Zealand respectively (assuming current uptake of voluntary fortification permissions remain the same). This is in addition to the estimated 108 µg per day Australian women and 62 µg per day New Zealand women currently receive through voluntary fortification. This is expected to reduce the number of NTD-affected pregnancies by a further 14-49 (or up to 14%) in Australia and by 4-14 (or up to 20%) in New Zealand.

- We have reviewed newly available scientific evidence since Final Assessment in relation to potential risks. Based on the totality of current evidence, including overseas experience with mandatory fortification, our conclusion that the proposed level of fortification does not pose a risk to public health and safety is unchanged. However as this is an active area of research and publication, FSANZ reiterates the importance of a monitoring strategy including the need to maintain a watching brief on any scientific developments which may potentially alter the understanding of risk to public health and safety.

- While acknowledging that there will be capital and ongoing costs to industry from the implementation of mandatory fortification, revised costing estimates indicate that the costs to the milling industry are likely to be $7.9 million up-front and $1.1 million per year. These costs vary with those proposed by industry ($28.6 million up-front and $12.1 million per year); with most of the difference in costs coming from assumptions from industry on the additional capital and process changes required to ensure compliance with the standard. An independent review[1] commissioned by industry concludes that there would be *substantial additional costs* to industry, specifically in relation to meeting a prescribed range of fortification. It is expected that these costs may be passed onto consumers at some stage and will be around 0.5 to 1% of the cost of a loaf of bread in Australia using FSANZ's cost data.

- Exemption of wheat bread-making flour represented as 'organic' will allow the organic milling and bread industry to comply with fair trading legislation[2], which takes precedence over the Code.

- Consumers will be informed of the presence of folic acid through ingredient labelling, and where bread is unpackaged will be informed through other means, such as communication and education strategies. Communication and education strategies will also increase awareness of, and inform consumers about, mandatory fortification.

[1] BRI Research, *An evaluation of two reports on the proposed mandatory fortification of flour with folic acid in Australia*, April 2007.
[2] In Australia, *Trades Practices Act 1974*; In New Zealand *Fair Trading Act 1986.*

Some important points to note in relation to this decision are:

- The draft variation to the Code has been drafted such that it requires the addition of folic acid to bread-making flour in both Australia and New Zealand.

- While it is intended that the requirements apply to bread-making flour in Australia and to bread in New Zealand, it was not possible for FSANZ to draft a variation to the Code that has a common outcome (for the bread) but with different single compliance points in Australia (at the mill) and New Zealand (at the bakery). Governments of both Australia and New Zealand have been advised that the best way to achieve this is for New Zealand to seek a variation under Annex D of the *Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System* (the Treaty). New Zealand has advised that it intends, once the Review process has been finalised, to seek a variation under Annex D of the Treaty, such that the requirement will be for bread to contain folic acid.

- Given that mandatory fortification is a significant public health initiative, monitoring and review is an essential risk management strategy. FSANZ is proposing a review of the standard within three years of implementation. While responsibility for establishing and funding a monitoring system is beyond FSANZ's remit, FSANZ is of the view that a decision to proceed with mandatory fortification with folic acid must be accompanied by effective monitoring. This is particularly important with regard to any possible role of folic acid, whether added to foods or in dietary supplements, in increasing risk of human cancer and may be most effectively addressed through engagement of the NHMRC. Given the importance of monitoring, FSANZ has firmly committed to undertake monitoring of certain elements such as tracking composition and labelling changes of fortified foods; tracking changes in food consumption patterns for different demographic groups in key food categories that are likely to be fortified; updating folic acid composition of foods in the food compositional databases; and researching consumer attitudes towards fortified foods.

- Mandatory fortification is an additional strategy for reducing the incidence NTDs and other strategies will continue to be important including existing voluntary fortification and the promotion of supplement use and education for women of child-bearing age. FSANZ will collaborate with a range of organisations, including the Government Food Communicator's Group, to maximise effectiveness of available resources.

SUMMARY TABLE

MATTERS ADDRESSED IN THE FIRST REVIEW

MINISTERIAL COUNCIL ISSUE	FSANZ'S RESPONSE
A. Is not consistent with existing policy guidelines set by the Ministerial Council	
Principle 1 – Be required only in response to demonstrated significant population health need taking into account severity and prevalence	**Approach:** • The Ministerial Council has made it clear that under the terms of the policy guideline, is it a matter for Ministers to determine whether mandatory fortification is required. • FSANZ's role is to provide evidence on the severity and prevalence of NTDs to inform Minister's decisions on this principle. **Conclusion:** • NTDs are severe birth defects with considerable associated morbidity and mortality. NTDs are estimated to affect between 300-350 pregnancies in Australia per year and between 70-75 pregnancies in New Zealand. • Their estimated prevalence in Australia and New Zealand is higher than NTD rates in the US, Canada, the UK and in many European countries.
Principle 2 – Most effective public health strategy	
(i) Thorough review of all options for increasing folic acid intake in the target group to determine most cost effective option	**Approach:** • The Ministerial Council has made it clear that under the terms of the policy guideline, it is a matter for Ministers to determine whether mandatory fortification is the most effective strategy. Cost-effectiveness can be seen as an important element in determining the 'most effective strategy'. Decisions on whether to pursue mandatory fortification or an alternative strategy are for Ministers and not within FSANZ's remit. • FSANZ engaged Professor Leonie Segal (University of South Australia), to undertake a cost effectiveness analysis of strategies for reducing for addressing NTDs through increasing folic acid intake. **Conclusion:** • Professor Segal notes that: – a mix of strategies is needed to maximise NTD reductions but that the evidence is not available to determine the optimal mix; – the most effective options for increasing folic acid intakes are the promotion of supplements and mandatory fortification; – while the analysis shows that mandatory fortification is more effective than some strategies, it is less cost-effective than others as FSANZ has imposed an upper limit on the amount of folic acid to be added to flour. There are considerable differences between the costs to industry estimated by FSANZ and those estimated by industry. If the costs supplied by industry represent the true costs of mandatory fortification, the cost-effectiveness of this strategy decreases considerably. However, these costs are predicated on assumptions about on site holding and analytical requirements which may not be essential for demonstrating compliance with a mandatory standard; and

MINISTERIAL COUNCIL ISSUE	FSANZ'S RESPONSE
	– the report findings are qualified as the evidence base for all options was of poor quality and with data gaps. The evidence base for the promotion of supplements was poor and therefore uncertainty surrounds the evaluation of this option. The option of extending voluntary fortification performed well in terms of cost-effectiveness but did not have the reach of the more effective options. Promoting the consumption of folate rich foods is not particularly effective or cost-effective. • FSANZ also notes that: – an Expert Panel convened by AHMAC[3] reached different conclusions to Professor Segal on the assessment of options in relation to equity, certainty and sustainability. These aspects are difficult to quantify, however Professor Segal did attempt to provide a qualitative assessment in her report addressing these issues; – research not referenced in the Segal Report shows that promotion of folic acid supplements as a strategy appears to favour women of higher socio-economic status (SES), posing equity issues; – while the evidence base around supplement use is limited, it is possible that the taking of supplements has reached (or may reach) a ceiling among audiences where awareness of folic acid supplementation is high. If so, then the modelling in the Segal Report could be optimistic by assuming that the previous gain of 16.6% in supplementation from a base of 14.0% can be replicated from a current level of 30%[4;] and – FSANZ modelled a number of different voluntary fortification options compared to mandatory fortification and found that by fixing the level of folic acid in wheat flour for bread making or bread, the certainty of outcome of fortification in relation to folic acid intakes increased considerably compared to voluntary fortification. This specific outcome differs from the more general conclusions in the Segal Report on the performance of the different options considered in terms of equity, feasibility and certainty, where the level of certainty or confidence in the evidence considered for the voluntary and mandatory options was considered to be the same for each option.
(ii) Demonstration that mandatory fortification alone is the most effective public health strategy	**Approach:** • Under the Policy Guideline the issue of whether mandatory fortification is to be preferred over other strategies in determining the optimal mix of strategies is a decision for Ministers. **Conclusion:** • FSANZ does not consider that increased folic acid intakes can prevent all NTDs nor does FSANZ consider that mandatory fortification (or any other single strategy) can prevent all NTDs. • Evidence indicates that up to 70% of NTDs could be prevented through increased folic acid intakes during the peri-conceptional period. Voluntary fortification combined with supplement use is already estimated to have contributed to a 10% - 30% reduction in NTDs in some States in Australia.

[3] The Expert Panel, consisting Prof Fiona Stanley, Prof Creswell Eastman, Prof Jim Mann and Prof Colin Binns, prepared a report titled: *The Effectiveness of Mandatory Fortification as a public health strategy to increase nutrient intakes, with reference to iodine and folate,* for AHMAC in June 2005.

[4] The current level of correct supplementation among women of child-bearing age was calculated at 30% by Segal et al. from data provided in Conlin et al 2006.

MINISTERIAL COUNCIL ISSUE	FSANZ'S RESPONSE
	• FSANZ considers that mandatory fortification will further increase folic acid intakes and by doing so, further reduce the incidence of NTDs. FSANZ does not consider it appropriate that food be used as a vehicle for preventing all NTDs which may be responsive to folic acid.
(iii) Other food vehicles that may have been considered but dismissed for scientific and efficacy reasons	**Approach:** • FSANZ further examined potential food vehicles. **Conclusion:** • Based on the criteria of wide consumption by women of child-bearing age as well as technical feasibility; milk and milk products and bread and bread products are the most suitable food vehicles for mandatory fortification. However, due to high consumption of milk by young children relative to adults, milk products are considered less suitable than bread. Fortification of flour and foods made from flour is consistent with overseas implementation of mandatory fortification.
Principle 3 – Consistency with national nutrition policies of Australia and NZ	**Conclusion:** • The addition of folic acid to breads (even where this includes breads that are high in sugar, fat or salt) is unlikely to encourage people to eat more of these breads (as compared to other breads) or to skew their diets over a long period of time, particularly as all types of breads will be fortified. • While sweet buns and certain bread products may contain varying proportions of fat and sugar, their contribution to folic acid intake is minimal for the target population and other age groups. • Instead of limiting the types of breads that are required to be fortified with folic acid, a more practical and useful risk management approach is to apply the requirements of the nutrition and health claims framework to folic acid fortified foods, to determine which foods are permitted to carry claims about the presence of folate or any other associated health claim. This issue will be considered under Proposal P293 – Nutrition, Health and Related Claims.
Principle 4 – Will not result in excesses or imbalances	**Approach:** • FSANZ assessed the proportion exceeding Upper Levels of Intake (UL) based on proposed fortification levels; assessed literature published since Final Assessment re potential health risks to the whole population; reconvened the Folate Scientific Advisory Group to review FSANZ's assessment; contracted an external peer reviewer to review the risk assessment on cancer. **Conclusion:** • 9% of 2-3 year olds are likely to exceed the UL for their age based on the proposed levels of fortification in Australia and New Zealand. • No child approaches the fivefold margin of safety inherent in the UL so this is not considered a risk to this age group. 95th percentile intakes of folic acid were less than twice the UL for both 2-3 and 4-8 year olds, and intakes were well within the fivefold margin of safety of intake (300-1500 µg folic acid /day for 2-3 year olds, 400-2000 µg folic acid /day for 4-8 year olds). • No-one aged 70 years and over is expected to exceed the UL, which is based on possible impacts on neurological sequelae of untreated vitamin B_{12} deficiency in adults. • Based on the totality of current evidence, there is no apparent risk to public health and safety (in particular twinning, cognitive function or miscarriage) from the estimated levels of folic acid intake from mandatory fortification in addition to those already obtained from voluntary fortification.

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	However, the literature on the risks and benefits of folic acid is evolving, including in relation to human cancer, and this confirms the importance of two elements of FSANZ's risk management strategy: – the imposition of a maximum upper level levels of folic acid mandated in flour; and – monitoring - including monitoring of the literature and other scientific evidence, with the potential for engagement of the NHMRC and NZ Ministry of Health in this process.
Principle 5 – delivers effective amounts to target group to meet health objective	**Conclusion:** • Mandatory fortification of bread-making flour in Australia (200 µg/100 g flour in the final product) and bread in New Zealand (135 µg/100 g bread) is expected to reduce the number of NTD-affected pregnancies by 14-49 in Australia and by 4-14 in New Zealand. This is likely to be a conservative estimate. • The best opportunity to reduce NTDs will be through a combination of strategies. The reduction in NTDs delivered by mandatory fortification will supplement those achieved through voluntary fortification and supplement use. • In requesting that FSANZ implement mandatory fortification provided it was clinically safe and that the benefits outweighed the costs, Ministers did not articulate a minimum acceptable target for NTD reduction. Consequently, FSANZ is only advising on the additional reductions in NTD pregnancies that are expected from mandatory fortification that can be safely achieved and where benefits outweigh costs.
B. Public health and safety	
Comparisons between Australian and New Zealand dietary modelling results for children	**Conclusion:** • The main differences between the two assessments were that the New Zealand children's assessment used a single day of data only whereas the Australian assessment used a second day adjustment; the age groups were slightly different (aged 5-8 years) compared to Australia (aged 4-8 years); and the New Zealand data were weighted according to the expected proportion of Maori and Pacific children. • The use of a single day un-adjusted methodology for the New Zealand children's assessment may account for a significant proportion of the differences in results. Using the second day adjustment decreased the proportion of children aged 4-8 years exceeding the UL from 9% to 3%.
Means for handling exceedances for children	**Conclusion:** • While there are children who will exceed the UL (and currently do so under voluntary fortification), because no young child approaches the safety margin for their age group, FSANZ does not consider the proportion of children exceeding the UL poses any risk to their health.
Absence of up to date data for dietary intake and nutritional status	**Conclusion:** • Baseline concentration data for voluntarily fortified foods have been updated based on new food composition data collected in 2006. The proportion of foods within each category that were fortified was also revised. All dietary intake assessments conducted for the First Review for dietary folate, dietary folate equivalents and folic acid used these new baseline values as a starting point. • FSANZ has undertaken research to find other sources of more recent food consumption data to validate the NNS data in order to assess potential changes in bread consumption since 1995 and 1997.

MINISTERIAL COUNCIL ISSUE	FSANZ'S RESPONSE
	• Trends in sales by volume and value of bread and other food categories are tracked by use of industry publications and more recent food consumption data for individual consumers has also been available through various surveys. • FSANZ's analysis of this additional data has shown that despite changes within the whole bread category, the proportion of people reporting consuming bread (80-85%), and overall amount consumed across different age and income groups, appears to be similar now to that reported in 1995 and 1997.
C. Does not provide adequate information to enable informed choice	
Whether the Proposal prevents people from accessing adequate information to enable informed choice	**Conclusion:** • By its very nature, mandatory fortification limits consumer choice. A separate issue is whether the consumer is provided with adequate information about the fact that bread will be fortified. • Under mandatory fortification, foods containing folic acid will be required to list folic acid as an ingredient in the ingredient list (if required to be provided), but in accordance with the Ministerial Policy Guideline for mandatory fortification, there is no mandatory requirement to label a food product as fortified. • Another means by which consumers will access information about the fact that breads will be fortified with folic acid is through the proposed communication and education strategy.
Unpackaged bread does not provide consumers with information on folic acid	**Conclusion:** • Declaration of folic acid as an ingredient in unpackaged breads should not to required, for the following reasons: – this is consistent with the approach for mandatory fortification of thiamin in bread-making flour in Australia; – this is consistent with the approach in the Code for labelling of other ingredients where declaration is not required for health and safety reasons; – a written declaration of folic acid as an ingredient and not accompanied by other ingredients, for example, 'Contains folic acid'; may be interpreted as a nutrition claim, potentially causing confusion for consumers and enforcement officers; and – information that folic acid will be added to most breads will be provided by other means, as a part of the communication and education strategy.
No mechanism to inform consumers about the amount of folic acid in bread	**Conclusion:** • There should be no requirement for a mandatory declaration of folic acid in the nutrition information panel (NIP) of products fortified with folic acid because: – a declaration of folate on the nutrition information panel would not inform consumers of the amount of folic acid in the product, while a declaration of folic acid would be incorrect with regard to the total folate level of foods; – folic acid supplements will continue to be recommended for women of child-bearing age for NTD prevention; – the objective of mandatory fortification is to increase the folic acid intake of women of child-bearing age; it is not intended that women calculate their daily folic acid intake from their dietary intake;

MINISTERIAL COUNCIL ISSUE	FSANZ'S RESPONSE
	– members of the target group who wish to calculate their daily folic acid intake from dietary sources are also likely to be aware of public health messages promoting the consumption of folic acid supplements under mandatory fortification; – consumer information should be provided through a communication and education strategy about the folic acid content of fortified foods and folic acid supplement recommendations; and – mandating the declaration of folate in the NIP would impose considerable costs on the suppliers of bread, which would include calculation and analysis of bread for folate/folic acid levels and relabelling for inclusion in the NIP.
D. Is difficult to enforce or comply with in both practical and resource terms	
Reconsider folic acid fortification of bread-making flour in Australia	**Approach:** • Contracted a consultant to investigate the Australian milling industry and fortification practice and provide advice on fortification requirements for the mandatory standard. • Contracted an international fortification and milling consultant to provide expert advice on flour fortification including overseas experience with folic acid fortification. **Conclusion**: • The Standard has been redrafted to require fortification of wheat flour for bread-making. New Zealand is able to seek a variation of the joint standard under the *Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System* (the Treaty) requiring fortification of bread. • Flour milled from grains other than wheat have been excluded from mandatory fortification because of practical difficulties for industry. The standard will therefore read 'wheat flour for making bread'. • The existing mandatory standard for thiamin will be amended for consistency to 'wheat flour for making bread'. • The mandatory fortification range will be increased to 200 – 300 µg of folic acid per 100 g wheat flour for making bread to provide industry with a greater tolerance range when adding folic acid to flour.
E. Places an unreasonable cost burden on industry or consumers	
Costs to industry of complying with fortification of bread-making flour	**Approach:** • FSANZ and consultants revised the costs for Australian industry for the mandatory fortification of bread-making flour in consultation with industry. FSANZ consultants reviewed the Flour Millers Council of Australia (FMCA) report on costs estimates for mandatory fortification. **Conclusion:** • FSANZ estimates the costs of folic acid fortification for bread-making flour in Australia which includes new more accurate fortification micro-feeder equipment will be A$7.886 million up front, and A$1.059 million ongoing. • An independent report commissioned by the FMCA provides cost estimates of A$28.586 million upfront and A$12.135 million per year ongoing cost.

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	The difference in these cost estimates is largely due to industry assumptions on the degree of capital and process changes required to ensure compliance with the new Standard. For example, purpose built on-site laboratory facilities and capacity to hold all flour produced on site while analyses of folic acid levels are undertaken. Industry also commissioned an evaluation on both the FMCA and FSANZ cost estimates. This report by BRI Research concurs with the assumptions behind the costs presented by FMCA for upgrades to micro-feeders, specifically in relation to meeting a prescribed range of fortification.
Difficult and costly for jurisdictions in Australia to enforce mandatory fortification of bread at the bakery level.	**Approach:** • All Australian jurisdictions were surveyed to definitively establish the cost of enforcing the fortification of bread-making flour in Australia. **Conclusion:** • Enforcement costs in Australia were reported to be very low, with upfront costs of A$27,169 and ongoing costs of A$121,336 per year (equivalent New Zealand enforcement figures for bread are NZ$7,920 and NZ$88,500 per year).
F. Does not promote consistency between domestic and international food standards where these are at variance	
Use of the terms 'organic' and 'natural'	**Approach:** • FSANZ consulted the New Zealand Commerce Commission and the Australian Competition and Consumer Commission on the status of products labelled 'organic' and 'natural' under mandatory fortification in relation to fair trading legislation. **Conclusion:** • Under fair trading legislation mandatorily fortified foods would not be able to be labelled as 'organic' or 'all natural'. • It is proposed that foods represented as 'organic' be exempt from mandatory fortification. • Foods labelled 'natural' will not be exempt from mandatory fortification as there is no certification criteria for 'all natural' foods, and manufacturers are able to use labelling descriptors which indicate the type of product without misleading consumers.
G. Other	
Adequate monitoring must be in place with mandatory fortification	**Conclusion:** • FSANZ strongly supports the need for adequate monitoring of mandatory fortification measures. Monitoring as an important risk management strategy. • The responsibility for establishing and funding a population wide monitoring system to assess the impact of a mandatory fortification is beyond FSANZ's responsibilities and will require the concomitant involvement of health and regulatory agencies at a Commonwealth, State and Territory level in Australia and the New Zealand Government. • A FRSC Subgroup has provided a generic framework for monitoring systems for mandatory fortification programs. FSANZ will continue to work with the Subgroup to identify suitable performance indicators. This issue was referred in March 2007 by FRSC to AHMAC for decision on funding and implementation.

MINISTERIAL COUNCIL ISSUE	FSANZ'S RESPONSE
	• As part of its ongoing work, FSANZ will contribute by directly by tracking changes in the food supply for fortified/unfortified foods in key food categories: – updating the Australian national food composition databases; – tracking labelling changes on fortified foods; – tracking changes in food consumption patterns of key food categories that are likely to be fortified for different demographic groups; – regular literature reviews relating to risk/benefits of folate and folic acid in the diet; and – researching changes in consumers' attitudes and behaviour towards fortified foods.
Communication and education	**Conclusion:** • FSANZ supports the need for other strategies in addition to mandatory fortification, but acknowledges that some activities and their funding are outside FSANZ's remit e.g. comprehensive consumer education program, maintenance of voluntary fortification program and ongoing promotion of folic acid supplements for the target group. • FSANZ has developed its Communication and Education Strategy in consultation with the Government Food Communicators' Group. The Strategy aims to increase awareness among all target audiences of the proposed standard for mandatory folic acid fortification and its implementation.
Organic bread industry Organics industry will be adversely affected	**Conclusion:** • As noted above it is proposed that foods represented as 'organic' will be exempt from mandatory fortification. • Foods labelled 'natural' will not be exempt from mandatory fortification as there is no certification criteria for 'all natural' foods, and manufacturers are able to use labelling descriptors which indicate the type of product without misleading consumers.
Cost methodology Cost methodology used to estimate the cost of NTDs was questioned.	**Conclusion:** • The assessment of morbidity and mortality in terms of 'disability adjusted life years' is well established in health economics. The reduction in disability adjusted life years can be expressed in financial terms by multiplying it by the 'value of a statistical life'. This is a widely used concept in health economics.
F. Specific Recommendations	
Thorough review of options	Refer Part A of this Table.
Reconsider the vehicle and consider developing one standard that addresses two vehicles for the respective countries (bread-making flour in Australia and bread in New Zealand)	**Conclusion:** • The draft variation to the Code has been drafted such that it requires the addition of folic acid to bread-making flour in both Australia and New Zealand. While it is intended that the requirements apply to bread-making flour in Australia and to bread in New Zealand, it was not possible for FSANZ to draft a variation to the Code that has a common outcome (for the bread) but with different single compliance points in Australia (at the mill) and New Zealand (at the bakery). Governments of both Australia and New Zealand have been advised that the best way to achieve this is for New Zealand to seek a variation under Annex D of the Treaty.

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	New Zealand has advised that it intends to do this once the Review process has been finalised.
Difference between Australian and New Zealand children re dietary modelling	Refer Part B of this Table.

GLOSSARY

Bioavailability	A measure of the body's ability to extract, absorb and metabolise a nutrient expressed as a proportion of the amount in food or supplements
Dietary folate	The term used to refer to folate that is consumed via the diet, both naturally occurring and folic acid added through fortification. This term does not encompass folate consumed through supplements
Dietary Folate Equivalents (DFEs)	DFEs is a term used to accommodate the various bioavailabilities of folate. One µg DFE = 1 µg food folate = 0.5 µg of folic acid on an empty stomach = 0.6 µg of folic acid with meals.
Estimated Average Requirement (EAR)	The EAR is the daily nutrient level estimated to meet the requirements of half the healthy individuals in a particular life stage and gender group.
Folate	Folate is a water-soluble B-group vitamin. The term *folate* is used generically to refer to the various forms of the vitamin, both naturally-occurring and synthetic, and its active derivatives (Department of Health, 2000).
Folic acid	Folic acid, also referred to as pteroylmono-glutamic acid (PGA), is the most common synthetic form of folate and is the form used in fortification and in the majority of supplements. As its name indicates, folic acid contains a single glutamate moiety attached to pteroic acid (Ball, 1998). Folic acid is rarely found occurring naturally in foods (NHMRC, 1995). Other forms of folate that could be used in food fortification in future include 5-methyltetrahydrofolate (5-Ch3H4PteGlu, or L-methylfolate) and mixtures of naturally occurring forms.
Naturally-occurring Folate	A form of folate found in a wide variety of foods including green leafy vegetables, cereals, fruits, grains, legumes, yeast extract, and liver. The term naturally-occurring folate is used in this document, to differentiate it from folic acid added to food in fortification. Naturally-occurring folate generally contains more than one, typically five to seven, glutamate moieties attached to pteroic acid (polyglutamate) (Ball, 1998).
Recommended Dietary Intake (RDI)	The RDI is the average daily dietary intake level that is sufficient to meet the nutrient requirements of nearly all (97-98%) healthy individuals in a particular life stage and gender group.
Upper Level of Intake (UL)	The UL is referred to in this Report in relation to folic acid. The UL is the highest daily nutrient intake level likely to pose no adverse health effects to almost all individuals in the general population. As intake increases above the UL, the adverse potential risk of adverse effects increases.
Women of child-bearing age	For the purposes of this Report, in particular the dietary intake assessment, women of child-bearing age refers to women aged 16-44 years.

1. INTRODUCTION

In 1994, the National Health and Medical Research Council (NHMRC) estimated that neural tube defects (NTDs) could be reduced by up to two-thirds if women increased their intake of folate (from both naturally occurring sources and fortified foods)[5]. It concluded that there was sufficient evidence to recommend mandatory fortification of flour and voluntary fortification of a number of other foods including breakfast cereals, cereal flours, yeast extracts and fruit and vegetable juice.

In response to the NHMRC recommendations, voluntary fortification permissions were introduced in 1995 with the aim of reducing NTD-affected pregnancies. The view at the time was that a voluntary fortification approach was a practical first step and that after a suitable period of time, the impact should be evaluated before deciding whether mandatory fortification should be considered. Following this, in 1998, a pilot health claim around folic acid and NTDs was introduced to support the uptake of folic acid voluntary permissions by industry, and to assist in providing advice to women around folic acid in food and its role in preventing NTD-affected pregnancies.

In May 2004, the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) asked FSANZ to investigate mandatory fortification with folic acid as a possible means of reducing the incidence of NTDs, which are serious birth defects.

FSANZ released an Initial Assessment Report in October 2004 and presented four options for public comment, namely:

- maintenance of the *status quo*;
- extension of permissions for voluntary folic acid fortification;
- mandatory folic acid fortification; and
- increased health promotion and education strategies to increase folate intakes.

In December 2004, FSANZ sought advice from the Food Regulation Standing Committee (FRSC) on whether mandatory fortification is the most effective public health strategy as FSANZ considered that this issue was more appropriately addressed by FRSC and the Ministerial Council. This issue was considered by the Ministerial Council who sought advice from the Australian Health Ministers' Advisory Council (AHMAC).

An Expert Panel[6] was then convened by AHMAC to advise on the most effective public health strategy for addressing NTDs. The Expert Panel advised Health Ministers that mandatory fortification represents 'the most effective public health strategy for increasing folate intake where safety can be assured and there is a demonstrated need'.

In October 2005, Health Ministers referred this advice to the Ministerial Council, who asked FSANZ to progress mandatory fortification with folic acid as a matter of priority, taking into account safety and cost effectiveness.

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[5] NHMRC (1994). Folate fortification: Report of the expert panel on folate fortification. Commonwealth of Australia, Canberra.

[6] The Expert Panel, consisting Prof Fiona Stanley, Prof Creswell Eastman, Prof Jim Mann and Prof Colin Binns, prepared a report titled: *The Effectiveness of Mandatory Fortification as a public health strategy to increase nutrient intakes, with reference to iodine and folate,* for AHMAC in June 2005.

Subsequently, at its May 2006 meeting, the Ministerial Council agreed to amend the fortification policy guideline[7] to include the following text in relation to decisions to request that FSANZ undertake work on mandatory fortification:

> *The Australian Health Ministers Advisory Council, or with respect to a specific New Zealand health issue, an appropriate alternative body, be asked to provide advice to the Australia and New Zealand Food Regulation Ministerial Council with respect to Specific Order Policy Principles 1 and 2, prior to requesting that Food Standards Australia New Zealand raise a proposal to consider mandatory fortification.*

This paragraph clarifies that the responsibility for determining whether mandatory fortification is the most effective strategy rests not with FSANZ, but is to be referred to Health Ministers for advice.

On this basis, in July 2006, FSANZ reduced the number of regulatory options considered at Draft Assessment to maintenance of the *status quo* and mandatory folic acid fortification of bread-making flour. FSANZ drew on international experience in the selection of bread-making flour (consumed as bread and bread products) as the food vehicle for mandatory folic acid fortification in Australia and New Zealand. Following further targeted consultation and consideration, FSANZ refined the approach at Final Assessment in October 2006, to specifically require mandatory fortification of bread as the final food consumed.

In November 2006, the Ministerial Council sought a First Review of the draft variations to the *Australia New Zealand Food Standards Code* (the Code), and allowed FSANZ six months to complete the review, with a due date 7 May 2007. At the time, the Ministerial Council reinforced their commitment to reduce the number of NTDs through mandatory fortification with folic acid as quickly as possible[8].

2. OBJECTIVES OF THE REVIEW

The objective of the First Review is to reconsider the draft variations as notified to the Ministerial Council by FSANZ in October 2006 in light of the Council's concerns as outlined in Section 3.

3. GROUNDS FOR THE REVIEW

A First Review was requested on the grounds that approval of the draft variations:

- is not consistent with existing policy guidelines set by the Ministerial Council;
- does not protect public health and safety;
- does not promote consistency between domestic and international food standards where these are at variance[9];
- does not provide adequate information to enable informed choice;

[7] See Attachment 4 - *Ministerial Council's Policy Guidelines on Fortification of Food with Vitamins and Minerals.*

[8] Ministerial Council communiqué available at: http://www.foodstandards.gov.au/newsroom/mediareleases/mediareleases2006/jointcommuniquefoodm3392.cfm

[9] Refer section 5.1.14 Organic and Natural. Mandatory fortification with folic acid has implications in terms of fair trading legislation with regard to use of the terms 'organic' and 'natural'.

- is difficult to enforce or comply with in both practical or resource terms; and
- places an unreasonable cost burden on industry or consumers.

Additional comments were also provided by Ministers which related to:

- a concern that mandatory folic acid fortification will jeopardise the organic bread industry;
- the need for adequate monitoring of mandatory fortification; and
- the need for consumer communication and education.

The Review Request also made specific recommendations including that FSANZ:

- undertake a review of all options for addressing NTDs through increasing folic acid intakes, including extensions to voluntary permissions and increasing health promotion and education strategies;
- identify the lowest cost option for increasing the level of folic acid intake in the target population which would generate the greatest public health benefit and net benefit to the community; and
- consider developing a single standard which allows Australia and New Zealand to fortify their preferred food vehicle, i.e. bread-making flour in Australia and bread in New Zealand.

4. FSANZ'S APPROACH TO THE REVIEW

Since receiving the Review Request in November 2006, FSANZ has worked intensively to develop responses to the issues raised. FSANZ has also undertaken further assessment and sought external, independent, expert assistance on a number of the issues.

The Review Request does contain a number of separate issues to be addressed. Some of these appear inconsistent with other elements of the Review Request, for example, undertaking a review of options to identify the most cost effective option to address NTDs whilst being asked to reinstate mandatory fortification of bread-making flour[10] in Australia. FSANZ's approach therefore seeks to address each issue separately rather than attempt to reconcile any apparent inconsistencies.

The following is a summary of the key inputs into this process.

4.1 Options for addressing NTDs

In December 2006, FSANZ engaged Professor Leonie Segal, Chair Health Economics, Division of Health Sciences, University of South Australia[11], to assess the cost-effectiveness of a number of intervention options for reducing the incidence of NTDs. This Report titled *Informing a Strategy for Increasing Folate Levels to Prevent Neural Tube Defects: A Cost-effectiveness Analysis of Options* (see Attachment 2) was circulated for public comment and was also peer reviewed.

[10] In this paper the term bread-making flour is used interchangeably with 'flour for making bread'.
[11] Formerly of the Centre of Health Economics, Monash University, Melbourne.

4.2 Assessment of scientific literature

FSANZ thoroughly reviewed all new papers relating to the effectiveness and safety of fortification and reconvened the Folate Scientific Advisory Group[12] to review and provide feedback on the updated assessment. Discussions were also held with relevant people in the United States (US) regarding the effectiveness and safety of mandatory fortification in their country.

A leading Australian cancer epidemiologist was also engaged to review FSANZ's assessment of folate and cancer risk and the preliminary results of trials investigating colorectal adenoma[13] risk from increased folic acid intake. These preliminary results were also discussed with a representative from the United Kingdom (UK) Food Standards Agency.

4.3 Dietary intake assessments

FSANZ has reviewed its dietary intake assessments. It has updated baseline estimates of the current naturally occurring and folic acid concentrations in foods based on new food composition data collected in 2006 along with the latest market share data for fortified products. It has also expanded the number of scenarios involving extension of voluntary fortification. Results are summarised in Attachment 7.

In addition, Dr Mike DiNovi, an international expert in dietary exposure assessments from the US Food and Drug Administration, recently reviewed all FSANZ dietary intake/exposure assessment principles and modelling. The folic acid intake assessments from the Final Assessment were also peer reviewed by Dr Philippe Verger, an external international expert from the National Institute for Agricultural Research (INRA), Paris, France.

4.4 Examination of the milling industry and the practical implications of requiring the addition of folic acid to bread-making flour in Australia

An independent consultant, Gerard McMullen, of GP McMullen Consulting, was engaged in December 2006 to consult with industry on the technical and compliance issues associated with the mandatory fortification of bread-making flour in Australia (see Attachment 3). FSANZ also engaged an international consultant, Quentin Johnson,[14] to review McMullen's report and provide advice on overseas experience with mandatory folic acid fortification of flour.

[12] This group consists of clinicians and public health nutritionists with expertise in epidemiology and/or folate nutrition. See further details at website address:
http://www.foodstandards.gov.au/foodmatters/fortification/folatescientificadvi3252.cfm

[13] Colorectal adenomas (the most common type of colorectal polyp) may develop into colorectal cancer over time. It is estimated that over 50% of persons over 60 years of age have one or more colorectal adenomas

[14] QUICAN Inc. Rockwood, Canada, March 2007.

4.5 Analysis of costs

In order to identify and verify the costs of fortification at the milling stage in Australia and of bread in New Zealand, FSANZ consulted further with industry in Australia and New Zealand and sought their advice regarding these costs. Through Gerard McMullen's consultation with industry, revised cost estimates were developed.

FSANZ also reviewed a report commissioned by the Flour Millers Council of Australia (FMCA)[15] examining the technical feasibility and cost implications for the Australian milling industry. Both sets of costs were provided to Professor Segal as an input to her analysis of the cost effectiveness of options.

In addition, FSANZ received a report from BRI Research[16] who were commissioned by the Australian Food and Grocery Council (AFGC) to provide an assessment of the McMullen and FMCA (Richard Eliott) reports.

FSANZ also surveyed all Australian jurisdictions to gain information about enforcement strategies and costs.

4.6 Consultations with stakeholders

Under the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ must prepare a response to a review requested by the Ministerial Council, but is not required to undertake any consultation in the course of doing so.

However, given the importance of mandatory folic acid fortification (and the high level of stakeholder interest), FSANZ held meetings with industry and jurisdictions in early March 2007 to explain the proposed approach and receive stakeholder views. Two teleconferences were also held with public health and consumer organisations to discuss the Review and relevant issues.

An Issues Paper outlining FSANZ's preliminary findings in relation to some key aspects of the Review, and seeking further stakeholder feedback on these issues, was released in April 2007 for a two week consultation period. Due to time constraints, the Report on the Review of Options by Professor Segal was unavailable at this time, and was subsequently released two weeks later for a two week consultation period later in April 2007.

5. ISSUES ADDRESSED IN THE FIRST REVIEW

The First Review of the draft variations to the Code has been undertaken addressing the matters stated in the Ministerial Council's Review Request. This Part has been structured around the Review Request and includes FSANZ responses to each of the issues raised.

[15] Richard Eliott, Milling Consulting Service Pty Ltd, February 2007.
[16] BRI Research, *An evaluation of two reports on the proposed mandatory fortification of flour with folic acid in Australia*, April 2007.

5.1 Consistency with policy principles[17]

5.1.1 Consistency with Principle 1 – Be required only in response to demonstrated significant population health need taking into account both the severity and the prevalence of the health problem to be addressed

5.1.1.1 Issues

Comments in the Review Request noted that:

- the prevalence of NTDs in Australia is relatively low and that the impact of fortification will have a small tangible effect; and

- there are no health benefits demonstrated to other segments of the non-target population through folic acid supplementation.

It is important to note that the history of this issue makes it clear that it is not the role of FSANZ to determine whether there is a demonstrated public health need warranting mandatory fortification.

Rather, this was a matter considered by AHMAC and Health Ministers on the basis of advice from an Expert Panel that mandatory fortification represents 'the most effective public health strategy for increasing folate intake where safety can be assured and there is a demonstrated need'. This advice was referred to the Ministerial Council who in turn asked FSANZ to progress mandatory fortification with folic acid as a matter of priority, taking into account safety and cost effectiveness

FSANZ therefore does not consider that it is for FSANZ to advise on whether mandatory fortification is justified taking into account severity and prevalence. Rather, it is the role of FSANZ to provide objective evidence on the severity and prevalence of NTDs to inform the decision of Ministers. The purpose of this section of the Review Report is to do this and also to note any evidence relating to health benefits for the non-target population (as requested).

5.1.1.2 Severity and prevalence of NTDs

<u>Severity</u>

NTDs are severe congenital malformations affecting the brain and spinal cord. They often result in foetal death, death early in life, or in developmental disabilities among surviving infants and children (Lancaster and Hurst, 2001).

NTDs include spina bifida, anencephaly and encephalocoele. Spina bifida results in incomplete closure of the neural tube and can cause lack of bladder or bowel control, epilepsy and intellectual impairment as a result of the spinal nerves not being fully developed. Anencephaly results in the total or partial absence of the cranial vault and brain tissue. It is always lethal and the majority of affected pregnancies are terminated (Lancaster and Hurst, 2001). Spina bifida and anencephaly account for about 90% of all NTDs.

[17] See Attachment 4 - *Ministerial Council's Policy Guidelines on Fortification of Food with Vitamins and Minerals.*

Infants with encephalocoele are born with a gap in the skull through which part of the brain protrudes. Surgery may be required to correct the encephalocoele but other conditions may prevail such as cerebral palsy, epilepsy or poor vision.

Prevalence

The actual number of affected pregnancies is difficult to estimate accurately because of the unknown number of NTD-affected foetuses which are miscarried and the variable quality of data on elected terminations due to an NTD diagnosis. Both these issues affect estimates of the prevalence of NTD-affected pregnancies and different recording practices in various states of Australia and countries can make inter-country comparisons difficult.

In Australia, only Western Australia, South Australia and Victoria collect sufficient information on elective terminations. Extrapolating the rates from these three jurisdictions, NTDs are the most common malformation of the central nervous system (1.33/1,000 births) and their prevalence is higher than many other birth defects excluding those of Down Syndrome (2.86/1,000 births) and heart defects (3.37/1,000 births)[18].
NTDs are estimated to affect between 300-350 pregnancies in Australia per year and between 70-75 pregnancies in New Zealand.

The incidence of NTDs among Indigenous populations in Western Australia is nearly double that of the non-Indigenous population (Bower *et al*., 2004). There are no comparable data from the Northern Territory or South Australia. NTD rates in Maori and Pacific peoples in New Zealand are similar to, or slightly lower than, those of the non-Maori population (NZMoH, 2003).

Bearing in mind the limitations associated with inter-country comparisons mentioned above, NTD rates (including terminations) in Australia appear to be higher than NTD rates in comparable countries with existing mandatory fortification (Canada and the US). The Australian NTD rates are also generally higher than in the UK and in several European countries (Table 1).

Table 1: NTD rates (including terminations) in Australia compared with similar countries pre and post mandatory fortification

Country	Year mandatory folic acid fortification was introduced	Pre-fortification NTD rate per 1,000 births (Reference time period)	Post-fortification NTD rate per 1,000 births (Reference time period)	Decline in NTD rate %
Australia[1]	**na**	**1.32 (1999-03)**	**na**	**na**
United Kingdom				
England and Wales[2]	na	**0.57** (2004)	na	**na**

[18] (based on data for 2001-2004 from the Victorian Perinatal Data Collection Unit, 2006).

Country	Year mandatory folic acid fortification was introduced	Pre-fortification NTD rate per 1,000 births (Reference time period)	Post-fortification NTD rate per 1,000 births (Reference time period)	Decline in NTD rate %
Scotland[2]	na	**0.99** (2003)	na	**na**
European countries(a)[3]	na	**0.72-1.35** (1990s-03)	na	**na**
Canada	1998			
Newfoundland[4]		**4.36** (1991-97)	**0.96** (1998-01)	**78%**
Nova Scotia[5]		**2.58** (1991-97)	**1.17** (1998-00)	**54%**
Ontario[6]		**1.13**(b) (Jan 94-Dec 97)	**0.58**(b) (Jan 98-Mar 00)	**48%**
United States[7]	1998	**1.06**(b) (1995-96)	**0.76**(b) (1999-00)	**26%**

(a) Based on birth defects registers in Norway, Northern Netherlands, Germany and France. (b) NTD rates are for spina bifida and encephalocoele only. 'na' – Not applicable.

Sources:

1. Bower and de Klerk, 2005 (The Australian rate is extrapolated from the NTD rate for Victoria, South Australia and Western Australia),
2. Botto *et al*. (2006).
3. SACN (2006b)
4. Liu *et al*. (2004).
5. Persad *et al.* (2002).
6. Ray *et al*. (2002).
7. USCDC (2004).

Considerable falls in incidence have been reported in Canada and US since mandatory fortification was introduced. Better ascertainment of NTDs in Canada compared with the US is thought to be the reason contributing to the lower prevalence and smaller fall in NTD rates in the US than Canada (Mills and Signore, 2004).

5.1.1.3 Health benefits for the non target population from mandatory folic acid fortification

Potential health benefits

At Final Assessment, FSANZ reviewed several potential health benefits from increased folic acid intake to the non-target population, including reduced risk of cardiovascular disease and cancer, improved cognitive function and a potentially beneficial effect on other birth outcomes (see Attachment 6 of the Final Assessment report). The conclusion from this review, based on the totality of evidence at the time, was that additional folic acid does not reduce cardiovascular risk, the evidence for a protective effect on cancer was inconclusive, and the evidence did not support an improvement in cognitive function. The evidence for a potentially beneficial effect on birthweight or Down Syndrome was insufficient to draw any conclusions.

Papers published since Final Assessment (see Attachment 5) do not change FSANZ's earlier conclusion that increased folic acid intake does not reduce the risk of cardiovascular disease, although it may improve vascular function in people with existing cardiovascular disease. Trials examining the effects of folic acid and vitamin B_{12} on stroke incidence are still underway.

Similarly, the additional evidence does not support a reduced risk of cancer nor improved cognitive function, although one recently reported randomised controlled trial was suggestive of a protective effect on cognitive function among individuals with an elevated homocysteine status after several years of folic acid supplementation.

Based on the results from meta-analyses (including case-controls, cohort studies and randomised control trials), there is emerging evidence that folic acid supplements may reduce the risk of some non-neural tube birth defects.

Potential impact on adequacy of dietary folate intakes

In relation to folate intakes, FSANZ estimated the impact of mandatory fortification on the prevalence of inadequate dietary folate intakes (naturally occurring folate and folic acid from food but excluding supplements, expressed as dietary folate equivalents or DFEs[19]) by calculating the proportion of each population sub group falling below the Estimated Average Requirement (EAR) for folate. The increase in the EAR for folate in the 2006 Nutrient Reference Values (NRVs)[20] was based on the effect of folate on lowering homocysteine levels, which was hypothesised to reduce the risk of heart disease. At baseline, 7% of the Australian population aged 2 years and above[21]and approximately 10-11% of adults aged 30 years and above had estimated dietary folate intakes below the EAR. .

For New Zealanders aged 15 years and above[22], 50% of the population had estimated dietary folate intakes below the EAR. .

A comparison between the food composition data available for each country reveals that there are differences in naturally occurring folate concentration levels between Australian and New Zealand foods. In addition, New Zealand and Australia have different uptakes of voluntary folic acid fortification. Both of these factors may contribute to the differences between the Australian and New Zealand estimated dietary folate intakes.

Mandatory fortification of 'wheat flour for making bread' in Australia reduced the proportion of the Australian population aged 2 years and above with estimated dietary folate intakes below the EAR from 7% to 1%. Mandatory fortification of 'all bread' in New Zealand reduced the proportion of the New Zealand population aged 15 years and above with estimated dietary folate intakes below the EAR from 50% to 4%.

[19] Dietary Folate Equivalent (DFE) = (naturally occurring food folate µg) + (folic acid µg x 1.67)
[20] The NHMRC/NZMoH (2006) document *Nutrient Reference Values for Australia and New Zealand including recommended dietary intakes* is available online at http://www.nhmrc.gov.au/publications/synopses/n35syn.htm
[21] Based on the 1995 National Nutrition Survey (NNS) food consumption data and updated Dietary Folate Equivalent (DFE) concentration data that assumed current levels of voluntary fortification (weighted means)
[22] Based on 1997 NNS food consumption data and updated DFE concentration data that assumed current levels of voluntary fortification (weighted means)

5.1.2 Consistency with Principle 2 – Be required only if it is the most effective public health strategy to address the health problem

5.1.2.1 Issues

In the Review Request:

- FSANZ was asked to undertake a review of the cost effectiveness of all options for addressing NTDs through increasing folic acid intakes, including extensions to voluntary permissions and increasing health promotion and education strategies;

- it was noted that FSANZ has not demonstrated that mandatory fortification of food with folic acid is the most effective public health strategy because mandatory fortification alone is insufficient to prevent NTDs; and

- it was noted that FSANZ's Final Assessment Report does not contemplate what other food vehicles or public health strategies may have been considered and dismissed for scientific or efficacy reasons.

As detailed in the Introduction to this Review Report, it is important to note that the Final Assessment Report did not contain a review of options because FSANZ had received Ministerial advice in 2005 which stated that mandatory folic acid fortification was an effective strategy and that FSANZ was to progress mandatory fortification with folic acid as a matter of priority taking into account safety and cost effectiveness.

As was the case in 2005, it is not the role of FSANZ to determine the most effective public health strategy to address the health problem. However, as FSANZ has been specifically requested to review the cost effectiveness of options which is an important element in assessing the relative effectiveness of strategies. FSANZ has commissioned such a review to assist Ministers in their deliberative processes.

5.1.2.2 Review of options for identifying the most effective public health strategy

FSANZ commissioned Professor Leonie Segal, Chair Health Economics, Division of Health Sciences, University of South Australia[23], to undertake this review (Attachment 2). The review included options to extend voluntary permissions and increase health promotion (including the promotion of folic acid supplements) and education strategies, as well as mandatory fortification. The review provides a comprehensive summary of relevant information and data on each option.

In summary, the Segal Report concluded that:

- the quality of available data is poor and data gaps exist, which limits the analysis and means that all estimates of effectiveness are subject to uncertainty;

- there is no one option identified as being fully effective on its own; rather a combination of strategies is likely to be the most effective approach for increasing folic acid intakes.

[23] Formerly of the Centre of Health Economics, Monash University, Melbourne.

However as the quality of evidence on the effectiveness of the different strategies is poor, the optimal mix of strategies is unclear;

- both promotion of supplement use and mandatory fortification have the greatest impact on the number of NTD prevented, although mandatory fortification appears less cost effective than some interventions;

- the findings on voluntary and mandatory fortification are likely to be more certain than for the other strategies;

- voluntary fortification appears to be more cost-effective but has a smaller impact on the number of NTDs prevented; and

- dietary interventions to increase naturally-occurring folate intake have limited effectiveness in reducing NTDs.

Professor Segal also noted an alternative approach may be to reintroduce nutrients into food staples in as natural a form as possible thereby incorporating a range of 'missing' nutrients. An example provided is of aleurone flour, a rich source of natural folate and other nutrients, which has yet to be fully explored at a population level.

Additional information on this issue

Whilst FSANZ does not intend to comment on which option or mix of options should be the preferred option (noting that this is a matter for consideration by Ministers), FSANZ considers that the following matters are also relevant to Ministers in the context of considering the options for addressing NTDs:

- **Views of AHMAC Expert Panel** - An Expert Panel convened by AHMAC reached different conclusions to Segal on some of the more qualitative matters relevant to the assessment of options such as equity, certainty and sustainability. This difference of option is presented in Table 2 below (from the Segal Report in Table 7).and Table 3 (adapted from page 11 of the Expert Panel Report[24]) overpage.

Table 2: Performance of Options –Other criteria (from the Segal Report)

	Equity	Feasibility/ sustainability	Certainty/confidence in estimates
Supplement use			
• health promotion campaign	#	#	#
• target minority young women	# # #	#	#
• physician advice	# #	#	#
Extended voluntary	#	# #	# #
Mandatory	#	# #	# #
Dietary folate	#	#	#

[24] Report entitled *The effectiveness of mandatory fortification as a public health strategy to increase nutrient intakes, with reference to iodine and folate* June 2005:

• targeted campaign- natural folate			
• targeted campaign natural + fortified	##	#	#
• National health promotion campaign-natural	#	#	#
• National health promotion campaign-natural + fortified	#	#	#

Note, # the more hatches the better.

Table 3: Assessment of potential public health strategies to increase folate intake (from the AHMAC Expert Panel Report)

	Mandatory Fortification	Voluntary Fortification	Supplements	Dietary Education	Maintaining Status quo
Effectiveness	✓	✓	× (required in early pregnancy but large % unplanned)	×	×
Equity	✓	×	×	×	na
Efficiency	✓	× (ongoing implementation costs)	?	×	na
Certainty	✓	×	✓ (although supplements vary in dose)	×	na
Feasibility	✓	✓	✓	✓	na
Sustainability	✓	×	×	×	na

Note: ✓ method achieves criterion , × method does not achieve criterion, and 'na' not applicable

- **Additional studies not referenced in Segal Report re equity** – Research shows that efforts to promote folic acid supplement use to women of childbearing age, such as large scale health promotion campaigns aimed at changing individual behaviour, encounter a number of issues pertaining to equity. This is because, in general, awareness, knowledge, and folic acid supplement use is positively correlated with higher socio-economic status (SES), as indicated by higher levels of education, and type of health insurance[25]. de Walle et al (1999) and van der Pal-de Bruin (2003) also demonstrate that differences between awareness and folic acid use among women of different SES was not able to be reduced by campaigns of differing magnitude (i.e. national and local scale).

- **Possible 'ceiling effects'** - It is possible that the taking of supplements may reach a ceiling among audiences where awareness of folic acid supplementation is high. This effect has been found in other public health campaigns targeting voluntary behaviour change (e.g. Jeffrey et al. 1995).

[25] Bower et al., 2005; de Walle et al., 1999; McDonnell et al., 1999; van der Pal-de Bruin, 2003.

For example, while women's awareness of the folate-spina bifida link has grown in response to promotion campaigns in Western Australia over 1993-95, the proportion of women who indicated an intention to take folic acid supplementation remained relatively stable over the same period. National data covering a ten year period in the United States shows that the level of folic acid supplementation has remained stable at about 33% (Lindsay et al. 2005).

This information may tend to suggest that the modelling in the Segal Report could be optimistic by assuming that the previous gain of 16.6% in supplementation from a base of 14.0% can be replicated from a current level of 30%[26]. However, given the limited evidence on the effectiveness of supplement promotion, it is not possible to draw firm conclusions either way.

- **FSANZ assessment of the certainty of outcome** - In order to ensure that a range of food vehicles and strategies were considered as part of the review of options, FSANZ examined expanded voluntary fortification options. Discussions with the food industry resulted in two new extended voluntary permission scenarios being developed involving higher levels of uptake of permissions across a broader range of food groups, in addition to that previously proposed by the industry and presented at FAR..

  Mean estimated folic acid intakes based on the market share[27]models for each scenario were higher for the *Mandatory Fortification* scenario (>200 µg/day) than for all of the voluntary fortification scenarios (*Lower*, *Moderate* and *Higher*[28]*)* (<160 µg/day). Estimated folic acid intakes from voluntary permissions increased, as expected, as the level of uptake of permissions increased, and the number of foods with permissions increased.

  Predicted folic acid intakes were more uncertain for voluntary fortification scenarios (*Lower*, *Moderate* and *Higher*) than mandatory fortification scenarios. The differences in potential ranges of intakes between *Baseline* and *Mandatory Fortification* scenarios and between *Mandatory Fortification* and voluntary (*Lower*, *Moderate* and *Higher*) scenarios indicate that bread and bread products make a significant contribution to total folic acid intakes.

  By mandating the level of folic acid in wheat flour for bread making or bread, the choice for consumers is limited for that one type of food but the certainty of outcome of fortification in relation to folic acid intakes increases considerably. This specific outcome differs from the more general conclusions in the Segal Report on the performance of the different options considered in terms of equity, feasibility and certainty (Table 2), where the level of certainty or confidence in the evidence considered for the voluntary and mandatory options was considered to be the same for each option.

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[26] The current level of correct supplementation among women of child-bearing age was calculated at 30% by Segal et al. from data provided in Conlin et al 2006.

[27] The 'market share' model aims to represent folic acid/ folate intakes for the **average consumer** i.e. reflects the typical patterns of dietary intakes over time for a whole population or population sub-group. Weighted mean folic acid concentration levels were assigned to each food to reflect the current or predicted market share for fortified and unfortified products within each food category.

[28] The three voluntary scenarios were all extensions of the current uptake of voluntary folic acid permissions (*'Baseline'*). Dietary intake estimates were calculated for lower, moderate and higher extensions where: *'Lower'* was a limited increase in uptake as proposed by industry at FAR; *'Moderate'* was the expected uptake as now agreed with industry; and *'Higher'* was the top end of expected uptake from the new industry proposal.

5.1.2.3 Whether fortification alone is sufficient to prevent NTDs

As FSANZ has noted in the Final Assessment Report, FSANZ does not consider that increased folic acid intakes can prevent all NTDs nor does FSANZ consider that mandatory fortification (or any other single strategy) can prevent all NTDs.

Evidence from supplement trials in the early 1990s indicated that up to 70% of NTDs could be prevented through increased folic acid intakes during the peri-conceptional period. Voluntary fortification combined with supplement use is already estimated to have contributed to a 10% - 30% reduction in NTDs in some States in Australia[29].

FSANZ's assessment of the likely effectiveness of mandatory fortification is detailed in section 5.1.5. In summary, FSANZ considers that mandatory fortification will further increase folic acid intakes and by doing so, further reduce the incidence of NTDs. Under the Policy Guideline the issue of whether mandatory fortification is to be preferred over other strategies in determining the optimal mix of strategies is a decision for Ministers.

5.1.2.4 Other food vehicles or public health strategies considered and dismissed for scientific or efficacy reasons

Other public health strategies are covered in the Segal Report, this section focuses on other food vehicles considered by FSANZ.

At the start of the proposal to consider mandatory fortification with folic acid, FSANZ considered suitable food vehicles for fortification, the criteria being that the food had to be regularly and consistently consumed by a large proportion of the target group in all socio-economic groups and that it was technically feasible to fortify the food. Foods considered as potential food vehicles included milks (full and reduced fat), fruit juices, breakfast cereals, yoghurts and soy beverage as well as bread and bread products. Milk and milk products and bread and bread products best met the initial criteria (See Attachment 7).

On further investigation of the NNS data and overseas experience, flour for bread making purposes and bread were considered suitable vehicles for mandatory fortification.
Reduced or low fat milks were considered more suitable as a potential vehicle for mandatory fortification than all milk or full fat milk because a higher proportion of women in the target group consumed these milks than children aged 2-3 years (for example in Australia, target group - 36%; children 2-3 years 10%).

However, reduced or low fat milk is not considered the preferred vehicle because:

- a lower proportion of the target group in consumed low fat milks than bread and bread products (for example, in Australia 38% consumed low or reduced fat milks and 85% bread and bread products); and

- more recent data indicated that a higher proportion of all population groups now consume reduced/low fat milks. Since milk forms a much larger component of young children's diets relative to adults, the mandatory fortification of reduced fat milk was considered likely to cause excessive folic acid intakes for this population group.

[29] Lancaster and Hurst, 2001; Bower, 2003; Victorian Perinatal Data Collection Unit, 2005

A more detailed assessment of women of child-bearing age investigated whether there were other foods that would be suitable for mandatory fortification that better targeted the women with low folic acid intakes. This indicated that there is no food consumed preferentially by women of child-bearing age with low folic acid intakes that was feasible to fortify.

The one possible exception was low or reduced fat yoghurt, which was consumed in greater amounts by women in the low folic acid intake group in both countries, but by a relatively low proportion overall of the women of child-bearing age (<10% in 1995/97 NNS) so did not meet the criteria for a suitable mandatory fortification vehicle[30].

However, the data would support the consideration of low and reduced fat yoghurt as a suitable food for voluntary fortification permissions in the future in addition to those currently in place, as it is intended under the current mandatory fortification proposal that voluntary permissions to add folic acid to certain foods remain in the Code (Attachment 7A).

5.1.3 Consistency with Principle 3 – Be consistent as far as possible with the national nutrition policies and guidelines in Australia and New Zealand

5.1.3.1 Issues

Comments from the Review Request noted that:

- breads with fat and sugar added during or after baking would contravene national nutrition policies and therefore be inappropriate for folic acid fortification; and
- it may be appropriate to apply qualifying or disqualifying criteria[31] to decisions about which types of bread were suitable for the addition of folic acid.

National nutrition policies in both countries advise a reduction of saturated fat, sugar and sodium intakes. Therefore comment on the sodium content of bread has been included in the FSANZ response to these comments.

In summary, FSANZ does not consider that the addition of folic acid to breads (even where this includes breads that are high in sugar, fat or salt) is likely to encourage people to eat more of these breads (as compared to other breads) or to skew their diets over a long period of time. While sweet buns and certain bread products may contain a moderate to high proportion of fat and sugar, their contribution to folic acid intake is minimal for the target population and other age groups.

Instead of limiting the types of breads that are required to be fortified with folic acid, FSANZ considers that a more practical and useful risk management approach is to apply the requirements of the nutrition and health claims framework to folic acid fortified foods, to determine which foods are permitted to carry claims about the presence of folate or any other associated health claim.

[30] See Sec 2.1.1, Attachment 7.
[31] Referred to as nutrient profiling scoring criteria in the Preliminary Final Assessment Report for Proposal P293 Nutrition, Health and Related Claims.

5.1.3.2 Fat and sugar in bread products

In Australia, the proportion of fat in plain bread and rolls ranges from 1-5%, and in New Zealand from 1-3%. In Australia, the proportion of fat in fancy bread with significant quantities of added fat and/or sugar ranges from 3-14%, whereas in New Zealand this proportion is as high as 28%. Breads containing the highest proportion of fat are garlic bread [32]and sweet buns.

In Australia, the proportion of sugar in plain bread and rolls ranges from 2-7% and from 1-6% in New Zealand. In Australia, the proportion of sugar in fancy bread with significant quantities of added fat and/or sugar ranges from 2-22% and from 1-28% in New Zealand. The breads containing the highest proportion of sugar are fruit bread and sweet buns.

The amount of sodium also varies in breads; in particular, sweeter breads such as fruit loaf and buns contain less sodium than plain breads.

While sweet buns and other bread products with added fat and/or sugar contain varying proportions of fat and sugar, their contribution to folic acid intakes is minimal for the target population (Australian and New Zealand females aged 16-44 years); and other age groups in the population The contributions of fancy breads with added fat and/or sugar to total folic acid intakes were <5% and 6% for the Australian and New Zealand population groups, respectively (see Attachment 7).

5.1.3.3 Qualifying and disqualifying criteria for types of bread which can be fortified

FSANZ considered the application of criteria to decisions about whether bread/bread products with added fat and sugar were suitable for fortification, and also whether consequent health claims were possible using the proposed nutrient profiling scoring criteria for general level health claims under Proposal P293 - Nutrition, Health and Related Claims.

In short, FSANZ considers it would be impractical, costly and unnecessary for suppliers to use qualifying and/or disqualifying criteria in order to determine whether the bread/bread product is suitable for mandatory fortification.

Furthermore as previously indicated, the contribution to folic acid intakes from bread products with added fat and/or sugar is minimal and the addition of folic acid to breads (even where this includes breads that are high in sugar, fat or salt) is unlikely to encourage people to eat more of these breads (as compared to other breads) or to skew their diets over a long period of time, particularly as all types of breads will be fortified.

Instead of limiting the types of breads that are required to be fortified with folic acid, a more practical and useful risk management approach is to apply the requirements of the nutrition and health claims framework to folic acid fortified foods, to determine which foods are permitted to carry claims about the presence of folate or any other associated health claim. This issue will therefore be considered further under Proposal P293.

[32] Breads containing garlic flavoured butter or spread

5.1.4 Consistency with Principle 4 – Ensure that the added vitamins and minerals are present in food at levels that will not result in detrimental excesses or imbalances of vitamins and minerals in the context of the total intake across the general population

5.1.4.1 Issues

The Review Request stated that:

- the Proposal is likely to result in excess or imbalance for many population sub-groups and that this may be a particular issue for:
  - young children;
  - individuals with vitamin B_{12} deficiency (particularly the elderly);
  - individuals on anti-convulsive medications; and
- FSANZ has requested a review of the NHMRC Upper Level of Intake (UL).

Each of these issues is discussed below.

While the Ministerial Council did not specifically ask FSANZ to re-examine potential health risks, this was an issue raised by stakeholders during consultation. FSANZ has undertaken a further review and assessment of the literature, and this builds on the comprehensive work completed by FSANZ at Final Assessment. The Folate Scientific Advisory Group[33] has also reviewed FSANZ's conclusions. A summary of the most recent findings is provided below, with further detail provided in Attachment 5.

5.1.4.2 Excesses or imbalances in population subgroups (including young children and the elderly)

Existing voluntary fortification permissions and the proposed mandatory fortification together will contribute on average about 200 µg of folic acid per day to the target group in Australia and New Zealand, assuming no significant changes to foods that are currently voluntarily fortified. FSANZ has estimated that this is the maximum increase in average folic acid intakes that can be achieved with fortification strategies without resulting in too many people, particularly young children, exceeding the UL.

The UL for all age groups is derived from case reports summarised in the U.S. Dietary Reference Intakes (Institute of Medicine, 1998) assessing neurological damage in 108 adult patients of various ages with pernicious anaemia (except for three who had vitamin B_{12} deficiency alone) who were treated with folic acid. These case reports suggested that folic acid might precipitate neurological effects of B_{12} deficiency, although the lack of control subjects makes other explanations possible.

[33] This group consists of clinicians and public health nutritionists with expertise in epidemiology and/or folate/vitamin B_{12} nutrition. See further details at website address: http://www.foodstandards.gov.au/foodmatters/fortification/folatescientificadvi3252.cfm

An uncertainty factor of five was applied owing to the severity of the outcome and because a lowest observed adverse effect level (LOAEL) rather than a no observed adverse effect level was used. However, the uncertainty factor 'is not larger than 5 on the basis of the uncontrolled observation that millions of people have been exposed to self-treatment with about one-tenth of the LOAEL (i.e., 400 µg in vitamin pills) without reported harm' (Institute of Medicine, 1998). ULs were extrapolated to younger age groups on a relative body weight basis.

In relation to excess intakes, several submitters on the Issues Paper expressed concerns about using the UL as a reference health standard to assess dietary intakes of folic acid then disregarding the potential implications when a significant number of the non-target group exceeded the UL.

Young children

In Australia, FSANZ has estimated that about 9%[34] of 2-3 year olds and 4% of 4-8 year olds will exceed the UL based on intake of foods that are voluntarily fortified and the proposed mandatory fortification of flour (but excluding folic acid intake from supplements).
In response to these results, FSANZ investigated the safety implications in a similar manner to that undertaken for all potential exceedances of an upper reference limit i.e. by how much the level is exceeded, the margin of safety inherent in the upper level and the severity of the health consequences based on the totality of current evidence.

While there are other potential health risks from high doses of folic acid (see section 5.1.4.4), the UL is not relevant to any other disease or condition except postulated exacerbation of neurological sequelae from the undiagnosed vitamin B_{12} deficiency.

This deficiency is more common in the elderly, mainly due to a reduced capacity to release vitamin B_{12} from food sources during digestion or as a result of malabsorption of the vitamin in the gut. Very little deficiency in this age group is caused by inadequate dietary intake of vitamin B_{12}. Vitamin B_{12} deficiency can lead to serious and sometimes irreversible neurological damage. The prevalence of this deficiency in children, however, is rare, although there have been case reports in breastfed infants of predominately vegan mothers (USCDC, 2003).

As described above, there is an uncertainty factor of five applied to the UL for folic acid.

Based on consumption patterns evident in the Australian national nutrition survey, the 95th percentile of folic acid intake in 2-3 year olds was 338 µg per day, with male and female intakes less than twice the UL and well within the fivefold margin of safety of 300-1,500 µg per day for this age group.

For 4-8 year olds the 95th percentile of intake was below the UL for this age group, though for males it was above the UL (all 388 µg per day, males 442 µg per day, females 328 µg per day (Table 4 overpage). As for the 2-3 year olds these estimated intakes were less than twice the UL and well within the fivefold margin of safety of 400-2000 µg per day for this age group.

[34] This proportion is higher than previously published at Final Assessment (6%) because intakes from voluntarily fortified foods have been adjusted upwards to account for new market share data and that the number of foods assumed to contain bread-making flour has increased slightly.

As 95th percentile intakes for young children were well within the fivefold safety margin for their age group, FSANZ does not consider the proportion of children exceeding the UL poses any risk to their health.

Table 4: Proportion of Australians and New Zealanders with folic acid intakes above the UL at baseline (voluntary fortification) and after mandatory fortification* and 95th percentile intakes

	Revised baseline	200 µg folic acid /100 g flour in the final product	95th percentile intakes (UL)
Population Group	**%**	**%**	**µg/day**
Australia			
2-3 years	1	9	338 (300)
4-8 years	<1	4	388 (400)
70+ years	0	0	456 (1,000)
Women aged 16-44 years	<1	<1	407 (1,000)
New Zealand*			
		135 µg folic acid/100 g bread	
70+ years	0	0	367 (1,000)
Women aged 16-44 years	<1	<1	359 (1,000)

* Per cent exceeding the UL excludes folic acid intakes from supplements.

** Data from the New Zealand national nutrition survey is only available for ages 15 years and over.

FSANZ also assessed dietary intakes based on hypothetical examples to provide an indication of the level of risk **for an individual** who eats large amounts of fortified foods and selects the fortified version wherever there is a choice (the models underpinning these examples are described in greater detail in Attachment 7). It should be noted that no information is available on the likely proportion of the population that may have high individual intakes due to always selecting voluntarily fortified foods.

The results (Table 5 overpage) show that for Australian children aged 2-3 years and 4-8 years, high intakes of folic acid (95th percentile) were estimated to exceed the UL at *Baseline* (based on implementation of current voluntary permissions*)*, as well as under the three extended voluntary fortification scenarios (*Lower*, *Moderate*, and *Higher*), and under *Mandatory Fortification.* In fact, exceedances of the UL were **less likely** with mandatory fortification (including existing voluntary permissions) (130% UL) compared with the extended moderate or high voluntary fortification scenarios (170% UL). These are theoretical scenarios only, particularly as young children are unlikely to be always given the voluntarily fortified version of a food, but they highlight the variability in intake that can arise with various voluntary fortification practices.

Table 5: Estimated 95th percentile folic acid intakes from food as a proportion of the UL for young children in Australia (% UL)

Population group	No. of respondents	95th percentile folic acid intake from food as a proportion of the UL (% UL)				
		'Baseline'	*'Lower' voluntary*	*'Moderate' voluntary*	*'Higher' voluntary*	*'Mandatory Fortification'*
2-3 years	383	140	140	170	170	130
4-8 years	977	120	120	150	150	110

Older people

Among adults, the proportion likely to exceed the UL from mandatory fortification (excluding supplement intake) in Australia or New Zealand is very low: 0-<1%. No-one aged 70 years and over is expected to exceed the UL based on dietary intake alone (i.e. excluding supplements) (95th percentile of folic acid intake in this age group is 456 µg per day in Australia and 367 µg per day in New Zealand).

Interaction of folic acid with anti-convulsive medication

Although there is the potential for an increased folic acid intake to interfere with certain medications, available scientific evidence has not demonstrated any clinically significant interaction with therapeutic medicines from folic acid intakes up to 1,000 µg/day.

Some anti-convulsant (or anti-epileptic) drugs have been found to reduce serum folate levels, and on rare occasions have been associated with the development of megaloblastic anaemia in treated individuals. In some individuals the use of folic acid supplements may affect the liver and lower circulating antiepileptic drug level. Treatment to correct the folate deficiency has occasionally precipitated seizures or increased the frequency/severity of seizures.

However, there appears to be very large individual differences in folic acid sensitivity with drug controlled epilepsy, and case reports have all been associated with very large doses of folic acid (5,000-150,000 µg). A number of studies have also shown no significant changes in seizure frequency/severity in folic acid treated individuals.

The Folic Acid Subcommittee of the United States Department of Health and Human Services has concluded that 1,000 µg/day oral folic acid supplementation is safe for individuals with controlled epilepsy (Expert Group on Vitamins and Minerals, 2002).

Target group taking the recommended supplement dose

Similar to the dietary intake assessment undertaken at Final Assessment, FSANZ has updated folic acid intakes from fortified foods and two supplement doses for women aged 16-44 years in Australia (200 and 500 µg) and in New Zealand (200 and 800 µg). New Zealand women who consume a daily 800 µg supplement (the dose recommended by the New Zealand Ministry of Health) are at greater risk exceeding the UL (42%) compared with just 3% of Australian women consuming a 500 µg supplement (Attachment 7, Part A, B).

5.1.4.3 NHMRC Upper Levels of Intake

Pernicious anaemia is a disease of the elderly, rather than children, so it is uncertain what the importance of exceeding the UL is for children. Therefore, FSANZ wrote to the NHMRC on 12 October 2006 suggesting that a review of the UL might be appropriate, because of doubts about the relevance of the UL to children based on studies in the elderly, and because there are no other apparent adverse health effects from higher levels of folic acid.

In response, the NHMRC advised that there was not a strong case to reassess the UL recommendations for folic acid at this time because of the potential to 'precipitate or exacerbate the neurological damage associated with vitamin B_{12} deficiency' (not the masking of early detection of vitamin B_{12} deficiency) which is irreversible, and because of the uncertainty of the prevalence of this deficiency in younger age groups. The NHMRC also advised of their intention to review these recommendations in 2010.

5.1.4.4 Other potential health risks

At Final Assessment, FSANZ included a comprehensive review of the literature on potential health risks from increased folic acid intakes (see Attachment 6 of the Final Assessment report). To ensure that the conclusions from this review remain current, FSANZ has updated the literature on potential health risks (see Attachment 5). A summary of the most recent findings is provided below.

FSANZ reconvened the Folate Scientific Advisory Group[35] to review and provide comment on the updated literature review in relation to potential health risks and benefits. Members were generally in agreement with FSANZ's conclusions. Two members continue to raise ongoing concerns about long-term exposure to folic acid, particularly among young children. FSANZ notes that their concerns are not based on evidence of harm, but on 'unknown' risks when compared with the expected health benefits.

Cancer

To date, there are no reports of cancer from large scale randomised controlled trials in humans using intakes of folic acid similar to that which would be encountered under mandatory fortification. Therefore FSANZ undertook a review of the epidemiological literature on total folate intake in conjunction with the three cancers most frequently mentioned in relation to folic acid fortification (see Attachment 6 of the Final Assessment Report). This review concluded that there was no increase in cancer risk from the increase in folic acid intakes likely from mandatory fortification.

Papers published since Final Assessment (see Attachment 5) on the potential risk or protective effect of increased total folate (dietary folate and supplemental folic acid) on colorectal cancer, prostate cancer, stomach cancer and breast cancer does not change FSANZ's conclusion at Final Assessment. Current peer-reviewed evidence, in totality, does not suggest an increase in risk of colorectal, prostate, stomach or breast cancer from the increase in folic acid intakes likely from mandatory fortification.

[35] This group consists of clinicians and public health nutritionists with expertise in epidemiology and/or folate/vitamin B_{12} nutrition. See further details at website address: http://www.foodstandards.gov.au/foodmatters/fortification/folatescientificadvi3252.cfm

Nevertheless, FSANZ is aware that this is a rapidly developing area of research and that some forthcoming, as yet unpublished, evidence in relation to colorectal adenoma may shed further light on any relationship with folic acid.

The recently released report from the UK 'Folate and disease prevention' (SACN, 2006a) also concluded that 'the evidence for an association between folic acid and increased or reduced cancer risk in humans is equivocal. No randomised controlled trials designed to investigate the relationship between folic acid and cancer incidence have yet been reported'.

In response to ongoing concerns about the potential for increased colorectal adenoma risk, FSANZ recently engaged a leading Australian cancer epidemiologist to review the relevant section on cancer from Final Assessment and the updated literature review. While broadly agreeing with FSANZ's conclusions, he noted that these unpublished studies may increase the uncertainty about the relationship between folic acid and cancer risk.

FSANZ also discussed the preliminary results of trials investigating colorectal adenoma risk from increased folic acid intake with a representative from the UK Food Standards Agency. Results of these trials are only available in preliminary abstract form and therefore there is insufficient information on which to assess their significance.

FSANZ concludes that the results of trials examining folic acid and risk of recurrent adenoma cannot be assessed until the final papers are published and available for review, expected later in 2007. It is not possible, at this time, to determine whether there is any appreciable change in risk of colorectal adenoma, and ultimately colorectal cancer, given that the population is already exposed to folic acid through voluntary fortification and dietary supplements. If any increased risk between folic acid and colorectal adenoma is confirmed, this may, depending on the nature of the results, have implications for current voluntary fortification practices and use of dietary supplements.

FSANZ does however note that it is critical that ongoing monitoring continue to occur. FSANZ has recommended that this form part of any fortification strategy and suggests that the assistance of the NHMRC and Ministry of Health could be sought if further consideration of cancer risk is needed.

Twinning

As reported at Final Assessment, current evidence does not support a significant increase in the risk of twinning as a result of the expected increases in folic acid intake from mandatory fortification. One study published since Final Assessment reported an increase in twinning among women undergoing fertility treatment (see Attachment 5).

Cognitive function

Similar to that reported at Final Assessment, the additional evidence (see Attachment 5) does not support an association between folate intake and cognitive function. The UK report also concluded that the evidence is inconclusive for a beneficial or harmful effect on cognitive function.

The recently reported results from the National Health and Nutrition Examination Survey in the US found poorer cognitive function among those with low serum vitamin B_{12} and high serum folate levels. However, a cross-sectional study cannot indicate whether low cognitive function preceded or followed the biochemical values observed. The results do, however, highlight the need for ongoing monitoring of vitamin B_{12} status among older people bearing in mind that a low B_{12} status is not always evident in haematological analysis and neurological symptoms may be the only clinical manifestation of vitamin B_{12} deficiency.

Miscarriage

FSANZ did not report the potential increased risk of miscarriage from increased folic acid intake at Final Assessment, but this was raised as an issue during the First Review consultations.

The original studies which reported that folic acid reduced NTD rates also ascertained miscarriages. There were three randomised trials, a large scale intervention study in China, and a Swedish case control study. They do not support an increased miscarriage rate as the explanation for some or all of the observed reduction in NTDs seen in these studies.

Other potential health risks

At Final Assessment, FSANZ noted two other potential health risks postulated to result from increased folic acid intake: an impact on the gene pool (and thus increasing the number of people who require high folic acid intakes) and the unknown long-term consequences of unmetabolised folic acid circulating in the blood. These potential risks were also discussed in the UK report. Both reports concluded that there is insufficient evidence examining these possible relationships, particularly over the long term, and so no conclusions can be drawn.

However, several submissions to the Issues Paper, expressing concerns about potential health risks, highlight that a lack of evidence of no adverse health effects is not evidence of safety, particularly in relation to systemic circulation of unmetabolised folic acid. A lack of up-to-date data on food and nutrient intakes was also raised as a limitation to adequately assessing health risks (as well as health benefits).

In relation to unmetabolised folic acid circulating in the blood, this has been observed in adults who consume single doses of 300 µg or more (Troen *et al*., 2006).
As national and international folic acid supplement recommendations for women of reproductive age tend to range between 400-800 µg per day, and because the use of voluntary fortification permissions by industry and the use of multivitamins containing folic acid is relatively common, a counter argument is that a substantial proportion of the population, including pregnant women and foetuses, have already been exposed to circulating unmetabolised folic acid for many years without any documented harm.

5.1.5 Consistency with Principle 5 – Ensure that mandatory fortification delivers effective amounts of added vitamins and minerals with specific effect to the target population to meet the health objective

5.1.5.1 Issues

Comments from the Review Request noted that:

- the levels of folic acid proposed for mandatory fortification are insufficient to deliver the specific effect in the target group.

5.1.5.2 Expected effectiveness of mandatory folic acid fortification in Australia and New Zealand

Mandatory fortification of bread-making flour in Australia, and bread in New Zealand, is estimated to increase average daily folic acid intakes among women aged 16-44 years by 100 µg per day and 136 µg per day, respectively, assuming current uptake voluntary fortification permissions remain.

This is expected to reduce the number of NTD-affected pregnancies by 14-49 (or up to 14%) in Australia and by 4-14 (or up to 20%) in New Zealand. While the increases in intake differ slightly from those reported at Final Assessment, the expected outcome is unchanged from that reported at Draft and Final Assessment.

Professor Carol Bower was commissioned by FSANZ to determine the likely estimates of NTD reductions based on increases in folic acid intake. She chose the Wald model (Wald *et al*., 2001) to calculate these estimates and her results were published in the Australian and New Zealand Journal of Public Health (Bower *et al*., 2006).

Wald had developed a model which estimated the increase in serum folate following increases of various doses of folic acid in the range of 0-1000 µg, from studies lasting at least three weeks. Others have commented that this model would underestimate the reductions in NTDs because serum folate continues to rise for 10-12 weeks after folic acid intake is increased and so Wald had included studies which underestimate the effect of folic acid on serum folate (T. Green, personal communication, 2007). Therefore the projected number of NTD reductions in the Final Assessment Report may be underestimates; however there does not seem to be a published alternative model for estimating the possible impacts.

The level of fortification selected is based on maximising effectiveness (i.e. reducing the number of NTD-affected pregnancies) whilst minimising any potential health risks to the non-target population. Mandatory folic acid fortification of enriched grain products in the US commenced in 1996, and has contributed to a significant reduction in the NTD rate (fall of 27%) since that time. To date, there have been no reports of harm (see Attachment 6).

5.2 Public health and safety

5.2.1 Issues

FSANZ has been asked to:

- provide dietary modelling for Australian children at the maximum level of the proposed range of fortification to enable a comparison with the New Zealand results identified in a recent study by the University of Otago;

- propose how exceedances above the UL for children should be handled if mandatory fortification proceeds; and

- address the issue that there is no up-to-date baseline data for dietary intake and nutritional status in the population, particularly in Australia.

5.2.1.1 Comparison between Australian and New Zealand data re children under 15 years

The main differences between the two assessments were:

- the New Zealand children's assessment used a single day of data only whereas the Australian assessment used a second day adjustment;

- the age groups were slightly different (aged 5-8 years) compared to Australia (aged 4-8 years); and

- the New Zealand data were weighted according to the expected proportion of Maori and Pacific children.

The use of a single day unadjusted methodology for the New Zealand children's assessment may account for a significant proportion of the differences in results. Generally the distribution of intakes for a one day survey is expected to be wider than that using an adjustment for a second day of intake as the latter aims to better represent 'usual' intake over time. Using the second day adjustment for the Australian children decreased the proportion of children aged 4-8 years exceeding the UL from 9% to 3%.

The impact of the age difference or population weighting is not known, though the New Zealand Food Safety Authority advised FSANZ that the weighting was not expected to contribute to differences in folic acid intakes.

However, if the different groups of New Zealand children had different bread consumption patterns it may have an effect. It is recognised that food consumption patterns for children may be different between the two countries, may vary according to the season when each survey was undertaken and also may have changed between 1995 and 2002. These changes may account for some differences in folic acid intakes (see Attachment 7). FSANZ will be in a position to use the 2002 NZ Children's Nutrition Survey data in DIAMOND[36] later in 2007, and so can rerun these estimates at that time.

5.2.1.2 How exceedances above the UL for children should be handled if mandatory fortification proceeds

As previously discussed (see section 5.1.4.2), while there are children who will exceed the UL (and currently do so under voluntary fortification), because no young child approaches the safety margin for their age group, FSANZ does not consider the proportion of children exceeding the UL poses any risk to their health. As previously indicated, an important component of the risk management strategy is the monitoring of dietary folate, supplement and folic acid intakes, as well as the potential for folic acid intakes to exceed the UL, as part of an overall monitoring program in the future, given our dietary modelling is predictive.

[36] DIAMOND (DIetAry Modelling Of Nutritional Data) is a SAS software system used for dietary modelling at FSANZ.

5.2.1.3 Absence of up-to-date baseline data for dietary intake and nutritional status in the population (particularly in Australia)

Nutrient concentration data

Baseline concentration data for voluntarily fortified foods have been updated following Final Assessment for Australia and New Zealand based on new food composition data collected in 2006 becoming available to FSANZ. The proportion of foods within each category that were fortified was also revised. All dietary intake assessments conducted for the First Review for dietary folate, dietary folate equivalents and folic acid used these new baseline values as a starting point.

Where the new data were based on analysis of foods in the market place, it was not necessary to consider overages (potential overages were considered only where the information on nutrient content was taken from the claimed amount on the food label). The mean rather than maximum concentration of naturally occurring folate, dietary folate and folic acid in foods as analysed was used to estimate dietary intakes as this reflects the expected distribution of nutrient content in the food over time i.e. a single consumer would not be expected to consume a food with maximum levels of the nutrient every occasion of eating.

Nutrient intake estimates

Dietary modelling based on 1995 or 1997 NNS food consumption data provides the best estimate of actual consumption of a food and the resulting estimated dietary intake of a nutrient for the population. However, it should be noted that the NNS data does have its limitations. These limitations relate to the age of the data and the changes in eating patterns that may have occurred since the data were collected.

Generally, consumption of the broad categories of staple foods such as fruit, vegetables, meat, dairy products and cereal products, which make up the majority of most people's diet, is unlikely to have changed markedly since 1995/1997[37]. However, in the dietary intake assessments for voluntary fortification proposals, the folic acid concentrations of foods consumed in the NNSs have been modified to take account of some changes in food consumption where foods now consumed were not available at the time of the survey (e.g. formulated beverages, ready to drink teas).

Potential changes in bread consumption since 1995 and 1997 are important to assess as it is the selected food vehicle for the mandatory fortification proposal.

FSANZ has undertaken research to find other sources of more recent food consumption data to validate the NNS data. It should be noted that it is difficult to directly compare the data from all sources given the different survey methodologies used, differences in the ways that breads are defined between the different surveys, age groups, foods included in the assessments etc.

Broad trends in sales by volume and value of bread and other food categories are tracked by use of industry publications, such as the annual Retail World's Australasia Grocery Guide[38].

[37] (Cook *et al*., 2001)
[38] (Flanagan, 2006)

However these data indicate food sold at a national level only and not food consumed, so are of limited use to estimate changes at an individual level that can then be used to estimate nutrient intake changes. These data are useful however to 'market weight' folic acid concentrations according to the market share of leading brands within any given food category, where required.

More recent food consumption data for individual consumers were available from the Single Source (Australia and New Zealand) and Young Australian Surveys[39], the Australian Dairy Corporation Survey (ADC)[40], Newspoll survey in Australia[41] and a UMR survey from New Zealand[42], as discussed in the Final Assessment Report. It is recognised that the type of bread being consumed may vary over time, for example, more focaccia may be consumed now than in the 1995 and 1997 NNS.

Despite these changes within the whole bread category, the proportion of people reporting consuming bread (80-85%) and overall amount consumed across different age and income groups appears to be similar now to that reported in 1995 and 1997.

Nutritional status

The folate status of the Australian or New Zealand populations has not been assessed to date on a national basis. Some regional studies in Victoria and Perth involving adults reported changes in folate status pre and post voluntary fortification. The Blue Mountains Eye Study in Australia and a small New Zealand study reported recent folate status among older people (see Attachment 5 of the Final Assessment report). Queensland included red blood cell folate status among adults aged 25 years and over in the 1999-2000 AusDiab study[43].

New Zealand is proposing to assess folate status in its adult national nutrition survey in 2008 and Western Australia is proposing to undertake a pre and post implementation survey which will include both dietary intake of folic acid as well as blood folate status.

5.3 Adequate information to enable informed choice

5.3.1 Issues

The Review Request:

- noted that it will be crucial for mandatory fortification to be accompanied by a comprehensive education campaign. This issue is addressed in section 5.7.2;

- noted that mandatory fortification will be insufficient on its own to achieve a reduction in NTDs and asked that FSANZ consider a range of cost-effective strategies to ensure the target group is aware of the need to maintain folic acid from a variety of sources even if mandatory fortification is introduced. This issue is also addressed in section 5.7.2; and

[39] The NHMRC/NZMoH (2006) document *Nutrient Reference Values for Australia and New Zealand including recommended dietary intakes* is available online at http://www.nhmrc.gov.au/publications/synopses/n35syn.htm
[40] (Australian Dairy Corporation, 2003),
[41] (George Weston Submission, 2006)
[42] (NZFSA submission, 2006)
[43] (International Diabetes Institute, 2002)

- asked FSANZ to consider the following issues:

  – whether the Proposal prevents the general population and the target group from accessing adequate information to make an informed choice. It was also noted that consumers will be unable to estimate their dietary consumption of folic acid, and therefore will be unable determine the amount of supplementation they require;
  – as unpackaged breads are exempt from general labelling requirements, there is no mechanism to inform consumers of the presence of folic acid in these breads; and
  – there is no requirement for the inclusion of the quantity of folate in the nutrition information panel (NIP) on folic acid fortified foods, unless a manufacturer chooses to make a claim about the folate in their product, and again no mechanism to inform consumers of the amount of folic acid in these breads.

5.3.1.1 Whether the Proposal prevents the general population and the target group from accessing adequate information to make an informed choice

By its very nature, mandatory fortification limits consumer choice. A separate issue is whether the consumer is provided with adequate information about the fact that bread will be fortified.

Under mandatory fortification, foods containing folic acid will be required to list folic acid as an ingredient in the ingredient list (if required to be provided), but in accordance with the Ministerial Policy Guideline for mandatory fortification, *there is no mandatory requirement to label a food product as fortified*. The policy guidance further states that *however, consideration should be given, on a case by case basis, to a requirement to include information in Nutrition Information Panel.* This issue is addressed further below.

Another means by which consumers will access information about the fact that breads will be fortified with folic acid is through the proposed communication and education strategy as discussed at section 5.7.2.

5.3.1.2 Labelling requirements for bread fortified with folic acid (including unpackaged bread)

Under the present conditions in the Code, the presence of folic acid would be indicated in the ingredient list on bread and products made from bread-making flour. In some situations, however, products are exempt from the requirement to label with an ingredient list and therefore consumers would not necessarily be informed about the presence of folic acid. These are the exemptions for:

- unpackaged foods;
- food made and packaged on the premises from which it is sold;
- food packaged in the presence of the purchaser; and
- declaration of the ingredients of compound ingredients - where the compound ingredient is less than 5% of the food it is not required to be in the declaration of ingredients.

Currently, retail bread and bread products that are sold unpackaged are estimated at approximately 30% in Australia and approximately 15% in New Zealand[44].

Ingredient lists simply provide information about the presence or absence of an ingredient and the amount present relative to the other ingredients in the food by its ranking in the ingredient list. FSANZ considers that this information is therefore most useful for consumers who want to avoid consumption of folic acid, and to a lesser degree, for those who want to increase consumption.

FSANZ considers that the current exemptions from the labelling provisions that apply to breads remain in place and that declaration of folic acid as an ingredient in these unlabelled breads is not required, for the following reasons:

- mandatory provision of ingredient information on unlabelled foods was recently debated under Proposal P272 (Labelling Requirements for Foods for Catering Purposes and Retail Sale) and rejected;
- this is consistent with the approach for mandatory fortification of thiamin in bread-making flour in Australia;
- this is consistent with the approach in the Code for labelling of other ingredients where declaration is not required for health and safety reasons;
- a written declaration of folic acid as an ingredient and not accompanied by other ingredients, for example, 'Contains folic acid'; may be interpreted as a nutrition claim, potentially causing confusion for consumers and enforcement officers; and
- information that folic acid will be added to most breads will be provided by other means, as a part of the communication and education strategy.

5.3.1.3 Folic acid and nutrition information panel labelling requirements

The mandatory declaration of folate on the nutrition information panel (NIP) is not required under Standard 1.2.8 which prescribes the nutrients that are to be declared in the NIP. If a voluntary declaration of folate was made in the NIP, this would be considered to be a nutrition claim.
Such claims are permitted only when the food contains at least 10% of the RDI for folate, per reference quantity of the food (Standard 1.3.2). This equates to at least 20 µg of dietary folate per 50 g of bread.

When determining whether a mandatory declaration of folic acid in the NIP would provide a useful mechanism for consumer information with respect to folic acid, FSANZ considered the purpose and usefulness of this information to the consumer, the likely level of consumer demand, alternate methods of providing consumer information, and the overall cost and impost on industry, and enforcement agencies.

FSANZ has concluded that there should be no requirement for mandatory declaration of folic acid in the NIP of products fortified with folic acid on the following grounds:

[44] Brooke-taylor & Co Pty Ltd, Report prepared for FSANZ P295 Final Assessment Report, Attachment 10, Appendix 1.

Folic acid is the recommended form of folate for the prevention of NTDs in women of child-bearing age. A declaration of the folate content of the product in the NIP would give a total of the naturally occurring folate **plus** added folic acid. This information would therefore be of limited use to consumers who wished to determine only their folic acid intake from dietary sources (noting that recommendations relate only to folic acid). A declaration of the folic acid content of the product in the NIP however would not provide any information on dietary folate and would therefore be incorrect with regards to the total folate content of foods;

- It is more likely that consumers from the target group who have awareness of folic acid and the technical knowledge to calculate their daily intake from fortified foods will be aware of the public health recommendation to take a folic acid supplement, or be aware of other sources of information on the folic acid content of fortified foods;

- The objective of mandatory fortification is to increase average folic acid intake in women of child-bearing age to further reduce the incidence of NTDs in the Australian and New Zealand population; it is not that women will calculate their folate acid intake each day to determine if they need to take a supplement that day;

- The promotion of folic acid supplements for women of child-bearing age will continue under mandatory fortification. Mandatory fortification is not intended as a replacement for folic acid supplementation for women of child-bearing age, rather it is only one strategy to increase the folic acid intake in women of child-bearing age; and

- Mandating the declaration of folate in the NIP would impose considerable costs on the suppliers of bread, which would include the analysis of levels of folic acid and of naturally occurring folate in fortified products, and initial relabelling for inclusion of the NIP.

5.4 Enforcement and Compliance

5.4.1 Issues

The Review Request raised concern that:

- the proposed standard would be difficult to enforce or comply with in practical or resource terms;
- significant resources would be required to enforce the standard, based on the fact that there are a number of products produced by numerous bakers that would need to be tested;
- a change in the fortification vehicle from bread-making flour to bread would greatly increase costs of enforcement; and
- the costs attributed to enforcement may not be based on provable data.

Given these concerns, FSANZ has been asked to:

- re-consider the originally proposed vehicle (bread-making flour) mandatory fortification of bread-making flour in Australia; and

- develop a mandatory fortification food standard which allows New Zealand to maintain the fortification of bread, while allowing the fortification of flour for bread-making purposes in Australia. This change was requested because of technical, compliance and cost issues relating to the fortification of bread in Australia. This matter is discussed further in section 5.8.

5.4.1.1 Context

In July 2006 at Draft Assessment for Proposal P295 - Consideration of Mandatory Fortification with Folic Acid, FSANZ proposed the mandatory fortification of bread-making flour in Australia and New Zealand with 2.3 – 2.8 mg/kg flour. FSANZ was guided by successful experiences in the United States and Canada in selecting flour as an effective and technically feasible food vehicle for fortification. The fortification of bread-making flour was also consistent with the existing mandatory requirement to fortify bread-making flour with thiamin, in Australia.

Following public submissions and further targeted consultation, industry expressed concerns about the high degree of impost, citing the inability of industry to fortify bread-making flour within the required parameters. The fortification of bread-making flour was considered particularly problematic for New Zealand, who did not have any fortification infrastructure in place.

At Final Assessment in October 2006, FSANZ therefore refined the approach to specifically require mandatory fortification of bread as the final food consumed at 80-180 µg of folic acid per 100 grams of bread. This would allow bread manufacturers to choose the method of addition of folic acid to bread i.e. either through use of fortified flour or adding later in the bread-making process.

In order to address the issues detailed above, FSANZ contracted GP McMullen Consulting (McMullen) to undertake an investigation of the Australian milling industry, and current practice in the fortification of bread-making flour in Australia. Industry was asked their view on effective compliance with the mandatory folic acid fortification standard as proposed at Draft Assessment. Potential difficulties and barriers to effective implementation of the standard were then identified, and are addressed. FSANZ also sought advice on overseas experience with fortification from an international fortification and milling consultant, Quentin Johnson[45].

The final report from McMullen is at Attachment 3. The following provides an overview of the key outcomes of this report. In addition, the Flour Millers' Council of Australia (FMCA) commissioned an independent report[46] examining the technical feasibility and cost implications for the Australian milling industry. This information has been considered by FSANZ's consultants and has also informed the consideration of costs associated with mandatory fortification of bread-making flour (see Section 5.5).

[45] Quentin Johnson, QUICAN Inc., March 2007.
[46] Richard Eliott, Milling Consulting Service Pty Ltd, February 2007.

5.4.1.2 Review of the fortification vehicle – Bread-making flour in Australia

As part of McMullen's investigation into Australian milling operations, the industry was consulted on their understanding of what type of flour constituted 'bread-making flour'. The main flour produced by Australian mills is 'Bakers flour' milled from wheat grain. 'Bakers flour' is pre-dominantly used for bread-making, and is also commonly used in a wide range of other products, such as muffins, bread crumbs, crumpets, scones and pikelets.

The majority of bread is made from wheat flour; although a range of other cereals and grains may be used in some types of bread e.g. barley, rye and triticale. The total of these other grains milled in Australia is estimated at less than 10%[47].

Industry noted that requiring fortification of other milled cereals would create difficulty in determining which flours should or should not be fortified and increase the need for flour segregation. These factors, and the resulting operational complexity, would have cost implications.

The milling industry has however raised concerns regarding their inability as a supplier to monitor the end use of 'wheat flour for bread-making'. 'Bakers flour' is used predominately for bread-making and millers might therefore be expected to have some understanding of the flour end use. However where this may not be clear, millers will need to indicate that flour has been fortified and the end user will therefore be informed and can ensure that other products containing fortified flour (through voluntary permissions) are labelled appropriately.

<u>Fortification process and infrastructure of flour milling in Australia</u>

Currently, flour for bread-making is required to contain no less than 6.4 mg/kg of thiamin in Australia. In addition, voluntary permissions for cereal flours allow the addition of other micronutrients e.g. folic acid and iron. Millers usually add more nutrient, or 'overage'[48], to ensure compliance with these regulations.

McMullen reports that feeders are typically used to fortify flour with thiamin or folic acid, whereby a feeder discharges a vitamin premix at a predetermined rate adjusted to the flour flow rate. Currently the equipment used is relatively crude and the level of monitoring could be described as minimal in many mills. Little or no sampling and testing of thiamin currently occurs. Mills rely on external commercial laboratories to test samples, which may be tested randomly, every week, or six monthly. Overages may be up to 30% in small to medium mills, and may be over 100% on some occasions.

Industry requirements with mandatory fortification

At Draft Assessment, FSANZ proposed the addition of folic acid at the level of 230 -280 µg/100 g of flour. Industry has raised concerns about their ability to meet this range citing a need for significant upgrades to their current milling operations in terms of equipment and processes. Industry has provided projected costings for these upgrades (see Sections 5.5.1.1).

[47] Based on industry estimates, personal communication, Gerard McMullen, April 2007.

[48] Overages are defined as 'the practice whereby manufacturers add more vitamins and minerals to account for losses during processing and storage'.

McMullen reports that based on international experience there is feeder equipment available which can be installed and operated based on existing mill operations that will enable industry to fortify flour with the required range of folic acid fortification. This will however, require a greater degree of control over the feeding rate and ability to detect changes in delivery rate than currently exists, in order to achieve compliance within the proposed range. Overseas experience indicates that mills can be retrofitted with feeders and feedback mechanisms which detect changes in the flour flow rate and folic acid feeding rate quite easily.

In addition, McMullen notes the following two concerns raised by industry:

- obligations under their procedures and quality systems to meet the proposed regulatory limits; and
- future legal liability should any food safety issues arise and it has been shown that the required range has not been met.

McMullen highlights the importance of enforcement agencies working with industry to constructively address issues in relation to fortification of bread-making flour when they arise. He also outlines a number of suggested actions to assist industry in their compliance with the proposed mandatory standard.

As previously discussed at Draft Assessment, FSANZ has sought advice from the Australian Government Solicitor who has advised that millers would be protected from liability where they have complied with a mandatory standard as defined in the *Trade Practices Act 1974*.

Fortification range

On the basis of the advice received, FSANZ is proposing a prescribed range of fortification for the mandatory folic acid standard. In order to fortify bread-making flour at residual levels of 200 µg of folic acid per 100 g of bread-making flour in the final food, the range should take into account inherent variability in the fortification process and folic acid baking losses (estimated at 20%).

A tolerance level of $\pm$ 20% is proposed by McMullen, who reports this would be a reasonable allowance based on discussions with industry. This range would allow for the use of feeders to be retrofitted to existing mills (both large and small) without the need for blending systems as proposed by the Eliott report.

This range will provide greater flexibility for compliance, compared with the $\pm$ 10% tolerance included in the fortification range proposed at Draft Assessment.

5.4.1.3 FSANZ proposed approach to the fortification vehicle

FSANZ proposes that, should mandatory fortification be endorsed by the Ministerial Council:

- only 'wheat flour used for bread-making' should be captured by the mandatory standard for folic acid fortification and that other flour milled from other grains should be excluded from mandatory fortification given the practical difficulties for industry;

- for consistency, the existing mandatory standard for thiamin be amended to clarify 'flour for making bread' as being 'wheat flour for making bread'. FSANZ understands that this is what currently occurs in practice; and

- a prescribed range for mandatory folic acid fortification of 200 – 300 µg of folic acid per 100 g bread-making flour be implemented. This range accounts for the average folic acid losses on baking of 20% (i.e. nutrient equivalent of 200 µg with 20% losses is 250 µg), and allows for a $\pm$ 20% accuracy in fortification during the milling process. Based on international milling practices and quantitative testing of fortified flour, this revised range is considered to be achievable using current international fortification practices.

5.2 Industry costs

5.5.1 Issues

The Review Request raised concern that:

- a change of vehicle from bread-making flour to an endpoint level in bread, would increase costs for Australian industry with consequent costs to consumers. It was noted that the higher cost bread option was difficult to justify, given that there would be little difference in health outcomes under either option; and

Given these concerns, FSANZ was asked to identify the lowest cost option and also to consider the economic effectiveness underpinning a population wide strategy in order to reach a small population sub group. This issue is addressed separately at Section 5.1.2.

5.5.1.2 Costs to industry of complying with fortification of bread-making flour

In consultation with industry, FSANZ has revised some costs for the Australian industry of mandatory fortification of bread-making flour with folic acid. The changes to the costs result from FSANZ amending the cost estimate for equipment and industry, represented by the Flour Millers Council of Australia (FMCA), proposing significantly higher costs of equipment and analytical testing. These cost measures are presented in Table 6 overpage.

Further to the FMCA providing costings, the Australian Food and Grocery Council commissioned BRI Research to provide an evaluation of the cost estimates provided by FSANZ (McMullen) and FMCA (Eliott). BRI Research's report[49] concurred with the assumptions behind the industry costs for upgrades to micro-feeders presented in the Eliott report, specifically in relation to meeting a prescribed range of fortification.

[49] BRI Research, *An evaluation of two reports on the proposed mandatory fortification of flour with folic acid in Australia*, April 2007.

Table 6: Industry compliance costs

	Australia (folic acid fortification in bread-making flour)	**Australia (folic acid fortification of bread-making flour)**	**NZ (folic acid fortification of bread)**
	LOW CASE[50]	*HIGH CASE*[51]	*MID CASE*
	(A$M)	(A$M)	(NZ$M)
Upfront Costs			
Labelling	2.486	2.486	0.436
Packaging write-off	4.000	4.000	0.500
Equipment	1.400	22.100	0.080
Total upfront costs	7.886	28.586	1.016
Ongoing			
Premix (incl. folic acid)	0.164		1.787
Analytical Testing	0.673	11.91452	2.25353
Administration	0.187	0.187	0.109
Clean Out Mill	0.035	0.035	
Total ongoing costs	1.059	12.136	4.149

The major differences in Australian costs relate to equipment and testing.

In relation to equipment:

- the low end or FSANZ derived costs are based on replacement of existing feeders by new micro-feeders that can more accurately deliver the prescribed range of folic acid and level of thiamin into the flour stream. No other equipment is identified as necessary (Cost: up to $50,000 per mill and $1.4 million for all Australian industry). This revised estimate for new equipment based is based on consultations with industry and advice from FSANZ's consultants. FSANZ understands that this new equipment (as detailed in Attachment 3) will achieve the more accurate dosages required under the proposed mandatory fortification; and

- the high end costs are based on the advice from industry that the narrow fortification range requires real time analytical testing and holding of batches of flour until cleared (Cost: up to $1 million per mill and $22.1 million for all Australian industry). Industry advises that these conditions require substantial modification to production systems and new equipment and facilities including:

  – new micro-feeders and modification to dosing systems (all 28 mills);
  – new premix plants for 2 (out of 28) mills;

[50] FSANZ cost measures with amended equipment costs.
[51] FMCA cost measures, with higher equipment and analytical testing costs.
[52] This figure includes costs of folic acid and premix as well as analytical testing.
[53] New Zealand industry has indicated that this is a minimum based on their expectations of enforcement activity.

- new folic acid testing equipment (all mills), new laboratory facilities (19 mills), new staff and training;
- new storage bins capable of holding 32 hours production;
- new returns areas (13 mills); and
- production re-design, modification and re-build (in some cases) to facilitate re-processing of non-compliant flour.

In relation to analytical testing:

- the low end costs are based on millers sampling and testing at least 2 times per month. Samples would be sent to external laboratories. Testing would not disrupt the continuous 24 hour production of flour and no on-site holding while awaiting test results would be required. Discussions with jurisdictions indicate that a low level of testing for enforcement purposes would be appropriate to meet compliance requirements; and

- the high end costs are based on industry estimates of millers sampling and testing 2–4 times per hour. Testing would occur onsite, at each miller's laboratory, and take 9–10 hours. Industry has indicated that for some sites this would necessitate building and staffing a 24 hour laboratory. Each batch of flour would also be held in storage until cleared. This is based on industry's expectations in relation to the compliance requirements of jurisdictions along with their own quality assurance requirements.

The flour milling industry, represented by the Flour Millers Council of Australia (FMCA), indicated that the specified range for fortification would have serious implications for the milling process. To meet the requirement of fortifying within a lower and upper limit, the FMCA indicated that each batch of flour would have to be tested and stored at the mill until the test results showed it to be within specification.

This would require millers to invest in new storage facilities, new analytical testing facilities, premix manufacturing facilities, re-configuring production systems including returns areas and capable of mixing back any out-of-specification batches. The FMCA have also indicated that this impost is likely to result in the closure of a number of the smaller mills.

However, FSANZ considers that this is unlikely to occur based on discussions with enforcement agencies who have clarified that they do not intend to implement overly burdensome enforcement strategies. Industry has argued that they would undertake this level of testing even if this was not required by enforcement agencies. They have argued that this would be necessary to ensure quality assurance and minimise potential liability should folic acid subsequently be found to be harmful.

International perspective

Flour millers in South Africa, Asia, the Pacific and North America routinely fortify bread-making flour with additives including minerals, vitamins and folic acid, through micro-feeders of volumetric or gravimetric design, and at a cost of between $5,000 to $30,000 per mill.

Both McMullen and Johnson indicated that the systems proposed by the FMCA appear to be unnecessary, based on international practice. Although fortification in these countries requires industry to meet minimum requirements rather than a range as proposed for Australia and New Zealand, outcomes achieved in practice indicate that the equipment used can deliver the proposed range.

New Zealand

The costs to New Zealand industry of fortifying bread with folic acid are virtually unchanged from those costs presented at Final Assessment. Industry has confirmed this is the case but has noted that the analytical testing costs are a minimum and are dependent on the level of testing needed to meet the requirements of the New Zealand Food Safety Authority (NZFSA).

5.6 Enforcement costs to government if fortification occurs at bread-making flour or bread production stage

5.6.1 Issues

Concern was raised in the Review Request that the proposed standard would be difficult to enforce in practical and resource terms and that the costs attributed to enforcement may not be based on provable data.

FSANZ appreciates the concerns around the costs attributed to enforcement in the Final Assessment Report. The reported costs were estimates obtained from a small sample of jurisdictions.

5.6.1.1 Costs to government

In response to these concerns, FSANZ has undertaken a census of enforcement costs in all Australian jurisdictions (New Zealand enforcement costs were reported in the Final Assessment Report). FSANZ has focussed on the costs of enforcing a standard to fortify bread-making flour in Australia.

The survey of Australian jurisdictions collected information on key enforcement activities: training staff; raising awareness of industry; auditing flour millers; auditing labels on packaged bread; administration; and complaints. The jurisdictions provided specific data about the level of resources required to undertake each activity, as well as indicating whether these costs would be an upfront expense or ongoing each year. They also reported their strategic approach to enforcing the mandatory standard. The data was collected using the methodology of the Business Cost Calculator.

Australian jurisdictions indicated that auditing flour mills was the most important element in their enforcement strategy. They adopted a fairly consistent approach, with half proposing to audit millers once a year and the other half proposing to audit twice a year.

Jurisdictions indicated that auditing could include sampling bread-making flour at the mill and/or an audit of quality assurance records. The jurisdictions indicated a diverse approach to issues such as training and complaints handling.

The total costs of enforcing a mandatory standard in Australia and New Zealand were reported to be very low, as indicated in Table 7 overpage.

Table 7: Jurisdictional costs of enforcement

	Australia (enforcing fortification of folic acid in bread-making flour) (A$)	**New Zealand** (enforcing fortification of folic acid in bread) (NZ$)
Upfront Costs		
Training & awareness	**27,169**	**7,920**
Ongoing Costs		
Training & awareness		2,400
Auditing content	74,391	
Auditing labels	19,017	80,000
Administration	13,604	1,320
Complaints	14,324	
Enforcement		4,780
Total Ongoing Costs	**121,336**	**88,500**

Industry has highlighted the importance of consistent enforcement approaches between jurisdictions. FSANZ raised this issue with the jurisdictions and as a result, it has been agreed that a pilot survey be organised to develop a nationally consistent approach (within Australia) to assessing compliance with and enforcement of standards for the mandatory fortification of the food supply with nutrients, such as folic acid or iodine. The pilot will involve an audit type survey with an analytical component to be trialled on thiamin levels in bread-making flour and resultant products.

Informal feedback from the jurisdictions indicates that relevant food industry businesses in Australia would likely be visited once or twice a year to assess compliance with a mandatory standard for the addition of folic acid to wheat flour for bread-making. In this case, the food industry would not be expected to hold flour or flour based products back for testing of nutrient levels prior to dispatch, rather it is expected that over time they would gain the experience of knowing what needs to be done to obtain the required outcome.

Please note that these costs do not include costs for monitoring and education as these costs are required under any option to increase the folic acid intake and reduce the incidence of NTDs.

5.7 Other Review Comments

5.7.1 Monitoring

5.7.1.1 Issues

The Review Request noted that there:

- is currently no agreement for national monitoring of the effect of fortification; and
- must be adequate monitoring and surveillance in place before any changes come into force.

5.7.1.2 FSANZ response

Given that mandatory fortification is a significant public health initiative, monitoring and review is an essential risk management strategy. FSANZ is proposing a review of the standard within three years of implementation. While responsibility for establishing and funding a monitoring system is beyond FSANZ's remit, FSANZ is of the view that a decision to proceed with mandatory fortification with folic acid must be accompanied by effective monitoring to measure the success of fortification in improving nutritional intake and status and to ensure the protection of public health and safety.

The responsibility for establishing and funding a monitoring system requires involvement of health and regulatory agencies at a Commonwealth, State and Territory level in Australia and the New Zealand Government.

In July 2006, a FRSC Subgroup provided a generic framework for the development of monitoring systems to complement mandatory fortification programs. The FRSC Subgroup also established an expert group on monitoring folic acid fortification. This group made recommendations to the Ministerial Council meeting in October 2006 on a national monitoring system for folic acid for Australia and New Zealand. In March 2007, FRSC agreed to seek AHMAC advice on a monitoring framework and that the framework for monitoring the impact of folic acid fortification be integrated with other existing and proposed nutrition and health outcome monitoring systems.

The development of a monitoring system should consider the collection of all relevant data including folic acid content of foods (food composition), changes in performance the measures of nutritional status (folic acid intakes, blood status) as well as expected health outcomes (NTD rates) and unexpected outcomes (potential for adverse health effects). The collection of baseline data prior to, or just after, the implementation of the fortification program and at some time in the future will also be an important aspect of assessing the effectiveness of the fortification program. Submissions to the Issues Paper noted that it is critical to ensure that up to date information from an ongoing bi-national food and nutrition monitoring system is available to evaluate the impact of fortification and assess the benefits or risks likely to accrue to the target population.

As part of its ongoing work, FSANZ will contribute by directly by tracking changes in the food supply for fortified/unfortified foods in key food categories:

- updating the Australian national food composition databases;
- tracking labelling changes on fortified foods;
- tracking changes in food consumption patterns of key food categories that are likely to be fortified for different demographic groups;
- regular literature reviews relating to risk/benefits of folate and folic acid in the diet; and
- researching changes in consumers' attitudes and behaviour towards fortified foods.

Issues of compliance and enforcement of fortification standards have also been considered. For folic acid it is proposed that a qualitative and/or analytical survey of the level of added nutrient in the proposed food vehicle could be undertaken, including comparison with label information, where appropriate. Currently a pilot survey on the levels of thiamin in bread-making flour and bread products using the proposed survey method is under way.

The results of this pilot survey will assist FSANZ and Jurisdictions in developing a consistent approach to assessing compliance and enforcement of mandatory fortification standards.

5.7.2 Communication and education

5.7.2.1 Issues

The Review Request noted that:

- there is a lack of commitment to, and funding for, an education campaign to increase folate intake in the target group;
- a comprehensive consumer education campaign would advise the target population about the need to continue to consume voluntary fortified foods and to take supplements to reach the optimum folic acid intake; and
- there is a need to address the risk of excessive folic acid consumption by particular groups, especially in reference to supplement intake.

5.7.2.2 FSANZ Response

FSANZ acknowledges:

- that optimal reduction in NTDs relies on implementation of a range of complementary strategies which are beyond FSANZ's regulatory role. Such strategies include maintenance of the existing voluntary folic acid fortification of other foods, the promotion of folic acid supplements and education for women of child-bearing age; and

- the need for a broad, consistent on-going education initiative involving a wide range of organisations.

Should the proposed mandatory standard for folic acid fortification proceed, FSANZ will implement a communication program focused on educating people about the new standard. All target audiences require clear, consistent, well-targeted messages about the Standard.

FSANZ has prepared a Communication and Education Strategy (with input from the Government Food Communicators' Group, a formal working group of the Implementation Sub-committee of FRSC) that aims to increase awareness among all target audiences of the proposed standard (see Attachment 8).

The Strategy identifies the following target audiences: consumers, particularly women of child-bearing age (and those who for health or cultural reasons may not consume fortified bread); industry, including manufacturers who currently have permissions to voluntarily fortify their product with folic acid, manufacturers who wish to obtain further permissions to voluntarily fortify their product with folic acid, manufacturers of bread who will be required to fortify (in New Zealand), the suppliers of bakers such as millers (in Australia), importers and exporters; health professionals, including those who provide consumer advice on dietary and nutrition issues; government agencies that are responsible for monitoring, enforcement and education; and the media.

Other consumers may need additional advice, support and information, such as people from low socio-economic backgrounds, people from non-English speaking backgrounds, Indigenous Australians, Māori, Pacific People, Asian communities, refugee and ethnic minorities, and others within the community with particular dietary/nutritional needs, for example, people with coeliac disease. In addition, the Strategy will address the needs of particular population groups that may be at risk of excessive folic acid consumption, especially in reference to supplement intake.

Increasing public awareness of the proposed standard can be best achieved through sustained, collaborative efforts which maximise the effectiveness of available resources. FSANZ will therefore seek opportunities to collaborate with organisations to provide information and education about the proposed standard.

5.7.3 'Organic' and 'Natural'

5.7.3.1 Issues

FSANZ has been asked to consider:

- issues arising from the New Zealand Commerce Commission (NZCC) view on 'organic' and 'natural' representations on bread and flour products fortified with folic acid. The NZCC had advised that in terms of the New Zealand *Fair Trading Act 1986* ('FTA') the ability of manufacturers of bread products to label products as 'organic' or 'natural' is likely to be affected by mandatory folic acid fortification.

The NZCC (in the context of the FTA) and the Australian Competition and Consumer Commission (ACCC) (in the context of the *Trade Practices Act 1974* (TPA)) have provided further advice on the status of products which are labelled 'organic' and 'natural' under mandatory fortification.

5.7.3.2 'Organic'

With regard to 'organic' representations of foods, it is the opinion of the NZCC and the ACCC that the use of the term 'organic' in relation to foods fortified with folic acid (without clear and meaningful qualification) may mislead consumers into believing that the product has been produced naturally and thus would risk breaching the New Zealand FTA or the Australian TPA.

If an organic certification system permitted fortification, then the product could be labelled 'certified organic' (logo or mark) providing the product complied with the rules. Australia and New Zealand have a number of national organic certification bodies[54], none of which have identical standards. However, organic standards generally do not allow synthetically produced substances into organic production systems, and vitamins and minerals are generally not permitted. While a labelling disclaimer could be added to indicate that the product had been fortified as required under the Code, this should not be obscurely placed on the label but presented for the consumer's consideration at the same time the headline claim 'organic' is made.

[54] Nine organic certification organisations in Australia, http://organic.com.au/certify/au/, and three in New Zealand http://www.organicsnewzealand.org.nz/organic_certification.htm

It is the opinion of the NZCC and ACCC that consumers are likely to expect that foods labelled 'organic', or 'certified organic' have ingredients derived from living organisms without the use of chemical fertilizers and/or pesticides, and would not contain synthetic vitamins such as folic acid.

As a result, FSANZ proposes that foods (i.e. bread and products containing bread-making flour) represented as 'organic' be exempted from mandatory fortification. The issue as to whether a food labelled 'organic' complies with consumer expectations of organic would be considered under the FTA and TPA, and is outside the domain of the Code.

5.7.3.3 'Natural'

Both the ACCC and NZCC consider that 'natural' claims imply that the product is made up of natural ingredients, i.e. ingredients nature has produced, not man made or interfered with by man. Folic acid is not a natural ingredient, therefore 'all natural' claims for foods containing folic acid could not be used, although the product may be labelled as 'contains natural ingredients'. Care must still however be taken when labelling a product as 'contains natural ingredients' to avoid providing the impression that all the ingredients in the product are natural.

Given that consumers may view what is 'natural' differently to manufacturers and food technologists, making it difficult to classify foods and ingredients, FSANZ is not considering an exemption from mandatory fortification for 'all natural' foods.

Unlike 'organic' foods which can be defined by adherence to an organic certification system, there is no certification criteria for 'all natural' foods. Manufacturers may however label foods using 'natural ingredients', and add additional qualifications in order to produce a label which is unlikely to mislead the consumer.

5.7.4 Cost Methodology

The Review Request:

- disputed the model that ascribes a dollar value of a lost lifetime to each NTD death on the grounds that this cost does not occur;
- stated that the cost benefit analysis data is flawed because it is based on the delivery of 1/4 of the target group's 400 µg folic acid requirement. Safety and effectiveness issues are dealt with in sections 5.1.4 and 5.1.5;
- noted that the cost of fortifying flour may need to be further investigated because it does not take into account the need for more accurate dosage equipment. This is not discussed below as it is discussed in section 5.5.1 in the context of costs to industry.

5.7.4.1 Modelling the loss of life and the impact of NTDs

In health economics there is a long tradition of assessing the morbidity and mortality associated with all known diseases and health conditions. For many years the health economics literature has contained estimates for morbidity and mortality, measured in terms of 'disability adjusted life years', which is a score between 0 and 1 depending on the level of disability multiplied by the number of years a person is disabled.

The disability adjusted life year associated with NTDs is well established. Hence a reduction in NTD cases in Australia and New Zealand equates to a specific reduction in the number of disability adjusted life years in these countries. The reduction in disability adjusted life years can be expressed in financial terms by multiplying it by the 'value of a statistical life'. This later concept, the 'value of a statistical life', is also widely cited in the health economics literature and it has both proponents and critics. Overall, the reduction in NTDs benefits the people of Australia and New Zealand by reducing the burden of disease. The benefit can be measured by the reduction in the number of disability adjusted life years or, applying the 'value of a statistical life', expressed in financial terms.

5.8 Other specific recommendations

The specific recommendations made in the Review Request have been dealt with elsewhere in this Report except the following recommendation:

- that FSANZ consider developing a mandatory fortification food standard which allows New Zealand to maintain the fortification of bread, while allowing the fortification of flour for bread making purposes in Australia. This change was requested because of technical, compliance and cost issues relating to the fortification of bread in Australia.

In developing the regulatory approach for folic acid fortification (for the purposes of undertaking a First Review), FSANZ has relied on the written advices of senior general counsel at the Australian Government Solicitor (AGS). These advices were requested by the Department of Health and Ageing and were provided to FSANZ.

The principle purpose of seeking AGS advice was to investigate whether a joint food standard could validly provide for an outcome where bread contains a range of folic acid, but that provides Australia and New Zealand with different methods to reach this outcome – with Australia fortifying the flour used to make bread, whilst New Zealand fortifying the bread directly. This would envisage different 'compliance points' for the presence of folic acid in different foods.

A close analysis of the AGS advice revealed that it was not possible to develop a valid joint food standard that met the needs of Australian jurisdictions and New Zealand and also had a common outcome (for the bread) but with different single compliance points in Australia (at the mill) and New Zealand (at the bakery).

As a result, FSANZ has decided that the proposed standard require the mandatory fortification of wheat flour for bread-making with folic acid. New Zealand has been consulted on the proposed standard and has advised that once the Review process has been finalised, it will be seeking a variation to the joint standard under Annex D of the Treaty. The intent of this variation will be the mandatory fortification of bread at the bakery in New Zealand. The proposed exemption of flour represented as organic will be applied to organic bread for New Zealand. Below is an example of the proposed New Zealand variation to the joint Standard.

To be inserted after clause 4 (Australia only provision requiring folic acid in wheat flour for making bread.

5 Mandatory fortification of bread (New Zealand only)

(1) This clause does not apply to bread sold or prepared for sale in, or imported into, Australia.

(2 Subclause 1(2) of Standard 1.1.1 does not apply to this clause.

(3) Bread must contain no less than 0.8 mg/kg and no more than 1.8 mg/kg of folic acid.

(4) Subclause 5(3) does not apply to bread, which is represented as organic

5.9 Other issues not specifically raised in the Review Request

Four additional issues were not raised in the Review Request but have been raised by stakeholders during the review consultations. These are:

- implementation timeframes;
- interactions with the proposal relating to mandatory fortification with iodine; and
- consequential changes to the standard relating to thiamin; and
- voluntary permissions for bread and cereal flour in Standard 1.3.2.

5.9.1 Implementation Timeframes

Fortification of bread-making flour with folic acid will require the milling industry to upgrade existing fortification equipment and systems, in order to achieve the level of precision required by the proposed mandatory standard for folic acid. This is likely to necessitate a different solution and mill set up for each flour mill, due to the individual variation between flour mills.

The transition time must therefore allow industry sufficient time to plan and upgrade fortification operations in each mill, and to develop the quality assurance procedures which meet compliance and enforcement requirements.

A transition time of two years is proposed for the implementation of a draft standard allowing for the fortification of bread-making flour in Australia, and bread in New Zealand.

The proposed draft variations to the Code as presented at Final Assessment proposed a transition period of 15 months from gazettal. This was extended from 12 months proposed at Draft Assessment, as it was anticipated that a proposal for mandatory iodine fortification (Proposal P230) would be implemented simultaneously.

Industry estimates for the implementation period for mandatory folic acid fortification ranged from as little as six months to over four years. McMullen recommends a lead-time of one to two years should be sufficient for industry to fully comply with the proposed folic acid mandatory fortification.

Should the Ministerial Council decide to adopt mandatory fortification, FSANZ will also (in association with industry) develop an implementation guide on the proposed Standard for dissemination through the milling and baking industry professional and training associations in Australia and New Zealand.

5.9.2 Interaction with proposal relating to mandatory fortification with iodine

Proposal P230 – Consideration of Mandatory Fortification with Iodine, is expected to be completed during 2007, and proposes the mandatory replacement of salt with iodised salt in bread. Should the mandatory iodine standard be agreed, ideally the implementation of the two standards would align to minimise costs to industry. FSANZ therefore proposes a transition period of two years for folic acid should mandatory fortification be introduced.

5.9.3 Consequential changes to thiamin standard

FSANZ proposes that the draft standard for mandatory folic acid fortification require that only wheat flour used for making bread be fortified with folic acid. For consistency FSANZ will amend the existing mandatory standard for thiamin to clarify 'flour for making bread' as being 'wheat flour for making bread'.

5.9.4 Voluntary permissions for bread and cereal flour in Standard 1.3.2

FSANZ proposes that the voluntary permissions currently in Standard 1.3.2 of the Code, which allow for the addition of folic acid to bread and cereal flour remain. This will allow the addition of folic acid to non-wheat cereal flours, and to breads which do not contain wheat flour. Manufacturers can therefore choose to fortify bread or cereal products which do not contain wheat. This may be advantageous to some consumers, including the target population, such as women of child-bearing age who avoid gluten-containing products because of coeliac disease.

6. ISSUES RAISED IN REVIEW CONSULTATIONS

Issues raised during stakeholder consultation which were relevant to the First Review have been addressed where possible. Those issues which were outside the scope of the First Review have not been addressed in this Report, apart from issues noted in section 5.9 of the Review. However, most issues raised had been considered previously as part of the Draft and Final Assessment Reports.

Stakeholders expressed strongly held views on mandatory folic acid fortification during the targeted consultations on the Review and in response to the Issues Paper released in April 2007.

Concerns were raised by a number of stakeholders relating to safety, particularly in relation to the percentage of children over the UL for folic acid. Other safety concerns related to cancer risks and masking of vitamin B_{12} deficiency.

Industry continued to strongly oppose mandatory fortification on a number of grounds including the 'medicalisation' of the food supply, concerns over safety and lack of effectiveness, cost to industry and loss of consumer choice.

Industry opposed the use of bread as a food vehicle as they did not consider women consumed sufficient amounts for effectiveness, and favoured instead the extension of voluntary fortification permissions and a well designed and resourced education campaign as a means of increasing folic acid intakes through both supplements and food.

The cost of fortification of flour was considered by industry to be prohibitive, and this view was presented in a report prepared by an independent milling consultant on behalf of the Flour Millers Council of Australia. Some of the findings of Gerard McMullen with regard to the fortification process and cost were questioned by industry.

The importance of ongoing monitoring of mandatory fortification was stressed by all stakeholder groups.

The importance of informing consumers, particularly the target group, was also noted by a number of submitters. Several jurisdictions suggested that the provision of folate or folic acid on the NIP would be beneficial for consumers. Industry, on the other hand, did not support this.

A number of submissions supported the proposed exemption for flour and bread represented as organic. Public health groups were predominantly supportive of mandatory fortification, with those against also citing safety concerns. Some of those supporting mandatory fortification recommended doubling the level of fortification to maximise folic acid intakes for the target group. Some public health groups and individuals questioned the need for mandatory fortification, preferring education campaigns promoting folic acid supplementation.

The majority of consumer comments were in favour of mandatory fortification. Stakeholders in support of mandatory fortification generally cited the success in the reduction of NTDs achieved in countries where mandatory fortification has been introduced, and felt confident of the safety of folic acid fortification because of the length of time that some countries (up to 30 years in the US) had been fortifying their food supply with folic acid.

Specific comments were also received in response to Professor Segal's Report on the cost-effectiveness analysis of options to increase folate levels to prevent neural tube defects. Contributions were received from Australian and New Zealand jurisdictions, the food industry, public health and consumer groups and individuals. Overall, comments were polarised and tended to support or challenge the findings in the Report, in line with their previous positions on mandatory fortification. However, there was strong support for the Report's conclusions that there is a need for high quality baseline data and monitoring of outcomes over time. A number of respondents considered that the cost of monitoring had not been adequately addressed in the Report.

Groups which supported mandatory fortification challenged the findings in the Report, particularly in relation to costs, effectiveness, equity, certainty and sustainability of voluntary fortification. Public health groups which supported mandatory fortification disputed the cost benefit analysis, especially the costs associated with the public health campaign and voluntary fortification. This group identified those most likely to benefit from mandatory fortification as younger women, who had no previous pregnancies, were not married, had no tertiary education, were public patients and who lived in rural and remote areas. Indigenous women were identified as of particular concern.

Groups which did not support mandatory fortification, predominantly industry and some public health groups, agreed with the Report's finding of the lack of cost-effectiveness of mandatory fortification and considered that further work was required to determine the best strategy for reducing NTDs. These respondents supported a public health campaign, targeted supplement promotion and an extension of voluntary fortification as the most cost-effective approach.

Many respondents also noted that it would have been preferable for Professor Segal to have more time to undertake the review of options and that this review should have ideally occurred earlier in the consideration of mandatory folic acid fortification.

7. REVIEW OPTIONS

Whenever FSANZ undertakes a Review, FSANZ examines three possible options – these options are:

1. re-affirm approval of the draft variations to the Code as notified to the Ministerial Council;

2. re-affirm approval of the draft variations to the Code subject to any amendments FSANZ considers necessary; or

3. withdraw approval of the draft variations to the Code as notified to the Ministerial Council.

8. CONCLUSION AND DECISION

In relation to the best means for implementing mandatory fortification, FSANZ has undertaken a comprehensive investigation of all issues raised in the Review Request and has concluded that the preferred option is Option 2 - re-affirm the approval of the draft variations to the Code subject to any amendments FSANZ considers necessary.

The proposed amendments to the draft variations to the Code (as at Attachment 1) are as follows:

- require the mandatory addition of folic acid to wheat flour for bread-making within the prescribed range of 200 -300 micrograms folic acid per 100 grams of flour in Australia;

- exempt wheat flour for bread-making represented as organic from this requirement;

- retain the voluntary permissions for addition of folic acid to bread and cereals flours to allow for the voluntary fortification of non-wheat breads and flours;

- consequential amendments to the mandatory thiamin standard (so to clarify that it also applies to wheat flour for bread-making); and

- allow a transition time of two years for implementation.

The reasons for this decision are:

- The proposed level of mandatory folic acid fortification is expected to increase average daily folic acid intakes among women aged 16-44 years by 100 µg per day and 140 µg per day, in Australia and New Zealand respectively (assuming current uptake of voluntary fortification permissions remain the same). This is in addition to the estimated 108 µg per day Australian women and 62 µg per day New Zealand women currently receive through voluntary fortification. This is expected to reduce the number of NTD-affected pregnancies by a further 14-49 (or up to 14%) in Australia and by 4-14 (or up to 20%) in New Zealand.

- We have reviewed newly available scientific evidence since Final Assessment in relation to potential risks. Based on the totality of current evidence, including overseas experience with mandatory fortification, our conclusion that the proposed level of fortification does not pose a risk to public health and safety is unchanged. However as this is an active area of research and publication, FSANZ reiterates the importance of a monitoring strategy including the need to maintain a watching brief on any scientific developments which may potentially alter the understanding of risk to public health and safety.

- While acknowledging that there will be capital and ongoing costs to industry from the implementation of mandatory fortification, revised costing estimates indicate that the costs to the milling industry are likely to be $7.9 million up-front and $1.1 million per year. These costs vary with those proposed by industry ($28.6 million up-front and $12.1 million per year); with most of the difference in costs coming from assumptions from industry on the additional capital and process changes required to ensure compliance with the standard. An independent review[55] commissioned by industry concludes that there would *substantial additional costs* to industry, specifically in relation to meeting a prescribed range of fortification. It is expected that these costs may be passed onto consumers at some stage and will be around 0.5 to 1% of the cost of a loaf of bread in Australia using FSANZ's cost data.

- Exemption of wheat bread-making flour represented as 'organic' will allow the organic milling and bread industry to comply with fair trading legislation[56], which takes precedence over the Code.

- Consumers will be informed of the presence of folic acid through ingredient labelling, and where bread is unpackaged will be informed through other means, such as communication and education strategies. Communication and education strategies will also increase awareness of, and inform consumers about, mandatory fortification.

[55] BRI Research, *An evaluation of two reports on the proposed mandatory fortification of flour with folic acid in Australia*, April 2007.
[56] In Australia, *Trades Practices Act 1974*; In New Zealand *Fair Trading Act 1986.*

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*

2. Informing a Strategy for Increasing Folate Levels to Prevent Neural Tube Defects: A Cost-effectiveness Analysis of Options, L Segal, K Dalziel and R Katz, April 2007.
3. Mandatory Folic Acid Fortification of Bread-making Flour in Australia; Gerard McMullen, March 2007.
4. Ministerial Council's Policy Guideline on Fortification of Food with Vitamins and Minerals.
5. Additional information on the effectiveness and potential health benefits and risks of increasing folic acid intakes in the population.
6. Impact of Mandatory Fortification in the United States of America.
7. Dietary intake assessment report.
8 Communication and Education Strategy.

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Attachment 1

Draft variations to the *Australia New Zealand Food Standards Code*

To commence: on gazettal

[1] ***Standard 1.1A.2*** *of the Australia New Zealand Food Standards Code is varied by omitting from the* Table to subclause 3(e), *all of the entries under the heading,* Bread, *substituting –*

Bread
Tip Top English Muffins
Tip Top Hyfibe White Muffins
Tip Top Multigrain 9 Grain Muffins
Tip Top Multigrain Muffins
Tip Top The White Stuff Muffins

To commence: 24 months from gazettal

[2] ***Standard 1.3.2*** *of the Australia New Zealand Food Standards Code is varied by –*

[2.1] *omitting* the Purpose*, substituting –*

This Standard regulates the addition of vitamins and minerals to foods, and the claims which can be made about the vitamin and mineral content of foods. Standards contained elsewhere in this Code also regulate claims and the addition of vitamins and minerals to specific foods, such as, the addition of folate to wheat flour for making bread in both Australia and New Zealand and the addition of thiamin in Australia only in Standard 2.1.1, the addition of vitamin D (Australia only) to table edible oil spreads and margarine in Standard 2.4.2, the addition of vitamins to formulated caffeinated beverages in Standard 2.6.4, the addition of vitamins and minerals to special purpose foods standardised in Part 2.9 and the addition of iodine to certain salt products in Standard 2.10.2.

[2.2] *omitting from the* Table to clause 3, *under the heading* Cereals and cereal products *the entry for* Bread, *substituting –*

Bread	50 g	Thiamin Riboflavin Niacin Vitamin B_6 Vitamin E Iron Magnesium Zinc	0.55 mg (50%) 0.43 mg (25%) 2.5 mg (25%) 0.4 mg (25%) 2.5 mg (25%) 3.0 mg (25%) 80 mg (25%) 1.8 mg (15%)	
- bread that contains no wheat flour		Folate	100 µg (50%)	

[3] ***Standard 2.1.1*** *of the Australia New Zealand Food Standards Code is varied by –*

[3.1] *omitting the* Purpose*, substituting –*

This Standard defines a number of products composed of cereals, qualifies the use of the term 'bread', and requires the mandatory fortification of wheat flour for making bread with folate in both Australia and New Zealand and thiamin, in Australia only.

[3.2] *omitting clause 4, substituting –*

4 Wheat flour for making bread

(1) Subclause 1(2) of Standard 1.1.1 does not apply to this clause.

(2) Wheat flour for making bread must contain –

(a) no less than 2 mg/kg and no more than 3 mg/kg of folic acid; and
(b) no less than 6.4 mg/kg of thiamin.

(3) For the purposes of this clause wheat flour includes wholemeal wheat flour for bread making.

(4) Subclause 4(2) does not apply to wheat flour for making bread, which is represented as organic.

(5) Paragraph 4(2)(b) does not apply to wheat flour for making bread sold or prepared for sale in, or imported into, New Zealand.

Editorial note:

The maximum limit for folic acid given in paragraph 4(2)(a) ensures the addition of folic acid to wheat flour for making bread in Australia and New Zealand is in controlled amounts to provide for a safe population intake of dietary folic acid. Paragraph 4(2)(a) will be reviewed, when sufficient monitoring data are available to assess the impact of this mandatory requirement.

Paragraph 4(2)(b) will be reviewed to assess the future need for this mandatory requirement for Australia and New Zealand.

Standard 1.3.2 regulates the voluntary addition of folate to both cereal flours and bread. These permissions will be retained to enable manufacturers to fortify specialised non - wheat flour and breads, such as, gluten free bread.