EXPLANATORY STATEMENT

PROPOSAL P295

CONSIDERATION OF MANDATORY FORTIFICATION WITH FOLIC ACID

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

EXECUTIVE SUMMARY

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

FSANZ released an Initial Assessment Report in October 2004 and presented four options, 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.

FSANZ reduced the number of regulatory options considered at Draft Assessment to maintenance of the *status quo* and mandatory folic acid fortification. FSANZ's assessment seeks to determine how mandatory fortification can be implemented in Australia and New Zealand as Ministerial advice received in 2005 is that mandatory folic acid fortification is an effective strategy and requested that FSANZ expedite its process.

Internationally, a number of countries have reported successful mandatory folic acid fortification programs as an equitable and sustainable means of increasing the folic acid intake of women of child-bearing age (the target population) to reduce the incidence of NTDs.

FSANZ drew on this international experience and selected bread-making flour (consumed as bread and bread products) as the food vehicle for mandatory folic acid fortification in Australia and New Zealand at Draft Assessment. Following further targeted consultation and consideration of the international experience with folic acid fortification and Australian experience with thiamin fortification, FSANZ has refined the approach to specifically require mandatory fortification of bread as the final food consumed. This approach provides a more predictable means of delivering folic acid intake to the target population whilst limiting intake in the non-target population and increases flexibility for industry in meeting the mandatory standard.

This Final Assessment Report therefore focuses on consideration of mandatory folic acid fortification of bread as a means of reducing the incidence of NTDs in Australia and New Zealand and includes:

- an assessment of the potential health benefits and risks of increased dietary intakes of folic acid by the Australian and New Zealand populations;
- technical issues regarding fortification of bread as the preferred food vehicle and level of folic acid concentration to achieve the desired health outcome;
- consideration of alternative approaches to mandatory fortification (as provided by several submitters) to achieve similar levels of effectiveness and safety;
- management of any identified health risks associated with the selected level of fortification;
- a revised cost-benefit analysis;

- associated communication and education strategies;
- monitoring and implementation issues; and
- presentation of a regulatory approach.

This report also addresses issues arising from public submissions and targeted stakeholder consultations.

The Decision

Mandatory fortification of bread[1] with folic acid is the preferred approach in Australia and New Zealand to further reduce the incidence of NTDs.

The proposed level of mandatory fortification is 80-180 micrograms (µg) of folic acid per 100 grams of bread.

The approach maintains current voluntary folic acid permissions except for bread which will be changed from a voluntary permission to a mandatory requirement.

Reasons for the Decision

The reasons for this decision are:

- fortifying bread with folic acid, learns from and builds on international experience of mandatory fortification to reduce the incidence of NTDs;
- bread is an effective and technically feasible food vehicle for mandatory fortification;
- bread and bread products are staple foods consumed widely (more than 80%), consistently and regularly by the target population of women aged 16-44 years;
- fortification of bread will deliver a mean increase in folic acid intake in the target population of 101 µg and 140 µg in Australia and New Zealand respectively, resulting in an estimated reduction of between 14-49 out of 300-350 pregnancies in Australia and 4-14 out of 70-75 pregnancies in New Zealand affected by an NTD each year;
- on the available evidence, including overseas experience with mandatory fortification, the proposed level of fortification does not pose a risk to public health and safety. The level has been set to minimise any potential health risks as a degree of uncertainty exists, particularly for the non-target population from increased folic acid intakes over the longer term;
- the cost-benefit analysis has indicated that mandatory fortification of bread with folic acid can deliver benefits that definitively exceed the costs:

[1] Bread is defined as 'the product made by baking a yeast-leavened dough prepared from one or more cereal flours or meals and water.'

- in Australia, when folic acid is added to bread making flour, the net-benefit from all NTDs avoided is $122 million each year ongoing. In the case of live births the net-benefit is $21 million each year ongoing;
- in Australia, when folic acid is added at the later stages of bread production, the net-benefit from all NTDs avoided is $99 million each year ongoing. In the case of live births there is a net-cost of $2 million each year ongoing;
- in New Zealand, when folic acid is added to bread making flour, the net-benefit from all NTDs avoided is $41 million each year ongoing. In the case of live births the net-benefit is $4.3 million each year ongoing; and
- in New Zealand, when folic acid is added at the later stages of bread production, the net-benefit from all NTDs avoided is $39 million each year ongoing. In the case of live births the net-benefit is $2.5 million each year ongoing.

- fortification of bread provides greater predictability in the level of folic acid consumed by the target and non-target groups and therefore greater confidence that the estimated reduction in NTDs will be achieved and that health risks to non-target groups will be minimised;

- fortification of bread provides flexibility for industry in determining the most appropriate and cost effective means of achieving mandatory fortification;

- the cost to consumers is likely to be less than 2% of the price of a loaf of bread;

- the fortification of bread does provide for some consumer choice through access to unleavened breads and unfortified flour; and

- it is consistent with Ministerial policy guidance on mandatory fortification.

Consultation

FSANZ received 148 submissions in response to the Draft Assessment Report for this Proposal during the public consultation period of 3 to 31 July 2006. A full summary of submissions is at Attachment 2.

FSANZ also conducted intensive targeted consultation through a range of consultative mechanisms to discuss key issues and impacts of mandatory fortification with all stakeholder groups, namely the Australian and New Zealand baking and milling industries, supermarket in-store bakery representatives, organic industry representatives, government agencies, and consumer and public health organisations.

There was divergence of views regarding mandatory folic acid fortification both between and within stakeholder groups. Most government submitters supported mandatory fortification on the condition that monitoring is in place prior to implementation. Some public health and consumers groups supported mandatory fortification whereas others were opposed. Industry was opposed to mandatory fortification.

Key issues raised included the effectiveness of mandatory fortification in reducing NTDs (based on the proposed fortification level) being not sufficient to justify population wide consumption of folic acid, possible health risks and future unknown health risks, lack of consumer choice, the impacts on industry, monitoring of mandatory fortification, enforcement and the importance of continuing other NTD risk reduction strategies.

Key issues

Will mandatory fortification of bread with folic acid result in other health benefits?

No other health benefits, apart from a reduced risk of NTDs, have been conclusively associated with an increase in folic acid intake.

Whilst a reduced risk of cardiovascular disease was previously reported as a potential health benefit, a review of current evidence (much of it published early in 2006) does not support this association.

Are there any possible health risks from mandatory fortification with folic acid?

The expected average increase in folic acid intake arising from mandatory folic fortification is unlikely to pose any increased risk of masking the diagnosis of vitamin B_{12} deficiency in older people or in the zinc status of the population. The available evidence also suggests that folic acid is unlikely to interfere with anti-epileptic, antifolate or some anti-inflammatory drugs at folic acid intakes below one milligram per day.

A small proportion of young children (7% of 2-3 year olds in Australia) are expected to exceed the Upper Level of Intake (UL) for folic acid based on the proposed level of fortification. Whilst this is undesirable, it is unlikely to pose a health risk as there is a considerable margin of safety inherent in setting the UL. No comparable data on folic acid intakes among children under five years are available for New Zealand.

In addition to the potential health risks described above, there remains some uncertainty about other potential adverse health effects (e.g. cancer incidence and an increase in multiple births) from increased folic acid. As a result of these uncertainties a risk management approach has been adopted consisting of:

- the requirement to ensure the level of folic acid in the final food meets a specified range, rather than placing the requirement on the folic acid content of the flour;
- a conservative approach to the level of fortification;
- the inclusion of an upper limit in the standard; and
- identifying the need to monitor potential health risks.

These elements together limit the intake in non-target populations, provide greater predictability regarding folic acid consumption and establish a mechanism to inform a review of the standard which is proposed within five years of implementation.

Does mandatory fortification allow for consumer choice?

Under mandatory fortification nearly all breads will be fortified. This will include bread and bread rolls, sweet buns, fruit bread, English style muffins, some flat breads and bread crumbs. Breads which fall outside the definition of 'bread' in the Australia New Zealand Food Standards Code2, will not be required to be fortified with folic acid.

Some unfortified products such as unleavened flat breads, hot plate products such as crumpets and pikelets, pizza bases, and retail flours will provide consumers with other options.

Consumers will be informed about the addition of folic acid to bread through labelling that requires all ingredients of a product to be identified in the ingredient list.

How will industry implement mandatory folic acid fortification?

Mandatory fortification will require all bread to contain folic acid within a prescribed range of 80-180 micrograms (µg) of folic acid per 100 g of bread. Bread manufacturers will need to decide the most suitable and cost effective methods of fortifying for their particular bread production process. Folic acid could be added through the use of flour fortified with folic acid, dry ingredients such as a bread improver[3] fortified with folic acid, a complete bread premix which has been fortified with folic acid, or a folic acid vitamin premix which is added to the dough.

FSANZ will prepare an implementation guide, education materials, and, if required, workshops to assist industry. Industry will have 15 months from when the new standard is gazetted to comply with the mandatory fortification requirements.

How will mandatory fortification be monitored?

Responsibility for establishing and funding a monitoring system extends beyond FSANZ's responsibility under the *Food Standards Australia New Zealand Act 1991*. FSANZ will, however, routinely monitor some elements of the system such as:

- tracking changes in voluntarily fortified foods;
- updating the folic acid composition of foods in the food composition databases;
- tracking labelling changes on fortified foods;
- tracking changes in food consumption patterns for different demographic groups in key food categories that are likely to be fortified; and
- researching consumers' attitudes and behaviour towards fortified foods.

[2] Bread is defined as 'the product made by baking a yeast-leavened dough prepared from one or more cereal flours or meals and water.'

[3] Bread improvers are combinations of ingredients, such as enzymes, emulsifiers and antioxidants that are added to dough to modify its characteristics and those of the bread in order to improve keeping quality, texture and flavour.

Monitoring other elements of the impact of mandatory folic acid fortification, particularly the main outcome measure of a change in the national rate of NTDs, will require involvement of health and regulatory agencies at a Commonwealth, State and Territory level in Australia and the New Zealand Government. Other outcome measures, such as cancer incidence, are already routinely collected and reported and will contribute to baseline data for the monitoring system.

Further information about the elements of and responsibilities for establishing a monitoring system are provided in Section 18 of this report and at Attachment 12.

What other strategies are planned to support mandatory fortification?

FSANZ recognises that mandatory fortification is one strategy in NTD prevention, and that other strategies will continue to be important including the existing voluntary fortification of other foods, the promotion of supplement use and education for women of child-bearing age.

FSANZ will talk with relevant industry members and government agencies to ensure that recommendations about supplement use take account of expected increases in dietary folic acid intake among women of child-bearing age.

FSANZ has prepared a communication and education strategy for mandatory folic acid fortification that aims to increase awareness among all target audiences of the proposed standard for mandatory folic acid fortification and its implementation. To implement the strategy, FSANZ will seek opportunities to collaborate with organisations to provide information and education about the proposed standard to consumers, industry, health professionals and other key stakeholders.

FSANZ has begun to collaborate with a range of organisations as optimal reduction in the incidence of NTDs depends on these strategies being collaborative and sustained.

Implementation

Following completion of the Final Assessment for this Proposal, the FSANZ Board will notify the Ministerial Council of the decision. Subject to any request from the Ministerial Council for a review, the proposed draft variations to the Code (Attachment 1) will come into effect 15 months from gazettal.

To assist industry, enforcement agencies and other stakeholders with the implementation of this mandatory fortification standard, FSANZ will develop an Implementation Guide.

CONTENTS

SEPARATE ATTACHMENTS (FINAL ASSESSMENT REPORT):

The following attachments are available on the FSANZ website at http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp295considerationofmandatoryfortificationwithfolicacid/index.cfm

ATTACHMENT 2 – SUMMARY OF SUBMISSIONS FROM THE DRAFT ASSESSMENT REPORT
ATTACHMENT 3 – POLICY GUIDELINE
ATTACHMENT 4 – IMPACT OF MANDATORY FORTIFICATION IN THE UNITED STATES OF AMERICA
ATTACHMENT 5 – CURRENT APPROACH TO INCREASING FOLATE INTAKE AMONG WOMEN OF CHILD-BEARING AGE
ATTACHMENT 6 – POTENTIAL HEALTH BENEFITS AND RISKS OF INCREASED FOLIC ACID INTAKE

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SEPARATE ATTACHMENTS (FIRST REVIEW REPORT – ATTACHMENT 2):

The following attachments are available on the FSANZ website at http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp295considerationofmandatoryfortificationwithfolicacid/index.cfm

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
ATTACHMENT 3 – *MANDATORY FOLIC ACID FORTIFICATION OF BREAD-MAKING FLOUR IN AUSTRALIA*; GERARD MCMULLEN, MARCH 2007
ATTACHMENT 4 – MINISTERIAL COUNCIL'S POLICY GUIDELINE ON FORTIFICATION OF FOOD WITH VITAMINS AND MINERALS
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ATTACHMENT 7 – DIETARY INTAKE ASSESSMENT REPORT
ATTACHMENT 8 – COMMUNICATION AND EDUCATION STRATEGY

INTRODUCTION

Neural tube defects (NTDs) are a group of birth defects, which occur *in utero* during the development of the brain or spinal cord. Since the early 1990s there has been convincing evidence that increased intakes of folic acid can reduce the risk of NTDs. As a result, a number of countries including Australia and New Zealand have adopted policies to increase the folate intake of women prior to and during pregnancy.

The primary prevention strategies in Australia and New Zealand have been, either singly or in combination: promotion of diets high in naturally occurring folate; promotion of folic acid supplements during the peri-conceptional period; and voluntary fortification of the food supply with folic acid.

Mandatory fortification has been under active consideration since May 2004 when the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) adopted a Policy Guideline on the *Fortification of Food with Vitamins and Minerals* (see Attachment 3). At that time, Ministers also requested that Food Standards Australia New Zealand (FSANZ) give priority consideration to mandatory fortification with folic acid. FSANZ raised this Proposal (Proposal P295) and released an Initial Assessment Report for public consultation in October 2004.

In December 2004, FSANZ sought advice from the Food Regulation Standing Committee (FRSC) on two policy issues:

- whether mandatory fortification with folic acid is the most effective public health strategy; and

- a process to establish a health monitoring and review system in support of mandatory fortification.

FRSC undertook a process to clarify these policy issues which included seeking advice from the Australian Health Ministers' Advisory Council (AHMAC) and the Australian Health Ministers' Conference (AHMC). An Expert Panel convened by AHMAC[4] reported that mandatory fortification fulfilled their criteria[5] of effectiveness, equity, efficiency, certainty, feasibility and sustainability required for an effective public health strategy and advised Health Ministers to support mandatory fortification as 'the most effective public health strategy for increasing folate intakes'.

In October 2005, the Ministerial Council noted the advice of AHMAC and AHMC that mandatory fortification with folic acid is an effective public health strategy subject to clinical safety and cost-effectiveness. FSANZ was asked to progress consideration of mandatory fortification with folic acid as a matter of priority and on this basis expedited the consideration.

[4] *The effectiveness of mandatory fortification as a public health strategy to increase nutrient intakes, with reference to iodine and folate*. Expert public health advice prepared for AHMAC, June 2005.
[5] Case studies of public health interventions to increase nutrient intakes were used to generate effectiveness criteria.

In July 2006, FSANZ released a Draft Assessment Report proposing mandatory folic acid fortification of bread-making flour (consumed as bread and bread products) as the preferred regulatory approach. FSANZ received 148 submissions with the majority of public health and government agencies in favour of mandatory fortification and with some public health and consumer groups and industry opposed.

This Final Assessment Report seeks to refine, following public consultation and other targeted consultation activities, the preferred regulatory option as proposed at Draft Assessment to reduce the incidence of NTDs in Australia and New Zealand. The Report provides a description of the current approach as well as an assessment of the health benefits and risks of mandatory fortification, refinement of the preferred food vehicle, management of any identified risks, a revised cost-benefit analysis, associated communication, education, monitoring and implementation issues and recommends a regulatory approach. Issues arising from public submissions and targeted stakeholder consultation have also been addressed where possible in this Report.

Work on developing a monitoring scheme for mandatory folic acid fortification is currently underway by a FRSC working group. FSANZ has adapted the draft framework prepared by the FRSC working group and outlined the potential elements of a monitoring system that aims to assess the impact of mandatory fortification of the food supply with folic acid on consumers (see Attachment 12). Responsibility for establishing and funding a monitoring system to assess the impact of a mandatory fortification on the population extends beyond FSANZ's responsibilities under the FSANZ Act 1991, 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.

Refer to the Glossary and Abbreviations and Acronyms for a list of definitions and abbreviations used in this Report.

Scope of this Proposal

At Initial Assessment four options were presented, 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.

On the basis of the Ministerial advice that mandatory fortification with folic acid is an effective strategy, FSANZ reduced the number of regulatory options considered to two at Draft Assessment and for this Final Assessment. These are maintenance of *status quo* (including existing voluntary folic acid fortification) and mandatory fortification.

The scope of this Proposal reflects the relative success of international experience with mandatory folic acid fortification programs and the experience to date of this being able to deliver an equitable, sustained and predictable response to further reducing the incidence of NTDs in Australia and New Zealand.

1. Background

1.1 Folate terminology and forms

The following terms are used frequently throughout the report. For further details about definitions refer to the Glossary.

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).

Naturally-occurring folate is the 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.

Folic acid, or 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. Folic acid is rarely found occurring naturally in foods (NHMRC, 1995).

Dietary folate refers to folate that is consumed in the diet, both naturally occurring and folic acid added through fortification. This term does not include folate consumed through supplements.

5-methyl tetrahydrofolate (5-methyl-THF) is the principal form of folate that circulates in the blood. 5-methyl-THF can be synthesised and added to food as a fortificant, however, this form of folate is less stable in the final product than synthetic folic acid.

Serum folate refers to the level of 5-methyl-THF that is present in the blood.

Unmetabolised free folic acid is folic acid that has not been converted to methyl-THF following digestion, and therefore circulates in the blood as a free form of folic acid.

1.2 Nutritional role of folate

Folate is used by the body in two important pathways: the DNA cycle and the methylation cycle. Folate is essential for DNA synthesis as without it living cells cannot divide. The need for folate is higher when cell turnover is increased, such as in foetal development. The methylation cycle provides the cell with an adequate supply of S-adenosylmethionine, which acts a methyl donor in a wide range of methylation reactions. Homocysteine is methylated by 5-methyl-THF to produce the amino acid methionine.

Recommended levels of intake of essential nutrients, including folic acid, have been established to:

- avoid deficiency in the majority of a healthy population;
- minimise health risks from excess nutrient consumption by setting an upper level of intake, where appropriate; and
- optimise nutrient intake for lowering chronic disease risk.

To capture the different levels, a range of values is given for each nutrient. For folate these include: an estimated average requirement (EAR[6]), a recommended dietary intake (RDI[7]) and an upper level of intake (UL[8]) for each age and gender group. These levels of intake are termed nutrient reference values (NRVs) and have been recently revised by the NHMRC[9].

The NRVs recommend increased levels of folate intake to those previously published in 1991. The increased folate recommendations are based on new data which looked at the association between folate intake and homocysteine levels in the blood. The new EAR and RDI for folate are expressed as 'dietary folate equivalents' or DFEs[10], which reflect the considerable difference in bioavailability (see Section 6.1.4) between naturally-occurring folate and folic acid. The new folate RDI for men and women is 400 µg as DFEs which replaces the previous folate RDI of 200 µg per day.

'Women capable of, or planning, pregnancies should consume additional folic acid as a supplement or in the form of fortified foods at a level of 400 µg/day folic acid for at least one month before and three months after conception, in addition to consuming food folate from a varied diet' (NHMRC and NZMoH, 2006).

The adult UL for folate (1,000 µg per day of folic acid) has been set based on the potential for regular intakes above this level, by the elderly in particular, to mask the diagnosis of vitamin B_{12} deficiency (see Section 5.2.1). The UL set for adults has been applied to younger age groups on a relative body weight basis. However, vitamin B_{12} deficiency is rare in children, and so the relevance of this endpoint and hence the risk to children is not clear.

Individual folate requirements can be affected by factors such as smoking, certain drugs and genetic variations. Inadequate folate intake leads to sub-optimal folate status. Limited data exist on the folate status of the Australian and New Zealand populations (see Section 2.4.2) although those 'at risk' of deficiency may be as high as one in three in some Australian population sub-groups (Abraham and Webb, 2001).

Foods naturally high in folate are green leafy vegetables (such as broccoli and spinach), nuts, orange juice, some fruits and dried beans and peas. Cereals are moderate sources of folate. Based on the national nutrition surveys conducted in Australia and New Zealand in 1995 and 1997 respectively, cereals and cereal-based dishes, vegetables and legumes contributed nearly 60% of naturally-occurring folate in the adult diet (NZMoH, 1999; ABS, 1999). These surveys were conducted prior to or about the time of the introduction of voluntary fortification.

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[6] 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.

[7] 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.

[8] The UL is the highest average daily nutrient intake likely to pose no adverse health effects to almost all individuals in the general population.

[9] The NHMRC 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

[10] 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.

1.3 Neural Tube Defects (NTDs)

NTDs are a group of birth defects, which arise during the development of the brain and spinal cord *in utero*. In the very early stage of pregnancy, a band of cells along the dorsal surface of the embryo develop into a hollow tube called the neural tube, which eventually forms the spinal column and central nervous system. This process, called neurulation, is completed by day 22 to 28 after ovulation (Van der Put *et al*., 2001a; Verity *et al*., 2003). Incomplete closure of the neural tube may lead to one of the following three neural tube defects:

- Spina bifida – This is a condition whereby incomplete closure of the neural tube results in the spinal cord being exposed or protruding through a gap in the spine. This may result in the spinal nerves not being fully developed. The proportion of infants with spina bifida who survive beyond one year of age in both Australia and New Zealand is likely to be in the range of 70-90%.

- Anencephaly – This condition is characterised by a failure of the anterior neural tube to close, resulting in the total or partial absence of the cranial vault and brain tissue. Infants are usually stillborn or die shortly after birth. Together spina bifida and anencephaly account for 90% of all cases of NTDs.

- Encephalocoele – This condition is characterised by the meninges and/or brain tissue extruding through a defect in the skull. This is the least frequent of the neural tube defects. The survival pattern of encephalocoele results in a low proportion of stillbirths, the majority of deaths occurring within the first year of life, although long-term survival after that is similar to children born with spina bifida.

The process of brain and spinal cord development can be disrupted by genetic and environmental factors. The risk of NTDs is increased by: certain single-gene disorders and chromosomal anomalies; maternal factors such as diabetes mellitus; use of anticonvulsant medication; and inadequate folate intake. The risk is also increased in women who have previously had a NTD-affected pregnancy. Differences in the distribution of NTD cases have also been associated with geographical location, ethnicity, seasonal variation, maternal age, and socioeconomic status (Van der Put *et al*., 2001b).

In Australia, 300-350 pregnancies are affected each year by a neural tube defect. In New Zealand there are approximately 70-75 cases per year (see Attachments 5 and 9).

The following terms in relation to NTDs are used frequently throughout the report. For further details about definitions refer to the Glossary (page 73).

Incidence: The number of live births, stillbirths and terminations affected by an NTD expressed as a rate per 1,000 total births[11]. As data on the number of terminations affected by an NTD is frequently incomplete, some authors use the term 'prevalence'.

Birth prevalence: The number of live births and stillbirths affected by an NTD expressed as a rate per 1,000 total births.

[11] Total births = live births + stillbirths.

The terms 'incidence' and prevalence' usually refer to a reference time period e.g. per year. In this report, however, these terms often refer to periods much longer than a single year and in some cases the reference time period is not specified.

1.4 Regulation of folic acid in foods in Australia and New Zealand.

Since 1995, in Australia, and 1996 in New Zealand, folic acid has been permitted to be voluntarily added to the following foods: flour; savoury biscuits; breads; breakfast cereals; vegetable and meat extracts; pasta; fruit and vegetable juices and drinks; and beverages derived from legumes. Folic acid may also be added to legume analogues of dairy foods and meat but in smaller amounts. More recently voluntary folic acid fortification permissions have been extended to cereal based beverages e.g. rice and oat 'milks'. These permissions are provided in Standard 1.3.2 – Vitamins and Minerals of the *Australia New Zealand Food Standards Code* (the Code).

Under the existing food regulations, permitted claims made on the presence of a vitamin and mineral in a food refer to the total of both naturally-occurring and added forms of the nutrient. In the case of dietary folate in food the amount declared on a label is the sum of naturally-occurring folate and added folic acid and is listed as 'folate' in the Nutrition Information Panel. The changes to the NRVs for folate will require amendments to relevant standards in the Code, which may in the future impact on composition and nutrition labelling requirements. These amendments will occur in a separate review process.

Under Standard 1.1A.2 – Transitional Standard – Health Claims, a health claim highlighting the link between increased maternal dietary folate intake and reduction in NTD risk is permitted for some fortified and non-fortified foods that contain at least 40 μg folate per serving. The claim should state that increased maternal folate consumption in at least the month before and three months following conception may reduce the risk of NTDs. It must also include the recommendation that women consume a minimum of 400 μg of folate per day during this time.

FSANZ is currently working on Proposal P293 – Nutrition, Health and Related Claims, to develop a new standard for nutrition and health claims. The new standard (draft Standard 1.2.7 – Nutrition, Health and Related Claims) will permit a wider range of claims in the future including a proposed revised folate-NTD health claim. The temporary provision for the current folate-NTD claim has been in place since 1998, and will cease to have effect two years from the commencement of the new health claim standard.

1.5 Existing mandatory fortification requirements

Mandatory fortification of food with thiamin and vitamin D has existed in Australia for over 15 years; however, there is currently no mandatory fortification of food in New Zealand. Standard 2.1.1 – Cereals and Cereal Products of the Code requires *flour for making bread* to be fortified with thiamin in Australia only. Mandatory fortification of table edible oil spreads and table margarine with vitamin D in Australia is regulated under Standard 2.4.2 – Edible Oil Spreads of the Code.

1.6 International regulation of folic acid in foods

1.6.1 Codex Alimentarius

The Codex Alimentarius does not mandate the addition of particular nutrients to certain foods other than some special purpose foods. For generally consumed foods, the *General Principles for the Addition of Essential Nutrients to Foods*[12] state that essential nutrients may be added to foods for the purposes of restoration, nutritional equivalence of substitute foods, fortification[13], or ensuring the appropriate nutrient composition of a special purpose food.

1.6.2 Countries with mandatory folic acid fortification

A number of countries have introduced mandatory requirements for folic acid fortification of foods in an effort to reduce the incidence of NTDs. These include Canada, the United States, Indonesia, and a number of African and South American countries including Chile. In these countries, the most common food fortified with folic acid is wheat flour. A number of other countries are currently considering mandating folic acid fortification of flour, and include the United Kingdom and Ireland. The Food Safety Authority of Ireland has recently recommended mandatory folic acid fortification of all bread, with a few minor exceptions to provide for some consumer choice[14].

Canada and the United States, countries with similar food supplies as Australia and New Zealand, have both mandated folic acid fortification of flour and other grain products (Table 1).

Table 1: Folic acid fortification in Canada and the United States

Country	Foods fortified with folic acid	Year of introduction	Minimum level of fortification (mg/kg)
Canada[1]	Flour (white, enriched[15], enriched white); enriched cornmeal, enriched pasta, enriched pre-cooked rice	1998	1.5 (or 150 µg/100 g)
	Bread (white, enriched)		1.0 (or 100 µg/100 g)
United States[2]	Enriched cereal grain products including: enriched wheat flour, enriched bread, rolls & buns, enriched cornmeal & grits, enriched farina, enriched rice and enriched macaroni products	1998	1.4 (or 140 µg/100 g)

Sources:
1. Canadian Government (1998)
2. USFDA (1996g)

[12] Codex Alimentarius CAC/GL 09/1987 (amended 1989, 1991).
[13] 'Fortification' or 'enrichment' means the addition of one or more essential nutrients to a food for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups.
[14] Food Safety Authority of Ireland. *Report of the National Committee on Folic Acid Food Fortification* 2006 http://www.fsai.ie/publications/reports/folic_acid.pdf
[15] In the United States, 'enriched' refers to the addition of a nutrient to a food that has been lost during the course of food processing or during normal storage and handling, up to the nutrient's level in the food before the processing, storage and handling.

In the United States, these food vehicles were chosen because they are staple food products for most of the population (including 90% of the target group) and have a long history of being successful vehicles for fortification (USFDA 1996e; USFDA 1996f, see Attachment 4). In addition, a cost-benefit analysis undertaken following the introduction of mandatory fortification in the United States found a considerable net benefit associated with the fall in NTDs (Grosse *et al*., 2005, see Attachment 11).

2. Current approaches to increasing folate intake

The primary prevention strategies employed in Australia and New Zealand since the early 1990s to reduce the risk of inadequate folate intake during the peri-conceptional period, and the attendant risk of NTDs, have been:

- promotion of folic acid supplements and diets containing foods naturally rich in folate;
- voluntary fortification of the food supply with folic acid and subsequent promotion of fortified foods; and
- a folate-NTD health claim.

These strategies are summarised below. Further detail about the current strategies to increase folate and/or folic acid intake, improve folate status and reduce the incidence of NTDs is described in Attachment 5.

2.1 Folic acid supplement recommendations and availability

Folic acid supplementation during the peri-conceptional period can reduce the likelihood of a pregnancy affected by an NTD (Bower and Stanley, 1989; MRC Vitamin Study, 1991; Czeizel and Dudas, 1992; Berry *et al*., 1999; Lumley *et al*., 2001).

Australia and New Zealand introduced health policies recommending women take folic acid supplements during the peri-conceptional period in the early 1990s.

2.1.1 Australia

In Australia, the current NHMRC recommendation is that women capable of, or planning a pregnancy, should consume additional folic acid as a supplement or in the form of fortified foods at a level of 400 µg per day for at least one month before and three months after conception, in addition to consuming naturally-occurring folate in foods (NHMRC and NZMoH, 2006).

Folic acid supplements and multivitamin supplements containing folic acid can be purchased at pharmacies, health foods stores and supermarkets. Folic acid supplements generally contain 500 µg, with 5,000 µg (or 5 mg) folic acid daily dose supplements available for women at high risk of an NTD-affected pregnancy. Multivitamins marketed to peri-conceptional, pregnant and breast-feeding women contain folic acid levels ranging from 200 µg to 800 µg.

2.1.2 New Zealand

In New Zealand, the Ministry of Health recommends that all women planning a pregnancy, or who are in the early stages of pregnancy, take an 800 µg[16] folic acid tablet daily for at least four weeks before, and 12 weeks after conception to reduce the risk of NTDs.

Women at high risk of a pregnancy affected by an NTD are recommended to take a daily 5,000 µg (or 5 mg) folic acid tablet for the same period of time (NZMoH, 2006).

Eight hundred microgram folic acid supplements are registered medicines, and can be purchased over the counter in pharmacies. Dietary supplements (such as multivitamins) containing folic acid doses ranging from 30-350 µg can be bought from supermarkets, pharmacies and health food shops (NZMoH, 1999). Dietary supplement regulations[17] limit folic acid in non-prescription folic acid tablets and multi-vitamin tablets to no more than 300 µg per tablet. New Zealand health authorities do not recommend non-medicine folic acid tablets for NTD prevention because the amount of folic acid does not meet the 400 µg recommended for NTD risk reduction.

2.1.3 Online sales

Online sales of pharmaceuticals are an emerging trend. Folic acid supplements with varying quantities of folic acid (up to 5,000 µg (or 5 mg) tablets) are available for purchase online.

2.2 Folic acid supplement use among women of child-bearing age

To maximise effectiveness, sufficiently high dose folic acid supplements must be taken consistently during the peri-conceptional period. The proportion of women of child-bearing age regularly taking folic acid during the recommended period is not high. Recent data from a study in Western Australia indicated that 28.5% of women who had had a live born baby without birth defects between 1997 and 2000 had taken 200 µg or more of folic acid from supplements daily in the peri-conceptional period (Bower *et al*., 2005). Better educated women and/or those 25 years or older were more likely to take this supplemental level of folic acid. This result is despite a sustained campaign in Western Australia promoting the use of folic acid supplements to women of child-bearing age.

Data collected in South Australia suggests evidence of an increase in folic acid supplement use before and in the first three months of pregnancy among women who had given birth in the last three years; although the dose is unknown (Haan pers. comm.). Watson *et al*. (2006a) report that 46% of recent mothers in NSW, but only 36% in Victoria, took folic acid appropriately and an additional 12% and 38%, respectively took some folic acid supplements, although the frequency and dosage is not reported and so it is not known whether this was sufficient to achieve the full benefit. An additional number of women either increased their intakes of naturally-occurring folate or did not alter their intake because they thought it was already adequate. In total, 80% and 82% of NSW and Victorian women who had recently given birth had taken some action to assess their folate intakes. It is not known how many took an inappropriate action.

[16] In New Zealand, 800 µg is recommended as a 400 µg folic acid supplement is not available (NZMoH, 2003).
[17] New Zealand Dietary Supplement Regulations 1985 http://www.legislation.govt.nz/browse_vw.asp?content-set=pal_regs

In New Zealand, results from two different studies found that the proportion of women who reported taking folic acid supplements during the peri-conceptional period (although not necessarily daily) ranged from 11-17% (Schader and Corwin, 1999; Ferguson *et al*., 2000). There are no data on supplement dosage taken in New Zealand. The lower percentage reporting taking supplements in New Zealand may be due to the fact that the New Zealand studies surveyed all women whereas the Australian studies surveyed women who had recently had a baby.

There are several impediments to the effectiveness of folic acid supplements as a strategy to reduce the incidence of NTDs including a high proportion (about 50%) of unplanned pregnancies; lack of knowledge and awareness among all women of child-bearing age of the appropriate action; knowledge about the dose and when to take folic acid supplements; and their cost and availability.

2.3 Promotion of folate-rich foods and folic acid supplements

Three national campaigns have been implemented in Australia, together with a number of State-based campaigns to promote increased consumption of folate-rich foods and folic acid supplementation. There have not been any publicly funded campaigns in New Zealand.

Evidence that the risk of NTDs can be reduced by increased consumption of naturally occurring folate alone is lacking (Green, 2005[18]). Thus, recommendations to reduce the risk of NTDs focus on 400 µg of synthetic folic acid per day either in supplements or from fortified foods, in addition to the naturally-occurring folate in foods.

2.4 Voluntary fortification of foods with folic acid

In 1994, the NHMRC estimated that NTDs could be reduced by up to two-thirds if women increased their folate intake. 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 juices (NHMRC, 1995). As a practical first step, voluntary fortification was recommended and in 1995, voluntary folic acid permissions for a range of foods were included in the Code.

In 1998, approval for a folate-NTD health claim pilot was granted for certain foods. In recent years there has been limited uptake of the folate-NTD health claim with the exception of breakfast cereals. Currently there are very few products using the health claim. The reasons for this are unclear, but may include the lack of broad appeal of the folate-NTD health claim which has been expressed by industry (ANZFA, 2000). The increased availability of folate-fortified foods has occurred independently of the health claim (Lawrence, 2006).

2.4.1 Current estimates of folic acid intake from voluntary fortification

FSANZ has estimated the current uptake of voluntary fortification permissions in Australia and New Zealand using the following sources:

- unpublished analytical data for a number of different types of common foods including breakfast cereals, bread and juice (Arcot *et al*., 2002; Arcot, 2005);

[18] FSANZ commissioned report available at www.foodstandards.gov.au

- current label data for foods where no analytical values were available; and
- recipe calculation for foods that contain a folic acid fortified ingredient using estimates of the proportion of these ingredients in a food.

Information from these sources matched against the 1995 and 1997 Australian and New Zealand National Nutrition Survey (NNS) data indicate that 149 foods in Australia and 101 foods in New Zealand were presumably fortified with folic acid. Foods most likely to be fortified were breakfast cereals and breads. For foods where a fortified version of the food was not specifically identified within the NNS, but where it is known that a significant proportion of the food category in the market place is now fortified, a folic acid concentration was assigned to the food and weighted to reflect the market share for that food.

The mean intake of folic acid from voluntarily fortified foods among women of child-bearing age is estimated to be 95 µg in Australia and 58 µg in New Zealand. However, the median[19] intake is much lower in both countries – just 57 µg and 21 µg in Australia and New Zealand, respectively (see Attachment 7). This indicates that some women in the target population are probably consuming larger amounts of fortified foods (thus increasing the mean intake) whereas a greater proportion are likely to be consuming relatively low amounts (hence the much lower median intake). The lower mean and median values for New Zealand reflect the lower uptake of voluntary fortification in that country.

In Australia, younger women (15-18 years) have higher median intakes of folic acid from fortified foods (77 µg) than older women (30-49 years) (44 µg) due to higher intakes of breakfast cereals.

2.4.2 Estimated improvement in folate status from voluntary folic acid fortification

Folate status is an indicator of folate intake. Both serum folate and red blood cell folate are used as measures to reflect folate status. While serum folate in the individual reflects daily fluctuations in intake, at a population level, (i.e. when the data are aggregated) it is a useful biomarker of folate status.

There have been two regional Australian studies on folate status since the introduction of voluntary fortification. In Victorian adults aged 15-45 years there was a mean increase in mean serum folate concentrations of approximately 19% for women and 16% for men (Metz *et al*., 2002c; Metz *et al*., 2002e) and a Perth study involving adults aged 27-77 years reported a 38% increase in mean serum folate between 1995-96 and 2001 (Hickling *et al*., 2005e).

There are no New Zealand studies examining changes in folate status since the introduction of voluntary fortification in that country.

2.4.3 Estimated reduction in neural tube defects from voluntary folic acid fortification

In Australia, South Australia, Western Australia and Victoria are the only States with good quality data on terminations. Falls in NTD rates of between 10-30% have been reported by these States (Lancaster and Hurst, 2001; Bower, 2003b; Victorian Perinatal Data Collection Unit, 2005) since the introduction of voluntary fortification.

[19] The median intake is the point at which 50% of the surveyed population is below this amount and 50% is above it.

Although there has been an overall fall in the incidence of NTDs in Western Australia, the disparity between the incidence of NTDs among Indigenous populations and that of the non-Indigenous population in this state has increased over time (Bower *et al*., 2004).

There are no data on trends in NTD incidence in New Zealand.

2.5 Summary of the current approach to increasing folate intake

There are limited data about the impact of voluntary folic acid fortification on health outcomes. In Australia, some States with good case ascertainment have reported a fall in the incidence of NTDs since the implementation of voluntary fortification. Among selected population sub-groups there has also been an apparent rise in serum folate status. There are no data on trends for either of these indicators in New Zealand. Since the introduction of voluntary folic acid fortification there have been modest increases in mean intake of folic acid from fortified foods among women of child-bearing age in both Australia and New Zealand. These increases have occurred despite the variable uptake by industry of voluntary permissions but do suggest that voluntary fortification has had an impact on reducing the NTD rate in Australia in recent years.

This variability demonstrates the inherent uncertainty in voluntary fortification. Although voluntary fortification can contribute to achieving public health objectives, the nature of voluntary fortification is such that manufacturers can choose whether to take up fortification permissions, and whether to continue to fortify products over time.

Similarly, extension of voluntary fortification permissions to other foods would, in theory, provide more folic acid in the food supply, but the level of fortification permission uptake into the future is impossible to predict. So although modest increases in folic acid intakes have been achieved through voluntary fortification there is no reason to expect that extension of voluntary folic acid fortification would present more certainty than the current approach, with regard to equity, efficacy, predictability and sustainability of the folic acid intake of the target population.

Confounding the impact of voluntary fortification is the impact of supplement intake on NTD incidence. Western Australia reports that only about 30% of women with healthy babies have taken supplements, despite a sustained campaign promoting supplement usage in that State over many years. Consequently, supplement usage at a national level among women of child-bearing age is not likely to be high. The limited data in New Zealand on the use of folic acid supplements restricts any comparison.

3. The Health Issue

In order to establish the regulatory response, the health issue under consideration needs to be clearly stated.

Neural tube defects (NTDs) are serious birth defects. Although the majority (about 70%) of pregnancies affected by an NTD will result in a late stage-termination (usually after 20 weeks), infants born with an NTD will either be stillborn, or in the case of spina bifida in particular, have minor to severe health problems. Live born infants with anencephaly or encephalocoele comprise only a small proportion of those with NTDs who survive beyond one year of age.

There is convincing evidence that increased folic acid intake among women of child-bearing age from supplements and/or fortified foods can reduce the risk of NTDs.

Various education initiatives have been undertaken to encourage women of child-bearing age to increase their dietary folate intake and take folic acid supplements. Despite these campaigns, current advice for supplemental folic acid is not followed by a majority of women in the target group. Reasons for this include:

- lack of knowledge among women about the benefits of folic acid;
- knowledge not always equating to behavioural change; and
- barriers to regular supplement use at the recommended dose, such as cost and access.

A significant issue in relation to supplementation is the fact that approximately half of all pregnancies are unplanned and the neural tube develops before a woman would know she is pregnant.

Voluntary fortification of certain foods with folic acid was first permitted in Australia in 1995 and in 1996 in New Zealand. Since that time it has resulted in modest increases in folic acid intake among women of child-bearing age. This is due primarily to the variable uptake by industry of the voluntary permissions, particularly in New Zealand.

Some States in Australia, with good quality data collection systems, have reported a fall in the NTD rate since voluntary fortification was introduced. While not all NTDs can be prevented, there are indications that the proportion of pregnancies affected by an NTD can be further reduced.

Internationally, a number of countries have reported successful mandatory folic acid fortification programs as an equitable and sustainable means of increasing the folic acid intake of women of child-bearing age and thereby reducing the incidence of NTDs.

4. Objectives

The specific objective of this Proposal is to reduce the incidence of NTDs in Australia and New Zealand through mandatory fortification of the food supply with folic acid.

The goal is to reduce the incidence of NTDs to the maximum extent possible by increasing dietary folic acid intakes in women of child-bearing age (the target population). The prime focus for achieving a reduction in this risk will be to increase the folic acid content of the food supply.

The health benefits and risks to the non-target population from increased folic acid intake are considered in making this determination.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in Section 10 of the *FSANZ Act 1991*. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

RISK ASSESSMENT OF MANDATORY FORTIFICATION

This risk assessment quantifies the NTD-related benefit that can be expected from a program of mandatory fortification of food with folic acid in Australia and New Zealand and considers other potential health benefits and risks for the population as a whole from an increase in the dietary consumption of folic acid.

To do this, a number of experts were commissioned to carry out literature reviews of benefits and risks and these are identified in the following discussion. The completed reviews were subsequently peer reviewed. A compilation of the main findings from the reviews is provided at Attachment 6 and the full text of the literature reviews is available at www.foodstandards.gov.au. An expert scientific group was also convened to obtain advice on a series of questions that arose during the initial assessment process.

To assess the impact of mandatory fortification on the target population and the population as a whole, a comprehensive dietary intake assessment has been undertaken based on the universal addition of folic acid to bread (see Attachment 7a). At Draft Assessment, a dietary intake assessment of mandatory folic acid fortification of bread-making flour was undertaken and this has been included at Attachment 7b. Comments and additional references have been considered and the risk assessment at Final Assessment has been amended, as appropriate.

Box 1: Key findings of the health benefits and risks from mandatory folic acid fortification

There is convincing evidence from a broad range of studies that increased folic acid intake reduces the risk of a pregnancy affected with a **neural tube defect**. Mandatory fortification at the proposed level will further reduce the incidence of NTDs in Australia and New Zealand by 4-14% and 5-15%, respectively.

At the levels of folic acid intake likely from mandatory fortification there is no evidence of an increased risk of **masking the diagnosis of vitamin B_{12} deficiency,** particularly as the diagnosis of vitamin B_{12} deficiency relies on a combination of tests at the clinical level.

Recent evidence concludes that folic acid does not reduce **cardiovascular disease** risk.

Recent evidence accords with FSANZ's conclusion at Draft Assessment that there is no apparent increase in **cancer** risk associated with higher folic acid intakes for the population as a whole. Some studies suggest that an increase in folic acid intake may be protective of cancer, however, the evidence is not conclusive.

Recent evidence does not support an improvement in **cognitive function** from increased folic acid intakes.

The evidence is inconclusive for an increased risk of **multiple births** from increased folic acid intake.

There is no evidence of an increased risk of **folate-drug interactions** at the proposed levels of fortification.

Concerns about **unmetabolised circulating folic acid** arising from mandatory fortification overseas have been raised. No apparent adverse effects have been reported. Consequently, the health significance of this remains uncertain.

5. What are the potential health benefits, particularly regarding rates of NTDs, and potential health risks from increases in folic acid intake?

The following section includes a discussion of the potential health benefits and risks associated with increased folic acid intake. Where data are available the benefits and risks arising from the international experience of mandatory folic acid fortification are discussed. Discussion on the benefits and risks associated with the proposed level of mandatory fortification in Australia and New Zealand is included in Section 7.

The **potential** health benefits and risks of increased folic acid intake are discussed in greater detail in Attachment 6.

5.1 Neural tube defects

There is convincing evidence from both cohort studies and randomised controlled trials that increased folic acid intake at doses ranging from 400-4,000 µg/day and a related increase in folate status reduces the risk of occurrence and recurrence of having a pregnancy affected with an NTD (MRC Vitamin Study 1991; Czeizel and Dudas 1992; Berry *et al.,* 1999; Lumley *et al.,* 2001).

5.1.1 Experience in other countries following mandatory fortification

Significant falls in NTD rates have been attributed to the introduction of mandatory folic acid fortification in countries such as Canada, the United States and Chile (Table 2).

In Canada, rates of NTDs have fallen markedly, ranging from 49-78% in different provinces with the extent of the reduction being inversely correlated with the pre-fortification NTD rate.

In the United States, rates of NTDs have fallen by 27% although the analysis underpinning the introduction of mandatory fortification predicted a reduction of 41% (see Attachment 4).

In addition to a decline in incidence and birth prevalence of NTDs, researchers in the United States have also recently reported improved first-year survival of infants born with spina bifida post-fortification; possibly due to the potential role of folic acid in reducing the severity of those NTDs that still occur (Bol *et al*., 2006).

Following the introduction of mandatory fortification in the United States, folic acid intake is estimated to have increased by more than 200 µg/day (Choumenkovitch *et al*., 2002; Quinlivan and Gregory, 2003) compared with the projected average increase in intake of 70-130 µg /day (USFDA 1993). As a result, the mean serum folate levels in all age and sex groups have more than doubled (Dietrich *et al*., 2005c). Folic acid supplement use remains relatively unchanged (USCDC, 2004). Despite improvements in folate status across the whole population, low red blood cell folate is still prevalent in non-Hispanic blacks (about 21%) (Ganji and Kafai, 2006c).

The greater percentage decline in Canada compared with the United States reflects the higher baseline NTD rates in Canada at the time mandatory fortification was introduced.

There are limited data from Canada to indicate if mandatory fortification has also led to a substantial increase in folate status in those provinces with previously high rates of NTDs. The exception is Ontario, Canada, where Ray *et al*. (2002a) reported a mean increase in folate status (measured as mean red cell folate) of 41% since mandatory fortification was introduced.

In Chile, the birth prevalence rates for spina bifida and anencephaly have halved. Induced pregnancy terminations, which are illegal in Chile, were not reported.

5.1.2 Comparative rates for Australia and New Zealand

Between 1999 and 2003, the incidence of NTDs in Australia (based on reported rates in Victoria, South Australia and Western Australia) was 1.32 per 1,000 total births (Bower and de Klerk, 2005[20]). Voluntary fortification is likely to have contributed to this fall, particularly as the contribution of folic acid supplement appears limited. These rates are similar to the pre-fortification rates in the United States and Ontario, Canada.

In New Zealand, the birth prevalence is estimated to be 0.66 per 1,000 (including live births and stillbirths, but not terminations). From 2004 onwards New Zealand has been collecting data on terminations although these data have yet to be reported.

Table 2: NTD rates in Canada, the United States and Chile: pre- and post-mandatory fortification compared with Australian NTD rates

Country	Year mandatory folic acid fortification was introduced	Pre-fortification NTD rate per 1,000 (Reference time period)	Post-fortification NTD rate per 1,000 (Reference time period)	Decline in NTD rate %
Australia[1]	na	**1.32*** (1999-03)	na	**na**
Canada[2]	1998	**0.75**** (1997)	-	**-**
Newfoundland[3]		**4.36*** (1991-97)	**0.96*** (1998-01)	**78%**

[20] FSANZ commissioned report available at www.foodstandards.gov.au

Country	Year mandatory folic acid fortification was introduced	Pre-fortification NTD rate per 1,000 (Reference time period)	Post-fortification NTD rate per 1,000 (Reference time period)	Decline in NTD rate %
Nova Scotia[4]		**2.58*** (1991-97)	**1.17*** (1998-00)	**54%**
Ontario[5]		**1.13***(a) (Jan 94-Dec 97)	**0.58***(a) (Jan 98-Mar 00)	**49%**
United States[6]	1998	**1.06***(a) (1995-96)	**0.76***(a) (1999-00)	**27%**
United States[7]		**0.38**** (Oct 95-Dec 96)	**0.31**** (Oct 98-Dec 99)	**19%**
Chile**[8]	2000	- (1990-00)	- (2001-02)	**51%****

(a) NTD rates are spina bifida and encephalocoele only.

'na' – Not applicable; '-' No data available; * Incidence (i.e. includes terminations); ** Birth prevalence

Sources:

1. Bower and de Klerk, 2005 (The Australian rate is extrapolated from the NTD rate for Victoria, South Australia and Western Australia).
2. Minister of Government Services and Public Works (2000).
3. Liu *et al*. (2004b).
4. Persad *et al.* (2002).
5. Ray *et al*. (2002b).
6. USCDC (2004).
7. Honein *et al.* (2001).
8. Lopez-Camelo *et al*. (2005a).

In summary, there is strong evidence from other countries that have introduced mandatory fortification that increases in intake of folic acid up to 200 µg/day are associated with significant reductions in the incidence of NTDs. The extent of the fall in incidence appears to depend on the prevailing background rate of NTDs prior to fortification.

5.2 Masking of the diagnosis of vitamin B_{12} deficiency

It has been suggested that high folic acid intakes (>1,000 µg per day) could delay the diagnosis and eventual treatment of severe vitamin B_{12} deficiency in older people (Capra *et al*., 2005[21]). This could occur by correcting the anaemia that may accompany vitamin B_{12} deficiency which is one of the clinical signs traditionally relied on for diagnosis.

Recent surveys conducted in Australia and New Zealand show a small to moderate prevalence of vitamin B_{12} deficiency among older people. Six to twelve per cent of those surveyed were classified as deficient and a further 16-28% classified as at risk of deficiency or marginally deficient (Flood *et al*., 2004b; Green *et al*., 2005b). Information as to whether those found to be deficient had associated haematological or neurological sequelae was not collected, however, they had not been previously suspected of being vitamin B_{12} deficient.

[21] FSANZ commissioned report available at www.foodstandards.gov.au

Vitamin B_{12} deficiency in older people is mainly due to a reduced capacity to release vitamin B_{12} from food sources (such as foods of animal origin, in particular red meat, dairy foods and eggs, but also foods fortified with vitamin B_{12} such as soy-based beverages and some yeast extracts) during digestion, or alternatively as a result of malabsorption of free vitamin B_{12} from the gut caused by gastrointestinal dysfunction. Very little deficiency in this age group is caused by inadequate dietary intake.

Vegetarians are also at risk of vitamin B_{12} deficiency due to a reduced vitamin B_{12} intake; vegans more so than lacto-ovo vegetarians because of a complete absence of animal products in vegans' diets. Hokin and Butler (1999a) report that serum B_{12} levels in 11 vegan Australian Seventh Day Adventist ministers was not different from serum B_{12} levels in non-vegan vegetarian ministers. There are no data on the prevalence of vitamin B_{12} deficiency among vegans in Australia or New Zealand (Capra *et al*., 2005).

Vitamin B_{12} deficiency may take decades to develop in adults and affected individuals may be asymptomatic or may present with a wide spectrum of haematological, neurological and/or psychiatric signs and symptoms. Vitamin B_{12} deficiency is recognised through presentation of clinical signs of abnormal haematology or neuropathy and a definitive diagnosis is usually obtained from serum vitamin B_{12} levels. Doctors are advised to consider vitamin B_{12} deficiency as a possible cause when presented with individuals who have clinical signs of anaemia or neuropathy.

The UL for folate (1,000 µg per day of folic acid) in adults has been set based on the potential to mask the diagnosis of vitamin B_{12} deficiency and the potential to exacerbate the related neurological symptoms (Institute of Medicine, 1998). However, the UL incorporates a fivefold margin of safety and intakes of folic acid above the UL are rare from fortification alone (see Section 7.2.2).

Among countries that have introduced mandatory fortification with folic acid, there have been no reports of adverse effects on neurological function, especially in people aged 65 years and over with low vitamin B_{12} status (SACN, 2005).

5.2.1 Effects of exceeding the upper level of intake (UL) for individuals who are not vitamin B_{12} deficient

In the absence of vitamin B_{12} deficiency, there is little information on adverse effects which may occur at levels about the UL.

The UL set for adults has been applied to younger age groups on a relative body weight basis. However, vitamin B_{12} deficiency is rare in children, and so the relevance of this endpoint and hence the risk to children is not clear. Due to their lower body weight and their consumption of more food per kilogram of body weight when compared to adults, children are more likely to exceed the UL for folic acid if staple foods are fortified.

In the United States, post mandatory fortification, approximately 15-25% of children aged 1-8 years were estimated to have folic acid intakes above the UL (some up to 2-3 times the UL) and 0.5-5% of adults were estimated to consume >1,000 µg of folic acid/day (Lewis *et al*., 1999b).

No adverse effects have been reported, although it is unclear if any surveillance is being undertaken, particularly as there was no commitment at the time mandatory fortification was introduced in the United States to monitor adverse health outcomes (Rosenberg, 2005).

5.3 Cardiovascular disease

Low folic acid intake increases total plasma homocysteine and high levels of homocysteine can damage the inner linings of arteries. Consequently, increased folic acid intake, because of its ability to lower homocysteine, has been investigated for its potential to lower cardiovascular disease risk (including heart disease and stroke) and early evidence strongly supported this association.

More recent evidence, however, from several large trials and some smaller randomised controlled trials all concluded that high folic acid doses (1 mg or more per day) did not reduce cardiovascular disease risk (see Attachment 6).

5.4 Cancer

Folate acts as a methyl donor in the synthesis of purines and ultimately DNA and therefore could affect the development of cancer. A number of epidemiological studies have suggested that people with higher folate intakes have lower rates of various cancers. An alternative hypothesis is that folate might increase progression of pre-cancerous lesions but lower the risk of cancer if no lesion exists.

The association between folate and cancer has been investigated as part of the development of this Proposal in relation to the incidence of all cancers, prostate cancer, breast cancer and colorectal cancer. A summary of the findings from these studies is provided below (also see Attachment 6).

5.4.1 Total cancer

Two recent and large trials investigating the association between folic acid and cardiovascular disease, also reported total cancer incidence among their study participants. A meta-analysis of the results yielded a non-significant increase of 5.6% (95% CI: 0.91-1.23) in the incidence of total cancer. Both trials involved folic acid supplements; in one, the dose was 2.5 mg of folic acid and in the other 800 μg. There are other similar trials underway which will add to the evidence base and possibly clarify the role, if any, of folic acid and cancer.

5.4.2 Prostate cancer

One trial and three cohort studies found no significant association between serum folate levels and incidence of prostate cancer. A large Swedish study, however, did observe a significant association between higher serum folate levels and increased risk of prostate cancer but only among study participants with a particular genetic make-up. In this study, 'higher' folate levels were below the pre-voluntary fortification mean in a Perth cohort.

Based on these findings, and the lack of intake studies, the evidence base is not sufficient to draw a conclusion about the relationship of folic acid and increased risk of prostate cancer.

5.4.3 Breast cancer

Results from five recently reported cohort studies investigating folate intake from diet and supplements and from one intervention trial collectively indicate no effect between folate intake and breast cancer risk. Eight case-control studies and one case-cohort study found mixed results, although three of these reported a protective effect among women at greater risk of breast cancer because of higher alcohol consumption.

Fewer studies have examined the relationship between blood folate levels and incidence of breast cancer but no significant associations have been reported.

These findings indicate that folic acid is not associated with an increased risk of breast cancer (and may reduce the risk among heavy consumers of alcohol).

5.4.4 Colorectal cancer

A 2005 meta-analysis investigating the effect of folate on colorectal cancer found an overall protective effect or no effect based on separate analyses of four different categories of studies including cohort and case-control studies. More recently published results (four cohort studies and one trial) report a slight increase in risk or a slight decrease with higher total folate intake and two studies using serum folate levels as indicators of folate intake reported conflicting results.

In summary, the more recent studies do not alter the conclusion from the 2005 meta-analysis that total folate intakes do not increase the risk of colorectal cancer.

5.4.5 Conclusion

Two large trials using much higher doses of folic acid than is proposed under mandatory fortification do not indicate a gradient of risk for total cancers. For the three specific cancer sites examined, the results of more recent studies do not alter the conclusion reached in earlier reviews (SACN, 2004; SACN, 2005; Sanjoaquin *et al*., 2005f) that there is no apparent increase in risk associated with higher folic acid intakes for the population as a whole. Although many of the studies suggest that some reduction in cancer might occur, most of these are observational and so might be affected by uncontrolled confounding by other factors.

5.5 Cognitive function

Earlier observational evidence suggested an association between low folate levels and increased risk of cognitive decline, dementia and Alzheimer's Disease.

More recent evidence from two studies published early in 2006 report no association between increased folic acid intake or increased serum folate and improved cognitive functioning. In one of the studies, lower red blood cell folate was, however, associated with poorer cognitive performance.

These findings are, however, not sufficient evidence to conclude that low folate levels are associated with cognitive decline.

5.6 Unmetabolised circulating folic acid

The potential impact of an increased intake of synthetic folic acid on unmetabolised circulating folic acid with suggestions of adverse health consequences is only just emerging in the scientific literature. The scientific discussion around this matter is not well developed, and cannot therefore be used to inform the assessment of risks associated with folate fortification.

5.7 Other effects during pregnancy

The evidence is inconclusive for an association between increased folic acid intake and increased risk of multiple births. Multiple births result in more complications and poorer outcomes than singleton births.

The evidence is inconclusive for a positive effect on birth weight or Down Syndrome from increased folic acid intake.

5.8 Other potential health risks

Other potential health risks from increased folic acid intake in the total population have also been reported in the literature. These include the likelihood of:

- folate-drug interactions;
- interactions with zinc status; and
- a negative impact on the gene pool.

Although, there is the potential for an increased folate intake to interfere with certain medications, available scientific evidence has not demonstrated any clinically significant interaction with therapeutic medicines from folate intakes up to 1,000 μg/day (Colinas and Cook, 2005[22]).

It is highly unlikely that increases in folic acid intake associated with mandatory fortification would have a negative impact on zinc status in the Australian and New Zealand populations.

One recent paper postulates that an increased folate status in the population is potentially associated with a negative impact on the gene pool. Whilst this is a possibility, this potential outcome does not differ from other interventions that seek to prolong the life of children affected by serious genetically inherited childhood diseases or conditions.

6. What is an appropriate food vehicle and what level of folic acid intake can be achieved among women of child-bearing age using mandatory fortification?

This section describes the rationale for the selection of the food vehicle(s) and the safety and technical issues associated with adding folic acid to the food vehicle. It also describes various fortification scenarios aimed at maximising folic acid intake to the greatest extent possible among women of child-bearing age based on recommended target levels while ensuring that there is no additional health risk to the population as a whole, including young children.

[22] FSANZ commissioned report available at www.foodstandards.gov.au

6.1 Selection of food vehicle

At Draft Assessment, FSANZ drew on international experience in narrowing the range of food vehicle options for mandatory folic acid fortification. In the majority of countries mandating folic acid fortification, flour has been selected as the food vehicle.

Guidance on the suitability of potential food vehicles for fortification is also provided by published international criteria (Codex Alimentarius Commission, 1991; Darnton-Hill, 1998; Nutrivit 2000). These criteria include the need for the selected vehicle(s) to:

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

Bread-making flour (consumed as bread and bread products) was considered to be a technically feasible vehicle due to the existing mandatory fortification requirement with thiamin in Australia. However, industry expressed considerable concerns at the high degree of impost and technical difficulties associated with fortifying bread-making flour as part of the flour milling process, to the required standard. For example, the level of precision required to meet the proposed range of folic acid amounts to be added. Additionally, the New Zealand milling industry indicated that segregation of bread-making flour would be prohibitively expensive because of the lack of infrastructure. On the basis of New Zealand industry's inability to segregate flours, concerns were also raised about the lack of choice for consumers to select non-fortified flour-based products and the resulting impact on population-wide increases in folic acid intakes beyond that intended through mandatory fortification.

In response to these issues, FSANZ considered alternative mechanisms for delivering folic acid into bread. Industry was canvassed from March 2006 on other means of adding folic acid during the bread-making process, for example in bread improvers, and yeast. At that time industry representatives asserted the addition of folic acid during the bread-making process presented a number of practical difficulties.

FSANZ subsequently sought additional information on alternative mechanisms from a consultant engaged in June 2006 to investigate the feasibility of adding folic acid in the bread-making process as well as advice from the Australian and New Zealand milling and baking industry.

More recent advice from the New Zealand industry has indicated that addition of folic acid during the bread-making process is feasible and provides greater control over the level of fortification going into the product. This has since been confirmed by FSANZ's consultant (see Attachment 10, Appendix 1).

Given the potential for New Zealand consumers to exceed safe folic acid intakes from a broader than intended range of products, it was important to explore alternate means to limit this possibility. Furthermore, the requirement to fortify bread with folic acid, rather than mandating where in the manufacturing process fortification was to occur, was seen as providing a more flexible outcome for industry, particularly in New Zealand, where bread-making flour is currently not fortified with thiamin.

Consequently, following further consultation, FSANZ has refined the approach at Final Assessment to require the mandatory fortification of bread. The mechanism for delivering the folic acid to the bread, however, has no longer been specified.

6.1.1 The suitability of bread as the selected vehicle

Bread is defined in Standard 2.1.1 – Cereals and Cereal Products of the Code as:

the product made by baking a yeast-leavened dough prepared from one or more cereal flours or meals and water.

This definition therefore includes the following products: bread and bread rolls, sweet buns, fruit bread, English muffins, bagels, yeast leavened flat breads and breadcrumbs.

Bread is widely and regularly consumed by the target group consistent with the first of the above criteria. Evidence from national nutrition surveys conducted in the mid to late 1990s indicates that 85% of Australian and 83% of New Zealand women of child-bearing age consume bread (a fall of just 3% of women in the target group who consumed products containing bread-making flour). This level of consumption has been supported by more recent survey data. Bread is therefore a staple, relatively low cost food regularly consumed by the majority of the target population.

Further analysis undertaken by FSANZ as part of Final Assessment also indicated that there are very few differences in the amount of bread consumed or folic acid intakes among women of child-bearing age from different socio-economic groups.

6.1.1.1 Australian Indigenous consumption of bread

Separate analyses by Indigenous identification are not possible because Indigenous people make up only 2% of the population and they were not over-sampled in the Australian 1995 NNS.

Slightly more than one-half of the Australian Indigenous population lives in areas that are classified as ‘major cities’ or ‘inner regional areas’. As such, they have access to the supermarkets and corner stores that serve the populations of these areas.

One-quarter of the Australian Indigenous population live in areas classified as remote or very remote and have restricted access to a wide range of shopping facilities. A survey of remote community store managers, most from the Northern Territory and some from Western Australia, were asked to nominate their 20 top selling items. Seventy-eight items were identified from the 18 store managers that responded. Bread was nominated by 17 of the 18 stores and achieved an average position of 6.1 in the list. By contrast, flour was nominated by only seven managers and had an average position of 10.4 in the list (DHCS, 2005).

Therefore the proposed strategy of fortifying bread would reach Indigenous populations in remote areas where folate status may be poorer.

6.1.2 Stability of folic acid added to bread

There are two key issues to consider in reviewing the stability of added folic acid: stability during storage and during processing (e.g. baking). Folic acid added to food is stable to a variety of processing and storage conditions. In contrast, natural folate is relatively unstable. Naturally occurring folates are easily destroyed during harvesting, storage, processing and preparation. Up to 75% of natural folate may be lost due to these processes (McKillop *et al*., 2002).

6.1.2.1 Storage losses in flour

Generally, the retention of folic acid is high during storage. Studies during the 1970s indicated that folic acid mixed with flour is stable (100% retention) after six months at room temperature or four weeks at 45°C.

Even after one year of storage at around 45°C, flour showed only small losses. Similarly, retention was 90-100% in pre-mix fortified yellow corn (NHMRC, 1995). A 1995 study in which folic acid was added at either 100 µg/100 g or 500 µg/100 g of flour showed around 100% retention at a range of temperatures (-23 to 48.8°C) after one year's storage (Morgan, 1996).

6.1.2.2 Processing losses

The average loss of folic acid from bread made with fortified flour appears from the literature to be about 25% but may be as high as 40%. To account for these losses in fortified flour, millers would apply an overage of 1.33 to 1.67.

In a study that examined sweet biscuits, the mean loss of folic acid in the biscuits was 15% under optimal conditions. In another study on crackers, mean loss was 7.2% (with a maximum of 15.3%) (NHMRC, 1995).

Further detailed discussions on the technical aspects of the chosen food vehicle, bread, are in the Food Technology report (see Attachment 10).

6.1.3 Bioavailability of folic acid

Bioavailability refers to the ability of the body to extract, absorb, and metabolise nutrients in food. The bioavailability of folate is not fully understood and there appear to be a number of factors that influence it.

It is difficult to predict the bioavailability of folate (both naturally-occurring and synthetic forms) from a mixed diet, based on studies of individual foods (Gregory, 1995; Brouwer *et al*., 2001; Sanderson *et al*., 2003).

Factors that influence folate availability from food include:

- composition of the food matrix (including the presence of antagonistic components most notably organic acids binding to other food components and encapsulation within plant cells leading to reduced exposure to digestive enzymes);
- amount of folate consumed;
- chemical form of folate; and
- host-related factors including nutrient and health status and genetic factors.

The bioavailability of naturally-occurring folates is thought to be only 50-60% while folic acid, used to fortify foods or as a supplement, is thought to be about 85% bioavailable. On this basis, folic acid added to bread is expected to have a similar bioavailability. A substantial increase in the folate status of populations exposed to mandatory folic acid fortification reflects its bioavailability[23]. Folic acid consumed as a supplement is almost 100% bioavailable on an empty stomach (NHMRC and NZMoH, 2006).

6.2 Dietary targets

The recommendation for women of child-bearing age to reduce the risk of having an NTD-affected pregnancy is 400 µg/day of folic acid from supplements or fortified foods, which equates to 670 µg DFEs, in addition to food folate (NHMRC and NZMoH, 2006).

While it is desirable to maximise the proportion of women who achieve this level of intake, the variability in intake among this group and in other population sub-groups limits the extent of folic acid fortification without a significant proportion of other population sub-groups exceeding the UL.

6.3 Fortification scenarios

In assessing the introduction of mandatory fortification of food with folic acid in Australia and New Zealand, a dietary intake assessment (see Attachment 7a) was conducted to compare the increase in folic acid intakes from the current voluntary permissions to the proposed mandatory fortification of all breads. The dietary intake assessment undertaken at Draft Assessment involving the mandatory addition of folic acid to all bread-making flour is at Attachment 7b.

The following two fortification scenarios are used as the basis for this comparison:

- 'Baseline' - Current folic acid intakes from foods voluntarily fortified[24]; and
- 'Scenario 1' (Preferred scenario at final assessment) - 'Baseline' (except bread) + the introduction of mandatory fortification of all bread at 135 µg/100 g.

The dietary intake assessment scenarios did not take into account naturally-occurring folate in food. There is little evidence to support naturally-occurring folate as protective against NTDs (Green, 2005[25]).

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[23] In Ontario, Canada, there has been a mean increase in folate status (mean red cell folate) of 41% since mandatory fortification was introduced in 1998 (Ray *et al*., 2002) and in the United States, the folate status (mean serum folate) in all age and sex groups has more than doubled (Dietrich *et al.,* 2005).

[24] Food intake data are derived from the 1995 and 1997 Australian and New Zealand national nutrition surveys. Estimates of folic acid intake are based on the current uptake by industry of voluntary permissions outlined in Standard 1.3.2 of the Food Standards Code.

[25] FSANZ commissioned report available at www.foodstandards.gov.au

The NHMRC recommendation of 400 µg per day to reduce the incidence of NTDs is based on additional folic acid from fortified foods or supplements and the model used in this Proposal to estimate the number of NTDs reduced from the introduction of mandatory fortification (see Section 7.1) is underpinned by incremental increases in folic acid intake.

The estimated intakes of folic acid from both fortified foods and folic acid supplements are discussed in Section 6.7.2.

6.4 Assessment of baseline folic acid intakes

For both Australia and New Zealand, 'Baseline' folic acid intakes were assessed using folic acid concentration data from analytical programs, current food labels and recipe calculations where foods contained a known folic acid fortified food as an ingredient (see Section 2.4.1). Label concentrations were not adjusted for under- or overage of folic acid as there was insufficient information available on which to reliably assess the extent of such under- or overages. Where information on natural folates was available, this was used to adjust the declared label folates value to estimate added folic acid.

6.5 Selection of folic acid concentrations

At Draft Assessment, a residual level of 200 µg of folic acid per 100 g of bread-making flour was the preferred option. This equates to a concentration of 120 µg/100 g in the average loaf of bread. Based on this estimate, folic acid concentrations of between 100-170 µg of folic acid per 100 g of bread were modelled with the aim of achieving the same level of effectiveness and safety.

Thus, at Final Assessment, the selected folic acid concentration is 135 µg of folic acid per 100 g of bread.

6.7 Dietary intake assessment for women of child-bearing age

6.7.1 Estimated folic acid intake from fortified foods

6.7.1.1 Baseline

It is estimated that Australian women aged 16-44 years are currently consuming about 95 µg of folic acid per day from food voluntarily fortified. In New Zealand, the amount is less due to the lower uptake of voluntary fortification in that country; about 58 µg per day among the target group.

In estimating the impact of mandating folic acid fortification, it has been assumed that the intake of folic acid from voluntary fortification remains constant.

6.7.1.2 Preferred scenario at Final Assessment

If intakes from voluntary fortification remain unchanged ('Baseline') then fortifying all bread at 135 µg/100 g results in an estimated mean intake of folic acid from fortified foods of 196 µg per day in Australia and 198 µg per day in New Zealand among women of child-bearing age.

However, even with this additional intake, just 4% of women in Australia and 2% in New Zealand would meet the recommended intake of 400 µg of folic acid per day from fortified foods.

6.7.1.3 Preferred scenario at Draft Assessment

The preferred scenario at Draft Assessment indicated that fortifying all bread-making flour at residual levels of 200 µg/100 g would result in an estimated mean intake of folic acid from fortified foods of 195 µg per day in Australia and 189 µg per day in New Zealand among women of child-bearing age. This additional intake resulted in 5% of women in Australia and 2% in New Zealand meeting the recommended intake of 400 µg of folic acid per day from fortified foods.

A comparison of the two scenarios is provided in Table 3 which shows that both result in very similar mean increases in folic acid intake among the target population.

Table 3: Comparison of estimated mean folic acid intake for women of child-bearing age* from the mandatory fortification of all bread or all-bread-making flour

Model	Concentration of folic acid (µg/100 g)		Mean folic acid intake (µg/day)	
			Australia	*New Zealand*
Baseline		Voluntary fortification	95	58
All bread **Final Assessment**	135 (in the bread)	Increase due to mandatory fortification	101	140
		Voluntary + mandatory	**196**	**198**
All bread-making flour **Draft Assessment**	200 (residual level in the flour)	Increase due to mandatory fortification	100	131
		Voluntary + mandatory	**195**	**189**

* Women aged 16-44 years.

6.7.2 Estimated folic acid intake from fortified foods and supplements

Additional calculations were conducted to estimate folic acid intakes for women of child-bearing age who consume a folic acid supplement as well as fortified food. Supplements containing folic acid concentrations of 200 µg (Australia and New Zealand), 500 µg (Australia only) and 800 µg (New Zealand only) were selected because folic acid supplements containing 500 µg of folic acid are widely available in Australia, whereas in New Zealand, 800 µg of folic acid supplements are recommended (see Section 2.1.2). In addition, a daily supplement containing 200 µg was selected on the basis of a recent study (Bower *et al.,* 2005).

When women receive 200 µg of folic acid per day from supplements in addition to fortified foods, their mean intake is only slightly below the recommended 400 µg of folic acid per day. To achieve 400 µg of folic acid per day a woman could consume one 40 g serve of voluntarily fortified breakfast cereal (containing 120 µg folic acid) + two slices of bread (weighing 60 g and therefore containing 81 µg based on a fortification level of 135 µg/100 g of bread) + a supplement containing 200 µg of folic acid. If supplements containing 500 µg (in Australia) and 800 µg (in New Zealand) are taken daily mean intakes increase substantially (Table 4).

It should be noted that these estimated folic acid intakes assume all females 16-44 years receive additional folic acid from folic acid supplements, which although unlikely to occur, highlights the resulting outcome if universal supplementation prevailed.

Table 4: Estimated folic acid intakes among women of child-bearing age* from fortified foods and supplements for Australian and New Zealand

Model	Concentration of folic acid in bread (µg/100 g)	Folic acid intake from fortified foods and supplements (µg/day)			
		Australia		*New Zealand*	
		Mean Intake + 200 µg	Mean Intake + 500 µg	Mean Intake + 200 µg	Mean Intake + 800 µg
Baseline		295	595	258	858
All bread	135	396	696	398	998

* Women aged 16-44 years.

6.8 Robustness of the estimates used to determine bread consumption and folic acid intakes

In response to concerns raised in submissions at Draft Assessment about the age of the data used to undertake the dietary intake assessment (the 1995 Australian National Nutrition Survey and the 1997 New Zealand National Nutrition Survey), FSANZ collated recent data on bread consumption from a variety of sources in Australia and New Zealand. Although there were difficulties in directly comparing the data due to differences in survey methodologies used, they did indicate that the proportion of the population consuming bread, including the target group, is about 80% in both countries. This is similar to the proportion determined in the 1995 and 1997 surveys (see Section 6.1.1). The quantity of bread consumed has also remained the same (about two slices per day). Attachment 7a provides further details about the surveys considered.

These results support the robustness of the national survey consumption data used to assess folic acid intakes under a mandatory fortification scenario which underpins the assessment of effectiveness and safety of the Proposal and indicates that bread consumption by the target group has not changed significantly in the last decade.

6.9 Alternative approaches to mandatory fortification

In response to submissions received at Draft Assessment, FSANZ assessed two alternative approaches to folic acid fortification. The first considers restricting the types of breads that are mandatorily fortified to enhance consumer choice and the second considers increasing the types of foods that are voluntarily fortified rather than mandatory fortification of all breads.

6.9.1 Restricting breads that are mandatorily fortified in response to concerns about consumer choice

Four options were considered by FSANZ involving various types of bread and these are compared with FSANZ's proposed strategy (Table 5).

Table 5: Per cent of women of child-bearing age* in Australia and New Zealand consuming different bread types

	Proportion of women of child-bearing age* consuming** (%)		
Option	**Australia**	**New Zealand**	**Bread Types Included**
Option 1	29	25	Includes light grain and wholemeal bread.
Option 2	77	73	Includes option 1 + plain white bread and bread in sandwiches and burgers.
Option 3	80	77	Includes option 2 + white high fibre bread and fruit bread.
Option 4	NA	79	Includes all breads except dark grain bread.
FSANZ proposed strategy	85	83	Includes option 3 + dark grain, rye bread, rolls, yeast containing flat breads (e.g. Pita bread, naan bread), focaccia, bagels, fancy bread/topped bread, English muffins, sweet buns, fruit bread, bread in sandwiches and burgers, bread crumbs#.

NA - Not assessed.

* Women aged 16-44 years.

** The estimates of consumption by the target group do not include any voluntary fortification permissions.

Does not include bread crumbs for New Zealand.

The results clearly indicate that FSANZ's proposed strategy, involving the mandatory fortification of all breads, will maximise the proportion in the target population consuming folic acid. Consumer choice will be provided by flat breads that don't contain yeast and consumers choosing to purchase flour and bread pre-mixes to make their own bread (see Section 9.3 for further discussion on consumer choice).

6.9.2 Increasing voluntary permissions to increase folic acid intake among the target population and minimise folic acid intake among the non-target population

One option considered by FSANZ involved a small expansion to the range of foods currently permitted to be voluntarily fortified. These foods comprised one brand of low/reduced fat natural yoghurts, some additional breads from one manufacturer and one brand of reduced/low fat/energy frozen meals.

Because no market share data other than bread was provided the dietary intake assessment assumed that all brands of foods in these categories were fortified, thus overestimating the increases in folic acid intakes. These estimates are compared with FSANZ's proposed strategy (Table 6). It was assumed that the market share for breads increased from 15% at Baseline to 20% for this alternative proposal to account for the extra breads that may be voluntarily fortified.

Table 6: Estimated mean folic acid intakes among women of child-bearing age* in Australia and New Zealand for different voluntary and mandatory fortification scenarios

	Mean dietary folic acid intake in µg/day (Increase in folic acid intakes from baseline in µg/day)	
Scenario	**Australia**	**New Zealand**
Baseline	95	58
Extension of voluntary permissions**	103 (+8)	62 (+4)
FSANZ's proposed strategy	196 (+101)	198 (+140)

* Women aged 16-44 years.

** Additional foods includes some breads across a range of types, all low/reduced fat natural yoghurt and all reduced/low fat/energy frozen meals.

The estimated folic acid intakes do not increase appreciably from Baseline for the alternative voluntary fortification scenario. This is due to the small number of consumers of low/reduced fat natural yoghurt (~1%), and all reduced/low fat/energy frozen meals (<1%), and because of the small increase in the bread market that is likely. Thus, the results clearly show that mandatory fortification of all breads with folic acid will maximise intake among the target population.

7. Based on the expected increase in folic acid intake from mandatory fortification what are the likely health benefits and risks?

7.1 Expected reduction in neural tube defects

The number of NTDs that could be prevented for Scenario 1 described in Section 6.7.1.2 has been estimated using an approach recommended by (Wald *et al*., 2001). The Wald model is underpinned by a dose-response relationship between folic acid intake and risk of NTDs according to serum folate concentrations (Attachment 9).

Fortifying bread with folic acid at a concentration of 135 µg /100 g of bread will result in an estimated 14-49 NTD-affected pregnancies being prevented in Australia and 4-14 NTD-affected pregnancies prevented in New Zealand. This represents a reduction of between 4-14% in Australia and 5-20% in New Zealand (Table 5).

Table 5: Estimated number of NTD pregnancies prevented based on adding 135 µg of folic acid per 100 g of bread in Australia and New Zealand

	Mean increase in folic acid intake* µg/day	Estimated number of NTD pregnancies prevented/year (95% CI)**	Estimated number of NTD live births/year	Estimated number of NTD stillbirths/year	Estimated number of NTD terminations /year
Australia	101	26 **(14-49)**	5	3	18
New Zealand	140	8 **(4-14)**	1	1	5

* Estimates of the mean increase in folic acid intake are based on dietary modelling using DIAMOND.

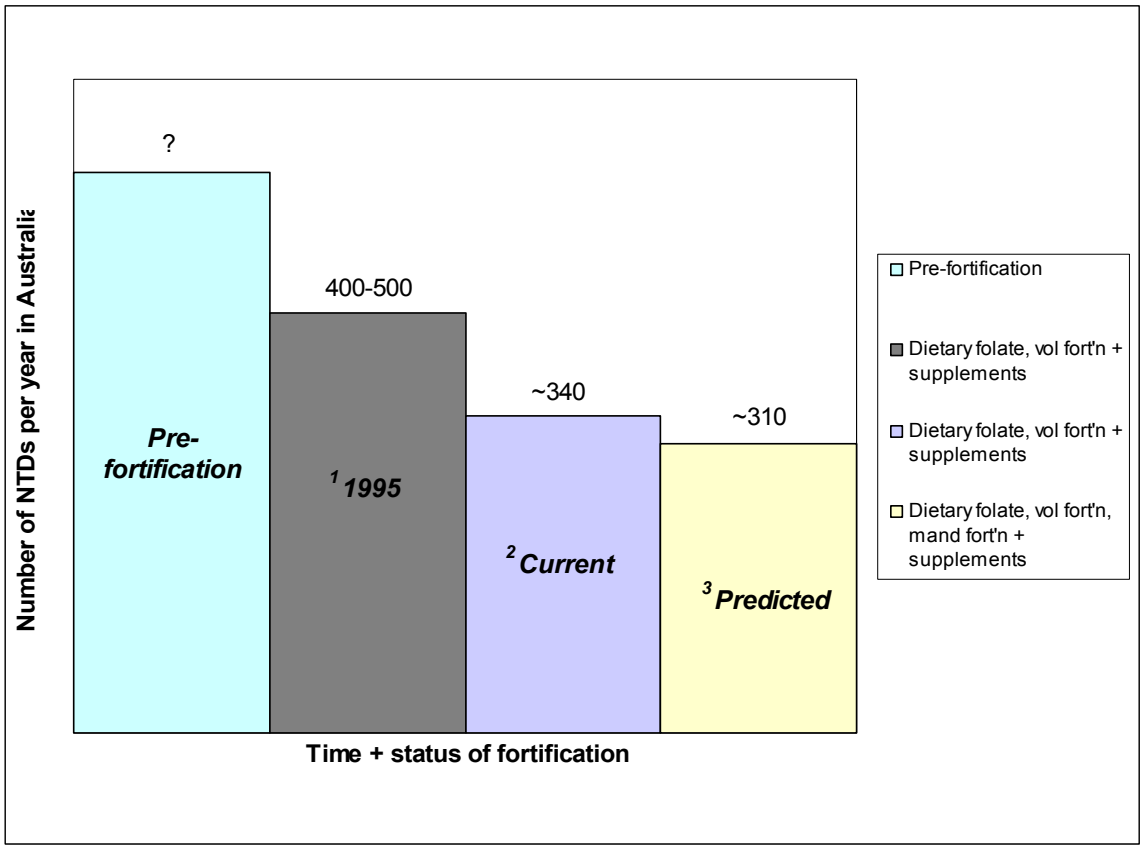
** Estimates of the number of NTDs prevented are based on the approach by Wald *et al*. (2001) (see Attachment 9).

As some Indigenous populations in Australia have double the NTD rate (2.56/1,000 total births) compared with the non-Indigenous population (1.32/1,000 total births) (Bower *et al*., 2006), the fall in NTD incidence among some Australian Indigenous populations may be greater.

It is estimated that up to 70% of NTDs could be prevented through universal use of folic acid supplements (Berry *et al.,* 1999) although the extent of the potential fall is dependent on the folate status of the target population.

The numbers of NTDs have been falling for some years and so the proportion potentially preventable will diminish with time. Where Australia and New Zealand are currently lying in relation to the potential fall of up to 70% of NTD-affected pregnancies from increased folic acid intake remains unknown. The available Australian data on the fall in the number of NTDs since the introduction of voluntary fortification is shown in Figure 1. Lancaster and Hurst (2001) reported the numbers and rates of NTDs in Australia between 1991-95 (pre-fortification) and 1996-97 but concluded that they were likely to be a substantial underestimate; hence the number of pregnancies affected with an NTD pre-fortification remains unknown for this period. The NHMRC (1995) reported 400-500 NTDs per year nationally based on extrapolation of State-based data. This period equates to the time voluntary fortification was introduced. More recently, Bower and de Klerk (2005) reported approximately 340 NTDs per year based on extrapolation of State-based data with good ascertainment rates. Thus, although a similar increase in mean folic acid intake is expected from mandatory fortification as has been achieved with voluntary fortification to date (about 100 µg), the number of NTDs potentially prevented declines because of the increase in the folate status of the population.

Figure 1: Decline in numbers of NTD-affected pregnancies since voluntary folic acid fortification was introduced in Australia in 1996



Sources:
1 NHMRC (1995)
2 Bower & de Klerk (2005)
3 Predicted by FSANZ at Final Assessment.

7.2 Health risks to the whole population

To assess health risks that might arise from mandatorily fortifying bread with folic acid, the folic acid intakes of population sub-groups were compared to the appropriate UL. The health risks to the whole population are discussed in greater detail in Attachment 8.

7.2.1 Comparison of estimated dietary folic acid intakes with the UL

The proportion of each population group exceeding the UL[26] is shown in Table 6.

[26] The UL (see Section 5.2.2), which is based on masking the diagnosis of vitamin B_{12} deficiency, has been set for different age groups on a relative body weight basis (see Figure 1, Attachment 6).

Table 6: Per cent of Australian and New Zealand respondents with folic acid intakes above the UL at Baseline and Scenario 1

Population Group	Baseline	Scenario 1: All bread 135 µg folic acid /100 g
Australia		
2-3 years	1	7
4-8 years	<1	3
9-13 years	<1	2
14-18 years	<1	1
19+ years	<1	<1
Women aged 16-44 years	<1	<1
New Zealand*		
15-18 years	0	<1
19+ years	<1	<1
Women aged 16-44 years	<1	<1

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

7.2.2 Masking of the diagnosis of vitamin B_{12} deficiency

7.2.2.1 Young children

Vitamin B_{12} deficiency is rare in children and so the relevance of the UL and hence the risk to children is not clear.

At all fortification levels, including the Baseline level, Australian children aged 2-3 years were the most likely population sub-group to exceed the UL, due to their relatively higher food consumption on a body weight basis. However, for Baseline and the mandatory fortification scenario, the percentage of respondents with intakes greater than the UL declined with increasing age.

Fortifying bread at 135 µg /100 g results in a small percentage of children aged 2-3 and 4-8 years exceeding the UL (7% and 3%, respectively; previously 6% of 2-3 year exceeded the UL based on the Draft Assessment proposal). Of the small proportion of children that are estimated to exceed the UL following the introduction of fortification at this level all are predicted to have intakes below those which would be expected to cause adverse effects. That is, these intakes still remain within the margin of safety. This, combined with the low probability of vitamin B_{12} deficiency within this age group, suggests that fortification up to 135 µg/100 g bread is very unlikely to put children at risk.

Based on assessments conducted for New Zealand children external to FSANZ using different methodologies[27] the results indicate that a similar proportion of New Zealand children 5-14 years would exceed the UL compared to Australian children of the same age.

7.2.2.2 Target group (women 16-44 years)

Only a very small percentage (<1%) of women aged 16-44 years exceed the UL at a fortification level of 135 µg/100 g of bread. This percentage is unchanged from the percentage of women exceeding the UL at Baseline and unchanged from the percentages exceeding the UL at Draft Assessment. Thus, there is no additional risk to health among women of child-bearing age from the level of folic acid intakes likely to arise from mandatory fortification.

The percentage of the target group exceeding the UL increases significantly when folic acid intake from supplements is considered, in addition to folic acid from fortified food. The 800 µg supplement recommended in New Zealand in conjunction with fortified foods could lead to 44% of New Zealand women in the target group exceeding the UL. However, due to the low prevalence of vitamin B_{12} deficiency in women of child-bearing age, intakes of folic acid at or above the UL are unlikely to have adverse effects.

7.2.2.3 Older people

The sub-group most at risk of adverse effects if the UL is exceeded are older people as vitamin B_{12} deficiency is most prevalent in this group (see Section 5.2.1). Dietary intake assessment showed none of the individuals aged 70 years and over exceeded the UL at a fortification level of 135 µg/100 g of bread. Only a very small proportion (<1%) of individuals aged 50-69 years exceed the UL at these fortification levels. This is unchanged from the percentage exceeding the UL at Baseline and unchanged from the percentages exceeding the UL at Draft Assessment. Therefore, it is unlikely that at a fortification level of 135 µg/100 g of bread will increase the risk of adverse effects in this population sub-group because of the increased incidence of masking the diagnosis of vitamin B_{12} deficiency.

7.2.2.4 Conclusion on masking of the diagnosis of vitamin B_{12} deficiency

Based on the dietary intake assessment, it is unlikely that fortification of all bread at a level up to 135 µg/100 g of bread will increase masking the diagnosis of vitamin B_{12} deficiency in either the target or non-target populations.

7.2.3 Uncertainties

In the absence of vitamin B_{12} deficiency, there is little information on the potential effects (adverse or beneficial) of an increase in folic acid intakes in the general population over the long term. Data from overseas do not indicate any particular cause for concern at this stage, however, there are significant uncertainties and insufficient evidence to be able to predict all possible outcomes from an increase in folic acid intakes.

[27] The methodology used to assess folic acid intake among New Zealand children differed from the FSANZ modelling in that it used different levels of fortification, involved a more restricted group of mandatorily fortified foods and excluded the contribution to folic acid intake from voluntary fortification.

There is significant uncertainty around how the use of voluntary fortification permissions might change following the implementation of mandatory fortification. If the uptake of voluntary fortification increases, intakes of folic acid could be higher than estimated in the dietary intake assessment. Due to the uncertainty around the impact of increased folic acid intakes on health in the long term, it will be essential to closely monitor all identified potential adverse health outcomes.

8. Risk assessment summary

In terms of the potential health benefits, there is strong evidence based on international experience of mandatory fortification in countries with pre-fortification NTD rates similar to Australia and New Zealand that mandatory folic acid fortification of bread will further reduce the incidence of NTDs. The extent of the reduction, however, depends on several factors including the initial folate status of women and the background prevalence of NTDs.

The totality and quality of evidence in support of a protective effect of folate on cardiovascular disease, considered probable for many years, has recently been challenged. The studies in question, however, have assessed only the secondary prevention of the disease (rather than primary prevention) and involve much higher doses (e.g. 2,500 µg of folic acid per day in capsule form) than would occur with mandatory fortification.

Improvements in cognitive function, considered in early literature as a potential positive benefit associated with increased folic acid intakes, have not been confirmed with more recent and robust scientific investigation. The evidence is also inconclusive for a positive effect on birth weight, increased risk of multiple births or reduced incidence of Down Syndrome from increased folic acid intake.

In terms of the potential health risks, there have been no reports of adverse effects on neurological function in older people with low vitamin B_{12} status among countries that have introduced mandatory fortification with folic acid and there are no clinically significant interactions with folic acid intakes up to 1,000 µg/day and therapeutic medicines.

The results of more recent studies on the incidence of all cancers and cancer of the prostate, breast and colorectum do not alter the conclusion reached in earlier reviews (SACN, 2004; SACN, 2005; Sanjoaquin *et al*., 2005e) that there is no apparent increase in risk associated with higher folic acid intakes for the population as a whole. Many of the studies suggest that some reduction in cancer risk might occur, however, most of these are observational and so might be affected by uncontrolled confounding factors.

Despite these conclusions indicating minimal or no risk, it cannot be concluded that mandatory fortification is completely without health risks either from the potential risks described above or uncertainties about health risk such as unmetabolised circulating folic acid from chronic, long-term exposure to significantly higher intakes among the population as a whole, but particularly from childhood onwards. As a result, a conservative approach to mandatory fortification is recommended.

With this view in mind, the dietary intake assessment indicates that fortification of all bread at a level of 135 µg of folic acid per 100 g of bread will result in an estimated mean increase in folic acid intake in the target population (women aged 16-44 years) of 101 µg and 140 µg per day, in Australia and New Zealand, respectively.

In response to this anticipated increase in intake, the number of pregnancies affected by an NTD is likely to reduce by an estimated 4-14% in Australia and 5-20% in New Zealand.

As just 4% of women of child-bearing age in Australia and 2% in New Zealand would meet the recommended intake of 400 µg of folic acid per day at this level of fortification, it will be necessary to continue to promote folic acid supplements. Also, due to the uncertainty of increased folic acid intakes on health in the long term, it will be essential to monitor all identified adverse health outcomes.

RISK MANAGEMENT OF MANDATORY FORTIFICATION

9. Identification of risk management issues

The following section identifies risks, other than the public health and safety risks identified by the Risk Assessment, and discusses associated issues relevant to consideration of mandatory folic acid fortification. These include social, consumer and economic issues particularly related to the selected food vehicle of bread and where raised in submissions or targeted consultations.

9.1 Technical and industry issues for mandatory fortification

9.1.1 Bread production in Australia and New Zealand

In Australia in 2000-2001, there were around 7,000 establishments involved in baking bread and bread products commercially. Based on industry estimates, New Zealand has eight major bakery companies with 19 plant bakeries, and between 2,000-3,000 small bakeries.[28]

The bread baking sector can be categorised into four groups: the corporate plant bakeries, independent bakeries and hot bread shops, franchised hot bread shops, and supermarket in-store bakeries[29]. The market share of these groups is presented in Figures 2 and 3 below.

Corporate plant bakeries account for the majority of bread production, and produce bread for wholesale distribution. Two national bakery companies, Goodman Fielder and George Weston Foods account for 90% of the plant bakery production in Australia, and between 80-85% of the plant bakery production in New Zealand. Supermarket in-store bakeries, traditional and franchised bakeries and hot-bread shops have on-site bread manufacturing and retailing, and represent a growing sector in the bread industry, with franchised hot bread shops representing the fastest growing sector of the Australian baking industry.

[28] Access Economics, report for FSANZ, Attachment 11.
[29] The Australian Baking Industry: A Profile, DAFF 2003; personal communication NZ Association of Bakers 2006.

Figure 2: Australian Bread sector Market Share[30]

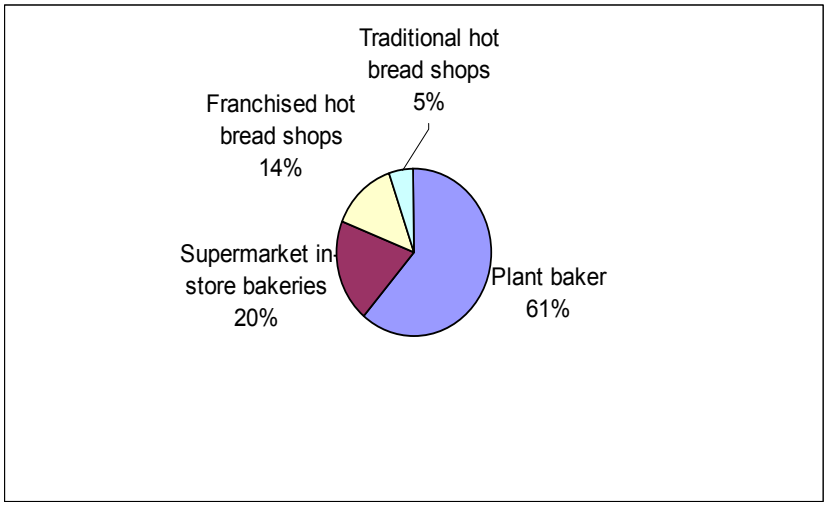
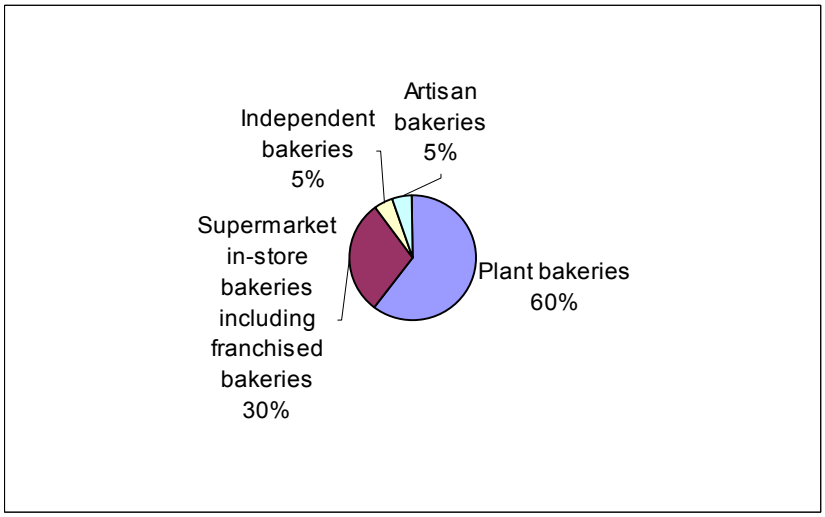


Figure 3: New Zealand Baking Sector Market Share[31]



Bread is produced using one of the following three general methods:

- 'from scratch' baking, where individual ingredients are weighed out and assembled for each batch of bread dough;
- premixes[32], to which flour, water, yeast and salt are usually added.
- frozen dough, where dough produced at a bakery site is on sold in a frozen state, for subsequent proving and baking by the purchaser.

Plant bakeries and a small proportion of independent bakeries, particularly artisan bakeries, characteristically produce bread 'from scratch'. Premixes of bread ingredients are widely used by in-store supermarket bakeries, hot bread shops, and some independent bakeries and franchised hot bread shops.

[30] Brooke-Taylor & Co Pty Ltd, Report prepared for FSANZ, Attachment 10 Appendix 1.
[31] Brooke-Taylor & Co Pty Ltd, Report prepared for FSANZ, Attachment 10 Appendix 1.
[32] Premixes are purchased blends of some, or all, of the dry minor and micro ingredients of bread, such as raising agents, processing aids, additives and ingredients, possibly including bread improvers used for bread, cakes and biscuits prior to developing the dough.

Frozen dough is used in some in-store supermarkets, and is widely used in fast food outlets providing bread 'baked on the premises'.

9.1.2 Bread and bread products

Apart from bread loaves, the bread sector produces a range of products, which include English muffins, rolls and buns, specialty bread, flat bread and breadcrumbs. It is therefore important to ensure that the bakery products required to be fortified under a mandatory fortification standard are clearly differentiated.

Bread is defined in Standard 2.1.1 – Cereals and Cereal Products of the Code as:

> *the product made by baking a yeast-leavened dough prepared from one or more cereal flours or meals and water.*

This definition therefore includes the following products: bread and bread rolls, sweet buns, fruit bread, English muffins, bagels, yeast leavened flat breads and breadcrumbs.

FSANZ will prepare an Implementation Guide to assist industry in complying with the mandatory standard. This will include guidance on identifying products which will be required to be fortified with folic acid.

9.1.3 Bread fortification methods

The method of adding folic acid to bread to meet the mandatory fortification requirement will vary according to bakery production methods, and quality control systems in place. Possible points of addition are:

- flour fortified with folic acid;
- single dry bread ingredient such as a bread improver[33] fortified with folic acid;
- complete premix of dry minor and micro ingredients which has been fortified with folic acid; or
- folic acid vitamin premix which is added to the dough with other dry minor and micro ingredients.

Both bread improvers and premixes are added to the bread ingredients on a weight basis in a batch system, and present a precise means of achieving fortification of bread with folic acid. Similarly, the use of a specific folic acid vitamin premix where the amount of folic acid is matched on a weight basis to the bread produced will also give a high degree of precision in fortification[34]. However, in bakeries where the level of improver or premix used varies from the manufacturer's recommendation, there may not be a consistent fortification level in bread production. The widespread use of bread improvers and premixes in the baking industry provides a controlled method of folic acid fortification for independent and in-store bakeries.

[33] Bread improvers are combinations of ingredients, such as enzymes, emulsifiers and antioxidants that are added to dough to modify its characteristics and those of the bread in order to improve keeping quality, texture and flavour.
[34] Brooke-Taylor & Co Pty Ltd, Report prepared for FSANZ, Attachment 10 Appendix 1

9.1.4 Range of addition

An additional consideration is the industry practice of 'overages' when adding vitamins and minerals to foods. This is where manufacturers usually add more nutrients to account for losses during processing and storage. Where no maximum is established, the actual amounts added can be considerably higher than the minimum required in the purchased food. This was the experience in the United States after mandatory folic acid fortification was introduced (see Attachment 4). The Australian milling industry have also indicated that over-fortification of thiamin estimated at 100% or greater, which is mandatorily added to bread-making flour in Australia, may occur during flour milling[35]. The usual practice of 'overages', suggests that applying a range rather than setting a minimum will reduce the likelihood of greater than desired levels of fortification.

9.1.5 Baking industry capacity for mandatory folic acid fortification

Because of the variation in bakery sizes, production methods and technical expertise available, individual bread manufacturers will make decisions as to the most suitable and cost effective method of folic acid fortification for their particular bread production site.

Plant bakeries, in-store supermarket bakeries and bread franchises will have access to technical support staff with the necessary expertise for decisions relating to achieving the best method of addition of folic acid to their bread products, and the correct level of folic acid. Independent bakeries, however, may not have access to technical support in the addition of folic acid. Folic acid fortification may present a particular challenge to artisan bakers who do not use premixed ingredients or emulsifiers. These groups may require support from the baking industry associations in determining the best method of folic acid fortification for their bread products.

Analytical testing and other methods of verification may be required to confirm the consistent and correct levels of fortificant in the bread. This may have cost implications for bread manufacturers, and is discussed in Section 11.2.2.

There are three, with two being owned by the same company, principal manufacturers of premixes for bakers in Australia and New Zealand, and at least one of these manufacturers have indicated the folic acid fortification of bread premix and bread improvers will not present any particular difficulty.

9.1.6 Domestic and export bread production

In Australia and New Zealand, bread is manufactured domestically to meet local market demands, and little bread is imported into either country. Australian figures from 2001-02[36] show sales from exports of bread products account for less than one percent of turnover in bread manufacturing, however there is a growing export market for frozen doughs and par-baked products for both Australia and New Zealand. The value of sales to meet Japanese Subway frozen dough exports has been estimated at NZ $12M per annum[37]. The addition of folic acid to bread at the bakery level has the advantage of flexibility for bakers in avoiding fortification of products for export.

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[35] Brooke-Taylor & Co Pty Ltd, Report prepared for FSANZ, Attachment 10 Appendix 1.
[36] Bread Research Institute Report on Australian Baking Industry, 2003
[37] Brooke-Taylor & Co Pty Ltd, Report prepared for FSANZ, Attachment 10 Appendix 1

9.1.7 Issues for speciality bakers and bread manufacturers

Mandatory folic acid fortification may be an issue for bakeries producing artisan breads using only 'natural ingredients', and for organic bread manufacturers. Artisan bakers may consider the fortification of their products will not fit with their niche market, and could be seen as detrimental to sales. Folic acid may not be considered a 'natural ingredient' as it is a synthetic form of folate, and may also conflict with organic industry standards.

Submitters from the organic production sector felt that mandatory folic acid fortification was incompatible with organic food production systems, which did not currently allow organic products to be fortified. A number of submitters asked that organic bread and flour be exempt from mandatory folic acid fortification. A few consumer and industry submitters also considered that folic acid would not be classified as a natural ingredient, and therefore breads could not be labelled as containing all 'natural ingredients'. This issue is discussed further at Section 13.3.2.

9.1.8 Labelling

All packaged bread will be required to list folic acid as an ingredient on the label of the bread. Additionally, folic acid will be required to be listed if it is present as part of a compound ingredient[38] making up more than 5% of the final food.

Labelling for the presence of folic acid will necessitate labelling modifications and as a result incur costs for manufacturers. Labelling was raised as an issue in industry submissions, who noted the time and costs involved in making labelling changes. Some industry submitters requested an extended transition time in order to change over packaging in a coordinated manner with other pending changes to the Code such as Proposal P230 - Consideration of Mandatory Fortification with Iodine, and Proposal P293 - Health, Nutrition and Related Claims.

9.1.9 Product liability and indemnity issues

9.1.9.1 Product Liability under VA of the Trade Practices Act 1974 ('TPA')

Industry submitters raised concerns about the potential product liability exposure for bread and/or flour manufacturers under Part VA of the *Trade Practices Act 1974* (TPA). For example one submitter has expressed concern as follows:

> *……that in relation to the possible health risks (especially in the longer term) FSANZ's proposal may entail, FSANZ is applying a different risk management (i.e. safety) standard to that which industry proposals are required to satisfy. When combined with the fact that FSANZ's proposal will not deliver any protection to manufacturers from long term product liability claims, this is particularly worrying.*

FSANZ has sought advice from the Australian Government Solicitor (AGS) on this issue and was advised that manufacturers are protected from liability where they have complied with a mandatory standard as defined in the TPA.

[38] A compound ingredient means an ingredient of a food which is itself made from two or more ingredients. Standard 1.2.4 of the Code requires the components of a compound ingredient to be labelled where the amount of compound ingredient in the food is 5 % or more.

It was further advised that where a standard is expressed as a minimum this is not considered to be a mandatory standard for the purposes of the TPA. Currently the Code sets minimum standards for the mandatory fortification of bread-making flour with thiamin and edible oils with vitamin D. FSANZ will be reviewing these standards in the future and will consider this issue at this time.

Alternatively, where a standard requires a range food X must contain between Y mg/kg and Z mg/kg of a vitamin, this may be a mandatory standard. In relation to this example it would turn upon the evidence as to why a range, rather than an absolute value was not possible. In the context of fortification, industry has indicated that the application of an absolute value is not achievable. This is further supported by the US experience previously discussed (see section 9.1.4) where use of 'overages' routinely occurs. The current drafting for folic acid requires bread to contain no less than 0.8 mg/kg and no more than 1.8 mg/kg of folic acid. Consequently, it is arguable that prescribing a range would be considered a mandatory standard within the meaning of the TPA. However, ultimately this would depend on how the Courts viewed the evidence submitted.

9.1.9.2 Other areas of potential liability

Industry also raised other areas of potential liability stating:

> *Even if we did have a defence in relation to an action under the product liability provisions contained in Part VA of the TPA, or subordinate legislation were passed by the Federal Government to deem a mandatory requirement under the Food Standards Code to fortify bread-making flour with folate to be a Mandatory Standard for the purposes of s75AA of the TPA, this would not prevent a successful action against the manufacturer:*
>
> *(i) under Division 2A of Part V of the TPA alleging that the goods were not of merchantable quality or fit for purpose; and/or*
> *(ii) for negligence (on the basis that given what was known at the time, the risk of injury/harm to some members of the public was reasonably foreseeable).*

Ultimately, whether an action is successful under Division 2A of Part V of the TPA and/or for negligence is a matter for the Courts. FSANZ cannot pre-empt any Court decision and notes that certain legal elements would need to be proven. This would be based on submissions made to the Court, together with, any evidence used to support those submissions.

9.1.9.3 Options to address liability issues

There has been a suggestion that FSANZ should seek agreement to have the TPA amended to deem the Code a 'mandatory standard' for the purposes of Part VA of the TPA.

To deem the Code a 'mandatory standard' under Part VA of the TPA would not be workable because not all standards in the Code contain 'mandatory' requirements.

Furthermore, the TPA is administered by the Department of Treasury and the Australian Consumer and Competition Commission (ACCC). A decision to amend the TPA ultimately rests with those agencies.

Also, any overarching government policy as it relates to these agencies would have to be considered as well as any possible inconsistency within the context of an agreement to amend the TPA.

9.1.9.4 Government to provide indemnity

Another two submitters requested that the Government issue an indemnity for incidences that may arise due to any adverse effects of folic acid fortification on consumers. The Australian Government as a matter of policy does not issue indemnities. In addition, the Australian Government does not issue indemnities to third parties dealing with statutory agencies covered under the *Commonwealth Authorities and Companies Act 1997* (CAC Act). FSANZ is a CAC Act body and as such, is not a Commonwealth body for legal and financial purposes.

9.2 Consistency with Ministerial Policy Guidance

The Ministerial Council's Policy Guideline on *Fortification of Food with Vitamins and Minerals* (the Policy Guideline, see Attachment 3) provides guidance on the addition of vitamins and minerals to food for both mandatory and voluntary fortification. In considering mandatory fortification as a possible regulatory measure, FSANZ must have regard to the Policy Guideline.

The Policy Guideline provides 'High Order' Policy Principles as well as 'Specific Order' Policy Principles and additional guidance for mandatory fortification. The 'High Order' Policy Principles reflect FSANZ's statutory objectives (see Section 4) and therefore take precedence over the 'Specific Order' Policy Principles.

The five 'Specific Order' Policy Principles state that mandatory fortification should:

1. be only in response to demonstrated significant population health need taking into account the severity and prevalence of the health problem;
2. be assessed as the most effective public health strategy to address the public health problem;
3. be consistent with national nutrition policies and guidelines;
4. not result in detrimental dietary excesses or imbalances of vitamins and minerals; and
5. deliver effective amounts of added vitamins or minerals to the target group to meet the health objective.

Advice from the Ministerial Council is that mandatory folic acid fortification is an effective public health strategy to reduce the incidence of NTDs in Australia and New Zealand, subject to assessment of clinical safety and cost-effectiveness. In recognition of this significant population health problem, FSANZ was asked to consider mandatory folic acid fortification.

However, a number of submitters asserted that mandatory folic acid fortification was inconsistent with the Specific Order Policy Principles. Whilst acknowledging the severity of NTDs, they felt the low prevalence did not justify the population wide approach of mandatory fortification. Other submitters stated that mandatory fortification was not the most effective public health strategy to prevent NTDs, and did not deliver sufficient folic acid to the target group, citing folic acid supplementation as a more effective means of NTD reduction.

Some submitters were also concerned that mandatory fortification had potential for detrimental excessive intake of folic acid, and that this needed more consideration by FSANZ.

As stated above, advice from the Ministerial Council is that mandatory fortification with folic acid is an effective strategy. This advice was based on an Expert Panel convened by AHMAC[39] which reported that mandatory fortification fulfilled their criteria[40] of effectiveness, equity, efficiency, certainty, feasibility and sustainability required for an effective public health strategy. They concluded that in considering strategies to increase folate intake *mandatory fortification represents the most effective public health strategy where safety can be assured and there is a demonstrated need*. It is on this basis that FSANZ has undertaken this assessment which is consistent with recently revised Ministerial policy guidance (at Attachment 3) which states that:

> *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.*

9.2.1 Consistency with Australia and New Zealand national nutrition guidelines

Both the Australian and New Zealand dietary guidelines[41] for all age groups promote eating plenty of cereals including breads with particular emphasis on wholegrain varieties. Therefore, the selection of a broad range of breads as the preferred food vehicle is consistent with, and supports, the current nutrition guidelines and healthy eating messages.

9.2.2 Safety and effectiveness

On the available evidence assessed in this proposal, including overseas experience with mandatory fortification, FSANZ has concluded that the proposed level of fortification does not pose a risk to public health and safety. The level of fortification has been set to minimise any potential health risks as a degree of uncertainty does exist, particularly for the non-target population, from increased folic acid intakes over the longer term. FSANZ recognises that mandatory fortification is one strategy in NTD prevention, and that other strategies for reducing the incidence of NTDs will continue to be important. These strategies include voluntary fortification, folic acid supplement use and education for women of child-bearing age

9.2.3 Additional Policy Guidance

The Policy Guideline provides additional policy guidance in relation to assessment of alternative strategies (see Section 2.5), labelling (see Section 13.3) and monitoring (see Section 17.1

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[39] *The effectiveness of mandatory fortification as a public health strategy to increase nutrient intakes, with reference to iodine and folate*. Expert public health advice prepared for AHMAC, June 2005.

[40] Case studies of public health interventions to increase nutrient intakes were used to generate effectiveness criteria.

[41] NHMRC. Dietary Guidelines for Australian Adults. Commonwealth of Australia, 2003; Ministry of Health. Food and Nutrition Guidelines for Healthy Adults: A background paper. Wellington. Ministry of Health, 2003.

9.3 Consumer issues

Mandatory fortification of bread with folic acid raises a number of important concerns from the perspective of consumers including:

- choice and availability of non-fortified products;
- awareness and understanding of folic acid fortification;
- impacts of mandatory fortification on consumption patterns; and
- labelling and product information as a basis for informed choice.

In understanding the impacts on, and responses of, consumers, FSANZ has drawn upon relevant consumer studies and literature regarding mandatory fortification, as well as more general literature review regarding the factors that influence health-related attitudes to food.

9.3.1 Choice and availability of non-fortified products

A range of socio-demographic variables influence health-related attitudes to food, for example age (Kearney *et al*., 1997; Worsley and Skrzypiec, 1998; Childs and Poryzees, 1998), gender (Worsley and Scott, 2000), income (Childs and Poryzees 1998), values (Ikeda, 2004) and personality (Cox and Anderson, 2004). Accordingly the response to mandatory fortification of bread with folic acid is unlikely to be uniform, but rather will be mediated by the particular circumstances of individuals and the communities within which they live. Attitudes and responses to mandatory fortification are also likely to vary within groups and over time.

The difficulty of assessing the likely responses of consumers to mandatory fortification is further exacerbated by a lack of specific studies exploring likely consumers' responses. Two recent studies of New Zealand consumers' responses to mandatory fortification of bread with folic acid have been carried out: one commissioned by the Baking Industry Research Trust (Brown, 2004) and one by the New Zealand Food Safety Authority (Hawthorne, 2005). No specific studies have been carried out in Australia. Additionally a range of New Zealand and Australian studies measuring the effectiveness of folate promotion campaigns provide information about the level of folate awareness and understanding among women of child-bearing age (Abraham and Webb, 2001). Currently the UK Food Standards Agency is undertaking consumer research to inform their assessment of mandatory folic acid fortification with the results expected to be available in September 2006 (UKFSA, 2006).

Consumer research has found varying levels of support for mandatory fortification. The two New Zealand studies mentioned above both found the majority of participants were opposed to mandatory fortification with folic acid (Brown, 2004; Hawthorne, 2005). This opposition was primarily based on strong support for individual rights rather than any specific concerns regarding folic acid fortification *per se*. A third survey of New Zealand adults found that 58% of respondents considered choice to be very or extremely important to them, with 16% of respondents considering choice to be slightly or not important at all. The survey also found that 49% of respondents neither agreed nor disagreed with the statement that 'folate should be added to bread' (Bourn and Newton, 2000).

Exposure to mandatory fortification is also likely to impact on the level of support for such measures. In Canada, there was significant change between the public response to thiamin fortification in 1930s and 1940s and the response to folic acid fortification in the 1990s.

The shift in response has been linked to a growing acceptance of fortification and of technological solutions (Nathoo *et al*., 2005). Unlike Australia which mandates the fortification of bread-making flour with thiamin and fat spreads with vitamin D, New Zealand currently has no mandatory fortification requirements.

The importance of consumer choice was raised by a large number of submitters, many of whom opposed mandatory fortification because consumers had little option but to purchase fortified bread products. Some submitters did not feel that purchasing unfortified flour for bread-making provided sufficient consumer choice. The fortification of bread, rather than bread-making flour will however provide a degree of further consumer choice in that flour products which do not meet the definition of bread will not be subject to mandatory fortification.

Some consumers may be opposed to mandatory folic acid fortification, and may wish to purchase unfortified bread. Whilst all commercially manufactured bread will be required to be fortified with folic acid there will be some degree of consumer choice in that retail flours and bread-mixes will not be mandatorily fortified, and consumers will be able to purchase some non-fortified flat breads. Additionally, through the use of labelling, consumers will be informed where products have added folic acid[42].

9.3.2 Awareness and understanding of folic acid fortification

Unlike some other nutrient disease relationships awareness and understanding of the link between folic acid and NTDs among the general community is low (National Institute of Nutrition, 1999; Abraham and Webb, 2001). Not surprisingly though, women and men generally have different levels of awareness and understanding, with women generally being more informed of the rationale for ensuring adequate intake of folic acid. Furthermore, the levels of awareness increases among women following public health campaigns targeted at pregnant women and women of child-bearing age (van der Pal-de Bruin KM *et al*., 2000; Abraham and Webb, 2001; Ward *et al*., 2004) although awareness does not necessarily lead to consumption of folic acid at the recommended time and dose (Watson *et al*., 2006b). Women with some experience with NTDs among relatives are more likely to be aware and use folic acid supplementation (Byrne *et al*., 2001).

While there is likely to be a link between awareness and understanding and the level of support for mandatory fortification, the link may not be simple nor in expected directions (Wilson *et al*., 2004). In one of the New Zealand studies, participants were provided with, and discussed, materials explaining the importance of folic acid in preventing NTDs (Hawthorne, 2005). Despite this, opposition to mandatory fortification of bread with folic acid was high. It is proposed to monitor the level of consumer awareness and understanding of folic acid fortification as part of the *Bi-national monitoring system to track the impact of regulatory decisions on mandatory and voluntary fortification* (Attachment 12).

9.3.3 Impacts of mandatory fortification on consumption patterns

The level of opposition to mandatory fortification raises a concern that consumers may change their consumption patterns to avoid fortified products.

[42] Folic acid will be required to be listed as an ingredient unless it is part of a compound ingredient making up less than 5% of the food. Standard 1.2.4 defines a compound ingredient as an ingredient of a food which is itself made from two or more ingredients.

The limited evidence available suggests that this is unlikely, however, it is possible that some individuals may consume less of the fortified food categories (Brown, 2004). A key element is the extent to which opposition is based on a notion of individual choice rather than other concerns such as health and safety. As noted above there will be some limited options for those who wish to avoid the consumption of folic acid fortified products.

By contrast, some women may feel that, in addition to the availability of voluntary fortified products, the mandatory fortification of bread will provide enough folic acid. This was a concern of a number of submitters, who noted that women of child-bearing age will still require supplementation to reach recommended levels of folic acid at the proposed level of folic acid in bread. Submitters felt strongly that public health campaigns and advice from medical practitioners must continue to be important mechanisms to ensure women of child-bearing age take adequate supplementation.

There may be some groups of women who will not receive the health benefit of mandatory folic acid fortification as a consequence of not eating bread. However there is little evidence that can be drawn upon to characterise these groups of women. A number of submitters also commented that it was not clear whether only wheat flour, or bread made from wheat, was to be fortified.

The dietary intake data indicate that bread is widely and regularly consumed by the target group. There is unlikely to be any substantial increase in the price of bread, and thus fortification will have insignificant financial impact.

Women whose diets do not normally include bread will not consume the recommended amount of folic acid through mandatory fortification and will require additional supplementation. This may include women who are intolerant to some cereals and therefore avoid wheat and other cereal flour based products. However, all breads using yeast are expected to be folic acid fortified, and therefore commercially produced yeast risen bread made from cereal flours other than wheat will contain folic acid. Women of ethnic and cultural groups who do not eat bread but other primary carbohydrate sources (e.g. rice) will also not receive the increase in folic acid through mandatory fortification. Home bakers that use unfortified retail flour for their home bread baking may also not receive the advantage of folic acid fortification. It will therefore be important that these groups are specific target audiences for the communication and education strategy on mandatory folic acid fortification (see section 17.3).

9.3.4 Labelling and product information as a basis for informed choice.

Consumers will be informed about the addition of folic acid to bread through general labelling requirements that require all ingredients of a product to be identified in the ingredient list (see Section 13.3). Additionally, if manufacturers choose to do so, or where a claim is made about a product and its folate content (naturally-occurring and added folic acid), folate will be declared in the Nutrition Information Panel. This information will enable consumers to choose products according to their preference.

Whilst all packaged bread will be required to list folic acid in the ingredient list, unpackaged bread is currently exempted from this requirement. In these instances, consumers can request information about the presence of specific ingredients in these foods. FSANZ will seek the assistance of retail bakeries in making this information available.

9.4 Factors affecting safe and optimal intake

The Risk Assessment raises a number of uncertainties with fortification associated with ensuring the sustainability and predictability of folic acid intake across the population.

9.4.1 Mandatory fortification

The amount of folic acid that can be delivered to the target population from mandatory fortification is dependent on:

- the consumption of the food vehicle;
- the level of fortification; and
- safety considerations for both the target and non target populations.

The food vehicle and fortification level have been selected to maximise folic acid intakes in the target group, while also preventing significant proportions of the non-target population exceeding upper safe levels of intake. This consideration is particularly relevant when the recommended intake for the target population differs markedly from the non-target group, as is the case for folic acid. The recommendation for the target population is 400 µg of folic acid, whereas for children aged 1-3 years the RDI expressed as DFEs is 150 µg per day.

Mandatory fortification can deliver additional amounts of folic acid in the food supply for women of child-bearing age. However, the amount delivered for women of child-bearing age does not by itself reach recommended levels. Thus, additional strategies will be needed to assist the target group to achieve the recommended folic acid intake to reduce the NTD risk as much as possible.

The method of adding folic acid to bread will affect the accuracy of fortification, though both the addition of an improver or a premix containing folic acid during dough mixing are considered to be a more precise and flexible means of fortifying bread[43].

The current industry practice of 'overages' to account for losses of folic acid on processing, baking and storage is an additional concern with mandatory fortification. The practice of 'overages' when used under a mandatory fortification scenario may result in an increase in folic acid intake greater than anticipated. For example, in the United States, mandatorily fortified foods have been found to contain nearly twice as much as their predicted levels (See Attachment 4). As there is a potential risk for some population groups to exceed the UL of intake for folic acid, this risk will need to be managed when setting the level of fortification.

9.4.2 Voluntary fortification

Folic acid intake from current voluntary fortification permissions formed the baseline for the dietary modelling scenarios. In general, there has been limited uptake of voluntary permissions across the food categories, with the exception of breakfast cereals.

It is uncertain how the use of voluntary folic acid fortification permissions might change following the implementation of mandatory fortification.

[43] Brooke-Taylor & Co Pty Ltd, Report for FSANZ , August 2006 Attachment 10 Appendix 1

There is potential for the implementation of mandatory fortification to increase consumer awareness of the relationship between folic acid and NTDs, creating more marketing opportunities for other food categories to be voluntarily fortified. As a result, more voluntary folic acid permissions may be utilised. Alternatively, mandatory fortification may result in loss of marketing advantage for products currently voluntarily fortified, resulting in less folic acid permissions being used. If uptakes do change significantly, this may impact on the effectiveness or safety of mandatory folic acid fortification.

The mandatory fortification scenario assumes that folic acid will be added to bread as defined in the Code, and not to other bread products such as pizza dough and some flat breads that do not meet this definition. However, current voluntary permissions allow cereal flours to be fortified with folic acid. This presents a situation where bread products that do not meet the definition of 'bread' in the Code may also be fortified with folic acid. These voluntary permissions also present the opportunity for food manufacturers to use folic acid fortified cereal flours in the production of foods that are consumed by subsets of the target population who do not eat traditional bread products. If this occurs, manufacturers will be required to comply with the labelling requirements of the Code and will need to include folic acid in the ingredient list.

9.4.3 Folic acid supplement use

Folic acid intake from mandatory fortification combined with folic acid intake contributed by foods voluntarily fortified with folic acid, is less than the 400 µg folic acid recommended for women of child-bearing years. Folic acid supplementation for women planning to, or capable of, becoming pregnant will therefore continue to be an important strategy in NTD prevention.

The dietary intake assessment demonstrated that when folic acid supplements of 500 µg (in Australia)[44] and 800 µg (in New Zealand) are taken daily by women of child-bearing age in addition to fortified foods, the mean intakes of folic acid increase substantially. This is of particular relevance for women who consume the 800 µg supplement, as it may result in some of these women exceeding the UL. As supplementation at this level is generally confined to the peri-conceptional period, long term exposure to this level of folic acid is unlikely.

However, it is uncertain if some women of child-bearing age will falsely believe that mandatory fortification of foods with folic acid delivers sufficient folic acid for NTD prevention, and therefore folic acid supplementation during the peri-conceptional period is not necessary.

The level of use by children of supplements containing folic acid is unclear. Estimated folic acid intake for children shows that if mandatory fortification is introduced a proportion of children are likely to exceed the UL (see Section 7.2.2.1). Therefore, if a child is given additional folic acid in the form of supplements, the likelihood of this child being exposed to folic acid at levels exceeding the UL would be raised. While there have been no reported health risks associated with increased folic acid intake from international experience, a conservative approach has been recommended due to the uncertainties about health risks, particularly for young children.

[44] In Australia, 800 µg folic acid supplements can be purchased by peri-conceptional women, however the recommended supplements contain 500 µg of folic acid. For the purpose of the dietary intake assessment, only 200 µg and 500 µg supplements were modeled for Australia.

9.5 Summary

A number of risks and issues affecting consumers and industry arising from mandatory folic acid fortification of bread have been identified. These are:

- factors contributing to a degree of uncertainty about the folic acid intake of the target group and the general population, notably uptake of voluntary permissions by industry, the possibility of overages in folic acid fortification, and future folic acid supplement use in women of child-bearing age, and the general population;
- the impact of mandatory fortification on consumer choice and provision of information to consumers to enable identification of fortified products; and
- the impact on the baking industry who will have to develop quality control systems for the addition of folic acid, and the impact on enforcement agencies who will have to develop manageable systems for establishing compliance in the baking industry.

Strategies for the management of these identified risks and issues as they relate to the preferred regulatory option are addressed later in this Report (see Section 13).

10. Regulatory options

Selection of bread as the food vehicle chosen for fortification is on the basis of its ability to effectively deliver and sustain an increase in the folic acid intake of the target population. Consequently at Final Assessment the following two options have been identified.

10.1 Option 1 – Current approach – the *status quo*

Maintenance of the *status quo* would see the continuation of the existing permissions for the voluntary addition of folic acid to certain foods as well as the continuation of the folate-NTD health claim. In recent years there has been limited uptake of voluntary permissions across food categories, with the exception of breakfast cereals. Currently, there are very few products using a folate-NTD health claim.

Australia and New Zealand have health promotion and education strategies in place to promote the use of folic acid supplements and increase folate intakes in women of childbearing age. These strategies would be expected to continue under the *status quo*.

10.2 Option 2 – Mandatory folic acid fortification of bread products

This Option requires all bread[45] to be fortified between 80-180 µg (on average 135 µg) of folic acid per 100 g of bread, a concentration that will reduce the rate of NTDs in Australia and New Zealand. Industry will be able to choose how to comply with this requirement. The options for industry include:

(a) adding folic acid to flour used in bread-making; or

(b) adding folic acid at a later stage of bread production, such as to the pre-mix, via improvers or to a vitamin pre-mix.

[45] Bread as defined in the Code – see Section 9.1.2.

Australia and New Zealand have health promotion and education strategies in place to promote the use of folic acid supplements and increase folate intakes in women of child-bearing age. These strategies would be expected to continue under this Option.

Under a mandatory fortification option, monitoring is necessary and would be an important part of the implementation of the proposed Standard. FSANZ believes that it is important to undertake an assessment of the incidence of NTDs in both Australia and New Zealand at the commencement of this Standard to provide a benchmark for future monitoring as well as other features bearing on the success of the Standard after gazettal. In addition, monitoring for the uncertainties is an important risk management aspect of this Option. Monitoring is discussed in more detail later in this Report. (see Section 18.1).

The responsibility for establishing and funding a monitoring system to assess the impact of mandatory fortification on the population extends beyond FSANZ's responsibilities under the FSANZ Act and will require the concomitant involvement of health and regulatory agencies at the Commonwealth, State and Territory level in Australia and the New Zealand Government.

11. Impact Analysis

11.1 Affected parties

The parties most likely to be affected by this Proposal are:

11.1.1 Industry

- Bakers and flour millers.
- Industry involved in bread production including pre mixing and baking.
- Specialist producers – e.g. organic, gluten free etc.

11.1.2 Consumers

- Women of child-bearing age i.e. target consumers.
- Other non-target consumers of bread.

11.1.3 Government

- Food standards enforcement agencies of New Zealand and Australian State and Territory Governments.
- Australian, State and Territories and the New Zealand Governments.

11.2 Cost-benefit analysis of regulatory options

FSANZ commissioned Access Economics in March 2006 to investigate the benefits and costs of fortifying bread-making flour in Australia and New Zealand with folic acid. A further cost analysis undertaken by Access Economics in August 2006, looked at the cost differences between the original proposal of fortifying bread-making flour, and allowing the fortification of bread during later stages of the production process.

A number of countries (for example, the United States and Canada) have adopted mandatory fortification but few cost-benefit analyses have been undertaken. However, an analysis of fortification with folic acid of enriched cereal products in the United States suggested that such a policy is associated with net benefits (Grosse *et al.,* 2005, see Attachment 11). This is consistent with the results of the first Access Economics study.

The following information is based on the two Cost-Benefit Analyses prepared by Access Economics, which are provided in full at Attachments 11a and 11b.

11.2.1 Methodology

The analysis of benefits focused on the costs avoided as a result of new cases of NTDs per year that could be prevented in future. The costs avoided through a fall in the occurrence of NTDs include pain and suffering from disability and premature mortality, total outlays on health care and personal care, productivity losses, and efficiency losses that arise from lower taxation revenues and higher welfare payments.

The costs of mandatory fortification include the costs to government of administering, enforcing mandatory fortification and the costs to industry of fortifying their product. The costs to consumers of reduced choice have been identified in-principle but were not able to be quantified. The costs also include monitoring mandatory fortification, which were not included in the original Cost-Benefit Analysis have been included in the second analysis prepared by Access Economics.

11.2.2 The benefits

The benefits of the Proposal follow from fortification of folic acid in the final bread product. In the previous report a suitable concentration of folic acid in the final bread could be delivered by fortifying bread-making flour. In this report the option has been broadened to allow choice of how to fortify bread products with folic acid; industry may choose bread-making flour as the vehicle or industry may choose to add folic acid in later stages of the bread making process.

In each case the concentration in the final bread will be the same at an average of 135µg of folic acid per 100 grams of bread. Hence benefits of the Proposal remain as described in the previous report.

New cases of NTDs prevented through mandatory fortification were estimated by FSANZ (see Section 7.1). Three scenarios were modelled: lower estimates of NTDs prevented, mean estimates and upper estimates of NTDs prevented. The projected mean number of incident cases prevented per year is presented in Table 7 below.

Benefits were calculated based on two scenarios:

- live NTD births prevented (i.e. excluding terminations and still births prevented by fortification on the basis of 'replacement' births); and
- all NTD births prevented (i.e. including NTD terminations and still births prevented by fortification on the basis of the intrinsic value of human life).

Table 7: Projected number of neural tube defect incident cases prevented per year

Food vehicle	Residual folic acid content per 100g flour in the final food	Total NTD incident cases prevented	Live NTD births prevented	Still NTD births prevented	Terminations of pregnancy prevented
	µg folic acid				
Australia					
All bread-making flour	200	26.0	5.0	3.0	18.0
New Zealand					
All bread-making flour	200	7.9	1.3	1.3	5.2

Source: FSANZ modelling

The benefits for Australia and New Zealand include:

- the pain and suffering from disability and premature mortality avoided through fortification (disability adjusted life years (DALYs) avoided). The value of these in dollars is the net burden of disease;
- production losses avoided through prevention of NTDs (the loss of lifetime earnings of people with NTDs who are not able to participate fully in the labour force, and of NTD pregnancies terminated or NTD still births who may otherwise have survived and accrued lifetime earnings);
- avoided outlays on health care and personal care ('other costs' in the table) — based on live NTD births prevented; and
- avoided efficiency losses that arise from lower taxation revenues and higher welfare payments as a result of the occurrence of NTDs.

The benefits of avoiding disability and premature death (net burden of disease) form the largest component of the benefits of mandatory fortification, followed by productivity losses.

Table 8: Summary of benefits of mandatory fortification for Australia and New Zealand

	Australia (A$)	New Zealand (NZ$)
Live born NTDs (excluding still births and terminations)		
Net value of burden of disease avoided	18,830,889	5,556,952
Health expenditure avoided	569,019	151,285
Avoided long term productivity loss	4,470,093	1,112,839
Other avoided costs	688,820	204,150
Efficiency loss avoided	534,760	93,613
Total benefits (excluding still births and terminations)	**25,093,582**	**7,118,839**

	Australia (A$)	New Zealand (NZ$)
All NTDs (including still births and terminations)		
Net value of burden of disease avoided	101,641,627	36,928,847
Health expenditure avoided	569,019	151,285
Avoided long term productivity loss	21,319,956	5,952,091
Other avoided costs	688,820	204,150
Efficiency loss avoided	1,484,250	285,248
Total benefits (including still births and terminations)	125,703,672	43,521,621

11.2.3 The costs

As a result of mandatory fortification, consumers will face reduced choice and potentially a slight increase in the price of bread. This increase is likely to be small, perhaps up to 2% per loaf. The price increase would occur because under mandatory regulatory measures all affected businesses typically pass on all or most costs that are incurred at some stage. The cost of reduced choice was not able to be quantified.

The costs to industry of mandatory fortification of all bread with folic acid are different under the two alternative methods for adding folic acid considered by Access Economics. These methods are adding folic acid to bread-making flour, and adding it during a later stage of bread production. Table 9 below sets out the costs under each alternative for industry and government in both Australia and New Zealand.

In the first year, industry in both Australia and New Zealand would incur costs associated with both changing labelling and packaging as well as costs related to the purchase of folic acid, preparation of premix, the per annum costs associated with additional machinery and equipment, analytical testing, flushing out mills, storage and administration. Industry advised very high costs of writing off existing stocks of labels, even with a twelve month transition period, that have been included in this analysis.

FSANZ has estimated the cost of equipment purchases under the fortification of flour option to be A$264,000. For the purposes of this calculation it was assumed that a folic acid feeder would be purchased by each of the eight largest Australian millers at a cost of A$33,000 per feeder. This was based on independent United States figures. The cost for the bread production fortification option, was estimated by Access Economics on the basis of information by New Zealand industry, at NZ$1,202,000.

We have assumed a cost of equipment in New Zealand under the fortification of bread option, using this same independent United States data, of NZ$80,000. An estimate has then also been included to cost the fact that other smaller producers may purchase equipment at lower cost. The upfront equipment cost for fortification of flour in New Zealand was calculated by Access Economics as NZ$1,470,000.

The once off (first year) costs of changes to labelling pre-packaged products are likely to affect a large number of product lines because labelling standards require that the ingredients

of a compound (such as bread-making flour) be declared if the amount of the compound ingredient in the final food is 5 per cent or more by weight.

The cost in the first year for industry under the fortification of bread flour option, is estimated at A$6,586,400 for Australia and NZ$2,385,620 for New Zealand. The upfront costs under the fortification of bread during the production stage, are less, at A$5,738,400 and NZ$996,063 for Australia and New Zealand respectively.

The upfront government costs, which include administration, enforcement and monitoring, are the same whether folic acid is added to flour or during bread production. The costs are estimated at A$1,273,000 for Australia and NZ$60,920 for New Zealand.

The ongoing costs for industry include the cost of maintenance of equipment, folic acid and premix, analytical testing to ensure compliance, administration and cleaning of mill. The cost figures for fortifying flour compared with fortifying bread during production vary considerably in some cases. Under the fortification of bread-making flour option the total ongoing industry costs per year for Australia are A$1,058,592, compared to A$24,486,067 for the fortification of bread option. In New Zealand these costs are NZ$2,377,738 for fortifying bread-making flour and NZ$4,149,593 for fortifying during bread production.

Access Economics took a conservative approach to calculating industry costs by accepting information provided by industry. These costs may be at the high end of a plausible range. FSANZ considers that the actual costs incurred by industry may be somewhat lower then the cost estimates in Table 9.

Access Economics' estimates for the annual costs of government administration and enforcement of mandatory fortification in both Australia and New Zealand include the costs of awareness raising and training, compliance auditing, administration and enforcement (dealing with complaints). These ongoing, annual costs for government are assumed to be the same whether fortification occurs at in bread-making flour, or during the production of bread. Ongoing administration and enforcement costs for Australia are A$2,210,000 and NZ$88,500 for New Zealand. Monitoring costs have been listed separately and are higher for the second year following introduction of the mandatory fortification proposal. These costs are A$455,000 for Australia in the second year and NZ$485,000 for New Zealand. For all years after the second year, monitoring costs are A$355,000 for Australia and NZ$378,000 for New Zealand.

Table 9: Summary of costs of mandatory fortification

		Australia (A$)		New Zealand (NZ$)	
	Residual folic acid content per 100g of the final food	**Fortification of bread-making flour 200µg**	**Fortification of bread 135µg**	**Fortification of bread-making flour 200µg**	**Fortification of bread 135µg**
Industry - upfront	Labelling	2,486,400	2,486,400	275,620	436,063
	Packaging write off	4,000,000	2,050,000	640,000	500,000
	Equipment	264,000	1,202,000	1,470,000	80,000
Total industry upfront		*6,750,400*	*5,738,400*	*2,385,620*	*1,016,063*
Government – upfront	Administration and enforcement	1,223,000	1,223,000	7,920	7,920
	Monitoring	50,000	50,000	53,000	53,000
Total government upfront		*1,273,000*	*1,273,000*	*60,920*	*60,920*
Total upfront costs (industry and government)		**8,023,400**	**7,011,400**	**2,446,540**	**1,076,983**
Industry – ongoing (per year)	Maintenance	na	591,500	117,600	na
	Folic acid	112,000	-*	23,496	-*
	Premix	51,893	13,773,500	343,200	1,786,818
	Analytical testing	673,077	10,036,567	141,202	2,253,497
	Administration	186,883	84,500	11,200	109,278
	Clean out mill	34,739	0	1,741,040	0
Total industry ongoing (per year)		*1,058,592*	*24,486,067*	*2,377,738*	*4,149,593*
Government – ongoing (per year)	Administration and enforcement	2,210,000	2,210,000	88,500	88,500
	Monitoring – year 2	455,000	455,000	485,000	485,000
	Monitoring subsequent years	355,000	355,000	378,000	378,000
Total government- year 2		*2,665,000*	*2,665,000*	*573,500*	*573,500*
Total costs year 2		3,723,592	27,151,067	2,951,238	4,723,093
Total government – subsequent years (per year)		*2,565,000*	*2,565,000*	*466,500*	*466,500*
Total ongoing costs – years 3 onwards (industry and government) (per year)		**3,623,592**	**27,051,067**	**2,844,238**	**4,616,093**

* - This cost is included in the premix cost figures.
na – figures are not available.

While there is a slight difference in timing between realisation of the benefits and outlays associated with costs of machinery and labelling which has not been taken into account in the modelling, this is unlikely to make a material difference to the results.

11.2.4 Net benefits

Table 10 summarises the net benefits of mandatory fortification of bread-making flour with folic acid in Australia and New Zealand for live NTD births (excluding the benefits associated with prevention of NTD terminations and still births).

Table 10: Net benefits live NTD births

	Australia (A$)		New Zealand (NZ$)	
Residual folic acid content per 100g of the final food	**Fortification of bread-making flour 200µg**	**Fortification of bread 135µg**	**Fortification of bread-making flour 200µg**	**Fortification of bread 135µg**
Benefit	25,093,582	25,093,582	7,118,839	7,118,839
Total upfront costs	8,023,400	7,011,400	2,446,540	1,076,983
Net benefit upfront	**17,070,182**	**18,082,182**	**4,672,299**	**6,041,856**
Total costs year 2	3,723,592	27,151,067	2,951,238	4,723,093
Net benefit year 2	**21,369,990**	**-2,057,485**	**4,167,601**	**2,395,746**
Total ongoing costs - years 3 onwards (per year)	3,623,592	27,051,067	2,844,238	4,616,093
Net benefit ongoing – years 3 onwards (per year)	21,469,990	-1,957,485	4,274,601	2,502,746

Table 11 summarises the net benefits of mandatory fortification of bread-making flour with folic acid in Australia and New Zealand for all NTDs (including terminations and still births). In all cases, the benefits outweigh the costs.

Table 11: Net benefits all NTDs

	Australia (A$)		New Zealand (NZ$)	
Residual folic acid content per 100g of the final food	**Fortification of bread-making flour 200µg**	**Fortification of bread 135µg**	**Fortification of bread-making flour 200µg**	**Fortification of bread 135µg**
Benefit	125,703,672	125,703,672	43,521,621	43,521,621
Total upfront costs	8,023,400	7,011,400	2,446,540	1,076,983
Net benefit upfront	**117,680,272**	**118,692,272**	**41,075,081**	**42,444,638**
Total costs year 2	3,723,592	27,151,067	2,951,238	4,723,093
Net benefit year 2	**121,980,080**	**98,552,605**	**40,570,383**	**38,798,528**
Total ongoing costs - years 3 onwards (per year)	3,623,592	27,051,067	2,844,238	4,616,093
Net benefit ongoing – years 3 onwards (per year)	**122,080,080**	**98,652,605**	**40,677,383**	**38,905,528**

11.2.5 Key findings

Mandatory fortification of bread products with folic acid delivers benefits that definitively exceed the costs.

Considering all NTDs that are avoided by mandatory fortification, substantial net-benefits are achieved in Australia and New Zealand whether fortification occurs through the bread-making flour or at a later stage of bread production.

Considering only the live born NTDs that are avoided, net-benefits are achieved in New Zealand and for fortification of flour in Australia. However net-costs would occur in the case where folic acid is added to the later stages of bread production in Australia. In this case Australian industry can choose the least cost option of fortifying bread-making flour.

The specific key findings from the impact analysis are:

- in Australia, in the case of live NTDs when folic acid is added at the later stages of bread production, the overall impact would be a net-cost of $2 million each year ongoing. However when all NTDs avoided are included in the analysis, the overall impact would be a net-benefit of $99 million each year ongoing;

- in Australia, in the case of live NTDs when folic acid is added to bread making flour, the overall impact would be a net-benefit of $21 million each year ongoing. When all NTDs avoided are considered, the net-benefit increases to $122 million each year ongoing;

- in New Zealand, in the case of live NTDs when folic acid is added at the later stages of bread production, the overall impact would be a net-benefit of $2.5 million each year ongoing. When all NTDs avoided are included, the net-benefits increase to $39 million each year ongoing; and

- in New Zealand, in the case of live NTDs when folic acid is added to bread making flour, the overall impact would be a net-benefit of $4.3 million each year ongoing. When all NTDs avoided are included, the net-benefits increase to $41 million each year ongoing.

12. Comparison of Options

The Options being put forward by this Proposal are Option 1, the maintenance of the *status quo,* and Option 2, mandatory fortification of bread on average at the level of 135 μg folic acid per 100 g bread.

The cost benefit analysis undertaken by Access Economics clearly indicates that Option 2 with mandatory fortification of bread delivers substantial net-benefits to Australia and New Zealand compared with the status quo. Option 2 allows industry the choice of method of fortifying bread with folic acid, including adding folic acid to bread via the bread-making flour, in a pre mix, through the use of an improver or via a vitamin pre mix. Hence industry will be able to choose the most efficient and cost effective method to meet this mandatory fortification requirement.

13. Strategies to manage risks associated with mandatory fortification

Issues relating to mandatory fortification have been identified as part of this assessment. Approaches to minimising risks associated with these issues are considered below.

13.1 Managing safety and effectiveness

Strategies to manage risks associated with the safety and effectiveness of mandatory fortification (see section 9.4) are outlined below, including prescribing the level of fortification as a range, monitoring possible changes in the uptake of voluntary permissions, and considering the need for changes to supplement use by the target and non-target population groups.

13.1.1 Level of fortification

The fortification of bread at a level of 135 µg folic acid per 100 g bread was determined by the dietary intake assessment to achieve effective and safe fortification of the food supply with folic acid.

The fortification level of 135 µg folic acid per 100 g of bread represents the amount of folic acid that is required in the final food, i.e. bread. As previously noted in Section 6.1.2.2, average losses of folic acid during the bread-baking process are 25% but may be as high as 40%. There appears to be no other significant losses of folic acid during processing or storage. Consequently, as the folic acid is to be added during the bread production process, folic acid losses on baking will need to be accounted for by the bread manufacturer and/or the manufacturer of the fortified premix or improver in order to achieve the required level of fortification in the final product. Bread ingredient manufacturers are able to add folic acid to improvers, premixes and folic acid vitamin premixes in precise amounts, and thereby provide a known level of folic acid fortification.

The food standard is drafted on the basis of final bread weight and therefore will mean that bakers are able to choose the most appropriate means of adding folic acid to bread for their plant and operating practices. The essential criteria is that bakers use the appropriate amount of premix, or improver, or folic acid fortified flour, in all relevant batches of bread dough.[46]

Due to the industry's usual practice of adding vitamins and minerals in amounts in excess of a fortification level (i.e. overage), such as the experience in the United States and with thiamin, there is concern that a higher than desired level of folic acid will result. Given the uncertainties and the need for a conservative approach to mandatory fortification, application of a prescribed range of fortification is considered necessary.

Therefore, the proposed prescribed range for mandatory folic acid fortification is 80-180 µg of folic acid per 100 g bread. This range allows for a ±35% accuracy of fortification during the bread production process rounded to the nearest 10 µg/100 g (0.1 mg/kg).

[46] Brooke-Taylor & Co Pty Ltd, Report prepared for FSANZ, Attachment 10, Appendix 1

13.1.2 Impact of voluntary fortification

The current voluntary folic acid permissions have provided additional amounts of folic acid in the food supply. However, by virtue of the nature of voluntary permissions, it is not possible to guarantee this level of uptake in the future.

Concerns were raised by submitters at the lack of certainty over the future status of voluntary permissions. Submitters noted the contribution voluntary permissions made to folic acid intakes in the general population, especially children, and some suggested the permission for fortifying breakfast cereals targeting children should be reviewed. Other submitters suggested that the use of existing and further voluntary permissions provided a means of increasing the folic acid intake of women whose diet does not traditionally include bread, or who omitted bread because of food intolerances. Suitable products suggested for further fortification included corn flour and rice.

To provide more regulatory certainty, different options could be considered. Voluntary permissions in some foods, could be made mandatory, levels of folic acid in voluntary permissions could be adjusted, and other permissions that currently have little uptake by industry or significant consumption by non-target groups such as children, could be removed. However, these actions have trade implications, imposts for industry and may create confusion for some consumers. In keeping with FSANZ's mandate of ensuring minimum effective regulations, robust and definitive evidence will be needed before pursuing this course of action.

In addition to the existing voluntary permissions[47], industry could in the future apply to have further voluntary folic acid permissions considered. These applications would need to be assessed in relation to the predicted mandatory folic acid fortification outcomes. It may be possible to deliver additional amounts of folic acid to women of child-bearing age, via voluntary fortification, without compromising the health and safety of other population subgroups such as children. Additional food vehicles, highly specific to the target population, may be identified as being suitable for consideration.

However given the difficulties in predicting future trends in voluntary fortification permissions for folic acid, FSANZ proposes to discuss with industry use of current voluntary fortification permissions and to monitor changes in the use of voluntary fortification permissions to determine if additional regulatory responses are necessary. This is particularly pertinent with regard to the folic acid intake of children. A possible future mechanism for lowering the folic acid intake of children is through reduction in the level of voluntary fortification in foods commonly consumed by children, or removal of permissions. FSANZ proposes to consult directly with industry regarding the use of existing voluntary fortification permissions and their potential future use.

As part of the proposed draft variation to the Code (see Attachment 1), removal of the current voluntary permission to add folic acid to bread has been incorporated. This voluntary permission will be redundant with the proposal to mandate folic acid fortification of bread.

[47] Folic acid has been permitted to be voluntarily added to flour, savoury biscuits, breads, breakfast cereals, pasta, fruit and vegetable juices and drinks, fruit cordials, beverages derived from legumes and legume analogues of dairy foods and meat.

13.1.3 Folic acid supplement use

Under mandatory fortification women of child-bearing age will not receive sufficient folic acid from fortified foods to reach the recommended folic acid intake of 400 µg per day. Health education information for NTD prevention under mandatory fortification should therefore continue to advise women planning pregnancies to take folic acid supplements for NTD prevention.

As shown by the dietary intake assessment, folic acid intake from both food and a 800 µg supplement substantially increases mean daily folic acid intakes to a level near the upper limit. The implications of mandatory fortification on the current New Zealand recommendation for peri-conceptional folic acid supplement were raised in the Draft Assessment Report. FSANZ noted that while this level of folic acid intake is not likely to have a negative impact on public health and safety, consideration could be given to providing access to 400 µg folic acid supplements in New Zealand. The New Zealand Food Safety Authority reported in their submission that they are currently engaged in discussions with the New Zealand Ministry of Health and Medsafe[48], with regard to providing a lower dosage folic acid supplement manufactured to a prescription medicine standard.

Under mandatory fortification it may also be necessary to consider guidelines in relation to supplement use by the non-target population groups. Vitamin and mineral supplements are generally not recommended for children, primarily due to concerns about the adverse effects related to the continued use of large numbers of certain vitamins and minerals[49]. FSANZ intends to raise this matter with the respective agencies responsible for providing guidance on supplement use.

Supplement use does impact on both the safety and effectiveness of mandatory fortification and for this reason has been included as a key element of the proposed monitoring system (See Attachment 12).

13.2 Consumer Choice

In delivering the public health benefits of mandatory fortification of bread with folic acid there will be few options for the consumption of unfortified bread products. On the limited evidence available, FSANZ has been unable to identify the extent to which this will be of continuing concern to Australian and New Zealand consumers. The lack of consumer choice posed by mandatory fortification was, however, raised by many submitters, many of whom considered the ability of consumers to make a choice should be maintained. However other submitters acknowledged that provision of consumer choice does not fit the principle of mandatory fortification and that other public health strategies such as seat belt wearing are implemented at the expense of consumer choice.

The views of stakeholders were specifically sought at Draft Assessment as to whether, and how, additional options for consumer choice could be accommodated within the preferred mandatory fortification option. Organic industry groups and some consumers supported an exemption for organic products.

[48] Medsafe – New Zealand Medicines and Medical Devices Safety Authority.
[49] NZMoH (1997).

The Australian and New Zealand industry, and the New Zealand Food Safety Authority, put forward alternative proposals aimed at providing consumer choice through the targeted fortification of products consumed by the target group, rather than mandatory fortification of all bread. The alternative proposals were considered and are discussed in Section 6.9, but did not result in as high a proportion of the target population increasing their folic acid intake as the proposed FSANZ option of fortifying all bread.

The fortification of bread does provide for some consumer choice as flour products which do not meet the definition of bread as defined in the Code will not be required to be fortified with folic acid. Some unfortified products such as unleavened flat breads, hot plate products such as crumpets and pikelets, pizza bases, and retail flours will provide consumers with other options.

FSANZ also intends to monitor the level of consumer awareness and understanding of folic acid fortification as part of the bi-national monitoring systems to track the impact of regulatory decisions on mandatory and voluntary fortification (Attachment 12).

13.3 Labelling and information provision

The purpose of food labelling is to provide consumers with information about food to enable them to make informed food choices. Labelling provides an important source of information for consumers regarding fortification, and enables consumers to make informed decisions regarding their consumption of fortified foods.

The generic labelling requirements of the Code applicable to foods fortified with folic acid include:

- listing of ingredients (Standard 1.2.4);
- nutrition information requirements for foods making nutrition claims (Standard 1.2.8);
- the conditions applying to nutrition claims about vitamins and minerals (Standard 1.3.2); and
- permissible health claims (Transitional Standard 1.1A.2)

Under mandatory fortification, foods containing folic acid will be required to list folic acid as an ingredient in the ingredient list, 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*.

A number of submitters asked that folic acid be required to be listed on the Nutrition Information Panel (NIP) label in order that women could calculate their daily intake of folic acid to allow for more informed choice. Some submitters also recommended that labelling reflect Nutrient Reference Values (NRVs) and that dietary folate equivalent (DFEs) nomenclature be used.

FSANZ considers the generic requirements of the Code to be appropriate for providing consumers with information and therefore does not believe mandating inclusion in the NIP is warranted. The ingredient listing of folic acid will alert consumers to the presence of folic acid, and may be used by consumers to assist in the selection of fortified foods for improving folate status, or conversely, to avoid folic acid fortified foods if they so wish.

The incorporation of NRVs and dietary folate equivalents into the Code will be managed as part of a separate review by FSANZ at a future date.

13.3.1 Use of nutrition and health claims

Mandatory fortification presents the opportunity for food manufacturers to make nutrition and health claims, as permitted under the Code, related to the folic acid content of bread and bread products in labels and related information. Although nutrition and health claims can be a useful source of information for consumers, it is noted that food manufacturers may not choose to use these claims to promote the folic acid content of their foods if no marketing advantage is perceived.

The types of claims currently possible in relation to the folic acid/folate content of bread and bread products are outlined below:

- nutrition content claims which are a claim about the presence of naturally-occurring folate plus folic acid, for example 'source' and 'good source' claims;

- a health claim under Transitional Standard 1.1A.2 which highlights the link between increased maternal dietary folate consumption and reduction in NTD risk; and

- claims which may include reference to function and health maintenance in relation to folate consumption, so long as they are not prohibited by the Code or the requirements of fair trading legislation in relation to making false or misleading statements.

A new Standard (Standard 1.2.7 – Nutrition, Health and Related Claims) is currently being drafted under Proposal P293 - Nutrition, Health and Related Claims. The Standard will permit a wider range of claims in the future, including a revised folate-NTD health claim. Transitional Standard 1.1A.2 will cease two years after the gazettal of Standard 1.2.7.

Submitters to the Draft Assessment Report raised several issues in relation to the ability of bread manufacturers to make health claims under provisions proposed by Proposal P293. Some submitters stated that the disqualifying criteria proposed under draft Standard 1.2.7 would preclude many existing breads from making a health claim in its present form. Several submitters also noted that the health claim under Transitional Standard 1.1A.2 applied to listed brands of bread, not to breads generally. The issue of a health claim in relation to NTD reduction and folic acid levels in mandatorily fortified bread has been recognised in the development process of Standard 1.2.7. Disqualifying criteria are being reviewed in order to prevent future anomalies and will be discussed in a Preliminary Final Assessment Report. This report will be released for public consultation in the near future.

FSANZ is proposing to include a consequential amendment to the Code (Attachment 1) to delete the listed brands of bread in the Table to subclause 3(e) in Transitional Standard 1.1A.2 and include a general permission for bread.

13.3.2 'Natural foods' and related descriptor labels

Food labelling or promotional claims must be factually correct and not misleading or deceptive under the fair trading legislation of Australia and New Zealand[50]. FSANZ is in discussions with the Australian Competition and Consumer Commission and the New Zealand Commerce Commission; to clarify the status of folic acid fortified foods and the use of descriptors such as 'natural food', and 'organic foods' with regards to fair trading labelling requirements.

A number of submitters requested that organic bread and flour be exempt from mandatory fortification. However, there are no agreed criteria for considering a food as organic in Australia or New Zealand at the present time. Therefore a reference to organic foods within the Code would not be enforceable. This issue has implications for the whole of industry and government and it is not feasible to address this within the proposed mandatory food standard. Organic standards bodies have been informed of this issue.

COMMUNICATION AND CONSULTATION

14. Communication and Education Strategy

FSANZ has prepared a communication and education strategy for the preferred regulatory option of mandatory folic acid fortification. The strategy aims to increase awareness among all target audiences of the proposed standard for mandatory folic acid fortification and its implementation. Target audiences, communication objectives, key messages and planned activity are detailed in the strategy. The strategy is informed by consumer research, targeted consultations with key stakeholder groups, and issues arising from submissions to FSANZ in response to the Draft Assessment Report. This strategy will particularly focus on developing resource materials and information to assist industry to understand and comply with the new mandatory fortification requirement. Section 17.2 provides further information about the strategy.

15. Consultation

15.1 Initial Assessment

FSANZ received a total of 72 submissions in response to the Initial Assessment Report for this Proposal during the public consultation period of 20 October to 24 December 2004.

Submitters' views were mixed in relation to a preferred regulatory option. In general, government submitters and organisations and individuals with a direct interest in NTDs supported mandatory fortification. Industry submitters primarily supported extension of voluntary fortification permissions in conjunction with increased health promotion and education strategies to increase folate intakes.

[50] *Trade Practices Act 1974*, State and Territory Fair Trading legislation and *Fair Trading Act 1986*.

15.2 Draft Assessment

There was support from most government and some public health submitters for mandatory fortification, with the importance of having a national monitoring and surveillance system in place prior to implementation highlighted by many submitters. Public health and consumer submitters expressed a range of views both for and against the proposed approach. Submitters raised concerns about lack of consumer choice, possible health risks and future unknown health risks, particularly for children, and the effectiveness of mandatory fortification in reducing NTDs (based on the proposed fortification level) was not sufficient to justify population wide consumption of folic acid.

Industry submitters were opposed to mandatory fortification proposal and expressed concerns about the high degree of impost and technical difficulties in being able to fortify bread-making flour within the required parameters. Industry primarily supported the extension of voluntary fortification permissions in conjunction with increased education and promotion strategies to increase folate intakes.

Key issues raised in submissions have been addressed in this Final Assessment Report where possible and include:

- the choice of food vehicle for fortification, including technical issues for industry fortifying the proposed food vehicle to the required level, and alternative proposals;
- potential health risks associated with an increased folic acid intake particularly long term effects for the non-target population;
- the lack of consumer choice associated with mandatory fortification;
- the cost and resulting impact on industry;
- the requirement for monitoring and surveillance;
- the perceived inconsistency with Ministerial Policy Guideline, in particular how it meets the Specific Order Policy Principles for mandatory fortification; and
- the need for ongoing health promotion and education strategies that are wide reaching and supported by the governments.

15.3 Targeted consultation process

During the public consultation period and afterwards, FSANZ also initiated a process of intensive targeted consultation to discuss the key issues and impacts of mandatory fortification.

Issues identified from submissions formed the basis of further targeted consultation with key stakeholder groups, particularly the milling and baking industries. This included FSANZ commissioning an independent consultant, Brooke-Taylor & Co Pty Ltd to consult in Australia and New Zealand regarding the technical capabilities of industry and possible alternative options to flour for fortifying bread.

Key stakeholder groups consulted were the Australian and New Zealand baking and milling industries, the Australian, State and Territory, and New Zealand governments, consumer and public health organisations. Key stakeholder groups consulted were the baking and milling industry, jurisdictions, consumer and public health organisations.

Industry consultations included leading milling and bread manufacturers, milling, baking and bread ingredient manufacturers, Australian and New Zealand peak industry bodies, national and regional baking associations and societies, and organic food associations. Consultations have involved face-to-face meetings, teleconferences, information updates and email correspondence.

Information received has informed FSANZ's process for reviewing and selecting the food vehicle, identification and investigation of risk management issues, further cost-benefit analysis, recommendations for implementation, and the monitoring requirements for mandatory fortification.

FSANZ again commissioned Access Economics, an independent economic consultancy organisation, to further investigate and revise the costs of fortifying bread with folic acid in Australia and New Zealand. Access Economics held further consultations with key stakeholders, particularly industry groups, in regard to the financial implications of mandatory fortification of bread.

As part of this targeted consultation process, FSANZ has engaged the Standards Development Advisory Committee (SDAC) to help identify views and issues while progressing work on this Proposal. The SDAC is comprised of members who have a broad interest in, and knowledge of, fortification-related issues and represent the following sectors: public health nutrition; food manufacturing; enforcement; food policy; health promotion; and consumer education.

To ensure a consumer perspective on the proposed standard, FSANZ has also undertaken consultation with the FSANZ Consumer Liaison Committee, a group formed to provide a consumers' perspective with members drawn from both Australia and New Zealand.

Given the increased incidence of NTDs among Indigenous population in some regions of Australia, FSANZ has made contact with key representatives of Indigenous groups during the consultation process. To date, members of the Reference Group for the National Aboriginal and Torres Strait Islander Nutrition Strategy and Action Plan (NATSINSAP) and the Maori Reference Group (Kahui Kounga Kai) have been involved in the consultation process.

15.4 Outcomes from targeted consultations

As indicated above, FSANZ undertook further intensive targeted consultation with key stakeholder groups particularly to gauge their views on the refined approach at Final Assessment. This consultation included public health and consumer organisations, Australian and New Zealand baking and milling industries, the supermarket chains with in-house bakeries, the Australian, State and Territory, and New Zealand governments, consumer and public health organisations.

Australian industry has maintained their opposition to mandatory folic acid fortification and support voluntary fortification of a selected range of branded products in association with education which industry offered to support. New Zealand industry, while opposing mandatory fortification, has suggested that if mandatory fortification were to go ahead, consideration should be given to exempting one or more classes of bread to allow for consumer choice.

In regards to the refined approach, industry has expressed concerns about costs, compliance, enforcement and transitional timeframes. There are concerns about the capacity of the baking industry, particularly with respect to small business bakeries, to meet the required standard.

The supermarket chains prefer the standard to be based on levels of folic acid in bread-making flour. They have argued that if the standard is to change to require folic acid in bread, then a longer transition period will be required to allow time for discussions with suppliers about whether folic acid will be added to flour or into a premix; to conduct recipe testing; and to undertake staff training.

The small bakers represented by the Australian and New Zealand Baking Industry Association (ANZBAKE) stated their position was that reductions in NTDs should be achieved through the provision of free (possibly mandatory) supplements for young women and that they were opposed to mandatory fortification. However, if it was introduced, a longer transition period would be required for similar reasons to those outlined by in-store bakers.

A number of public health and consumer groups in support of the approach at Draft Assessment expressed concern with the proposed move away from fortification of bread-making flour. In particular there was concern that the fortification of bread presented greater compliance and enforcement issues than fortification of flour. Other public health and consumer groups oppose mandatory fortification or support on condition that effective monitoring and review occurs. Monitoring is considered a essential component of mandatory fortification by all stakeholder groups.

15.5 World Trade Organization

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards and amending the Code to require the mandatory fortification of bread with folic acid is unlikely to have a significant effect on international trade. This is because bread is principally produced for domestic markets. However, FSANZ recognised that a requirement to mandatory fortify a staple food such as bread may have trade implications that had not yet been identified.

Therefore, WTO member nations were notified of the proposed mandatory fortification regulations in accordance with the WTO Technical Barrier to Trade Agreement by both Australia and New Zealand. No responses to the notifications were received by FSANZ.

CONCLUSION

16. Conclusion and the decision

As requested by the Ministerial Council, FSANZ has considered the feasibility of mandatory fortification of the food supply with folic acid as a means of reducing the incidence of NTDs in Australia and New Zealand.

On the basis of the available evidence, FSANZ concludes that mandatory folic acid fortification of bread at a level of 135 µg / 100 g of bread can deliver definitive net-benefits to Australia and New Zealand.

In addition to mandatory fortification, other strategies for reducing the incidence of NTDs will continue to be important. These strategies include the promotion of increased folate intakes in women of child-bearing age through education, voluntary fortification and supplement use. The optimal reduction in the incidence of NTDs depends on these strategies continuing, including a commitment to the ongoing promotion of folic acid supplements.

FSANZ approves the draft variations to the Code for the following reasons:

- fortifying bread with folic acid, learns from and builds on international experience of mandatory fortification to reduce the incidence of NTDs;

- bread is an effective and technically feasible food vehicle for mandatory fortification;

- bread and bread products are staple foods consumed widely (more than 80%), consistently and regularly by the target population of women aged 16-44 years;

- fortification of bread will deliver a mean increase in folic acid intake in the target population of 101 µg and 140 µg in Australia and New Zealand respectively, resulting in an estimated reduction of between 14-49 out of 300-350 pregnancies in Australia and 4-14 out of 70-75 pregnancies in New Zealand affected by an NTD each year;

- on the available evidence, including overseas experience with mandatory fortification, the proposed level of fortification does not pose a risk to public health and safety. The level has been set to minimise any potential health risks as a degree of uncertainty exists, particularly for the non-target population from increased folic acid intakes over the longer term;

- the cost-benefit analysis has indicated that mandatory fortification of bread with folic acid can deliver benefits that definitively exceed the costs:

    - in Australia, when folic acid is added to bread making flour, the net-benefit from all NTDs avoided is $122 million each year ongoing. In the case of live births the net-benefit is $21 million each year ongoing;
    - in Australia, when folic acid is added at the later stages of bread production, the net-benefit from all NTDs avoided is $99 million each year ongoing. In the case of live births there is a net-cost of $2 million each year ongoing;
    - in New Zealand, when folic acid is added to bread making flour, the net-benefit from all NTDs avoided is $41 million each year ongoing. In the case of live births the net-benefit is $4.3 million each year ongoing; and
    - in New Zealand, when folic acid is added at the later stages of bread production, the net-benefit from all NTDs avoided is $39 million each year ongoing. In the case of live births the net-benefit is $2.5 million each year ongoing.

- fortification of bread provides greater predictability in the level of folic acid consumed by the target and non-target groups and therefore greater confidence that the estimated reduction in NTDs will be achieved and that health risks to non-target groups will be minimised;

- fortification of bread provides flexibility for industry in determining the most appropriate and cost effective means of achieving mandatory fortification;

- the cost to consumers is likely to be less than 2% of the price of a loaf of bread;

- the fortification of bread does provide for some consumer choice through access to unleavened breads and unfortified flour; and

- it is consistent with Ministerial policy guidance on mandatory fortification;

Monitoring is an important component of implementing this Proposal. It will provide a mechanism to gauge both the ongoing effectiveness and safety of mandatory folic acid fortification, particularly in further reducing the incidence of NTDs. It is also an important risk management strategy for identifying potential adverse health effects resulting from mandatory fortification in the population as a whole.

The Australian Government Office of Regulation and Review considered the Final Assessment Report for this Proposal and advised in a letter dated 29 August 2006 that the report was compliant with the Council of Australian Government's regulatory best practice requirements.

17. Implementation and Review

17.1 Transitional Period

Upon approval by the FSANZ Board of the proposed draft variations to the Code as presented at Final Assessment, the Ministerial Council will be notified of that decision. Subject to any request from the Ministerial Council for a review, the proposed draft variation to the Code are expected to come into effect 15 months from gazettal.

At Draft Assessment, a 12 month transitional period was proposed. However consultation with industry indicated that a longer transitional time would assist industry in a number of ways. A longer period will allow time for bread manufacturers to make the required changes to manufacturing and labelling. In particular, manufacturers will have more time to determine the most suitable and cost effective method of fortification for their business, establish a supply of fortified ingredients e.g. fortified flour, pre-mixes etc, undertake personnel training and any necessary recipe testing and re-formulation. Additionally, extending the transitional time to 15 months will allow the requirements for mandatory folic acid fortification to most likely coincide with the commencement of mandatory iodine fortification, which is currently being considered as a separate proposal (Proposal P230). Allowing manufacturers the opportunity to meet both of these regulatory changes simultaneously, particularly labelling change, will provide some cost savings for industry.

As noted in the Editorial note to the draft standard, bread manufacturers may also take up the voluntary permission to add folic acid to bread continued in Standard 1.3.2 in preparation for the commencement of the mandatory requirement. Additionally, the transitional period will allow for consumers to be informed about the changes.

It should be noted that the success of this important public health strategy extends beyond implementing mandatory fortification as the sole strategy, and incorporates the key components of education, folic acid supplementation policy and monitoring. A proposed approach to monitoring is discussed below in Section 18.1. Extending the transitional period will allow sufficient time to collect baseline data as part of the monitoring system.

17.2 Regulatory compliance issues

The fortification of bread may present challenges in achieving regulatory compliance for bread manufacturers, particularly for small bakeries, and also for enforcement agencies with responsibility for ensuring bread manufacturers are compliant

FSANZ considers that enforcement at the retail level would be analogous to the enforcement of a number of other compositional standards contained within the Code, for example, the requirement for 25% meat content in meat pies, the 10% milk fat requirement in ice-cream and the 50 ml/L minimum fruit requirement in fruit drinks. Advice from one enforcement agency is that the enforcement burden could be reduced by the use of a paper audit trail (in the first instance) rather than food analysis, to demonstrate that the amount of folic acid added complied with the standard. Appropriate production records, maintained in a form consistent with normal food industry quality assurance procedures, could be used to demonstrate to food enforcement authorities that a correct amount of folic acid had been and was being added to each batch of bread.

FSANZ will be developing an industry implementation guide on the proposed Standard for dissemination through the baking industry professional and training associations in New Zealand and Australia. These professional organisations provide expertise and advice to the baking industry, including independent bakers, and have indicated they are the appropriate bodies to assist bakers deal with the issues arising from the requirement to fortify all bread with folic acid[51].

17.3 Communication and education strategy for the preferred regulatory option

FSANZ's communication and education strategy for mandatory folic acid fortification aims to increase awareness among all target audiences of the proposed standard and its implementation.

Optimal reduction in NTDs relies on implementation of a range of complementary strategies which are beyond FSANZ's regulatory role. Such complementary strategies include promotion of increased folate intakes in women of child-bearing age through education, voluntary fortification and supplement use. Some jurisdictions have already recognised the need for ongoing education and/or health promotion activity, and FSANZ supports these efforts.

[51] Personal communication, NZ Association of Bakers & ANZBAKE. August 2006.

The communication and education strategy identifies the following target audiences: consumers, particularly women of child-bearing age; 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, the suppliers of bakers such as millers, 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. Subgroups of 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.

All target audiences require clear, consistent, well-targeted messages about the proposed standard. FSANZ has developed key messages for the different target audiences, drawing on advice from key stakeholders and key themes arising from consultations and submissions. These messages will be delivered through a range of mechanisms, including print and electronic media.

To implement the strategy, FSANZ will seek opportunities to collaborate with organisations to provide information and education about the proposed standard to consumers, industry, health professionals and other key stakeholders. Several submitters have indicated their willingness to work with FSANZ on complementary strategies, and FSANZ has commenced a process to engage with those organisations. FSANZ believes that increasing public awareness of the proposed standard can be best achieved through sustained, collaborative efforts which maximise the effectiveness of available resources.

FSANZ will report on implementation of the communication and education strategy as part of monitoring the standard's implementation.

18. Monitoring

18.1 Monitoring and review of the impact of mandatory folic acid fortification

Monitoring and review is a fundamental component of any mandatory fortification program. The Ministerial Policy Guideline states any agreement to mandate fortification should require that it be monitored and formally reviewed to assess the effectiveness of, and continuing need for, the mandating of fortification.

Monitoring of the impact of mandatory folic acid fortification is an important risk management consideration in order to deal with the uncertainties in the data and risk assessment. As noted in the editorial note to the draft variation of the Code (see Attachment 1), this mandatory fortification requirement will be reviewed when sufficient monitoring data become available. It is intended that the review would be completed within five years from the date of implementation of a new standard.

At Draft Assessment, FSANZ provided information in relation to the components that could be considered in an overall monitoring framework for folic acid fortification.

However, the responsibility for establishing and funding a monitoring system to assess the impact of a mandatory fortification on the population extends beyond FSANZ's responsibilities under the FSANZ Act 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.

For the purposes of progressing discussion on the proposal to mandate folic acid fortification, at Draft Assessment, FSANZ adapted the draft monitoring framework prepared by the FRSC working group for mandatory fortification of nutrients and outlined the potential elements that could be considered for inclusion in a monitoring system for assessing the impact of folic acid fortification on consumers (see Attachment 12). In July 2006 FRSC endorsed the generic monitoring framework. For nutrients such as folate, where there are already voluntary permissions in the Code to fortify some food products with folic acid as well as the proposed folic acid mandatory permissions, it was recognised that the monitoring system will need to include information on the cumulative impact of both sets of regulatory decisions on consumers.

FSANZ has recently been a participant on a FRSC coordinated expert group for determining a proposed monitoring program for folic acid. This expert group first met in July 2006 and used the proposed monitoring framework from Draft Assessment as a basis for beginning discussions on a monitoring program for folic acid. The expert group will meet again in September 2006 to progress the development of the monitoring system, with the expectation that a paper on the proposed monitoring system will be presented to the October meeting of the Australia New Zealand Food Regulation Ministerial Council (ANZFRMC).

A folic acid monitoring program will also fit into a broader national food and nutrition monitoring program, which has been discussed among various Government departments over recent years.

As the main objective of a mandatory fortification program for folic acid is to reduce the incidence of NTDs, measurement of change in NTD incidence (including stillbirths and terminations) would be an essential component of any monitoring system that aims to assess the effectiveness of the fortification measure. It would also be essential to collect information on potential unintended adverse health effects of increasing folic acid intakes for the target and non target groups in the population as this is a key part of the risk management strategy for managing the scientific uncertainties. As for any monitoring system, the collection of baseline data prior to or just after the implementation of the fortification program and at some time in the future to assess changes in performance measures is essential.

In order to determine the impact of mandatory fortification on folic acid intake, it is also helpful to collect additional data on changes to the fortified food products available and their folic acid content, consumer attitudes and purchase behaviour in relation to fortified foods, actual consumer food and supplement consumption patterns and on biochemical markers of folic acid status such as folic acid and homocysteine levels in blood serum or red blood cells. Attachment 12 gives details on possible data collection methods for each of these elements of a more comprehensive monitoring system. These data collections would provide extremely valuable information on how the fortification policy has affected the whole food system. This would be particularly important if implementation of mandatory fortification did not achieve the desired end outcome of reducing the incidence of NTDs by the expected amount or if there was evidence that it was adversely affecting the population in general.

A comprehensive monitoring system should provide sufficient data to answer the question 'why is it not working?' and be able to identify the best intervention point for improving the system in the future to achieve a better outcome.

FSANZ recognises that the costs for establishing an ongoing monitoring system have only globally been included in the cost-benefit analysis presented elsewhere (see Section 11.2) because the inter agency discussion on the elements (and hence specific costs) to be included in such a system has yet to take place. However, the cost of a monitoring system will need to be considered by the Ministerial Council when making their final decision on the Proposal.

Preliminary costings for various elements of a monitoring system based on current estimates have been included in Attachment 12 as a basis for future discussion with key stakeholders, including the food industry as well as the government agencies involved.

As part of its ongoing work, FSANZ will contribute directly to the following elements of the monitoring system:

- tracking changes in the food supply for fortified/unfortified foods in key food categories in consultation with the food industry;
- updating the food composition databases;
- tracking labelling changes on fortified foods;
- tracking changes in food consumption patterns for different demographic groups in key food categories that are likely to be fortified; and
- researching changes in consumers' attitudes and behaviour towards fortified foods.

FSANZ may also be involved indirectly in other program activities.

18.2 Comments on monitoring in submissions

Numerous submissions were received in relation to the proposed monitoring program based on the Draft Assessment Report. There were a multitude of monitoring activities suggested in addition to data collection on the incidence of NTDs, including monitoring of the safety and effectiveness of the fortification program. Monitoring of food consumption data, supplement use, changes to the food supply and many aspects of health status were all noted. The need for monitoring in both Australia and New Zealand was raised.

Many submissions and comments from consultation stated that any fortification strategy must be accompanied by a well funded monitoring system, that includes the collection of baseline data and an ongoing monitoring program with recurrent funding allocated. Some stakeholders indicated support for mandatory fortification only if appropriate monitoring was in place prior to implementation The need to allocate responsibilities for different monitoring tasks was also noted.

The need for monitoring of thiamin fortification was also identified in a number of submissions. After the review of the Code (1998-2000), FSANZ made an undertaking to assess thiamin fortification in the future. The Ministerial Council has also requested this review. This monitoring would also be captured under any national food and nutrition monitoring programs.

18.2.1 Baseline data

Many submissions commented on the lack of baseline data and the need to collect baseline data to determine the current health and food related status in relation to folate prior to mandatory fortification being introduced. There are currently a lot of monitoring activities that could provide some baseline data. This includes monitoring activities conducted by FSANZ and activities conducted external to FSANZ. The baseline data FSANZ has collected and reviewed to date for this Proposal are outlined in detail in Attachments 7a and 7b to this report. FSANZ has also collated data on NTD rates, folate status and other health related data (e.g. vitamin B_{12} deficiency) across Australia and New Zealand. These data will provide some indicators of these issues at baseline.

Data were also been collated by FSANZ on other health related factors such as cancer rates and linkages with cardiovascular disease. Cancer rates are reported by the Australian Institute of Health and Welfare every year, and have been assessed by FSANZ. Therefore, baseline data are available prior to any implementation of mandatory fortification. However, it will always be difficult to attribute any changes in cancer trends specifically to the food supply being fortified with folic acid, as there are many factors that influence the development of cancer.

National Nutrition Surveys (NNSs) are sources of data on food consumption, nutrient levels in the food supply, nutrient intakes and in some cases, supplement intakes. NNSs already conducted will provide baseline data as an indication of these parameters at the time of the survey and prior to the implementation of mandatory fortification. NNSs, as part of an ongoing food and nutrition monitoring system would continue to provide data for monitoring purposes post fortification. A rolling NNS program has been implemented in New Zealand, and a proposed monitoring system is currently being considered in Australia with the new Australian Children's Nutrition and Physical Activity Survey which is proposed to be in the field in the first half of 2007.

FSANZ has collected folic acid concentration data for the food supply in recent years. This has been through such avenues as analysis and the collection of food label information. These data were used to compile the folic acid concentration databases for Australia and New Zealand which was used in the dietary modelling for this proposal. this database will be used to analyse results from the 2007 children's survey,

Attachments

1. Draft variation to Australia New Zealand food standards code
2. Summary of submissions from the draft assessment report
3. Fortification policy guidelines
4. Impact of mandatory fortification in the United States
5. Current approach to increasing folate intake among women of child-bearing age
6. Potential health benefits and risks of increased folic acid intake

7a. Methodology and Results of Dietary Modelling at final assessment
7b. Methodology and Results of Dietary Modelling at draft assessment

8. Evaluation of health risk from mandatory folic acid fortification
9. Wald Model: NTD Risk according to increments of folic acid intake
10. Food Technology Report

11a. Fortification of bread with folic acid
11b. Cost benefit analysis of fortifying the food supply with folic acid

12. Development of a bi-national monitoring system to track the impact of regulatory decisions on mandatory and voluntary fortification

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Attachment 1

Draft variation to the A*ustralia 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

To commence: 15 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 thiamin to flour for making bread (Australia only) and the addition of folic acid to bread in Standard 2.1.1, the addition of vitamin D 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 headings* Cereal and cereal products*,* Bread*, the entry for* folic acid*.*

[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 addition of thiamin to flour for making bread (Australia only) and the addition of folic acid to bread.

[3.2] *inserting after clause 5 –*

6 Mandatory addition of folic acid to bread

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

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

Editorial note:

The maximum limit for folic acid given in subclause 6(2) ensures the addition of folic acid to bread in Australia and New Zealand is in controlled amounts to provide for a safe population intake of dietary folic acid. Subclause 6(2) will be reviewed when sufficient monitoring data are available to assess the impact of this mandatory requirement.

Between gazettal and commencement of clause 6, manufacturers may take up the voluntary permission to add folic acid to bread contained in Standard 1.3.2, in preparation for the commencement of the mandatory requirement in subclause 6(2).

Attachment 2

FIRST REVIEW REPORT

PROPOSAL P295

CONSIDERATION OF MANDATORY FORTIFICATION WITH FOLIC ACID

CONTENTS

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[52] 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[53], 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.

[52] BRI Research, *An evaluation of two reports on the proposed mandatory fortification of flour with folic acid in Australia*, April 2007.
[53] 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

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	– 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[54] 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%[55]; 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.

[54] 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.

[55] 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.

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	• 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.

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	• 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;

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	– 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

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	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. • 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	**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

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countries (bread-making flour in Australia and bread in New Zealand)	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. 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)[56]. 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[57] 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'.

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

[57] 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.

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.

Subsequently, at its May 2006 meeting, the Ministerial Council agreed to amend the fortification policy guideline[58] 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[59].

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[60];
- does not provide adequate information to enable informed choice;

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

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

[60] 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[61] 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[62], 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.

[61] In this paper the term bread-making flour is used interchangeably with 'flour for making bread'.
[62] 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[63] 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[64] 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,[65] to review McMullen's report and provide advice on overseas experience with mandatory folic acid fortification of flour.

[63] 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
[64] 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
[65] 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)[66] 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[67] 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.

[66] Richard Eliott, Milling Consulting Service Pty Ltd, February 2007.
[67] 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[68]

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

Severity

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.

[68] 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)[69].
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**

[69] (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[70]) 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)[71] 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[72]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[73], 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%.

[70] Dietary Folate Equivalent (DFE) = (naturally occurring food folate μg) + (folic acid μg x 1.67)
[71] 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
[72] 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)
[73] 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[74], 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.

[74] 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[75]) overpage.

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

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

Dietary folate			
• 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[76]. 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).

[76] 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%[77]. 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[78]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*[79]) (<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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[77] 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.

[78] 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.

[79] 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[80].

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.

[80] 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[81].

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[82] 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.

[81] See Sec 2.1.1, Attachment 7.
[82] 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 [83] 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.

[83] 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[84] 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.

[84] 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%[85] 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.

[85] 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[86] 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.

[86] 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[87] 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.

[87] 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[88]. 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[89].

[88] (Cook *et al*., 2001)
[89] (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[90], the Australian Dairy Corporation Survey (ADC)[91], Newspoll survey in Australia[92] and a UMR survey from New Zealand[93], 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[94].

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

[90] 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
[91] (Australian Dairy Corporation, 2003),
[92] (George Weston Submission, 2006)
[93] (NZFSA submission, 2006)
[94] (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[95].

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:

[95] 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[96].

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[97] 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).

[96] Quentin Johnson, QUICAN Inc., March 2007.
[97] 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%[98].

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.

Fortification process and infrastructure of flour milling in Australia

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'[99], 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).

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

[99] 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 ± 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[100] 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.

[100] 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 CASE101 *(A$M)*	HIGH CASE102 *(A$M)*	MID CASE *(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*	*11.914103*	*2.253104*
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;

[101] FSANZ cost measures with amended equipment costs.
[102] FMCA cost measures, with higher equipment and analytical testing costs.
[103] This figure includes costs of folic acid and premix as well as analytical testing.
[104] 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[105], 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.

[105] 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[106] 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[107], 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.

[106] BRI Research, *An evaluation of two reports on the proposed mandatory fortification of flour with folic acid in Australia*, April 2007.
[107] 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.

Attachment 3

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

Subsequent to the consideration by the Australia and New Zealand Food Regulation Ministerial of the First Review Report, New Zealand has decided to vary from clause 4 of Standard 2.1.1 below under Annex D of the *Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System*, and will issue a food standard under section 11C of the *New Zealand Food Act 1981*.

(Post-Ministerial Council Consideration)

To commence on 13 September 2007

[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 on 13 September 2009

[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 Australia 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 - bread that contains no wheat flour	50 g	Thiamin Riboflavin Niacin Vitamin B_6 Vitamin E Iron Magnesium Zinc Folate	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%) 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 Australia and thiamin, in Australia only.

[3.2] *omitting clause 4, substituting –*

4 Wheat flour for making bread

Note:

This clause does not apply in New Zealand.

It is the intention that a variation to this clause will be developed for New Zealand. In the interim, however, New Zealand has varied from this clause under Annex D of the *Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System*, and has issued a food standard under section 11C of the *New Zealand Food Act 1981*.

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

(2) Wheat flour for making bread must contain –

(c) no less than 2 mg/kg and no more than 3 mg/kg of folic acid; and
(d) 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 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.

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.