FIRST REVIEW REPORT

PROPOSAL P295

CONSIDERATION OF MANDATORY FORTIFICATION WITH FOLIC ACID

ATTACHMENTS 4-8

TABLE OF CONTENTS

ATTACHMENT 4 - POLICY GUIDELINE FORTIFICATION OF FOOD WITH VITAMINS AND MINERALS 3
ATTACHMENT 5 - ADDITIONAL INFORMATION ON THE EFFECTIVENESS AND POTENTIAL HEALTH BENEFITS AND RISKS OF INCREASING FOLIC ACID INTAKES IN THE POPULATION 7
ATTACHMENT 6 - IMPACT OF MANDATORY FORTIFICATION IN THE U.S. 31
ATTACHMENT 7 - DIETARY EXPOSURE ASSESSMENT: MAIN REPORT 38
ATTACHMENT 7A - DIETARY INTAKE ASSESSMENT REPORT – MANDATORY FORTIFICATION WITH FOLIC ACID 89
ATTACHMENT 7B - DIETARY INTAKE ASSESSMENT REPORT – EXTENDED VOLUNTARY FORTIFICATION WITH FOLIC ACID 153
ATTACHMENT 7C - DIETARY INTAKE ASSESSMENT REPORT – DIETARY FOLATE 205
ATTACHMENT 8 - MANDATORY FOLIC ACID FORTIFICATION COMMUNICATION AND EDUCATION STRATEGY ... 257

Attachment 4

Policy Guideline Fortification[1] of Food with Vitamins and Minerals

This Policy Guideline provides guidance on development of permissions for the addition of vitamins and minerals to food.

The Policy Guideline does not apply to special purpose foods the formulation and presentation of which are governed by specific standards in Part 2.9 of the Australia New Zealand Food Standards Code (the Food Standards Code).

The policy should only apply to new applications and proposals. There is no intention to review the current permissions.

The policy does not apply to products that should be or are regulated as therapeutic goods. This should not lead to a situation were generally recognised foods, through fortification, become like or are taken to be therapeutic goods.

The policy assumes the continuation of a requirement for an explicit permission for the addition of a particular vitamin or mineral to particular categories of foods to be included within the Food Standards Code. Currently the majority of permissions are contained in Standard 1.3.2 – Vitamins and Minerals.

Regard should be had to the policy in development of regulatory measures applying to the mixing of foods where one, or both of the foods may be fortified.

The policy for regulation of health and nutrition claims on fortified food is covered by the Policy Guideline on Nutrition, Health and Related Claims. Claims should be permitted on fortified foods, providing that all conditions for the claim are met in accordance with the relevant Standard.

'High Order' Policy Principles

The Food Standards Australia New Zealand Act 1991 (the Act) establishes a number of objectives for FSANZ in developing or reviewing of food standards.

1. The objectives (in descending priority order) of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures are:
    (a) the protection of public health and safety
    (b) the provision of adequate information relating to food to enable consumers to make informed choices; and
    (c) the prevention of misleading or deceptive conduct.

[1] Within the context of this policy Fortification is to be taken to mean all additions of vitamins and minerals to food including for reasons of equivalence or restoration.

2. In developing or reviewing food regulatory measures and variations of food regulatory measures the Authority must also have regard to the following:
   (a) the need for standards to be based on risk analysis using the best available scientific evidence;
   (b) the promotion of consistency between domestic and international food standards;
   (c) the desirability of an efficient and internationally competitive food industry;
   (d) the promotion of fair trading in food; and
   (e) any written policy guidelines formulated by the Council for the purposes of this paragraph and notified to the Authority.

These objectives apply to the development of standards regulating the addition of vitamins and minerals to food.

A number of other policies are also relevant to the development of food standards including the Council Of Australian Governments document 'Principles and Guidelines for national Standard Setting and Regulatory Action by Australia and New Zealand Food Regulatory Ministerial Council and Standard Setting Bodies(1995, amended 1997)(Australia only), New Zealand Code of Good Regulatory Practice (November 1997), the Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System and relevant World Trade Organisation agreements.

Specific Order Policy Principles - Mandatory Fortification

The mandatory addition of vitamins and minerals to food should:

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.
2. Be required only if it is assessed as the most effective public health strategy to address the health problem.
3. Be consistent as far as is possible with the national nutrition policies and guidelines of Australia and New Zealand.
4. Ensure that the added vitamins and minerals are present in the food at levels that will not result in detrimental excesses or imbalances of vitamins and minerals in the context of total intake across the general population.
5. Ensure that the mandatory fortification delivers effective amounts of added vitamins and minerals with the specific effect to the target population to meet the health objective.

Additional Policy Guidance - Mandatory Fortification

The specified health objective of any mandatory fortification must be clearly articulated prior to any consideration of amendments to the Food Standards Code to require such 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,

The assessment of public health strategies to address the stated health problem must be comprehensive and include an assessment of alternative strategies, such as voluntary fortification and education programs.

Consideration should be given, on a case by case basis, to a requirement to label foods that have been mandatorily fortified by including the information in the Nutrition Information Panel of the food label.

An agreement to require mandatory fortification also requires that it be monitored and formally reviewed to assess the effectiveness of, and continuing need for, the mandating of fortification.

Specific order policy principles – Voluntary fortification

- The voluntary addition of vitamins and minerals to food should be permitted only:
  - Where there is a need for increasing the intake of a vitamin or mineral in one or more population groups demonstrated by actual clinical or subclinical evidence of deficiency or by data indicating low levels of intake.

  or
  - Where data indicates that deficiencies in the intake of a vitamin or mineral in one or more population groups are likely to develop because of changes taking place in food habits.

  or
  - Where there is generally accepted scientific evidence that an increase in the intake of a vitamin and/or mineral can deliver a health benefit.

  or
  - To enable the nutritional profile of foods to be maintained at pre-processing levels as far as possible after processing (through modified restoration[2]).

  or
  - To enable the nutritional profile of specific substitute foods to be aligned with the primary food (through nutritional equivalence).
- The permitted fortification has the potential to address the deficit or deliver the benefit to a population group that consumes the fortified food according to its reasonable intended use.

---

[2] The principle of Modified Restoration as derived from The FSANZ document *Regulatory principles for the addition of vitamins and minerals to foods*. (Canberra, 2002) is as follows:
Vitamins and minerals may be added, subject to no identified risks to public health and safety, at moderate levels (generally 10-25% Recommended Dietary Intake (RDI) per reference quantity) to some foods providing that the vitamin or mineral is present in the nutrient profile, prior to processing, for a marker food in the food group to which the basic food belongs. The vitamin or mineral must be naturally present at a level which would contribute at least 5% of the RDI in a reference quantity of the food. This regulatory principle is based on the restoration or higher fortification of the vitamin or mineral to at least pre-processed levels in order to improve the nutritional content of some commonly consumed basic foods.

- Permission to fortify should not promote consumption patterns inconsistent with the nutrition policies and guidelines of Australia and New Zealand.
- Permission to fortify should not promote increased consumption of foods high in salt, sugar or fat.
- Fortification will not be permitted in alcoholic beverages.

6. Permissions to fortify should ensure that the added vitamins and minerals are present in the food at levels which will not have the potential to result in detrimental excesses or imbalances of vitamins and minerals in the context of total intake across the general population.

- The fortification of a food, and the amounts of fortificant in the food, should not mislead the consumer as to the nutritional quality of the fortified food.

Additional Policy Guidance - Voluntary Fortification

Labelling – There should be no specific labelling requirements for fortified food, with the same principles applying as to non-fortified foods. An added vitamin or mineral is required to be listed in the Nutrition Information Panel only if a claim is made about it and the vitamin or mineral is present at a level for which a claim would not be misleading. An added vitamin or mineral must be listed in the ingredient list under current labelling requirements.

Monitoring/Review - A permission to voluntary fortify should require that it be monitored and formally reviewed in terms of adoption by industry and the impact on the general intake of the vitamin/mineral.

Attachment 5

Additional information on the effectiveness and potential health benefits and risks of increasing folic acid intakes in the population

Effectiveness

Situation at Final Assessment

Public health strategies to increase folic acid intake include: the promotion of folic acid supplements to women of child-bearing age, voluntary fortification and mandatory fortification. Women are also advised to increase their intake of foods high in natural folate although this strategy to reduce NTD incidence has never been tested in a trial and so its efficacy is uncertain (Green and Green, 2005[3]).

Folic acid supplements have been promoted in Australia and New Zealand since the early 1990s. Despite strategies to increase awareness and use of folic acid supplements by women of child-bearing age, reported use at the appropriate time (peri-conceptionally) and in the recommended dose (400 µg per day) is relatively low – less than one in three women who had had a liveborn baby (Bower *et al*., 2005). Approximately 40-50% of all pregnancies in Australia and New Zealand are unplanned (Marsack *et al*., 1995; Schader and Corwin, 1999; Watson *et al*., 2006; Conlin *et al*., 2006) which is likely to be contributing to the low uptake of folic acid supplements among women of child-bearing age.

Voluntary folic acid fortification of selected foods has been permitted in Australia and New Zealand since 1995. While a range of foods can be fortified, breakfast cereals and breads make up the majority of currently fortified foods. Voluntary fortification is estimated to have increased mean daily folic acid intakes among the target population by 108 µg in Australia and by 62 µg in New Zealand[4]. Median intakes in both countries are much lower, suggesting that some women are consuming larger amounts of fortified foods whereas the majority are consuming low amounts.

Both folic acid supplements and voluntary fortification are likely to have contributed to increases in folate status in Australia (Metz *et al*., 2002; Hickling *et al*., 2005) and falls in reported NTD rates in some states in Australia (South Australia, Western Australia and Victoria) of between 10-30% since the mid 1990s (Lancaster and Hurst, 2001; Bower, 2003; Victorian Perinatal Data Collection Unit, 2005).

FSANZ has estimated that mandatory fortification of bread-making flour[5] (200 µg/100 g flour in the final product) will further increase mean daily folic acid intakes (i.e. in addition to current folic acid intakes from voluntary fortification) by 100 µg among women of child-bearing age in Australia. Mandatory fortification of bread (135 µg/100 g bread) in New Zealand is estimated to increase mean daily intakes among the target population by 136 µg.

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

[4] FSANZ estimates of the contribution of voluntary fortification have increased slightly from those reported at Final Assessment due to updated market share data.

[5] The Review requested that FSANZ consider a standard for bread-making flour in Australia and bread in New Zealand. At Final Assessment the standard referred to bread in both countries.

These increases in intake are estimated to further 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.

The expected reductions in NTDs are lower than has been achieved in the U.S. and Canada. The reduction in NTDs in the U.S. is associated with a mean increase in folic acid intakes among women of child-bearing age of about 200 µg/day following the introduction of mandatory folic acid fortification – although an increase of 100 µg/day was predicted (Choumenkovitch *et al*., 2002). The U.S. aimed for a 50% fall in NTDs but achieved about 26% in the period 1995-96 to 1999-00 (USCDC, 2004); although this is likely to be an under-estimate because of poor case ascertainment rates.

In Canada, folic acid intakes increased by 150 µg/day (Quinlivan and Gregory, 2003). Canada anticipated an overall reduction of approximately 20% in the NTD rate but achieved much higher reductions in several provinces. There were considerable differences in NTD rates in Canadian provinces pre-fortification with mandatory fortification having the greatest impact among those provinces with the highest initial rates.

Papers published since Final Assessment

Folic acid supplement use

A 2005 Adelaide study reported that just 30% of a sample of 304 pregnant women complied with the recommendations for folic acid supplement use (both timing and dose) (this is a similar proportion to the earlier study reported by Bower *et al*. (2005)) and 27% took no folic acid supplements at all (Conlin *et al.,* 2006).

A small New Zealand study involving just over 100 women aged 17-44 years who had just given birth found that among women who planned their pregnancy, 53% used folic acid before conception. The use of folic acid supplements by women who had not planned their pregnancy or were younger (<25 years) was much lower (about 10%) (Dobson *et al*., 2006). Neither dose nor duration of peri-conceptional folic acid supplementation was considered in the study, although the authors noted that the main folic acid supplement available for sale in New Zealand contains 800 µg.

The March of Dimes Foundation[6] reported that between 1995 and 2005, there was a modest increase in folic acid supplement use among non-pregnant women in the U.S. (from 25% to 31%) but the majority of women aged 18-45 years, particularly younger women (18-24 years) those with less education (less than high school) and those with lower household incomes do not take folic acid supplements daily (Green-Raleigh *et al*., 2006).

In the Shanxi Province of Northern China, a sub-study involving 480 women in the control group of a population-based case control study, just 10.2% reported using folic acid at any time during their last pregnancy and just 3.3% took supplements during the peri-conceptional period (Li *et al*., 2007).

[6] The March of Dimes Foundation was established in the United States more than 80 years ago to improve the health of babies by preventing birth defects, premature birth, and infant mortality.

International folate/folic acid intakes and NTD rates

Note: the U.S. situation in relation to folic acid intakes and NTD rates following mandatory fortification is covered in more detail in Attachment 6.

In an international assessment of surveillance systems between 1988 and 1998 in Australia, Europe, the United Kingdom, Canada and the U.S. there was a statistically significant downward trend in NTDs in seven out of the 13 registers – Victoria, Western Australia, Canada, two in the U.S.A., Dublin and Northern Netherlands. NTD rates increased significantly in Norway and Finland and remained relatively unchanged in France and in parts of Germany. Only the U.S. and Canada have implemented mandatory fortification and Australia has implemented voluntary fortification (Botto *et al*., 2006).

A regional French study[7] reported no discernible change in NTD rates between the period 1988-1992 and 1996-2002 despite recommendations implemented in the mid 1990s to increase folic acid supplement use (400 µg per day during the peri-conceptional period) to reduce NTDs rates (Stoll *et al*., 2006). However, there was no description about the extent to which the recommendation has been adopted by women. Botto *et al*. (2006) also note the lack of effect on NTD rates in countries relying on supplements alone.

In Canada, an assessment of the dietary folate intake[8] (using three days of weighed food records) among 62 highly educated pregnant and lactating women following mandatory fortification found that about 2 in 3 of the pregnant women in the sample would meet the recommended folate intake from dietary sources alone. Without mandatory folic acid fortification just 2% of the women would meet the folate recommendations (Sherwood *et al*., 2006). During pregnancy, average intake from naturally occurring folate was estimated to be 337 µg per day and folic acid from fortified foods 132 µg per day.

Implications of the new findings

Additional papers considering folic acid supplement use reaffirm earlier findings that few pregnant women use supplements at the correct time and dose, particularly younger women and women with unplanned pregnancies.

NTD rates continue to fall significantly in some countries with and without mandatory folic acid fortification although in other countries the NTD rates are unchanged or have increased, significantly in some cases – all of these countries do not have mandatory fortification.

The small Canadian study affirms earlier studies that mandatory folic acid fortification of staple foods makes a substantial contribution to daily folic acid intakes among women.

[7] France does not have mandatory folic acid fortification but does allow voluntary fortification of breakfast cereals.
[8] Includes naturally-occurring folate and folic acid in fortified foods.

Potential health benefits

Folic acid has been investigated for its potential benefit in a range of conditions affecting the population as a whole including cardiovascular disease, cancer, cognitive function and other birth defects.

The following discussion presents the situation at Final Assessment and where relevant, papers published since Final Assessment

Cardiovascular disease

While it is known that increased folic acid intake reduces total plasma homocysteine – long regarded as a risk factor for cardiovascular disease – recent evidence from several large trials and some smaller randomised controlled trials (RCTs) does not support a protective effect of folic acid and cardiovascular disease outcomes (Liem *et al*., 2003; Toole *et al*., 2004; Lange *et al*., 2004; Liem *et al*., 2005; Bonaa *et al*., 2006; Lonn *et al*., 2006; Zoungas *et al*., 2006). In fact, there is strong evidence of a null effect.

Papers published since Final Assessment

A meta-analysis of RCTs (six included folate) found no evidence of a protective effect of vitamin B supplements (including folic acid) and progression of atherosclerosis – a precursor to cardiovascular disease (Bleys *et al*., 2006). The dose of folic acid supplements ranged from 1-15 mg/day and the follow up period did not exceed one year.

A meta-analysis of 12 RCTs (including several of the studies referred to at Final Assessment) concluded that folic acid supplements (ranging from 0.5-15 mg/day) did not reduce subsequent risk of cardiovascular disease, coronary heart disease or stroke among people with a prior history of cardiovascular or renal disease (Bazzano *et al*., 2006).

In an examination of recent RCTs assessing folic acid and cardiovascular disease risk Wald *et al*. (2006) conclude that the randomised trials to date may not have been large enough or of sufficient duration to detect an effect. However, the paper places greater weight on observational studies than RCTs.

In an RCT involving 56 non-folate-fortified patients with atherosclerosis about to undergo coronary artery bypass graft surgery, folic acid treatment (400 µg/day) improved vascular function[9](Shirodaria *et al*., 2007). No additional improvement was seen among the group taking a high dose supplement (5 mg/day). The lack of additional effect at the higher dose is reflected in insignificant differences post treatment between tissue levels of 5-methyl-tetrahydrofolate[10] rather than plasma levels.

Trials examining the effects of folic acid and vitamin B_{12} on stroke incidence are still under way.

[9] Significant changes in vascular function occurred in aortic and carotid artery distensibility and vascular BH4 levels.
[10] 5-methyl-tetrahydrofolate is the principal circulating form of folic acid.

Cancer

At Final Assessment, FSANZ included an update of the epidemiological literature investigating the effect of folic acid and/or dietary folate on total cancer, prostate cancer, breast cancer and colorectal cancer. The overall conclusion from this analysis was that the evidence of either an adverse or protective effect is inconclusive. (The references to support this conclusion are many and are cited in Attachment 6 of the Final Assessment Report).

Papers published since Final Assessment which consider the potential benefits or risks of folic acid and cancer are considered under the Potential health risks section of this Attachment.

Cognitive function

At Final Assessment, FSANZ included an update of the epidemiological literature investigating serum folate or the effect of folic acid supplements on cognitive function. FSANZ reported that the current level of evidence is inconclusive to support an association between folic acid and cognitive function (see Attachment 6 of the Final Assessment Report).

Papers published since Final Assessment which consider the potential benefits or risks of folic acid and cognitive function are considered under the Potential health risks section of this Attachment.

Other birth defects

The results from recent studies investigating folic acid and the prevention of other birth defects are mixed.

Birth defect registers and birth certificate data

In an international assessment of birth defect trends including data up to 2003 from 11 countries, Botto *et al*. (2006) reported significant falls in some birth defects in some areas although the results did not support an overall trend. Based on a review of birth certificate data for 45 U.S. states and the District of Columbia, Yazdy *et al*. (2007) reported a small reduction (about 6%) in orofacial cleft prevalence since the introduction of mandatory fortification.

Case controls

In an Australian case control study, Bower *et al*. (2006) reported that folate did not prevent the non neural birth defects: orofacial clefts, congenital heart defects, urinary tract defects, limb reduction defects or other major birth defects. Similarly, in an observational case-control study in Hungary, Czeizel *et al*. (2006) found no association between multivitamin use containing folic acid and infants with multiple birth defects[11].

[11] Multiple birth defects were defined as two or more birth defects in the same person affecting at least two different organ systems. They are associated with a higher rate of stillbirths, preterm births and low birthweight newborns.

Meta-analyses

Goh *et al*. (2006) in a meta-analysis including 41 studies (case-controls, cohorts and RCTs), concluded that multivitamins were associated with a significant reduction in risk of several birth defects (based on cohort and RCT studies significant reductions were obtained for cardiovascular defects (RR = 0.61 95% CI 0.40, 0.92 and limb defects (RR = 0.57 95% CI 0.38, 0.85)). The authors acknowledged, however, that the folic acid composition of multivitamins may have varied between studies. A meta-analysis involving folic acid and risk of oral clefts reported a protective effect from folic acid supplements (for prospective studies RR = 0.55 95% CI 0.32, 0.95) (Badovinac *et al.,* 2007).

Other conditions

The recently released U.K. report investigating folate and disease prevention (SACN, 2006) included a review of the possible role of folate in depression and bone health but found insufficient evidence of an association – either protective or harmful.

Implications of the new findings

Papers published since Final Assessment 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.

Based on the results from meta-analyses, there is emerging evidence that folic acid supplements may reduce the risk of some non neural birth defects.

Potential health risks

This section assesses potential health risks to the population as a whole from habitual high levels of folic acid intake as well as the potential role of folate and/or folic acid intake in increasing the risk of a range of conditions including cardiovascular disease, cancer, cognitive function and other birth defects.

Potential health risk from high folic acid intakes

Population models

Existing voluntary fortification permissions together with mandatory fortification will contribute on average about 208 µg of folic acid per day to the target group in Australia (based on 200 µg of folic acid/100 g flour in the final food) and 198 µg per day in New Zealand (based on 135 µg of folic acid/100 g bread), 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 upper level of intake (UL[12]).

[12] The UL is the 'highest average daily nutrient intake level likely to pose no adverse health effects to almost all individuals in the general population' (NHMRC and NZMoH, 2006).

FSANZ used the UL for folate as the cutpoint to assess excessive intakes of folic acid among various population sub-groups following mandatory fortification (Table 4). The proportion of children exceeding the UL in Australia, particularly very young children aged 2-3 years, is about 9%[13] with this proportion decreasing with increasing age. It is worth noting that the UL is derived from a small number of case studies in the elderly. The level used in these studies was divided by five to yield a value for adults then extrapolated to children on a body weight basis. While it would be preferable for no child to exceed the UL, no child approaches a level of intake five times higher than the UL for their age. Intake assessments conducted external to FSANZ indicate that a higher proportion of New Zealand children aged 5-14 years would exceed the UL compared with Australian children of the same age. FSANZ has assessed the reason for the difference and concluded that it is most likely due to different methodologies[14] rather than a real disparity in intakes. Among adults, the proportion likely to exceed the UL from mandatory fortification in Australia or New Zealand is very low: 0-<1%.

Evidence suggests that folic acid intakes up to 1,000 µg per day (the adult UL for folic acid) are not associated with delayed diagnosis of vitamin B_{12} deficiency in older people. Vitamin B_{12} deficiency occurs most commonly in older people due to malabsorption of vitamin B_{12} in food or pernicious anaemia – it is rarely caused by inadequate dietary intakes. No-one aged 70 years and over is expected to exceed the UL of 1,000 µg of folic acid per day (the 95th percentile of folic acid intake in this age group is estimated to be 456 µg per day).

[13] 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 the number of foods assumed to contain bread-making flour has increased slightly.

[14] The methodology used to assess folic acid intake among New Zealand children used a single day adjusted method and the data were population weighted whereas FSANZ used a two-day adjusted method without any population weighting to assess intakes among Australian children. The latter method minimises day-to-day variation in intakes thus narrowing the range of very low and very high individual intakes. The folic acid concentrations and foods assumed to be fortified were similar between Australia and New Zealand.

Table 4: Per cent of Australian and New Zealand respondents with folic acid intakes above the UL at baseline (voluntary fortification) and after mandatory fortification*

Population Group	Revised baseline	200 µg folic acid /100 g flour in the final product
Australia		
2-3 years	1	9
4-8 years	<1	4
9-13 years	<1	2
14-18 years	<1	2
19-29 years	<1	<1
30-49 years	<1	<1
50-69 years	<1	<1
70+ years	0	0
Women aged 16-44 years	<1	<1
New Zealand*		
		135 µg folic acid/100 g bread
15-18 years	0	<1
19-29 years	0	<1
30-49 years	<1	<1
50-59 years	0	<1
70+ years	0	0
Women aged 16-44 years	<1	<1

* 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.

Similar to the dietary modelling undertaken at Final Assessment, FSANZ has re-estimated folic acid intakes from fortified foods and two supplement doses in Australia (200 and 500 µg) and New Zealand (200 and 800 µg) (Table 5). The estimated mean intakes are higher than published at FAR because intakes from voluntarily fortified foods have been adjusted upwards to account for new market share data and the number of foods assumed to contain bread-making flour has been increased. Despite these increases in mean intake, only New Zealand women who consume a daily 800 µg supplement (46%) would be at risk of exceeding the UL. This estimate is based on every New Zealand woman of child-bearing age consuming a daily 800 µg dose of folic acid.

Table 5: Estimated folic acid intakes among women of child-bearing age* in Australia and New Zealand from mandatory fortification and supplements*****

	Mean intake		Proportion above the UL	
Australia	**200 µg**	**500 µg**	**200 µg**	**500 µg**
Revised baseline	308	608	<1	2
Mandatory + voluntary	408	708	<1	4
New Zealand	**200 µg**	**800 µg**	**200 µg**	**800 µg**
Revised baseline	262	862	<1	10
Mandatory + voluntary	402	1,002	<1	46

* Women aged 16-44 years.

** Based on a level of fortification of 200 µg of folic acid/100 g flour in the final food in Australia and 135 µg of folic acid/100 g bread in New Zealand.

*** Assumes all respondents in the survey consume folic acid supplements at the doses specified.

Potential individual intakes

FSANZ has undertaken additional dietary modelling for the Review to assess potentially excessive intakes among consumers who always choose a voluntarily fortified product in addition to mandatory fortification (Table 6) [15]. This scenario results in further increases in intakes at the 95th percentile compared with the mandatory plus voluntary fortification proposal in Australia but less so in New Zealand because of the lesser number of voluntarily fortified products in New Zealand. In particular, young children who always consume the voluntarily fortified food brands (as a result of their parent's purchasing behaviour) would be more likely to exceed the UL for their age group.

Although this scenario is unlikely to affect many individuals it does illustrate the effect of a particular type of consumer behaviour. This scenario assumes that the current voluntary fortification practices remain unchanged, however, were they to change then folic acid intakes among the 'always chooses' consumers would also change – highlighting the unpredictability of voluntary fortification.

[15] This model is based on hypothetical individual choices. A comparison of an individual's folic acid intake determined using this model with the UL is valid but it is not appropriate to group these theoretical intakes into a particular age group and report the proportion that exceeds the UL. Instead the 95th percentile of folic acid intakes representing the upper end of the distribution is reported in Table 6.

Table 6: Comparison of 95th percentile folic acid intakes

Population Group	UL	Revised baseline	Mandatory fortification + voluntary	Mandatory fortification + 'always chooses' voluntarily fortified foods
Australia				
2-3 years	300	232	338	384
4-8 years	400	282	388	464
9-13 years	600	367	495	588
14-18 years	800	378	566	634
19-29 years	1,000	365	585	629
30-49 years	1,000	342	516	552
50-69 years	1,000	368	480	533
70+ years	1,000	357	456	495
Women aged 16-44 years	800-1,000	283	407	455
New Zealand*				
15-18 years	800	195	485	500
19-29 years	1,000	194	447	461
30-49 years	1,000	223	460	469
50-59 years	1,000	238	438	448
70+ years	1,000	187	367	379
Women aged 16-44 years	800-1,000	190	359	369

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

Other potential health risks

FSANZ's review of the epidemiological literature on folate and cancer undertaken at Final Assessment (material included above) concluded that there was no increase in cancer risk from the increase in folic acid intakes likely from mandatory fortification. The recently released report from the United Kingdom 'Folate and disease prevention' (SACN, 2006) also concluded that 'the evidence for an association between folic acid and increased or reduced cancer risk in humans is equivocal. No RCTs designed to investigate the relationship between folic acid and cancer incidence have yet been reported'. The U.K. report did, however, highlight concerns about a possible relationship between folic acid fortification and increased progression of colorectal cancer. Based on animal models only, there is the suggestion that folic acid has a dual action in cancer progression with high intakes potentially suppressing early tumours while possibly increasing the progression of existing cancers. This aligns with the conclusion by Kim (2007) who reviewed the evidence of folate and colorectal cancer. RCTs are therefore required to confirm or refute this association.

FSANZ's Final Assessment report stated that there was no evidence of an interaction with anti-epileptic drugs at the levels of folic acid intake likely from mandatory fortification.

The U.K. report (SACN, 2006) also concluded that there was no evidence to suggest that mandatory fortification of flour leading to increased folic acid intakes of 200 µg/day would 'adversely modify the pharmacokinetic[16] effects of phenytin, a drug used for anticonvulsant treatment of epilepsy'.

FSANZ addressed other potential health risks from increases in folic acid intake in its Final Assessment report including: multiple births, impact on the gene pool and unmetabolised folic acid circulating in the blood. Each of these was also addressed in the U.K. report. Both reports concluded that there is insufficient evidence linking increased folic acid intake, particularly over the long term, to deleterious health outcomes from these conditions. More recently, Lucock[17] (2006), reiterated his earlier concerns (Lucock and Yates, 2005) about long term exposure to unmetabolised folic acid[18] as a result of mandatory fortification[19] as well as several other potential risks (the majority of which have already been addressed in this or in earlier FSANZ assessment reports).

In response to the potential health risks and uncertainties (outlined in greater detail at Final Assessment), FSANZ has adopted a conservative approach to mandatory fortification.

Papers published since Final Assessment

Cancer

Several papers have been published on folate/folic acid intake and cancer since Final Assessment. These are summarised in Table 7.

Colorectal cancer

Results from the Melbourne Colorectal Cancer Study involving cancer cases diagnosed between 1980 and 1981 (i.e. pre voluntary fortification) indicated that the second and third quintiles of dietary folate intake were protective against rectal cancer but not colon cancer, although, there was a non-significant increased risk of colorectal cancer at the highest level of dietary folate consumption (Kune and Watson, 2006). However, the increase in risk from this study was within the range of risks reported by previous case-control studies (Sanjoaquin *et al.,* 2005) and so this study does not alter the overall conclusion based on all similar studies (i.e. that dietary folate may be slightly protective). The highest quintile of dietary folate intake was between 419 and 1,367 µg per day. This appears to be a large daily intake and is much higher than the dietary folate intake reported in the 1995 National Nutrition Survey (90^{th} percentile of second-day adjusted intake was about 300 µg per day for adult women aged 19 years and over and just over 400 µg per day for adult men) (ABS, 1998). The reason for the high intakes in the Kune and Watson study may be related to the use of a food frequency questionnaire containing more than 500 items. It has been well documented that apparent intakes increase as the number of items on a food frequency questionnaire increases.

[16] Pharmocokinetics refers to the way the body handles an administered substance/drug: how it's absorbed, distributed, metabolised and excreted.
[17] Dr Lucock is a member of the Folate Scientific Advisory Group who reviewed an earlier draft of this paper.
[18] The absorption and biotransformation of synthetic folic acid into 5 methyl tetrahydrofolate is saturated at doses of about 400 µg. Doses above this lead to synthetic folic acid circulating in the blood (Lucock, 2006).
[19] Synthetic folic acid has been voluntarily added to commonly eaten foods in Australia and New Zealand since 1995 and 1996, respectively. Regular consumers of these foods would also be exposed to these potential health risks.

Recent publications from the U.S. and Canada show that the incidence of colorectal cancer has remained steady or declined over recent years (National Cancer Institute, 2007; Canadian Cancer Society/National Cancer Institute of Canada, 2007).

The US SEER (Surveillance, Epidemiology, and the End Results) Program based at the National Cancer Institute, Bethesda, undertook some special analyses of trends before and after fortification prior to a visit by a FSANZ employee in February 2007. This analysis did not indicate any change in colorectal cancer incidence that was contemporaneous with the introduction of mandatory fortification.

In the United Kingdom Colorectal Adenoma Prevention (UKCAP) trial, a multicentre, double-blind, RCT, Hubner *et al*. (2006) reported a significant reduction in risk of colorectal adenoma[20] recurrence among folic acid-treated (with or without aspirin) subjects with specific gene polymorphisms. In the group with genetic results, who were a subset of the total trial population, folic acid was associated with a non-significant increase in recurrent adenoma (RR 1.08 95% CI 0.82-1.42). The paper reporting the folic acid data for the full trial population has been submitted for review (J. Baron, personal communication, 2007), but final publication date is uncertain. FSANZ is aware of two U.S. trials examining the effect of folic acid on recurrence of colonic adenoma that have been completed but which have not yet published their results. There is insufficient information currently available about these trials to assess their significance.

In the interim, FSANZ has discussed the preliminary results of the U.K. trial and a conference abstract from one of the U.S. trials with the U.K. Food Standards Agency and a leading Australian cancer epidemiologist.

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.

Prostate cancer

Recent analysis of a cohort of over 27,000 male smokers in Finland found no association between folate intake (assessed with a dietary history questionnaire) and prostate cancer risk (Weinstein *et al*., 2006). However, as smoking is inversely associated with folate status, the authors concluded that for protection against prostate cancer, smokers may require higher folate intakes than was observed in their study.

Stomach cancer

In the Swedish Mammography Cohort, Larsson *et al*. (2006) reported no association between dietary folate intake (assessed with a food frequency questionnaire and validated via four 1-week weighed diet records among a sub-sample of women) and stomach cancer among over 61,000 women. A sub-analysis including total folate intake (i.e. folate from foods and dietary supplements) also found no increased risk, although the authors acknowledge that the much smaller sample size in the sub-analysis may have been too small to detect an association.

[20] Colorectal adenomas are precursors to most colorectal cancers, but not all adenomas progress to carcinoma.

Breast cancer

In a meta-analysis involving 14 case-control studies and nine prospective studies, Larsson *et al*. (2007) reported mixed results for folate and breast cancer risk. Analysis of the case-control studies indicated a statistically significant 20% reduction in risk from an increase of 200 µg/day of dietary folate (folate from foods only, not supplements) but the prospective studies did not support any association for either dietary folate or total folate. In addition, several studies indicated a potential reduced risk of breast cancer among women with moderate to high alcohol consumption from an adequate to high folate intake.

Similar results were obtained by Lewis *et al*. (2006) in their meta-analysis of folate intakes or levels and breast cancer risk. The case-control studies (14 identified) showed a significant reduction in breast cancer risk (among all women combined and among pre menopausal women) but the cohort studies (11 identified) did not.

Table 7: Summary of results from recently published studies investigating folate and cancer

Study (Reference)	Study design	Exposure variables	Outcome variables	Results (95% CI)
UKCAP trial (Hubner *et al*., 2006)	Multicentre, randomised, double-blind, placebo-controlled trial of 546 genotyped patients with mean age of 57 years with earlier colorectal adenoma removal; 3 years or earlier follow up	Folic acid supplements (500 µg daily) and aspirin	***Colorectal adenoma***	All patients exposed to folic acid RR 1.08 (0.82-1.42) N.B. This is a sub-analysis on just one half of the randomised subjects; full study results have not yet been published.
Melbourne Colorectal Cancer Study (Kune and Watson, 2006)	Case control study of 715 cases (identified between 1980 and 1981) and 727 controls with mean age of 57 years; food intake assessed by 587 item FFQ	Dietary folate intake	***Colorectal cancer***	Folate intake (adjusted model) 1st Q: (UL of intake 246 µg/d) 1.0 (reference); 2nd Q: (UL of intake 297 µg/d) OR 0.76 (0.53, 1.08); 3rd Q: (UL of intake 347 µg/d) OR 0.71 (0.50, 1.02); 4th Q: (UL of intake 419 µg/d) OR 0.75 (0.51, 1.10); 5th Q: (UL of intake 1,367 µg/d) OR 1.24 (0.81, 1.89)
ATBC Cancer Prevention Study (Weinstein *et al.,* 2006)	Cohort study nested in a placebo-controlled trial of 29,133 men aged 50-69 years	Dietary folate and folic acid from supplements	***Prostate cancer***	Folate intake 1st Q: (<=283 µg/d) 1.0 (reference); 2nd Q: (>283 µg/d and <=313 µg/d) RR 0.91 (0.77, 1.09); 3rd Q: (>313 µg/d and <=341 µg/d) RR 1.00 (0.84, 1.19); 4th Q: (>341 µg/d and <=378 µg/d) RR 0.95 (0.80, 1.13); 5th Q: (>378 µg/d) RR 0.96 (0.81, 1.15)
Swedish Mammography Cohort (Larsson *et al*., 2006)	Population-based prospective cohort of 61,433 women; food intake assessed by FFQ; 18 years of follow up	Dietary folate	***Stomach cancer***	Hazard ratio comparing the highest with lowest level of: - dietary folate intake 1.04 (0.61-1.86); and - dietary folate + supplements 0.88 (0.40-1.93)

Table 7: Summary of results from recently published studies investigating folate and cancer (continued)

Study (Reference)	Study design	Exposure variables	Outcome variables	Results (95% CI)
Larsson *et al*. (2007)	*Meta-analysis*: 9 Prospective studies 14 Case control studies	Dietary folate intake (folate from foods only) Total folate intake (Folate from foods and supplements) Serum or plasma folate levels	***Breast cancer*** incidence or mortality	*200 µg/day increments* *Cohort studies* – dietary folate: pooled estimate 0.97 (0.88, 1.07) – total folate: pooled estimate 1.01 (0.97, 1.05) *Case-control studies* – dietary folate: pooled estimate 0.80 (0.72, 0.89) – total folate: pooled estimate 0.93 (0.81, 1.07)
Lewis *et al*. (2006)	*Meta-analysis*: 11 Cohort studies 14 Case control studies	Folate intake Serum folate levels	***Breast cancer***	*100 µg/day increments* *Cohort studies* – dietary folate: pooled estimate 0.99 (0.98, 1.01) – dietary folate, pre-menopausal: pooled estimate 1.01 (0.98, 1.04) *Case-control studies* – dietary folate: pooled estimate 0.91 (0.87, 0.96) – dietary folate, pre-menopausal: pooled estimate 0.87 (0.78, 0.97)

Twinning

In a summary of the evidence (including both supplement and fortification studies), Levy and Blickstein (2006) did not find a cause-effect relationship between folic acid intake and increased twinning rates although the authors acknowledge that the data are frequently flawed by lack of adjustment for maternal age and fertility treatments. More recently, in a prospective cohort study of 602 women undergoing fertility treatment in Scotland, high folate status increased the likelihood of twin births after multiple embryo transfer among women likely to have a livebirth[21] but not the likelihood of a successful pregnancy (Haggarty *et al*., 2006).

In a systematic review of folic acid and risk of twinning the authors reported no significant increases in twinning rates (Muggli and Halliday, 2007). The review included studies which accounted for fertility treatments. This work was commissioned by FSANZ and the results reported at Final Assessment.

Cognitive function

Several papers have been published on folate/folic acid intake and cognitive function since Final Assessment. These are summarised in Table 8.

Randomised controlled trials

In a randomised, double-blind, placebo controlled trial involving 195 older persons with mild vitamin B_{12} deficiency, 400 µg of folic acid in combination with 1,000 µg of vitamin B_{12} did not improve cognitive function after 24 weeks, despite significant improvements in B_{12} status among those in the treatment groups (Eussen *et al*., 2006). These results are similar to the results reported by McMahon *et al*. (2006) after a two year follow up period (referred to in the Final Assessment report).

In the Folic Acid and Carotid Intima-media Thickness (FACIT) trial, Durga *et al*. (2007) reported a significant improvement in cognitive function after three years among the group taking a daily 800 µg folic acid supplement. It is worth noting, however, that participants were selected into the FACIT trial on the basis of their high plasma total homocysteine. As a result, serum folate concentrations increased by nearly 600% over the duration of the trial. Participants were also vitamin B replete at the start of the study.

C*ohort studies*

In a follow up study of nearly 1,000 men and women aged 65 years or more before fortification was implemented, Luchsinger *et al*. (2007) reported a significantly reduced risk of Alzheimer Disease (AD) among participants in the highest quartile of folate intake (>= 488 µg per day). Those who developed AD were on average three years older, had less education and were more likely to have diabetes and heart disease than those who didn't develop AD – these factors may explain some of the results seen in this observational study.

[21] Haggarty *et al*. (2006) postulate that women with the MTHFR genotype are more likely to produce good quality embryos and thus a livebirth, although the associated increase in livebirths was not observed in this study.

Analysis of data from the Nurses Health study found that among older women, high levels of plasma folate or vitamin B_{12} were not associated with better or worse cognitive function (Kang *et al*., 2006). High folate and high B_{12} status was initially associated with better cognitive performance but the association did not hold over time (four years). The authors did not compare high folate levels and low B_{12} with other nutrient states – as was done in the Morris *et al*. (2007) study (see below).

Cross sectional studies

A paper by Morris *et al*. (2007) using data from the 1999-2000 U.S. National Health and Nutrition Examination Survey (NHANES) on nearly 1,500 older people (average age 70 years) reported that while a low vitamin B_{12} status was associated with a significantly increased risk of anaemia and cognitive impairment (as might be expected); the prevalence was greatest in those with high serum folate status compared to participants with normal B_{12} and folate status.

Systematic reviews

A systematic review of 14 randomised trials by Balk *et al*. (2007) concluded that there was inadequate evidence that folic acid supplements influenced cognitive function – either positively or negatively.

Table 8: Summary of results from recently published studies investigating folate and cognitive function

Study (Reference)	Study design	Exposure variables	Outcome variables	Results (95% CI)
FACIT trial (Durga *et al*., 2007)	Randomised, double blind, placebo controlled trial of 818 men and women (mean age = 60 years) followed up for 3 years	Daily 800 µg folic acid supplement	Domains of cognitive function that decline with age	*Global cognitive function*: folic acid vs. placebo (cognitive change attributed to folic acid, mean difference) 0.050 (0.004-0.096) P value for trend: 0.033
Netherlands (Eussen *et al.,* 2006)	Randomised, double blind, placebo controlled trial of 195 men and women (mean age = 83 years) living independently or in care followed up for 24 weeks	Daily 1,000 µg vitamin B_{12} Daily 400 µg folic acid supplement + 1,000 µg vitamin B_{12}	Domains of cognitive function	Significant improvement in memory among the placebo group and vitamin B_{12} group (p=0.0036), but not the folic acid + vitamin B_{12} group and placebo. There were no other significant differences in cognitive function between the folic acid + B_{12} group and placebo.
Dunedin, NZ (McMahon *et al*., 2006)	Randomised, double-blind, placebo-controlled, clinical trial of 276 men and women (mean age = 74 years) followed up for 2 years	Daily 1,000 µg of 1-5-methyltetrahydrofolate + 500 µg vitamin B_{12} + 10 mg vitamin B_6	8 tests of cognitive function	*Combined standard deviation score for the difference between treatment and controls*: -0.11 (-0.22-0.0) i.e. cognitive function was marginally worse with vitamins than with placebo
U.S. (Luchsinger *et al*., 2007)	Longitudinal cohort study of 965 healthy men and women aged 65+ years followed up for a mean period of 6.1 years	Total dietary and supplement intake of folate, vitamin B_6 and B_{12} assessed via a semi-quantitative food frequency questionnaire	Incidence of Alzheimer Disease (AD)	*Quartile of folate intake and risk of AD:* 1st Q: 1.0 (reference); 2nd Q: 0.9 (0.6, 1.3); 3rd Q: 0.7 (0.5, 1.1); 4th Q: 0.5 (0.3, 0.9) P value for trend: 0.02

Table 8: Summary of results from recently published studies investigating folate and cognitive function (continued)

Study (Reference)	Study design	Exposure variables	Outcome variables	Results (95% CI)
Nurses Health Study (Kang *et al.,* 2006)	635 women aged 70+ years, 3 repeated tests over 4 years	Quartiles of plasma folate and vitamin B_{12} levels	Tests of cognitive decline	*Cognitive test performance* (global score, multivariate adjusted): *Plasma folate* 1st Q: 0 (reference); 2nd Q: 0.13 (-0.02, 0.29); 3rd Q: 0.05 (-0.11, 0.21); 4th Q: 0.06 (-0.10, 0.22) *Plasma vitamin B12* 1st Q: 0 (reference); 2nd Q: 0.10 (-0.06, 0.25); 3rd Q: -0.08 (-0.23, 0.07); 4th Q: 0.15 (0.00, 0.31)
NHANES (Morris *et al.*, 2007)	1,459 participants (mean age = 70 years) in the 1999-2002 National Health and Nutrition Examination Survey	Serum folate as a continuous variable Low vitamin B_{12} status (serum B_{12} <148 pmol/L or serum methylmalonic acid >210 nmol/L)	Cognitive function Anaemia	*Cognitive impairment*: normal folate, normal B_{12} status: 1.0 (reference); high folate, normal B_{12} status: 0.5 (0.2, 0.96) normal folate, low B_{12} status: 1.6 (0.95, 2.8) high folate, low B_{12} status: 4.9 (2.6, 9.2)

Implications of the new findings

Papers published since Final Assessment do not change FSANZ's earlier conclusion that based on current evidence increased folic acid intake does not increase or reduce cancer risk. This conclusion is drawn from relative risks close to one in the RCTs and in the two meta-analyses for breast cancer.

There is no significant evidence of increased risk of twinning as a result of the expected increases in folic acid intake from mandatory fortification.

Similar to that reported at Final Assessment, the additional evidence does not support an association between folate intake and cognitive function although the RCT by Durga *et al*. (2007) is suggestive of a protective effect among individuals with an elevated homocysteine status after several years of folic acid supplementation.

In Australia, based on data from the Blue Mountains Eye Study, nearly 23% of study participants had low serum B_{12} levels (<185 pmols/L) (Flood *et al*., 2006). More recent analysis of these data indicate that those with the highest quintile of folate intake (from diet and supplements) had significantly higher serum B_{12} levels (Flood and Mitchell, 2007) indicating that in this population high folate intake is not associated with increased likelihood of low serum B_{12} levels. While the NHANES results linking increased cognitive decline with a low vitamin B_{12} status and high folate status are unusual and suggestive of a vitamin B_{12}/folic acid interaction, a cross-sectional study does not indicate a causal relationship. The results do, however, highlight the need for ongoing monitoring of 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 maybe the only clinical manifestation of vitamin B_{12} deficiency.

References

ABS (1998) *National nutrition survey: nutrient intakes and physical measurements. Australia. 1995*. catalogue No 4805.0, ABS, Canberra.

Badovinac, R.L., Werler, M.M., Williams, P.L., Kelsey, K.T. and Hayes, C. (2007) Folic acid-containing supplement consumption during pregnancy and risk for oral clefts: A meta-analysis. *Birth Defects Res.A Clin.Mol.Teratol.* 79(1):8-15.

Balk, E.M., Raman, G., Tatsioni, A., Chung, M., Lau, J. and Rosenberg, I.H. (2007) Vitamin B6, B12, and folic acid supplementation and cognitive function: a systematic review of randomized trials. *Arch.Intern.Med.* 167(1):21-30.

Bazzano, L.A., Reynolds, K., Holder, K.N. and He, J. (2006) Effect of folic acid supplementation on risk of cardiovascular diseases: a meta-analysis of randomized controlled trials. *JAMA* 296(22):2720-2726.

Bleys, J., Miller, E.R., III, Pastor-Barriuso, R., Appel, L.J. and Guallar, E. (2006) Vitamin-mineral supplementation and the progression of atherosclerosis: a meta-analysis of randomized controlled trials. *Am.J.Clin.Nutr.* 84(4):880-887.

Bonaa, K.H., Njolstad, I., Ueland, P.M., Schirmer, H., Tverdal, A., Steigen, T., Wang, H., Nordrehaug, J.E., Arnesen, E. and Rasmussen, K. (2006) Homocysteine lowering and cardiovascular events after acute myocardial infarction. *N.Engl.J.Med.* 354(15):1578-1588.

Botto, L.D., Lisi, A., Bower, C., Canfield, M.A., Dattani, N., De, V.C., De, W.H., Erickson, D.J., Halliday, J., Irgens, L.M., Lowry, R.B., McDonnell, R., Metneki, J., Poetzsch, S., Ritvanen, A., Robert-Gnansia, E., Siffel, C., Stoll, C. and Mastroiacovo, P. (2006) Trends of selected malformations in relation to folic acid recommendations and fortification: An international assessment. *Birth Defects Res.A Clin.Mol.Teratol.*

Bower, C. (2003) Fortification of food with folic acid and the prevention of neural tube defects. *N.Z.Med.J.* 116(1168):U292.

Bower, C., Miller, M., Payne, J. and Serna, P. (2005) Promotion of folate for the prevention of neural tube defects: who benefits? *Paediatr Perinat Epidemiol* 19:435-444.

Bower, C., Miller, M., Payne, J. and Serna, P. (2006) Folate intake and the primary prevention of non-neural birth defects. *Aust.N.Z.J.Public Health* 30(3):258-261.

Canadian Cancer Society/National Cancer Institute of Canada (2007) *Canadian Cancer Statistics 2007*., Toronto, Canada.

Choumenkovitch, S.F., Selhub, J., Wilson, P.W.F., Rader, J.I., Rosenberg, I.H. and Jacques, P.F. (2002) Folic acid intake from fortification in the United States exceeds predictions. *J Nutr* 132:2792-2798.

Conlin, M.L., Maclennan, A.H. and Broadbent, J.L. (2006) Inadequate compliance with periconceptional folic acid supplementation in South Australia. *Aust.N.Z.J.Obstet.Gynaecol.* 46(6):528-533.

Czeizel, A.E., Puho, E.H. and Banhidy, F. (2006) No association between periconceptional multivitamin supplementation and risk of multiple congenital abnormalities: a population-based case-control study. *Am.J.Med.Genet.A* 140(22):2469-2477.

Dobson, I., Devenish, C., Skeaff, C.M. and Green, T.J. (2006) Periconceptional folic acid use among women giving birth at Queen Mary Maternity Hospital in Dunedin. *Aust.N.Z.J.Obstet.Gynaecol.* 46(6):534-537.

Durga, J., van Boxtel, M.P., Schouten, E.G., Kok, F.J., Jolles, J., Katan, M.B. and Verhoef, P. (2007) Effect of 3-year folic acid supplementation on cognitive function in older adults in the FACIT trial: a randomised, double blind, controlled trial. *Lancet* 369(9557):208-216.

Eussen, S.J., de Groot, L.C., Joosten, L.W., Bloo, R.J., Clarke, R., Ueland, P.M., Schneede, J., Blom, H.J., Hoefnagels, W.H. and van Staveren, W.A. (2006) Effect of oral vitamin B-12 with or without folic acid on cognitive function in older people with mild vitamin B-12 deficiency: a randomized, placebo-controlled trial. *Am.J.Clin.Nutr.* 84(2):361-370.

Flood, V.M. and Mitchell, P. (2007) Folate and vitamin B12 in older Australians. *Med J Aust.* 186(6):321-322.

Flood, V.M., Smith, W.T., Webb, K.L., Rochtina, E., Anderson, V.E. and Mitchell, P. (2006) Prevalence of low serum folate and vitamin B12 in an older population. *Aust N Z J Public Health* 30(1):38-41.

Goh, Y.I., Bollano, E., Einarson, T.R. and Koren, G. (2006) Prenatal multivitamin supplementation and rates of congenital anomalies: a meta-analysis. *J.Obstet.Gynaecol.Can.* 28(8):680-689.

Green-Raleigh, K., Carter, H., Mulinare, J., Prue, C. and Petrini, J. (2006) Trends in folic Acid awareness and behavior in the United States: the gallup organization for the march of dimes foundation surveys, 1995-2005. *Matern.Child Health J.* 10 Suppl 7:177-182.

Haggarty, P., McCallum, H., McBain, H., Andrews, K., Duthie, S., McNeill, G., Templeton, A., Haites, N., Campbell, D. and Bhattacharya, S. (2006) Effect of B vitamins and genetics on success of in-vitro fertilisation: prospective cohort study. *Lancet* 367(9521):1513-1519.

Hickling, S., Hung, J., Knuiman, M., Jamrozik, K., McQuillan, B., Beilby, J. and Thompson, P. (2005) Impact of voluntary folate fortification on plasma homocysteine and serum folate in Australia from 1995 to 2001: a population based cohort study. *J Epidemiol Community Health* 59(5):371-376.

Hubner, R.A., Muir, K.R., Liu, J.F., Sellick, G.S., Logan, R.F., Grainge, M., Armitage, N., Chau, I. and Houlston, R.S. (2006) Folate metabolism polymorphisms influence risk of colorectal adenoma recurrence. *Cancer Epidemiol.Biomarkers Prev.* 15(9):1607-1613.

Kang, J.H., Irizarry, M.C. and Grodstein, F. (2006) Prospective study of plasma folate, vitamin B12, and cognitive function and decline. *Epidemiology* 17(6):650-657.

Kune, G. and Watson, L. (2006) Colorectal cancer protective effects and the dietary micronutrients folate, methionine, vitamins B6, B12, C, E, selenium, and lycopene. *Nutr.Cancer* 56(1):11-21.

Lancaster, P. and Hurst, T. (2001) *Trends in neural tube defects in Australia*. Australian Food and Nutrition Monitoring Unit, Commonwealth of Australia, Canberra.

Lange, H., Suryapranata, H., De, L.G., Borner, C., Dille, J., Kallmayer, K., Pasalary, M.N., Scherer, E. and Dambrink, J.H. (2004) Folate therapy and in-stent restenosis after coronary stenting. *N.Engl.J.Med.* 350(26):2673-2681.

Larsson, S.C., Giovannucci, E. and Wolk, A. (2006) Folate intake and stomach cancer incidence in a prospective cohort of Swedish women. *Cancer Epidemiol.Biomarkers Prev.* 15(7):1409-1412.

Larsson, S.C., Giovannucci, E. and Wolk, A. (2007) Folate and risk of breast cancer: a meta-analysis. *J.Natl.Cancer Inst.* 99(1):64-76.

Levy, T. and Blickstein, I. (2006) Does the use of folic acid increase the risk of twinning? *Int.J.Fertil.Womens Med.* 51(3):130-135.

Lewis, S.J., Harbord, R.M., Harris, R. and Smith, G.D. (2006) Meta-analyses of observational and genetic association studies of folate intakes or levels and breast cancer risk. *J.Natl.Cancer Inst.* 98(22):1607-1622.

Li, Z., Ren, A., Zhang, L., Liu, J. and Li, Z. (2007) Periconceptional use of folic acid in Shanxi Province of northern China. *Public Health Nutr.* 10(5):471-476.

Liem, A., Reynierse-Buitenwerf, G.H., Zwinderman, A.H., Jukema, J.W. and van Veldhuisen, D.J. (2003) Secondary prevention with folic acid: effects on clinical outcomes. *J.Am.Coll.Cardiol.* 41(12):2105-2113.

Liem, A., Reynierse-Buitenwerf, G.H., Zwinderman, A.H., Jukema, J.W. and van Veldhuisen, D.J. (2005) Secondary prevention with folic acid: results of the Goes extension study. *Heart* 91(9):1213-1214.

Lonn, E., Yusuf, S., Arnold, M.J., Sheridan, P., Pogue, J., Micks, M., McQueen, M.J., Probstfield, J., Fodor, G., Held, C. and Genest, J., Jr. (2006) Homocysteine lowering with folic acid and B vitamins in vascular disease. *N.Engl.J.Med.* 354(15):1567-1577.

Luchsinger, J.A., Tang, M.X., Miller, J., Green, R. and Mayeux, R. (2007) Relation of higher folate intake to lower risk of Alzheimer disease in the elderly. *Arch.Neurol.* 64(1):86-92.

Lucock, M. and Yates, Z. (2005) Folic acid-vitamin and panacea or genetic time bomb? *Nat Reviews* 6:235-240.

Lucock, M.D. (2006) Synergy of genes and nutrients: the case of homocysteine. *Curr.Opin.Clin.Nutr.Metab Care* 9(6):748-756.

Marsack, C.R., Alsop, C.L., Kurinczuk, J.J. and Bower, C. (1995) Pre-pregnancy counselling for the primary prevention of birth defects: rubella vaccination and folate intake. *Med.J.Aust.* 162(8):403-406.

McMahon, J.A., Green, T.J., Skeaff, C.M., Knight, R.G., Mann, J.I. and Williams, S.M. (2006) A controlled trial of homocysteine lowering and cognitive performance. *N.Engl.J.Med.* 354(26):2764-2772.

Metz, J., Sikaris, K.A., Maxwell, E.L. and Levin, M.D. (2002) Changes in serum folate concentrations following voluntary food fortification in Australia. *Med J Aust.* 176(2):90-91.

Morris, M.S., Jacques, P.F., Rosenberg, I.H. and Selhub, J. (2007) Folate and vitamin B-12 status in relation to anemia, macrocytosis, and cognitive impairment in older Americans in the age of folic acid fortification. *Am.J.Clin.Nutr.* 85(1):193-200.

National Cancer Institute (2007) *Surveillance, Epidemiology, and End Results (SEER) Cancer Statistics Review, 1975-2004*., Bethesda, MD. http://www.seer.cancer.gov/csr/1975_2004/ .

NHMRC and NZMoH (2006) *Nutrient reference values for Australia and New Zealand including recommended dietary intakes*. NHMRC, Canberra.

Quinlivan, E.P. and Gregory, J.F. (2003) Effect of food fortification on folcc acid intake in the United States. *Am J Clin Nutr* 77:221-225.

SACN (2006) *Folate and disease prevention*. UK Food Standards Agency and the Department of Health, United Kingdom. http://www.sacn.gov.uk/reports.

Sanjoaquin, M.A., Allen, N., Couto, E., Roddam, A.W. and Key, T.J. (2005) Folate intake and colorectal cancer risk: a meta-analytical approach. *Int.J.Cancer* 113(5):825-828.

Schader, I. and Corwin, P. (1999) How many pregnant women in Christchurch are using folic acid supplements early in pregnancy? *New Zealand Medical Journal* 112:463-465.

Sherwood, K.L., Houghton, L.A., Tarasuk, V. and O'Connor, D.L. (2006) One-third of pregnant and lactating women may not be meeting their folate requirements from diet alone based on mandated levels of folic acid fortification. *J.Nutr.* 136(11):2820-2826.

Shirodaria, C., Antoniades, C., Lee, J., Jackson, C.E., Robson, M.D., Francis, J.M., Moat, S.J., Ratnatunga, C., Pillai, R., Refsum, H., Neubauer, S. and Channon, K.M. (2007) Global Improvement of Vascular Function and Redox State With Low-Dose Folic Acid. Implications for Folate Therapy in Patients With Coronary Artery Disease. *Circulation* :

Stoll, C., Alembik, Y. and Dott, B. (2006) Are the recommendations on the prevention of neural tube defects working? *Eur.J.Med.Genet.*

Toole, J.F., Malinow, M.R., Chambless, L.E., Spence, J.D., Pettigrew, L.C., Howard, V.J., Sides, E.G., Wang, C.H. and Stampfer, M. (2004) Lowering homocysteine in patients with ischemic stroke to prevent recurrent stroke, myocardial infarction, and death: the Vitamin Intervention for Stroke Prevention (VISP) randomized controlled trial. *JAMA* 291(5):565-575.

USCDC. (2004) Spina bifida and anencephaly before and after folic acid mandate - United States, 1995-1996 and 1999-2000. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5317a3.htm . Accessed on 7 May 2004.

Victorian Perinatal Data Collection Unit. (2005) Victorian birth defects bulletin. No. 1: Victoria.

Wald, D.S., Wald, N.J., Morris, J.K. and Law, M. (2006) Folic acid, homocysteine, and cardiovascular disease: judging causality in the face of inconclusive trial evidence. *BMJ* 333(7578):1114-1117.

Watson, L.F., Brown, S.J. and Davey, M.A. (2006) Use of periconceptional folic acid supplements in Victoria and New South Wales, Australia. *Australian and New Zealand Journal of Public Health* 30(1):42-49.

Weinstein, S.J., Stolzenberg-Solomon, R., Pietinen, P., Taylor, P.R., Virtamo, J. and Albanes, D. (2006) Dietary factors of one-carbon metabolism and prostate cancer risk. *Am.J.Clin.Nutr.* 84(4):929-935.

Yazdy, M.M., Honein, M.A. and Xing, J. (2007) Reduction in orofacial clefts following folic acid fortification of the U.S. grain supply. *Birth Defects Res.A Clin.Mol.Teratol.* 79(1):16-23.

Zoungas, S., McGrath, B.P., Branley, P., Kerr, P.G., Muske, C., Wolfe, R., Atkins, R.C., Nicholls, K., Fraenkel, M., Hutchison, B.G., Walker, R. and McNeil, J.J. (2006) Cardiovascular morbidity and mortality in the Atherosclerosis and Folic Acid Supplementation Trial (ASFAST) in chronic renal failure: a multicenter, randomized, controlled trial. *J.Am.Coll.Cardiol.* 47(6):1108-1116.

Attachment 6

Impact of mandatory fortification in the U.S.

Background

In December 1996, the United States Food and Drug Administration (USFDA) reviewed its voluntary regulations for folic acid fortification and required that enriched cereal grains products be fortified on a mandatory basis at 140 µg folic acid per 100 g cereal grain product by January 1998 (USFDA 1996). In addition, ready to eat breakfast cereals were permitted to be voluntarily fortified with folic acid up to 400 µg per serve and meal replacement products at levels not to exceed 400 µg per serve (for use once per day) and 200 µg per serve (for use twice per day).

This decision was based on modelling and public consultation on the proposal to amend the standards of identity for enriched cereal grain products to require folic acid fortification. Modelling was undertaken for cereal grains, dairy products and fruit juices, at levels of 70, 140 and 350 µg per 100 g, using the 1987-88 national food consumption data and the safe upper limit of 1 mg per day as recommended by the United States Centers for Disease Control (USCDC). The amount of folic acid added to enriched cereal grains was chosen so that approximately 50% of all reproductive-age women would receive a total of 400 µg of folate from all sources (USCDC, 1992) and increase the typical folic acid intake by approximately 100 µg per day (Jacques *et al*., 1999). The selected fortification level of 140 µg was considered to be a compromise between safety and prevention of NTDs (USCDC 1992; Daly *et al*., 1997). This amount of fortification was estimated to reduce the incidence of NTDs by up to 41%, (Daly *et al.,* 1997; Wald *et al*., 2001).

The cereal foods enriched with folic acid included enriched: wheat flour; bread, rolls and buns; corn grits and cornmeal; farina; rice and macaroni products. These food vehicles were chosen on the basis of being staple food products for most of the US population (including 90% of the target group), and a long history of being successful vehicles for fortification (USFDA 1996). Unenriched cereal-grain products are not fortified with folic acid to allow for consumer choice (USFDA, 1996), although these constitute a minority of the entire available product.

Implementation by industry

Mandatory fortification of folic acid in cereal grains commenced in 1996 and was basically complete by mid 1997 (Jacques *et al.,* 1999). As a result, it was estimated that the folic acid content of more than one third of available foods had increased (Lewis *et al*., 1999).

It appears that the actual folate content of fortified foods was greater than had been assumed in predicting folate intakes under mandatory fortification. Initial studies comparing the analysed folate content of enriched cereal-grain products to the levels required by Federal regulations showed that mandatorily fortified foods contained up to 160-175% of their predicted folate content (Rader *et al*., 2000; Choumenkovitch *et al*., 2002). Similar results were found with fortified breakfast cereals (Whittaker *et al*., 2001).

The high levels of total folate were thought to be due to overages used by manufacturers to ensure food products contained at least the amount of nutrient specified on the label throughout shelf life, as well as higher than expected levels of naturally-occurring folate and/or problems with the analysis method used (Rader *et al.,* 2000; Whittaker *et al.,* 2001).

Public health impact of mandatory fortification

Impact on folic acid intake

Following the introduction of mandatory fortification, folic acid intake is estimated to have increased by up to 200 µg/day across the community, including the target group of reproductive-age women (Choumenkovitch *et al.,* 2002; Quinlivan and Gregory, 2003).

The Framingham Offspring cohort study showed that among non-supplement users in the cohort, the prevalence of older individuals who consumed less than the recommended daily intake of folate (defined as 320 µg DFE[22] per day) decreased from 48.6% prior to the FDA-mandated folic acid fortification to 7.0% post-mandatory fortification. Consumption of greater than 1 mg folic acid occurred only in individuals who regularly consumed supplements containing folic acid (frequency of use was not defined). The proportion of individuals who exceeded this limit rose from 1.3% prior to fortification to 11.3% after mandatory fortification (Choumenkovitch *et al.,* 2002).

Papers published since Final Assessment

Similar to the increases in intake described above, a comparison of two NHANES[23] surveys (pre fortification 1988-1994 and post fortification 1999-2000), indicated an increase in the proportion of women aged 15-44 years exceeding 400 µg per day of folate from all food sources including fortified foods (from 26% to 38%), although the target of 50% consuming the recommended level had not been reached (Bentley *et al*., 2006). Of particular note, however, was a decline in the proportion of women of child-bearing age who reported taking folic acid supplements[24].

Despite overall increases in folic acid intake in the U.S. since mandatory fortification was introduced there remain significant ethnic differences in total folate intake (Bentley *et al*., 2006) and this is reflected in significant differences in plasma concentrations of total homocysteine, with non-Hispanic blacks having a higher concentration than non-Hispanic whites or Hispanic populations based on an age-adjusted comparison (Ganji and Kafai, 2006a).

Impact on folate status

The USCDC compared pre-fortification folate status data from the 1988-94 NHANES with post-fortification folate status from the 1999 NHANES III.

[22] 1 µg Dietary Folate Equivalent = 1 µg food folate OR 0.5 µg folic acid on an empty stomach OR 0.6 µg folic acid with meals or as fortified foods (NHMRC and NZMoH, 2006).
[23] U.S. National Health and Nutrition Examination Surveys.
[24] Folic acid supplement use was based on use over a one month period.

The mean serum folate concentration in participating women aged 15-44 years increased by 157%, from 14.3 nmol/L during NHANES III to 36.7 nmol/L in NHANES 1999. For non-supplement users, the mean serum folate concentration increased by 167%, from 10.7 nmol/L to 28.6 nmol/L over this time (USCDC, 2000).

In the above group of subjects, mean red blood cell folate concentration, indicating long-term folate status, increased from 410.1 nmol/L to 713.8 nmol/L, an average increase of 74% (data not adjusted for supplement use). In addition, women with the lowest initial folate values showed the greatest improvement in folate status (USCDC 2000).

Looking at a wider sector of the US population, serum folate data from a US clinical laboratory were analysed from 1994 to 1998. The majority of men and women were aged between 12 and 70. Median serum folate values increased by 50% from 28.6 nmol/L in 1994 (prior to fortification) to 42.4 nmol/L in 1998 (post-mandatory fortification) (Lawrence *et al*., 1999). These values were not corrected for vitamin supplement intake, however, surveys conducted by the March of Dimes indicate that folic acid supplement use remains relatively unchanged (USCDC, 2004).

Among non-supplement users of the Framingham Offspring cohort, the mean serum folate concentrations increased from 10.4 nmol/L (pre-mandatory fortification) to 22.7 nmol/L (post-mandatory fortification), an increase of 117% in the study population.

The mandatory folic acid fortification program has virtually eliminated the presence of low folate concentrations (defined as serum folate levels below 7 nmol/L) from the cohort of older adults, with a decrease from 22% to 1.7% of the cohort exhibiting low folate status since mandatory fortification (Jacques *et al.,* 1999).

More recently published results using the NHANES data indicate similar findings. Comparison of data from surveys in 1988 and 1994 with NHANES 1999-2000 showed that among women aged 20-39 years, mean serum folate increased from 10.3 nmol/L to 26.0 nmol/L (Dietrich *et al*., 2005) and the prevalence of low serum folate concentrations (<6.8 nmol/L) in the population aged three years or more decreased from 16% prior to fortification to 0.5% after fortification (Pfeiffer *et al*., 2005).

Overall, the mandatory fortification of the food supply with folic acid has led to a significant positive increase of serum and red blood cell folate levels for all sectors of the US population, including the target group. Despite these improvements, the prevalence of low red blood cell folate continues to be high in non-Hispanic blacks (about 21%) (Ganji and Kafai, 2006b).

Papers published since Final Assessment

The USCDC (2007) recently reported a statistically significant decline in median serum folate concentrations of 16% between 1999-2000 and 2003-2004 among women aged 15-44 years.

The folate status of women of child-bearing age, however, is still well above the level reported prior to mandatory fortification (median of 4.8 ng/mL among all women aged 15-44 years in the 1988-94 NHANES survey (USCDC 2000) compared with 10.6 ng/mL among non-pregnant women aged 15-44 years in the 2003-04 NHANES survey (USCDC, 2007)) (Figure 1).

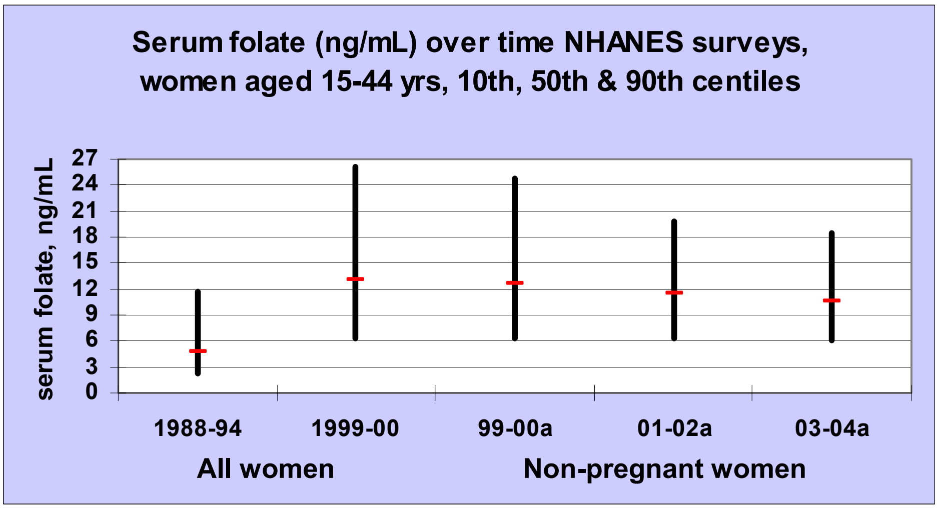


Figure 1: Changes in folate status among women of child-bearing age in the U.S. – pre and post mandatory fortification

As the recently reported fall in folate status contradicts earlier trends, various explanations for the decline were considered by the authors including: changes in supplement usage (the authors reported no evidence of this, although the paper by Bentley *et al*. (2006) indicates that this has occurred[25]); a fall in consumption of naturally-occurring folate rich foods (limited evidence of this); changes in the amount of folic acid added to fortified foods (some evidence for this); and increases in the prevalence of risk factors for lower folate status such as obesity (there is limited evidence of this among women, see Ogden *et al*. (2006)). In addition, low carbohydrate diets were popular several years ago in the U.S. and this may also have contributed to the decline.

The USCDC report did not mention potential changes in voluntary fortification practices. As there is no systematic program to assess voluntary fortification in the U.S. it is unknown to what extent there have been changes in the numbers of voluntarily fortified foods or in the levels of folic acid added to these foods.

Impact on NTD rate

An average decrease of 27% in pre-natally ascertained NTD-affected pregnancies was found after the introduction of mandatory folate fortification, which the USCDC attributes to the introduction of mandatory folate fortification (USCDC, 2004). Overall, the total number of NTD-affected pregnancies declined from 4,000 prior to the folic acid mandate to 3,000 after mandatory fortification. In addition, various economic models have shown that mandatory fortification results in favourable benefit-to-cost ratios (Romano et al, 1995; Horton, 2003; Grosse, 2004; Grosse *et al*., 2005).

There have no reports of changes in the NTD rate in the U.S. since the recently reported fall in folate status among women of child-bearing age.

[25] The greater fall in the 90th centile of serum folate levels (Figure 1) over the period 1999-00 to 2003-04 compared with the fall in median levels also suggests that a fall in supplement intake is contributing to the overall decline.

Potential adverse health effects

In the U.S. there is no commitment to ongoing monitoring (Rosenberg, 2005), hence consistent reporting of potential adverse health effects from high intakes, particularly among the non target population, has not occurred (Rader and Schneeman, 2006). Despite the lack of systematic monitoring, there have been several reports of foods containing much higher amounts of folic acid than the regulated level (Lewis *et al*., 1999; Rader *et al*., 2000; Choumenkovitch *et al*., 2002) and considerable increases in high serum folate concentrations among children under six of age and the elderly (Pfeiffer *et al*., 2005).

Specific studies:

Masking the diagnosis of vitamin B_{12} deficiency - A study of 1,573 mainly African American women and men from a Veterans Affairs Centre found that the proportion of people who had poor vitamin B_{12} status without anaemia did not change significantly from the pre-fortification period (39.2%) to after full implementation of mandatory fortification (37.6%). This study concluded that mandatory fortification did not increase the prevalence of masking the diagnosis of vitamin B_{12} deficiency (Mills *et al*., 2003). The introduction of mandatory fortification was found to increase the number of people who would be considered at-risk for masking of vitamin B_{12} deficiency, however, this value still remains below 1% and no actual cases of masking were reported in the United States.

Twinning - Out of more than 2.5 million births in California, there has been no reported increase in the incidence of twinning after the mandatory fortification of the US food supply relative to the pre-fortification period (Shaw *et al*., 2003). Similar results were found when comparing data from over one million births in Texas. A general increase in the prevalence of twinning has been noted to have occurred over the past decade, which was attributed to factors such as increasing maternal age at parity, rather than the fortification program (Waller *et al*., 2003).

Cancer – There has not been any evidence of an increase in breast or colorectal cancers since the introduction of mandatory fortification. Secular trends show that age-adjusted incidence of breast cancer in women aged 50 years and older and of colorectal cancer in men and women aged 50 years and over have declined since 1998 (National Cancer Institute, 2005). For colorectal cancer there was a non-significant increase in incidence of 1.2% per year between 1995 and 1998 across ages followed by a significant decline in incidence of 2.1% per year between 1998 and 2003. The increased incidence between 1995 and 1998 might be explained by improved screening for colorectal cancer during the mid 1990s.

References

Bentley, T.G., Willett, W.C., Weinstein, M.C. and Kuntz, K.M. (2006) Population-Level Changes in Folate Intake by Age, Gender, and Race/Ethnicity after Folic Acid Fortification. *Am.J.Public Health* 96(11):2040-2047.

Choumenkovitch, S.F., Selhub, J., Wilson, P.W.F., Rader, J.I., Rosenberg, I.H. and Jacques, P.F. (2002) Folic acid intake from fortification in the United States exceeds predictions. *J Nutr* 132:2792-2798.

Daly, D., Mills, J.L., Molloy, A.M., Conley, M., Lee, Y.J., Kirke, P.N., Weir, D.G. and Scott, J.M. (1997) Minimum effective dose of folic acid for food fortification to prevent neural tube defects. *Lancet* 350:1666-1669.

Dietrich, M., Brown, C.J. and Block, G. (2005) The effect of folate fortification of cereal-grain products on blood folate status, dietary folate intake, and dietary folate sources among adult non-supplement users in the United States. *J.Am.Coll.Nutr.* 24(4):266-274.

Ganji, V. and Kafai, M.R. (2006a) Population reference values for plasma total homocysteine concentrations in US adults after the fortification of cereals with folic acid. *Am.J.Clin.Nutr.* 84(5):989-994.

Ganji, V. and Kafai, M.R. (2006b) Trends in serum folate, RBC folate, and circulating total homocysteine concentrations in the United States: analysis of data from National Health and Nutrition Examination Surveys, 1988-1994, 1999-2000, and 2001-2002. *J.Nutr.* 136(1):153-158.

Grosse, S. (2004) Economic evaluation in maternal and child health: principles and cases.

Grosse, S., Waitzman, N., Romano, M. and Mulinare, J. (2005) Reevaluating the benefits of folic acid fortification in the United States: Economic analysis, regulation and public health. *American Journal of Public Health* 95(11):1917-1922.

Horton. (2003) The economic impact of micronutrient deficiencies, Presentation at 54th Nestle Nutrition Workshop, San Paola, Brazil.

Jacques, P.F., Selhub, J., Bostom, A.G., Wilson, P.W. and Rosenberg, I.H. (1999) The effect of folic acid fortification on plasma folate and total homocysteine concentrations. *The New England Journal of Medicine* 340(19):1449-1454.

Lawrence, J.M., Petitti, D.B., Watkins, M. and Umekubo, M.A. (1999) Trends in serum folate after foods fortification. *Lancet* 354:915-916.

Lewis, C.J., Crane, N.T., Wilson, D.B. and Yetley, E.A. (1999) Estimated folate intakes: data updated to reflect food fortification, increased bioavailability, and dietary supplement use. *Am.J.Clin.Nutr.* 70(2):198-207.

Mills, J.L., Von Kohorn, I., Conley, M.A., Zeller, J.A., Cox, C., Williamson, R.E. and Dufour, D.R. (2003) Low vitamin B12 concentrations in patients without anaemia: the effect of folic acid fortification of grain. *Am J Clin Nutr* 77:1474-1477.

National Cancer Institute. (2005) Surveillance, Epidemiology, and End Results (SEER) Program. Released April 2005. www.seer.cancer.gov.

NHMRC and NZMoH (2006) *Nutrient reference values for Australia and New Zealand including recommended dietary intakes*. NHMRC, Canberra.

Ogden, C.L., Carroll, M.D., Curtin, L.R., McDowell, M.A., Tabak, C.J. and Flegal, K.M. (2006) Prevalence of overweight and obesity in the United States, 1999-2004. *JAMA* 295(13):1549-1555.

Pfeiffer, C.M., Caudill, S.P., Gunter, E.W., Osterloh, J. and Sampson, E.J. (2005) Biochemical indicators of B vitamin status in the US population after folic acid fortification: results from the National Health and Nutrition Examination Survey 1999-2000. *Am.J.Clin.Nutr.* 82(2):442-450.

Quinlivan, E.P. and Gregory, J.F. (2003) Effect of food fortification on folcc acid intake in the United States. *Am J Clin Nutr* 77:221-225.

Rader, J.I. and Schneeman, B.O. (2006) Prevalence of neural tube defects, folate status, and folate fortification of enriched cereal-grain products in the United States. *Pediatrics* 117(4):1394-1399.

Rader, J.I., Weaver, C.M. and Angyal, G. (2000) Total folate in enriched cereal-grain products in the United States following fortification. *Food Chemistry* 70:275-289.

Romano et al. (1995) Folic acid fortification of grain: an economic analysis. *AJPH* 85(5):667-676.

Rosenberg, I.H. (2005) Science-based micronutrient fortification: which nutrients, how much, and how to know? *Am J Clin Nutr* 82:279-280.

Shaw, G.M., Carmichaels, S.L., Nelson, V., Selvin, S. and Schaffer, D.M. (2003) Food fortification and twinning among California infants. *Am J Med Genet* 119A:137-140.

USCDC. (1992) Recommendations for the use of folic acid to reduce the number of cases of spina bifida and other neural tube defects. *MMWR* 41:1-7.

USCDC. (2000) Folate status in women of childbearing age - United States 1999. *MMWR* 49:962-965.

USCDC. (2004) Spina bifida and anencephaly before and after folic acid mandate - United States, 1995-1996 and 1999-2000. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5317a3.htm . Accessed on 7 May 2004.

USCDC (2007) *Folate status in women of childbearing age, by race/ethnicity - United States, 1999-2000, 2001-2002, and 2003-2004*. 55(51), 1377-1380. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5551a2.htm.

USFDA (1996) *Folic acid fortification fact sheet*. http://www.babybag.com/articles/wh-folic.htm. Accessed on 27 June 2006.

USFDA. (1996) Food standards: amendment of standards of identity for enriched cereal grain products to require the addition of folic acid (final rule). In: US Food and Drug Administration. eds. Federal Register vol 61 (44): 8781-8797.

Wald, D.K., Law, M.R., Morris, J.K. and Wald, D.S. (2001) Quantifying the effect of folic acid. *Lancet* 358:2069-2073.

Waller, D.K., Tita, A.T. and Annegers, J.F. (2003) Rates of twinning before and after fortification of foods in the US with folic acid, Texas 1996 to 1998. *Paediatr Perinat Epidemiol* 17:378-383.

Whittaker, P., Tufaro, P.R. and Rader, J.I. (2001) Iron and folate in fortified cereals. *Journal of the American College of Nutrition* 20(3):247-254.

Attachment 7

Dietary Exposure Assessment: Main Report

CONTENTS

EXECUTIVE SUMMARY 39

1. BACKGROUND 43

2. DIETARY INTAKE ASSESSMENT APPROACH FOR THE FIRST REVIEW 44

3. ASSUMPTIONS USED IN THE DIETARY INTAKE ASSESSMENTS 50

4. CHANGES IN FOOD CONSUMPTION OVER TIME 50

5. RESULTS 51

6. ADDITIONAL CALCULATIONS TO ESTIMATE FOLIC ACID INTAKES FROM FOOD AND SUPPLEMENTS 61

7. OTHER FORTIFICATION ISSUES ASSESSED FOR THE FIRST REVIEW 69

8. DIETARY FOLATE INTAKES 74

9. LIMITATIONS OF THE DIETARY INTAKE ASSESSMENTS 75

APPENDIX 1: SUMMARY OF CONCENTRATION DATA USED FOR VARIOUS FOODS FOR DIETARY MODELLING PURPOSES 76

APPENDIX 2: COMPLETE INFORMATION ON DIETARY INTAKE ASSESSMENT RESULTS 78

APPENDIX 3: COMPLETE INFORMATION ON RISK CHARACTERISATION 85

APPENDIX 4: COMPLETE INFORMATION OF FOLIC ACID INTAKE FROM FOOD AND SUPPLEMENTS 87

EXECUTIVE SUMMARY

In the Ministerial Council review request ('First Review'), a number of issues were raised that related to dietary intake assessments for folic acid. The dietary intake assessments undertaken for the First Review assumed that, as previously, the overall aim of any fortification program is to ensure that folic acid intakes are maximised for the target groups whilst minimising the proportion of all population groups that exceed the upper level of intake (UL).

In order for the issues raised in the First Review request for be addressed, a number of changes were made to the dietary intake assessments for both Australia and New Zealand. These changes were:

1. Review the **Fortification Vehicle** for Australia with a view to mandating 'wheat flour for making bread' at 200 μg of folic acid per 100 g of bread-making flour. For New Zealand, the mandatory fortification food vehicle remained unchanged from Final Assessment – 'all bread' fortified at 135 μg folic acid per 100 g of bread[26].

2. **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 updated.

3. **Additional modelling** was undertaken to estimate dietary folic acid intakes for 'individuals' assuming that, where individuals have a choice between a fortified and non-fortified product they: (1) avoid the fortified food; and (2) they always select the fortified food.

4. **Food consumption patterns** were assessed for Australian and New Zealand women aged 16-44 years who have low and high intakes of folic acid to identify whether women with low folic acid intakes have different food consumption patterns in comparison to those with high folic acid intakes.

5. Further dietary intake assessments undertaken by the New Zealand Food Safety Authority and LINZ unit at the University of Otago using the **New Zealand 2002 National Children's Nutrition Survey** data were analysed and compared with the dietary intake assessments conducted by FSANZ.

6. An analysis of the contribution of **higher fat and/or higher sugar content breads and bread products** to folic acid intakes was undertaken.

7. FSANZ investigated the potential impact of **extending voluntary fortification** at higher levels of uptake (i.e. higher market share) of current permissions and across a broader range of food groups. Impact was measured by determining folic acid intakes among the target group (women of child-bearing age), and the general population.

[26] Amounts of folic acid refer to the amounts of folic acid in the flour portion of the final food (Australia) or in bread (NZ); the Draft Standard refers to a range of folic acid permitted to be added to achieve this outcome.

8. Submissions to the DAR for P295 indicated confusion about the differences between folate and folic acid intakes. As a result, FSANZ has estimated the intake of **naturally occurring folate** and **folate** (total of naturally occurring folate and folic acid intakes, expressed as dietary folate equivalents, DFEs)[27] by general population groups within Australia and New Zealand for the First Review, providing a full set of information on folate intakes for the first time.

The results of the dietary intake assessment for folic acid indicate that:

Estimated dietary folic acid intakes

- Current folic acid intakes from food by the target groups were low.

- New Zealand had lower *Baseline* folic acid intakes from food for all age groups considered compared to Australian populations.

- By mandating or fixing the level of folic acid in 'wheat flour for making bread' in Australia, 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 in comparison 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 (Attachment 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.

- Mean folic acid intakes for the target group increased from Baseline to Mandatory Fortification by +100 µg/day and +140 µg/day for Australia and New Zealand, respectively. Mean folic acid intakes for the target group increased from Baseline to extended voluntary fortification by +7-45 µg/day and +35-74 µg/day for Australia and New Zealand, respectively. The Mandatory Fortification scenario investigated by FSANZ provides a greater increase in mean folic acid intakes for the target group compared to the Baseline and extended voluntary fortification scenarios examined.

- Despite these increases in folic acid intakes from food, the mean dietary folic acid intake from food alone for the women of child bearing age did not achieve the desired folic acid intake of 400 µg per day for *Baseline*, the extended voluntary fortification(*Lower*, *Moderate* and *Higher*) scenarios or *Mandatory Fortification*. Hence supplementation would still be required for women of child bearing age as part of the overall strategy to reduce NTDs.

Risk characterisation

- The proportion of the target group exceeding the UL for Australia and New Zealand was <1% for Baseline, the extended voluntary fortification scenarios (Lower, Moderate and Higher) and Mandatory Fortification.

[27] Dietary Folate Equivalent (DFE) = (naturally occurring food folate µg) + (folic acid µg x 1.67)

- Children aged 2-3 and 4-8 years were the most likely of the non-target groups to have intakes exceeding the upper level (UL under the *Baseline,* extended voluntary fortification (*Lower*, *Moderate* and *Higher*) and *Mandatory Fortification*.

- Investigation of high consumer (95th percentile) intakes of folic acid and the maximum estimated dietary folic acid intakes indicated that estimated dietary folic acid intakes under *Mandatory Fortification* for Australian children aged 2-3 years and 4-8 years were acceptable and within the margin of safety for folic acid.

Dietary intakes from food and supplements

- Without the consumption of folic acid supplements, 5% of Australian and 3% of New Zealand women of child-bearing age were estimated to meet the recommended 'target intake' of 400 µg folic acid per day under the Mandatory Fortification scenarios.

- Without the consumption of folic acid supplements, <1-3% of Australian and New Zealand women of child-bearing age were estimated to meet the recommended 'target intake' of 400 µg folic acid per day under the extended voluntary fortification scenarios (*Lower, Moderate* and *Higher*).

- When a 200 µg per day folic acid supplement was considered in conjunction with Mandatory Fortification, approximately 40% of Australian and New Zealand women of child-bearing age were estimated to meet the target intake of folic acid. Under extended voluntary fortification (*Lower*, *Moderate* and *Higher*), 4% and 21% of Australian and New Zealand women of child-bearing age were estimated to meet the recommended intake of folic acid.

- If a 500 µg or 800 µg folic acid supplement was consumed by all women of child-bearing age, 100% of women of child-bearing age would meet the target intake of folic acid for Baseline, extended voluntary fortification (*Lower*, *Moderate* and *Higher*) and *Mandatory Fortification* scenarios.

- The proportion of Australian and New Zealand target population exceeding the UL with a folic acid supplement of 200 µg per day for Baseline, extended voluntary fortification (*Lower*, *Moderate* and *Higher*) and *Mandatory Fortification* scenarios was <1%.

- With a 500 µg supplement, the proportion of the Australian target population exceeding the UL increased slightly from 2% at Baseline and the extended voluntary fortification scenarios (*Lower*, *Moderate* and *Higher*) to 3% under the *Mandatory Fortification* scenario.

- In New Zealand, the Ministry of Health advises women capable of planning a pregnancy to take folic acid supplements containing 800 µg of folic acid four weeks before and 12 weeks after conception. With consumption of an 800 µg supplement, the proportion of the New Zealand target population exceeding the UL increased from 10% at *Baseline* to 14- 22% under extended voluntary fortification (*Lower*, *Moderate* and *Higher*) to 46% under the *Mandatory Fortification* scenario.

Food Consumption Patterns

- There does not appear to be a single food or food group that is consumed preferentially and by a significant proportion of women of child bearing age in the low folic acid intake group that could be fortified to effectively target these women.

- Mandatory fortification of wheat flour for bread making in Australia and bread in New Zealand would effectively target women with low folic intakes without overly increasing intakes for women who currently have higher folic acid intakes.

- Mean folic acid intakes from food did not meet the NHMRC target for any of the women of child bearing age when grouped according to quintiles of folic acid intake; therefore, increasing the folic acid in the food supply would assist all these groups.

Dietary folic acid intakes derived using New Zealand 2002 Children's Nutrition Survey data

- The results for the proportion of New Zealand children exceeding the upper level (UL) for folic acid for the proposed mandatory fortification of bread were submitted to the Ministerial Council in October 2006 at the same time as the FAR and were higher than those reported for Australian children at FAR for the same age group.

- In both the FSANZ and the University of Otago (LINZ Research group) assessments, the mandatory folic acid fortification concentrations used and the foods assumed to be fortified were similar.

- The methodologies for the two studies were different. The methodology used by the LINZ Research group was a single day un-adjusted method and the methodology used by FSANZ was a two-day adjusted method. It was concluded that using a single day un-adjusted methodology may account for some of the differences in results since using the second day adjustment for Australian children of a similar age decreased the proportion of children exceeding the UL from 9% to 3%.

- The difference in results could also be due to different food consumption patterns, differences in seasonality of food consumption and/or lower levels of uptake of voluntary fortification permissions in New Zealand in comparison to Australia. It is also recognised that changes in food consumption over the 7 year period from 1995 to 2002 may account for some differences in the estimated folic acid intakes.

Contribution of higher fat and/or higher sugar content breads and bread products to folic acid intakes

- Whilst some breads and bread products contain moderate to high proportions of fat and/or sugar, their contribution to folic acid intakes was low in comparison to other plain breads and bread products. The contributions of fancy breads with added fat and/or sugar to folic acid intakes were <5% and 6% for the Australian and New Zealand population groups, respectively.

Dietary intake assessment for folate

Estimated dietary folate intakes[28], differ between genders and ages as well as between countries. Australia has higher estimated dietary folate intakes than New Zealand for all population groups. Females in both countries were found to have lower dietary folate intakes than males in each age group.

New Zealand, as a population, has lower estimated intakes of dietary folate in comparison to Australian both at *Baseline* and under *Mandatory Fortification*. This difference in dietary folate intakes between countries is likely due to the higher naturally occurring folate concentrations in similar foods reported from analysis in Australia in comparison to New Zealand and a lower uptake of voluntary folic acid fortification permissions in New Zealand compared to Australia.

Cereals and cereal products were the highest contributors to dietary folate intakes for the Australian population as a whole under both *Baseline* and *Mandatory Fortification* scenarios. Breads and breakfast cereals were the major food group contributors for New Zealand, however, breads contributed to a greater extent under the *Mandatory Fortification* scenario.

Dietary folate intakes were compared to the Estimated Average Requirement (EAR) for folate[29]. In the absence of any folic acid fortification (i.e. intake of naturally occurring folate only), 31% Australians aged 2 years and over and 92% New Zealand population aged 15 years and over were estimated to have dietary folate intakes below the EAR, with slightly higher proportions below the EAR for the target group, women of child bearing age (52% Australia, 97% New Zealand).

Under the current (*Baseline*) voluntary folic acid fortification situation, estimated dietary folate intakes increased compared to those from naturally occurring folate only as would be expected, resulting in lower proportions of the Australian and New Zealand populations with dietary folate intakes below the EAR (7% Australian population, 50% NZ population), thus indicating that current voluntary fortification with folic acid makes a significant contribution to dietary folate intakes. Under *Mandatory Fortification*, less than 10% of all population sub-groups were estimated to have dietary folate intakes below the EAR. This indicates that *Mandatory Fortification* has the potential to further reduce the proportion of the Australian and New Zealand population with dietary folate intakes below the EAR.

1. Background

In the Ministerial Council review request, a number of issues were raised that relate to dietary intake assessments for folic acid. The dietary intake assessments undertaken for the First Review assumed that, as previously, the overall aim of any fortification program is to ensure that folic acid intakes are maximised for the target group whilst minimising the proportion of all population groups that exceed the upper level of intake (UL).

[28] Dietary folate refers to folate from food sources only and excludes supplements, expressed as µg DFE/day.
[29] The EAR for folate was set in 2006 by NHMRC, was higher than that set previously and was based on the effect of folate on lowering homocysteine levels, which was hypothesised to reduce the risk of heart disease (NHMRC, 2006).

In the First Review, FSANZ was asked to review the fortification vehicle selected for the addition of folic acid to the food supply by exploring the option of mandating bread-making flour as the food vehicle for Australia (to minimise the regulatory burden on industry and regulators) but retain the option of bread as the food vehicle in New Zealand. Therefore, the dietary intake assessments undertaken for the First Review reflect these options.

In order to present a comprehensive review to the Ministerial Council in response to their First Review request, FSANZ investigated the potential impact of extending voluntary fortification at higher levels of uptake (i.e. higher market share) of current permissions and across a broader range of food groups. Discussions with the Australian Food and Grocery Council (AFGC) resulted in two new scenarios being developed with input obtained from relevant AFGC members on the foods to be included and predicted proportion of each food category that could be fortified in the future. At Final Assessment (FAR), a more limited extension in voluntary fortification was assessed. This scenario was reassessed for the First Review.

Submissions to the DAR for P295 indicated confusion about the differences between naturally occurring folate and folic acid intakes. As a result, FSANZ has estimated the intake of naturally occurring folate, and dietary folate (expressed as DFEs)[2] by general population groups within Australia and New Zealand for the First Review, providing a full set of information on folate intakes for the first time.

Baseline folic acid 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 updated. All dietary intake assessments conducted for the First Review used these new baseline values as a starting point.

2. Dietary Intake Assessment Approach For The First Review

For an overview of dietary intakes assessments, how dietary folic acid intakes were estimated and the population groups assessed refer to Attachment 7 of the P295 – Consideration of Mandatory Fortification with Folic Acid Final Assessment report.

Dr Mike DiNovi, an international expert in dietary exposure assessments from the US Food and Drug Administration, recently reviewed all FSANZ dietary exposure assessment principles and modelling procedures and the supporting systems. The conclusions from the peer reviewer were overall very positive in terms of the FSANZ dietary modelling capability, expertise of staff and that the methodologies used by FSANZ being consistent with international best practice. The peer reviewer prepared a report on his findings which included some recommendations to enhance FSANZ capabilities further. A strategy had been put in place to deal with the recommendations. The Final Assessment Report on folic acid intake assessments was also peer reviewed by an external international expert from France[30] and comments made incorporated into the dietary intake estimates undertaken for the First Review report.

[30] Dr Philippe Verger, Directeur de l'Unité INRA (French National Institute for Agricultural. Research), Paris, France

2.1 Overview of the dietary intake assessments for the First Review

An overview of the dietary intake assessments conducted for the First Review can be found in Figure 1.

2.2 Scenarios assessed

Six scenarios were assessed as part of the dietary intake assessment for the First Review.

1. ***Baseline* -** to estimate current folic acid intakes from food alone based on current uptake of voluntary folic acid permissions by industry.

2. ***Lower*** proposed extension in voluntary fortification– to estimate folic acid intake from food alone based on current uptake of voluntary folic acid permissions by industry and an increase in uptake of voluntary fortification as proposed by the food industry at Final Assessment.

3. ***Moderate*** proposed extension in voluntary fortification – to estimate folic acid intake based on *Baseline* with an additional Moderate increase in voluntary folic acid fortification as agreed to by industry.

4. ***Higher*** proposed extension in voluntary fortification – to estimate folic acid intake based on *Baseline* with an additional Higher increase in voluntary folic acid fortification as agreed to by industry.

5. ***Mandatory Fortification*:** to estimate folic acid intakes based on current uptake by industry of voluntary folic acid permissions (excluding bread) and the introduction of mandatory fortification.

    a. For **Australia**, 'wheat flour for making bread' as the food vehicle, fortified at 200 μg of folic acid per 100 g of bread-making flour.
    b. For **New Zealand**, the food vehicle remained unchanged from Final Assessment – 'all bread' at 135 μg folic acid per 100 g of bread.

6. **Dietary folate**– to estimate intake of naturally occurring folate and dietary folate for both *Baseline* and *Mandatory Fortification* folic acid fortification scenarios.

Each of these scenarios are discussed in more detail in Attachments 7A, 7B and 7C – Attachment 7A for mandatory fortification, Attachment 7B for voluntary fortification and Attachment 7C for dietary folate intakes.

Within each of the scenarios listed above, two different model types were assessed:

a) Market share model; and
b) Consumer behaviour models.

The market share and consumer behaviour model types are discussed in detail below.

A summary of the scenarios and model types conducted for the First Review can be found in Table 1.

Figure 1: Overview of the dietary intake assessment approach used for the First Review for Australia and New Zealand

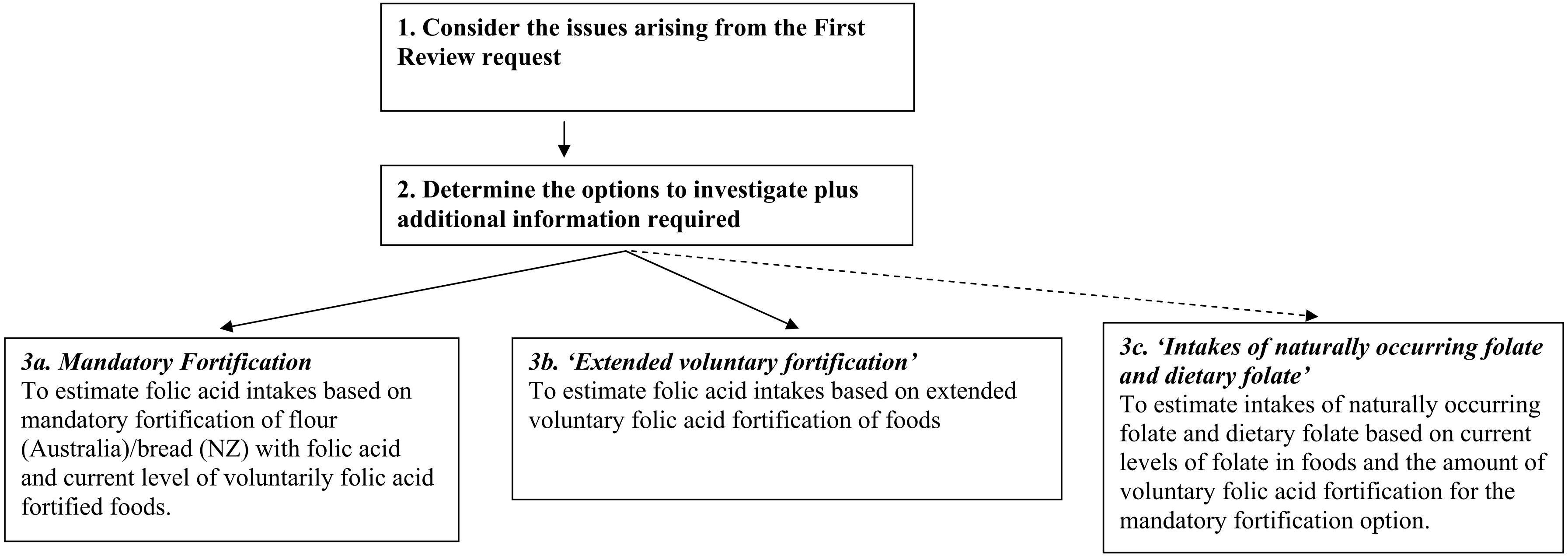


Table 1: Summary of scenarios examined for the First Review

Matrix of models	***Baseline***	***Mandatory Fortification***	**Voluntary fortification**			**Naturally occurring folate and dietary folate**
			Lower	***Moderate***	***Higher***	
Market share model	✓	✓	✓	✓	✓	✓
Consumer behaviour model – avoids fortified product where possible	✓	✓	✓	✓	✓	✓
Consumer behaviour model – selects fortified product where possible	✓	✓	✓	✓	✓	✓

2.2.1 *Market share model (or population estimate)*

This 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. A limitation of the market share model is that it only gives an estimate of population intakes over time. It can not estimate individual behaviour or estimate folic acid intakes for individuals due to the use of weighted mean folic acid concentration values.

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. If a fortified version of a food was not specifically identified within the NNS, but it was known that a significant proportion of the food category in the market place is now fortified with folic acid, a folic acid concentration was assigned to the food, and weighted to reflect the proportion of the market for that food that is now believed to be fortified. It is important to note that some foods in the NNSs were described as being folate fortified (e.g. certain breakfast cereals), therefore market weighted folic acid concentrations were not applied to these foods.

For example, the Australian NNS does not distinguish between the consumption of folic acid fortified white bread and unfortified white bread. The market share for folic acid fortified bread in Australia was estimated at 16% of all breads, based on sales information for a major bakery retail chain (Bakers Delight, 2006). A value representing 16% of the analysed or labelled concentration of folic acid in fortified breads was assigned to all white breads. Based on available information, fortification of breads with folic acid does not appear to be as common in New Zealand as in Australia so different market weights were assigned.

2.2.2 *Consumer behaviour model (or individual choices model)*

The voluntary permission to fortify some foods with folic acid presents the grocery buyer with a choice, to avoid or positively select these foods according to the needs of their household. To reflect the potential differences in **individual** consumer behaviour, two options were investigated for these foods:

(a) where it was assumed that individuals always avoid the products that contain folic acid; and
(b) where it was assumed that individuals always select the products that contain folic acid.

This choice was given for the foods reported as consumed in the NNS that did not have a sufficiently detailed description to determine whether the food was folic acid fortified or not, yet it is known that there are fortified foods currently in the market place. The model was limited as a consumer behaviour model as it was assumed that respondents ate as reported in the 1995 Australian National Nutrition Survey (NNS) and 1997 New Zealand NNS and did not change or substitute one kind of food for another. For example, it is important to note that some foods in the NNSs were described as being fortified (e.g. breakfast cereals), therefore the above options for consumer choice were not applied to these foods. The consumer behaviour models assess folic acid/folate intake **for individuals only**, based on folic acid/naturally occurring folate concentrations in certain foods. Where mean dietary folic acid intakes or dietary folate intakes have been presented as a range, the lower bound represents option (a) and the upper bound represents option (b).

A limitation of this model type is that it is not a population estimate but rather gives the top and bottom ends of a range of possible intakes for an individual because it is not known how respondents in the NNS would actually have behaved had they been presented with a choice of products.

2.3 Comparison of concentration data used in different models

As discussed in Section 0, the folic acid concentrations in foods were weighted for the 'market share' model to take into account current and predicted market share of fortified versus unfortified products. For the 'consumer behaviour' models (Section 0), two different folic acid concentrations were used: option (a) where it is assumed that individuals always avoid the products that contain folic acid; and option (b) where it is assumed that individuals always select the products that contain folic acid. Figure 2 outlines how folic acid concentrations were calculated to be assigned to one food for the 'market share' and 'consumer behaviour' models.

Figure 2: Derivation of 'market share model' and 'consumer behaviour model' folic acid concentrations

Example: Fruit Juice

Currently, 50% of juice on the market contains folic acid at 30 µg folic acid/100 g

Market share model folic acid concentration:
Folic acid concentration = folic acid concentration in fortified juice x market share
= 30 µg folic acid/100 g x 50%
= 15 µg/100 g

Consumer behaviour model folic acid concentrations:

a) Consumer avoids fortified products
Folic acid concentration = 0 µg/100 g

b) Consumer selects fortified products
Folic acid concentration = 30 µg/100 g

The derivation of folic acid/ folate concentration data is discussed in detail in Attachment 7A for mandatory fortification, Attachment 7B for voluntary fortification and Attachment 7C for dietary folate intakes.

2.4 Food vehicles

At First Review, FSANZ was asked to review the fortification vehicle selected with a view to mandating flour for bread-making as the food vehicle for Australia to minimise the regulatory burden on industry and regulators. For New Zealand, the mandatory fortification food vehicle remained as 'all bread' in the First Review. The food vehicles for mandatory fortification for the First Review are discussed in detail in Attachment 7A – Mandatory Fortification.

In each of the three extended voluntary fortification scenarios (*Lower*, *Moderate* and *Higher*), either a new food group was added to the list of foods to be fortified or there was an increase in the proportion of foods within the group to be fortified (i.e. increased market share). The differences between the *Baseline*, *Lower*, *Moderate* and *Higher* voluntary fortification scenarios are outlined in detail in Attachment 7B – Voluntary Fortification.

3. Assumptions used in the dietary intake assessments

The general assumptions used in the dietary intake assessments for folic acid were provided in detail in Attachment 7 of the Final Assessment Report (FAR) for P295 – Consideration of Mandatory Fortification with Folic Acid. Those assumptions specific for the voluntary fortification assessments are given in Attachment 7B, and those for the dietary folate assessments in Attachment 7C

For the mandatory and voluntary folic acid fortification scenarios, it was assumed that there are no reductions in folic acid concentrations from storage.

4. Changes in food consumption over time

As discussed in the Final Assessment Report, dietary intake assessments based on 1995 or 1997 NNS food consumption data provide 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 (Cook *et al*., 2001). 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 'wheat flour for making bread' (Australia only) and 'bread' (New Zealand only) are the selected food vehicles 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*. 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 and Young Australian Survey (Roy Morgan, 2006a; Roy Morgan, 2006b), the Australian Dairy Corporation Survey (ADC) (Australian Dairy Corporation, 2003), Newspoll survey in Australia (George Weston Submission, 2006) and a UMR survey from New Zealand (NZFSA submission, 2006), as discussed in the FAR 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. However, despite these changes within the whole bread category, the proportion of people reporting consuming bread and overall amount consumed across different age and income groups appears to be similar now to that reported in 1995 and 1997.

5. Results

The overall aim of any fortification program is to ensure that folic acid intakes are maximised for the target groups whilst minimising intakes for all population groups that exceed the upper level of intake (UL). The estimated dietary folic acid intakes under the mandatory proposal for Australia and New Zealand at First Review gave equivalent outcomes to those presented at Final Assessment.

5.1 ***Baseline*** **dietary folic acid intakes**

The Baseline folic acid concentrations in foods were updated for the First Review, due to the availability of new concentration data. This resulted in an increase in estimated mean folic acid intakes for each population group assessed by FSANZ. For the target group of women aged 16-44 years, mean dietary folic acid intakes increased by 13 µg/day for Australia and 4 µg/day for New Zealand.

5.2 Comparison between estimated folic acid intakes for ***Baseline, Lower, Moderate and Higher*** extended voluntary fortification scenarios and ***Mandatory Fortification***

5.2.1 Market share (or population) model results

While folic acid intakes were estimated for a broad range of population sub-groups, the focus of the risk assessment was women of child-bearing age. Therefore, the results section of this report is primarily focussed on this population sub-group.

The estimated mean dietary folic acid intakes for Australian and New Zealand women of child-bearing age are shown in Table 2 and Figure 3 for *Baseline*, *Mandatory Fortification*, and the three extended voluntary fortification scenarios (*Lower*, *Moderate* and *Higher*).

Under *Mandatory Fortification*, there was an increase in folic acid intake from *Baseline* of 100 µg for Australia and 140 µg for New Zealand (see Table 2). Under the increased voluntary fortification scenarios (*Lower*, *Moderate* and *Higher*), there was an incremental increase in folic acid intake from *Baseline* of between 7-45 µg per day for Australia and 35-74 µg per day for New Zealand. Full results can be found in Appendix 2 (Table A2.1). Mean estimated folic acid intakes from food alone for women of child-bearing age did not achieve the desired folic acid intake of 400 µg per day for any of the scenarios.

The results indicate that New Zealand women of child-bearing age have a larger incremental increase in folic acid intake from *Baseline* for all scenarios compared to the same population group for Australia. This is due to fewer voluntary folic acid permissions being taken up by industry in New Zealand at *Baseline*.

Table 2: Estimated mean folic acid intakes from food, and increase in folic acid intake from *Baseline*, for Australian and New Zealand women of child-bearing age (16-44 years)

Scenario	Mean dietary folic acid intake (increase in folic acid intake from *Baseline*) (µg/day)[1]	
	Australia[2]	New Zealand[3]
Baseline	108	62
Mandatory Fortification[4]	208 (+100)	202 (+140)
Lower voluntary	115 (+7)	97 (+35)
Moderate voluntary	136 (+28)	119 (+57)
Higher voluntary	153 (+45)	136 (+74)

[1] Concentration of folic acid in foods is weighted according to the proportion of a food group that is fortified. This estimates dietary intakes over the long-term and across the population.
[2] Number of Australian respondents aged 16-44 years = 3,178.
[3] Number of NZ respondents aged 16-44 years = 1,509.
[4] For Australia: mandatory folic acid fortification of bread-making flour. Folic acid concentration is 200 µg/100 g flour. For New Zealand: mandatory folic acid fortification of bread. Folic acid concentration is 135 µg/100 g bread.

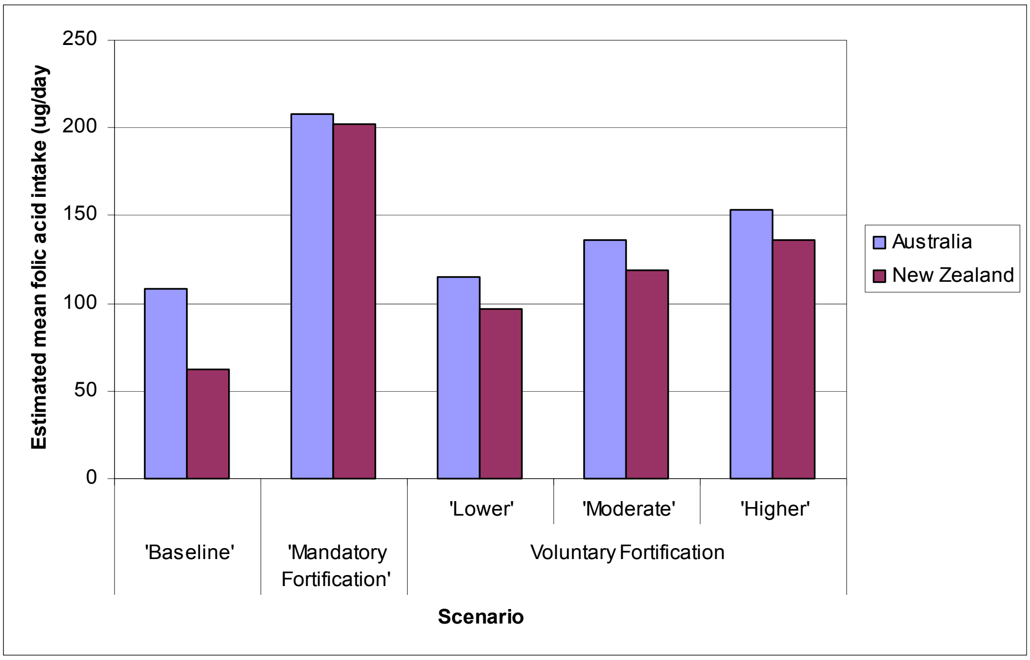


Figure 3: Estimated mean folic acid intakes from food, and increase in folic acid intake from Baseline, for Australian and New Zealand women of child-bearing age (16-44 years)

5.2.2 Consumer behaviour (or individual choices) models

Figure 4 for Australia and Figure 5 for New Zealand show the ranges of estimated mean folic acid intakes for women of child-bearing age. The lower and upper ends of the range represent results from the 'consumer behaviour' model: the lower bound indicates mean folic acid intakes for individuals who always avoid the products that contain folic acid; and the upper bound indicates mean folic acid intakes for individuals who always select the products that contain folic acid. The results from the 'market share' model are indicated by the black line within the range of estimated dietary folic acid intakes, and are representative of mean **population** intakes over a period of time.

Mean estimated folic acid intakes based on the 'market share' 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*), (<160 µg/day). Estimated folic acid intakes from voluntary permissions increased, as expected, as the level of uptake of permissions increased and number of foods with permissions increased.

The 'consumer behaviour' model range of results give an indication of the uncertainty of the outcome of a mandatory or extended voluntary approach for estimated folic acid intakes. Predicted folic acid intakes were more 'uncertain' for voluntary fortifications scenarios (*Lower*, *Moderate* and *Higher* extension) than mandatory fortification scenarios. The differences in potential ranges of intakes between *Baseline* and *Mandatory Fortification* scenarios and *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 or fixing 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 (Attachment 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.

The 'consumer behaviour' model results indicate that if an individual does select the fortified product wherever possible higher folic acid intakes can be achieved, depending on their food consumption amounts, but it is unknown how consumers would actually behave.

5.2.3 Food consumption patterns for women of child bearing age with low and high folic acid intakes

There were differences in the food consumption patterns between those with low folic acid intakes and those with high folic acid intakes. Generally, lower proportions of women of child bearing age with low folic acid intakes consumed breads, breakfast cereals, yeast extract spreads, milks, fruit juices and soy beverage than those with high folic acid intakes. Additionally, women of child bearing age with low folic acid intakes, on average, consumed lower amounts of these foods than those with high folic acid intakes. There did not appear to be a food consumed preferentially by women of child bearing age with low folic acid intakes that was feasible to fortify. The one possible exception was natural yoghurt and reduced or low fat flavoured yoghurt, which was consumed in greater amounts by Australian women in the low folic acid intake group, as was diet/low fat yoghurt in New Zealand, but by a relatively low proportion overall of the women of child bearing age (<10%) so did not meet the criteria for a suitable mandatory fortification vehicle[31]. However these data would support the consideration of low and reduced fat natural and flavoured 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 (see Attachment 7A Mandatory fortification for more details).

5.3 Estimated dietary intakes of folic acid for the non-target groups

Dietary folic acid intakes were estimated for the non-target group to assess the impact the mandatory and voluntary scenarios would have on public health and safety. Full results for the estimated dietary folic acid intakes for the non-target groups can be found in Appendix 2 (Table A2.2) for Australia and Table A2.3 for New Zealand). These results show a higher increase in estimated dietary folic acid intakes from *Baseline* under mandatory than voluntary fortification. As for women of child-bearing age, non-target groups in New Zealand have a larger incremental increase in folic acid intakes than Australia due to fewer voluntary folic acid permissions being taken up by industry in New Zealand at *Baseline*.

[31] See Sec 4.2, p72 FSANZ Issues Paper for criteria. Full fat yoghurt was also consumed in larger amounts by the low folic acid intake group but this is not considered a suitable vehicle for fortification as a greater proportion of children consume yoghurt than women of child bearing age and they are more likely to consume full fat yoghurt than reduced or low fat yoghurt (see Sec 4.2, p75 FSANZ Issues Paper)

Figure 4: Estimated mean folic acid intakes from food for Australian women of child-bearing age (16-44 years)

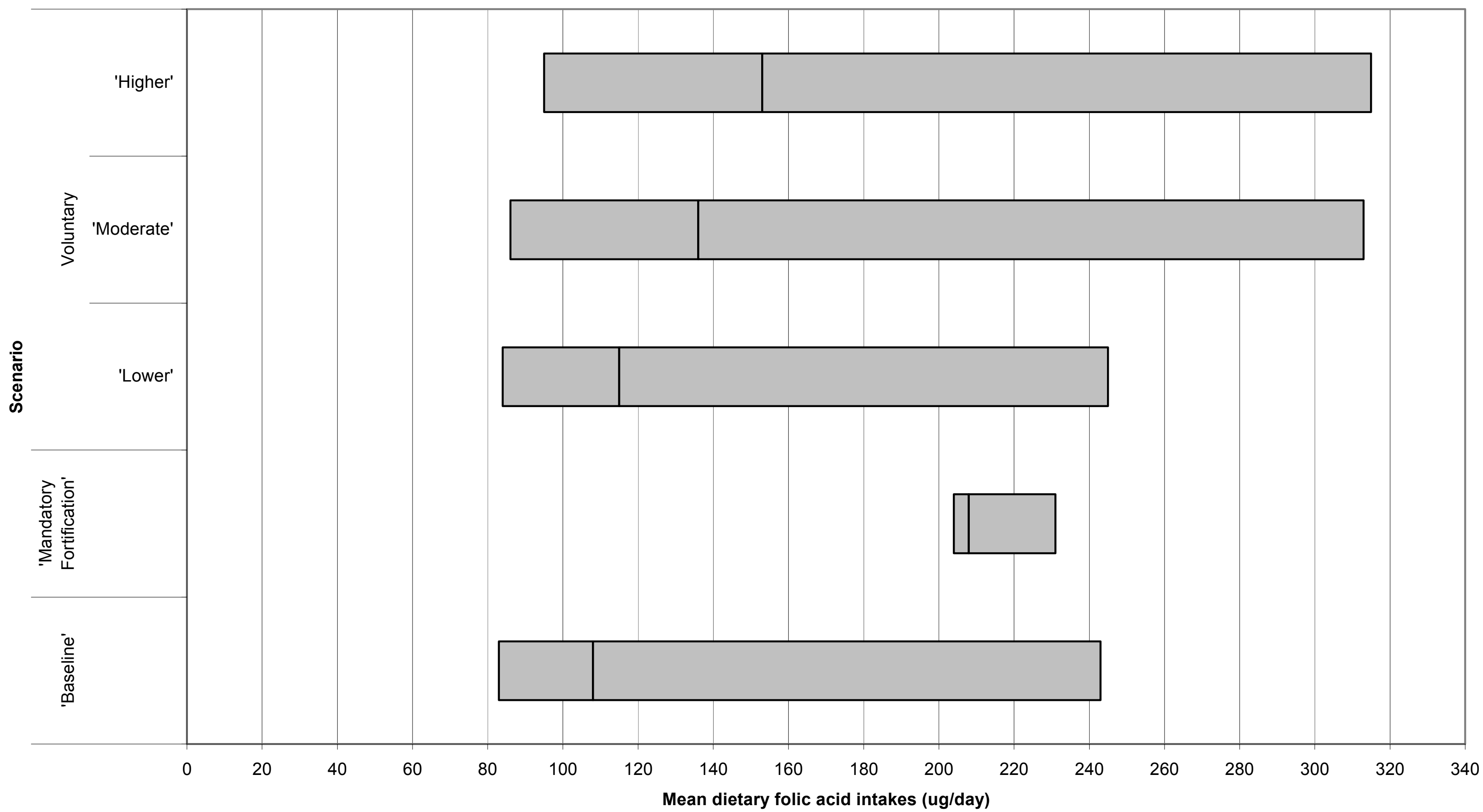
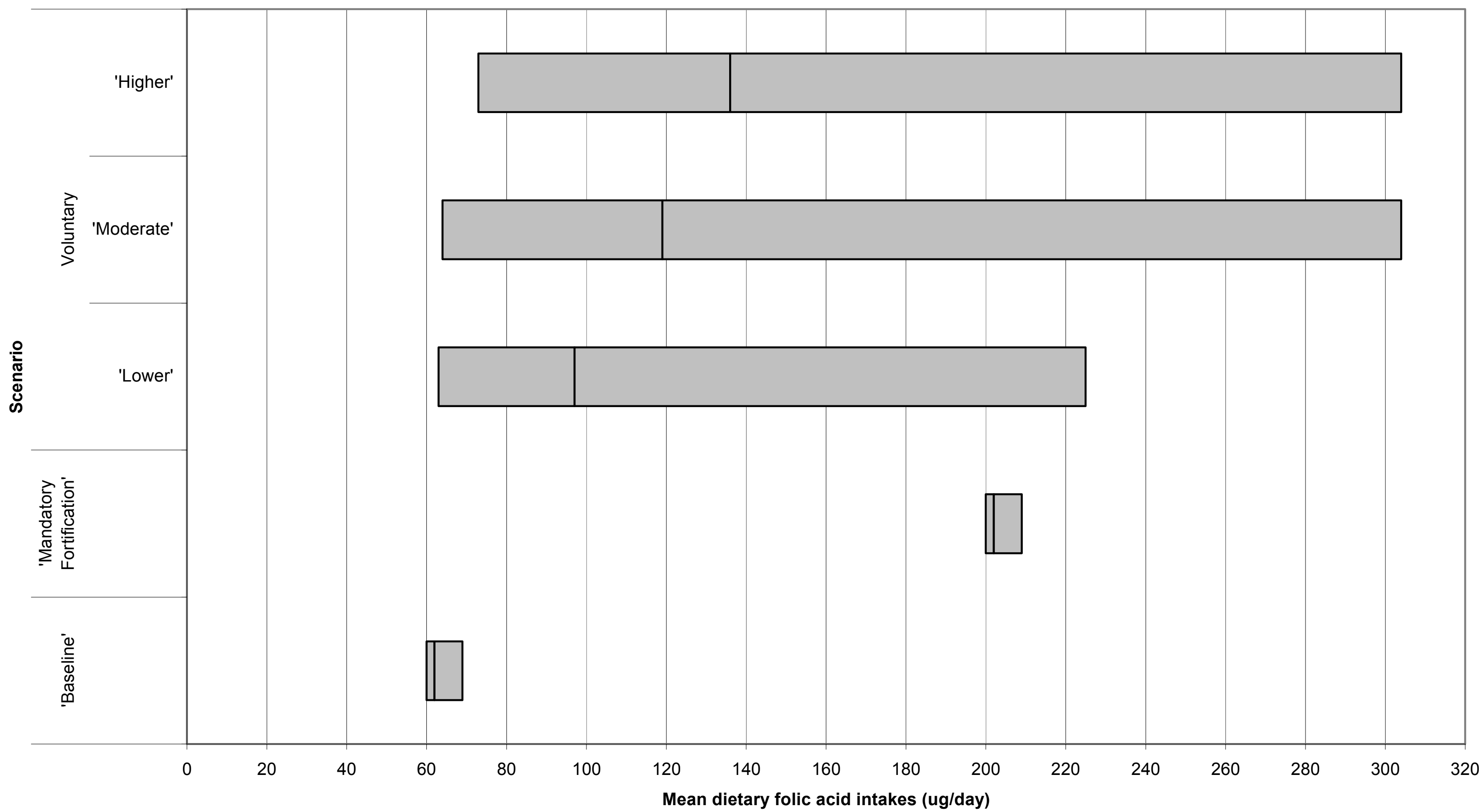


Figure 5: Estimated mean folic acid intakes from food for New Zealand women of child-bearing age (16-44 years)



5.4 Comparison of estimated dietary folic acid intakes with the Upper Level

In order to determine if the proposed level of increased uptake of voluntary folic acid fortification might be a concern to public health and safety, the estimated folic acid dietary intakes were compared with the Upper Level (UL). The UL is 'the highest average daily nutrient intake level likely to pose adverse health effects to almost all individuals in the general population' (National Health and Medical Research Council 2006).

The estimated dietary intakes for folic acid were determined for each individual and were compared to the relevant UL for the individual's age group and gender.

5.4.1 Proportion of the target group exceeding the Upper Level

The proportion of Australian and New Zealand women of child-bearing age exceeding the UL is shown in Table 3. The table illustrates that less than 1% of this population group exceeded the UL under all scenarios.

Table 3: Proportion of respondents with folic acid intakes above the Upper Level for Australian and New Zealand women of child-bearing age (16-44 years)

	% of respondents with folic acid intakes > UL[1]	
Scenario	**Australia[2]**	**New Zealand[3]**
Baseline	<1	<1
Mandatory Fortification[4]	<1	<1
Lower voluntary	<1	<1
Moderate voluntary	<1	<1
Higher voluntary	<1	<1

[1] Concentration of folic acid in foods is weighted according to the proportion of a food group that is fortified. This estimates dietary intakes over the long-term and across the population.
[2] Number of Australian respondents aged 16-44 years = 3,178.
[3] Number of NZ respondents aged 16-44 years = 1,509.
[4] For Australia: mandatory folic acid fortification of bread-making flour. Folic acid concentration is 200 µg/100 g flour. For New Zealand: mandatory folic acid fortification of bread. Folic acid concentration is 135 µg/100 g bread.

Table 4: Proportion of respondents with folic acid intakes above the Upper Level for various Australian population non-target sub-groups

			% of respondents with folic acid intakes > UL[1]				
Pop. group	**Upper level (µg/day)**	**No. of respondents**	***Baseline***	***Mandatory Fortification***[2]	***Lower voluntary***	***Moderate voluntary***	***Higher voluntary***
2-3 yrs	300	383	2	9	2	2	4
4-8 yrs	400	977	1	4	1	2	3
9-13 yrs	600	913	1	2	1	1	2
14-18 yrs	800	734	<1	2	<1	<1	<1
19-29 yrs	1,000	2,203	<1	<1	<1	<1	<1
30-49 yrs	1,000	4,397	<1	<1	<1	<1	<1
50-69 yrs	1,000	3,019	<1	<1	<1	<1	<1
70 yrs & above	1,000	1,232	0	0	0	0	0

[1] Concentration of folic acid in foods is weighted according to the proportion of a food group that is fortified. This estimates dietary intakes over the long-term and across the population.
[2] Mandatory folic acid fortification of bread-making flour. Folic acid concentration is 200 µg/100 g flour.

Table 5: Proportion of respondents with folic acid intakes above the Upper Level for various New Zealand population non-target sub-groups

			% of respondents with folic acid intakes > UL[1]				
Pop. group	**Upper level (µg/day)**	**No. of respondents**	***Baseline***	***Mandatory Fortification[2]***	***Lower voluntary***	***Moderate voluntary***	***Higher voluntary***
15-18 yrs	800	246	0	<1	0	0	0
19-29 yrs	1,000	804	0	<1	0	0	0
30-49 yrs	1,000	1,883	<1	<1	<1	<1	<1
50-69 yrs	1,000	1,147	0	<1	0	0	0
70 yrs & above	1,000	556	0	0	0	0	0

[1] Concentration of folic acid in foods is weighted according to the proportion of a food group that is fortified. This estimates dietary intakes over the long-term and across the population.
[2] Mandatory folic acid fortification of bread. Folic acid concentration is 135 µg/100 g bread.

5.4.2 Proportion of the non-target population groups exceeding the UL

The proportion of each non-target population group exceeding the UL is shown in Table 4 for Australia and Table 5 for New Zealand. Results on gender differences can be found in Appendix 3 (Table 3A.1 for Australia and table 3A.2 for New Zealand).

For Australia, respondents aged 2-3 years and 4-8 years were the most likely of the non-target groups to have intakes exceeding the UL under all scenarios. For 2-3 year old children, 2-4% were expected to exceed the UL under voluntary fortification and 9% under mandatory fortification. For 4-8 year old children, 1-3% were expected to exceed the UL under voluntary fortification and 4% under mandatory fortification.

5.5 For New Zealand no population sub-group exceeded the UL, with the exception of the population aged 30-49 years (less than 1%). Estimated 95th percentile dietary folic acid intakes as a proportion of the Upper Level

An assessment was made of 95th percentile folic acid intakes as a proportion of the UL under the 'consumer behaviour' model to provide an indication of the level of risk **for an individual** who eats large amounts of the fortified foods and goes out of their way to select the fortified version wherever there is a choice. This is not a prediction of expected 95th percentile intakes for the population as a whole.

Estimated 95th percentile folic acid intakes from food, as a proportion of the UL, for various Australian population sub-groups are shown in Table 6 and in Table 7 for New Zealand. The results show that high consumer (95th percentile) intakes of folic acid for the Australian population aged 2 years and above and the New Zealand population aged 15 years and above were either at or below the UL. For Australian children aged 2-3 years and 4-8 years, high consumer intakes of folic acid were estimated to exceed the UL at *Baseline*, under the three extended voluntary fortification scenarios (*'Lower*, *Moderate*, and *Higher*), and under *Mandatory Fortification*. However, it is considered very unlikely that young children would always be given the fortified version wherever there is a choice on a regular basis, as these products are not targeted at this age group.

The high consumer (95th percentile) folic acid intakes, as a proportion of the UL, were estimated to be lowest for the *Mandatory Fortification* scenario for both Australia and New Zealand. By mandating or fixing the level of folic acid in wheat flour for bread making or bread, the resultant level in some breads may decrease compared with that added under current permissions.

Table 6: Estimated 95th percentile folic acid intakes from food as a proportion of the Upper Level for various Australian population sub-groups

Population group	No. of respondents	95th percentile folic acid intake from food as a proportion of the UL (%) Baseline	*Lower voluntary*	*Moderate voluntary*	*Higher voluntary*	*Mandatory Fortification*
Females 16-44 years	3,178	50	50	60	60	45
2-3 years	383	140	140	170	170	130
4-8 years	977	120	120	150	150	110
2 years and above	13,858	80	80	100	100	75

Table 7: Estimated 95th percentile folic acid intakes from food as a proportion of the Upper Level for various New Zealand population sub-groups

Population group	No. of respondents	95th percentile folic acid intake from food as a proportion of the UL (%) Baseline	*Lower voluntary*	*Moderate*	*Higher*	*Mandatory Fortification*
Females 16-44 years	1,509	20	40	55	55	35
15 years and above	4,636	25	50	65	65	45

5.6 Major contributors to estimated dietary folic acid intakes

The major contributors to folic acid intakes were estimated for women of child-bearing age and the general population. Percent contributors were calculated from data from a single 24-hour recall. The results are shown in Table 8.

Breakfast cereal, bread and yeast extract were major contributors (>5%) to folic acid intakes for the population groups assessed under all scenarios. The contribution of bread under mandatory fortification was the highest of the scenarios. Under voluntary fortification, the contribution of bread increased as the market share increased. Under the higher proposed extension in voluntary fortification, low and reduced fat yoghurt (plain and fruit or flavoured) and fruit juice were also major contributors.

6. Additional calculations to estimate folic acid intakes from food and supplements

Currently women planning pregnancy are advised to take folic acid supplements. Consequently, additional calculations were undertaken by FSANZ to estimate folic acid intakes assuming women of child-bearing age received folic acid from folic acid supplements in addition to receiving folic acid via fortification of foods.

Additional calculations were not conducted for each of the non-target groups due to limited information available on supplement use. Also, there are no specific nutrition policies that specify that members of the population other than the target group should take folic acid supplements.

6.1 Calculation of estimated folic acid intakes from food and supplements

Two calculations were made for Australian and New Zealand women of child-bearing age. For Australia, it was assumed that the target group received an additional 200 µg or 500 µg of folic acid a day from supplements. For New Zealand, it was assumed the target group received an additional 200 µg or 800 µg of folic acid a day from supplements. These concentrations were selected because in Australia, folic acid only supplements typically contain 500 µg of folic acid, while New Zealand folic acid supplements typically contain 800 µg of folic acid (NZ Ministry of Health advice is for women capable of planning a pregnancy to take the 800 µg of folic acid supplement 4 weeks before and 12 weeks after conception). The lower concentration of 200 µg was based on recently published results (Bower *et al*., 2005) which found that 28.5% of women in the Western Australian study reported taking 200 µg or more per day from supplements.

To estimate folic acid intake from food and supplements, the intake of folic acid from supplements was added to the estimated mean folic acid intake from food for this population group. It was assumed that all women aged 16-44 years consumed a folic acid supplement. The Australian 1995 NNS indicated 7.6% of females aged 18-24 years and 11.4% of females aged 25-44 years took a folic acid supplement on the day before the NNS survey (Lawrence *et al*., 2001). Naturally occurring folates in food were not taken into account.

6.2 Estimated dietary intakes of folic acid from food and supplements for the target group

The estimated mean dietary folic acid intakes from food and supplements for Australian and New Zealand women of child-bearing age are shown in Table 9 and Figure 6 for Australia and Figure 7 for New Zealand. Full results can be found in Appendix 4 (Table A.4.1 for Australia and table A4.2 for New Zealand).

These results show an increase in estimated dietary folic acid intakes from baseline for all scenarios when additional folic acid is consumed from supplements. The highest increase was under mandatory fortification.

Table 8: Major contributors (>5%) to folic acid intakes for Australia and New Zealand population sub-groups

Country	Population group	Scenario	Major contributors (%)				
			Breads	**Breakfast cereals**	**Yeast extracts**	**Low/Red. fat yoghurt**	**Fruit juice**
Australia	2 years and above	*Baseline*	19	51	24		
		Lower voluntary	23	48	22		
		Moderate voluntary	23	48	22		
		Higher voluntary	27	38	17	5	5
		Mandatory Fortification[1]	55	27	13		
	Females 16-44 years	*Baseline*	20	47	28		
		Lower voluntary	23	44	26		
		Moderate voluntary	23	44	26		
		Higher voluntary	26	33	19	6	7
		Mandatory Fortification[1]	56	24	14		

Country	Population group	Scenario	Major contributors (%)				
			Breads	Breakfast cereals	Yeast extracts	Low/Red. fat yoghurt	Fruit juice
New Zealand	15 years and above	*Baseline*		61	35		
		Lower voluntary	33	40	23		
		Moderate voluntary	33	40	23		
		Higher voluntary	36	29	17	7	5
		Mandatory Fortification[1]	69	19	11		
	Females 16-44 years	*Baseline*		58	37		
		Lower voluntary	34	36	23		
		Moderate voluntary	34	37	23		
		Higher voluntary	35	26	17	8	7
		Mandatory Fortification[1]	70	18	11		

Note: the shaded areas indicate that the food was not a major contributor to folic acid intakes for the population group.
[1] For Australia: mandatory folic acid fortification of bread-making flour. Folic acid concentration is 200 µg/100 g flour. For New Zealand: mandatory folic acid fortification of bread. Folic acid concentration is 135 µg/100 g bread.

Table 9: Estimated mean folic acid intakes from food and supplements for Australian and New Zealand women of child-bearing age (16-44 years)

	Mean folic acid intake from food and supplements (µg/day)[1]			
	Australia[2]		New Zealand[3]	
Scenario	+ 200 µg	+ 500 µg	+ 200 µg	+ 800 µg
Baseline	308	608	262	862
Mandatory[4]	408	708	402	1002
Lower voluntary (FAR)	315	615	297	897
Moderate voluntary	336	636	319	919
Higher voluntary	353	653	336	936

[1] Concentration of folic acid in foods is weighted according to the proportion of a food group that is fortified. This estimates dietary intakes over the long-term and across the population.
[2] Number of Australian respondents aged 16-44 years = 3,178.
[3] Number of NZ respondents aged 16-44 years = 1,509.
[4] For Australia: mandatory folic acid fortification of bread-making flour. Folic acid concentration is 200 µg/100 g flour. For New Zealand: mandatory folic acid fortification of bread. Folic acid concentration is 135 µg/100 g bread.

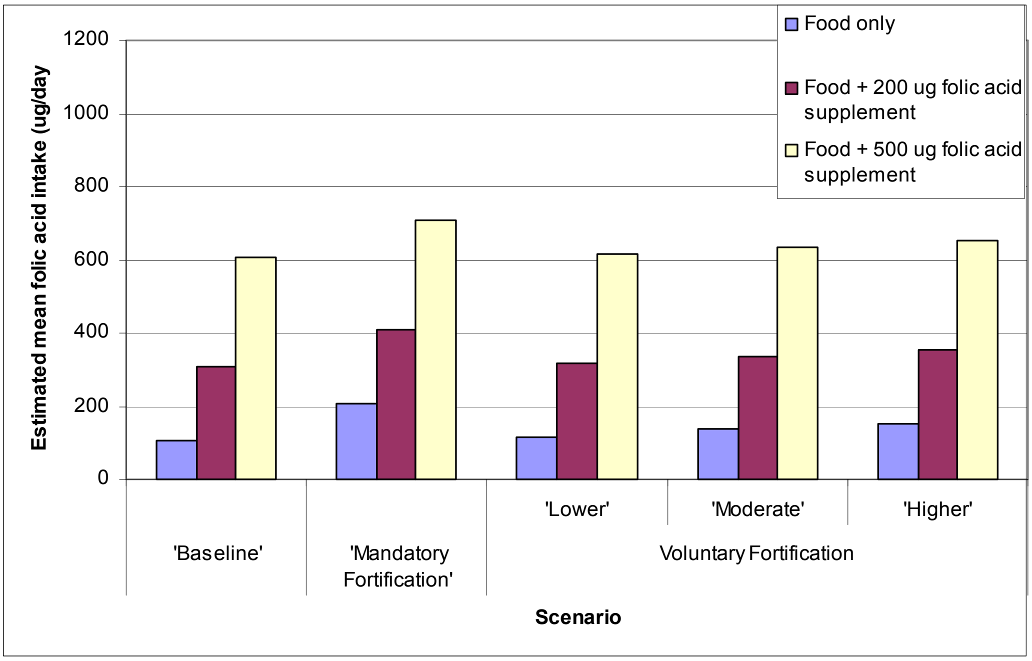


Figure 6: Estimated mean folic acid intakes from food and supplements for Australian women of child-bearing age (16-44 years)

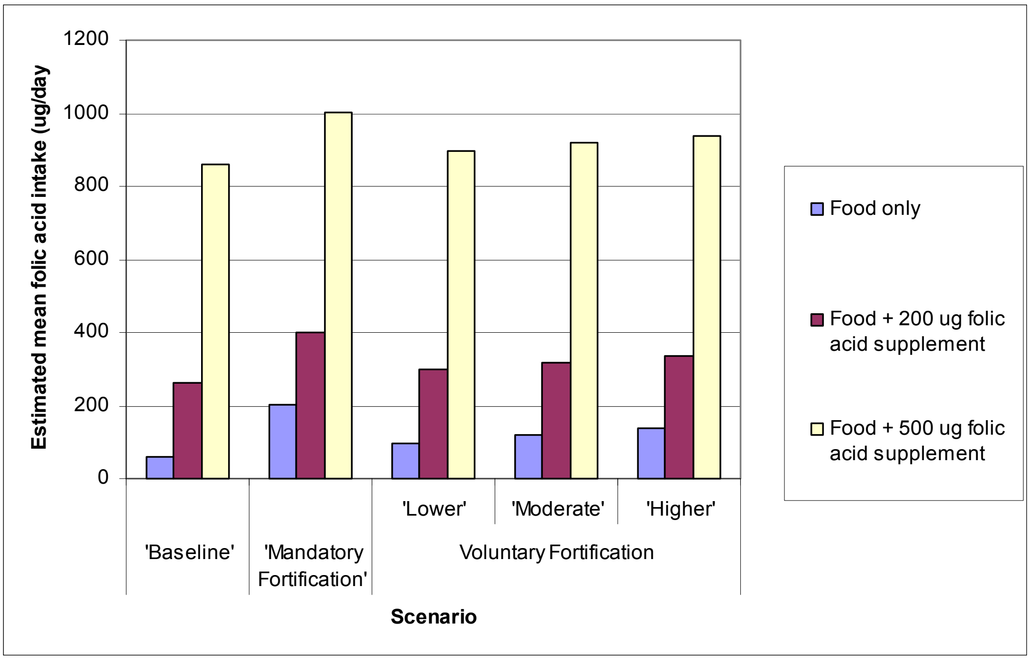


Figure 7: Estimated mean folic acid intakes from food and supplements for New Zealand women of child-bearing age

6.3 Comparison of estimated dietary intakes from food and supplements with the recommended intake

The proportion of Australian and New Zealand target group with folic acid intakes of at least 400 µg per day from food and supplements are shown in. The results indicate that, without the consumption of folic acid supplements, around 5% of Australian and 3% of New Zealand women of child-bearing age met the recommended 400 µg of folic acid per day under all scenarios.

When a 200 µg folic acid per day supplement was considered, under voluntary fortification, between 4% and 21% of Australian and New Zealand women of child-bearing age were estimated to meet the recommended intake of folic acid. Under mandatory fortification, approximately 40% of Australian and New Zealand women of child-bearing age were estimated to meet the recommended intake of folic acid.

If a 500 µg or 800 µg folic acid supplement were to be consumed by all women of child-bearing age, irrespective of voluntary or mandatory fortification, 100% of women of child-bearing age would meet the recommended daily amount of folic acid.

Table 91: Proportion of respondents with folic acid intakes of at least 400 µg/day from food and supplements for Australian and New Zealand women of child-bearing age (16-44 years)

	% respondents with folic acid intakes ≥ 400 µg[1]					
		Australia[2]			New Zealand[3]	
Scenario	**Mean intake no supp.**	**Mean intake + 200 µg**	**Mean intake + 500 µg**	**Mean intake no supp.**	**Mean intake + 200 µg**	**Mean intake + 800 µg**
Baseline	2	11	100	<1	4	100
Mandatory[4]	4	38	100	3	42	100
Lower voluntary proposal (FAR)	3	12	100	<1	8	100
Moderate voluntary proposal	3	16	100	1	12	100
Higher voluntary proposal	3	21	100	2	17	100

[1] Concentration of folic acid in foods is weighted according to the proportion of a food group that is fortified. This estimates dietary intakes over the long-term and across the population.
[2] Number of Australian respondents aged 16-44 years = 3,178.
[3] Number of NZ respondents aged 16-44 years = 1,509.
[4] For Australia: mandatory folic acid fortification of bread-making flour. Folic acid concentration is 200 µg/100 g flour. For New Zealand: mandatory folic acid fortification of bread. Folic acid concentration is 135 µg/100 g bread.

6.4 Comparison of the estimated dietary intakes from food and supplements with the Upper Level

The proportion of the Australian and New Zealand target group exceeding the UL when supplements are taken is shown in Table 11 and Figure 8. The results indicate that when Australian and New Zealand women of child-bearing age consume additional folic acid from a supplement, there is likely to be an increase in the proportion of the target group exceeding the UL of 800 µg of folic acid per day for women aged 16-18 years and 1000 µg of folic acid per day from women aged 19-44 years.

The proportion of respondents exceeding the UL increased as the concentration of folic acid in the supplement increased. There was no change in the proportion of the Australian target population exceeding the UL with a folic acid supplement of 200 µg per day under all scenarios. There was no change in the proportion of the Australian target group exceeding the UL with a folic acid supplement of 500 µg per day from *Baseline* to the voluntary scenarios. There was a 50% increase in the proportion of the Australian target population exceeding the UL with a folic acid supplement of 500 µg per day from *Baseline* to the *Mandatory Fortification* scenario (from 2% to 3%).

There was also no change in the proportion of the New Zealand target population exceeding the UL with a folic acid supplement of 200 µg per day under the all scenarios. Due to the high folic acid content of the supplement at 800 µg, a large proportion of New Zealand women were likely to exceed the UL, particularly under *Mandatory Fortification*. There was a 320% increase in the proportion of the New Zealand target population exceeding the UL with a folic acid supplement of 800 µg per day from *Baseline* to the *Mandatory Fortification* scenario (from 10% to 42%). There is a 120% increase in the proportion of the New Zealand target population exceeding the UL with a folic acid supplement of 800 µg per day from the *Baseline* to the *Higher* proposed voluntary fortification extension (from 10% to 22%).

One of the potential concerns with extended voluntary fortification is that an individual consumer who always selects the product containing folic acid may in fact consume an excessive amount of folic acid if they also consume high amounts of the fortified foods i.e. high folic acid consumer, as intakes tend to be higher than for a mandatory scenario at the top end of the range (see Figure 4 and Figure 5). Assessment of the 95th percentile folic acid intake for this consumer behaviour model indicates that intakes in the target group may exceed the UL from food alone, and were these products also always consumed by children in the household, their intakes were also more likely to exceed the UL than for a mandatory scenario, however it is considered unlikely that children would always select or be given the fortified product (see Table A2.2 and Table A2.3 in Appendix 2).

Table 112: Proportion of respondents with folic acid intakes above the Upper Level from food and supplements for Australian and New Zealand women of child-bearing age (16-44 years)

	% respondents with folic acid intakes from diet and supplements > UL[1]			
	Australia[2]		New Zealand[3]	
Scenario	**Mean intake + 200 µg supplement**	**Mean intake + 500 µg supplement**	**Mean intake + 200 µg supplement**	**Mean intake + 800 µg supplement**
Baseline	<1	2	<1	10
Mandatory Fortification[4]	<1	3	<1	46
Lower voluntary	<1	2	<1	14
Moderate voluntary	<1	2	<1	18
Higher voluntary	<1	2	<1	22

[1] Concentration of folic acid in foods is weighted according to the proportion of a food group that is fortified. This estimates dietary intakes over the long-term and across the population.
[2] Number of Australian respondents aged 16-44 years = 3,178.
[3] Number of NZS respondents aged 16-44 years = 1,509.
[4] For Australia: mandatory folic acid fortification of bread-making flour. Folic acid concentration is 200 µg/100 g flour. For New Zealand: mandatory folic acid fortification of bread. Folic acid concentration is 135 µg/100 g bread.

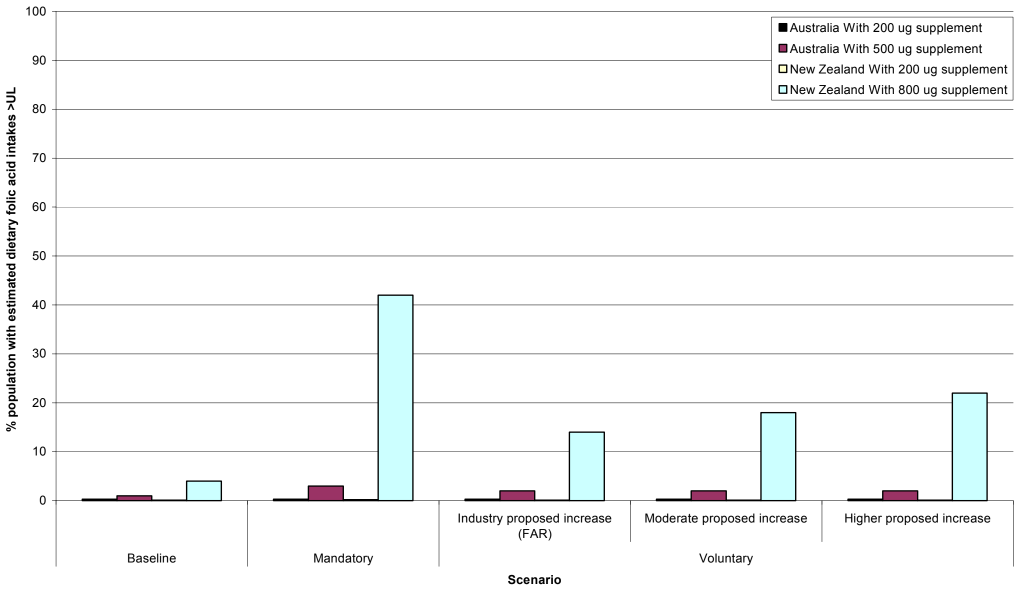


Figure 8: Proportion of respondents with folic acid intakes above the Upper Level from food and supplements for Australian and New Zealand women of child-bearing age (16-44 years)

7. Other Fortification Issues Assessed For The First Review

7.1 New Zealand 2002 National Children's Nutrition Survey data

FSANZ does not currently hold food consumption data for New Zealand children aged 2-14 years from the 2002 National Children's Nutrition Survey (CNS). The New Zealand Food Safety Authority (NZFSA) commissioned the University of Otago (LINZ Research group) to undertake a dietary intake assessment for children aged 5-14 years, based on data from the 2002 New Zealand Children's Nutrition Survey. The results for the proportion of children exceeding the upper level (UL) for folic acid for the proposed mandatory fortification of bread were submitted to the Ministerial Council in October 2006 at the same time as the FAR and were higher than those reported for Australian children at FAR for the same age group. The level of folic acid fortification as proposed by FSANZ for FAR was 135 micrograms per 100 grams of bread and assessments for this analysis of New Zealand 2002 CNS are based on this scenario.

As part of the First Review, FSANZ assessed the difference between the proportion of New Zealand children and Australian children exceeding the upper limit. To do this FSANZ analysed the dietary intake data from LINZ, specifically:

1. the methodology;
2. folic acid concentrations; and
3. foods assumed to be fortified.

A summary of the methodologies used for the FSANZ and LINZ assessments for Australian and New Zealand children are outlined in Figure 9 below.

	University of Otago (LINZ Research group)	FSANZ
Methodology	1. Single day un-adjusted model 2. Population weighted	day adjusted model opulation weighted
Folic acid concentrations	Similar	
Population group assessed	5-8 years for New Zealand, 2002 NNS	4-8 years for Australia, 1995 NNS
Other differences	1. Similar foods assumed to be fortified but foods coded slightly differently in the 2002 NZ survey compared to the 1995 NNS 2. Uptake of voluntary fortification permissions is different between the countries. 3. Potentially different food consumption patterns between the two survey periods and/or countries.	

Figure 9: Summary of the methodologies used for the FSANZ and LINZ Research Group assessments of folic acid intakes in children for Australia and New Zealand

In both the FSANZ and the LINZ Research group assessments, the mandatory folic acid fortification concentrations used and the foods assumed to be fortified were similar. The dietary intake assessments for *Baseline* were performed using analytical food composition data, where available, which take into account overages (overages were considered only where the information on folic acid content was taken from the claimed amount on the food label). The mean rather than maximum concentration of folic acid in foods reported was used to estimate dietary intakes of folic acid as this reflects the expected distribution of folic acid 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.

The methodologies for the FSANZ and the LINZ Research group assessments were different. The methodology used by the University of Otago (LINZ Research group) was a single day un-adjusted method and the methodology used by FSANZ was a two-day adjusted method. Using a single day of food consumption data can result in a broader distribution of folic acid intakes and, potentially, a higher estimated proportion of the population group with intakes above the UL which, in turn, overestimates the level of risk to the population group. Adjusted nutrient intakes better reflect 'usual' daily nutrient intakes (see Appendix 1: How were the estimated dietary intakes estimated in Attachment 7a of the FAR).

However, it is important to note that there are limitations in comparing the results from the FSANZ assessment and the LINZ assessment since different age groups were investigated (4-8 years, for Australia; 5-8 years for New Zealand). FSANZ investigated whether using a single day un-adjusted modelling method for 4-8 year old Australian children would explain the difference between Australian and New Zealand children. These data are presented in Table 12 below. It was concluded that using a single day un-adjusted methodology may account for some of the differences in results as using for the second day adjustment for the Australian children decreased the proportion of children exceeding the UL from 9% to 3%.

In the 2002 New Zealand Children's Nutrition Survey, there was over-sampling of the Maori and Pacific children. Population weighting was therefore used by the LINZ Research group in their assessment to make the survey sample better reflect the New Zealand children's population so that conclusions could be drawn about New Zealand children in general. The 1995 Australian National Nutrition Survey did not require weighting in order to make comments about the folic acid intakes of Australian children.

The impact of weighting is unknown but FSANZ has been advised by the NZFSA that weighting is not expected to be a major contributor to the reported differences in the proportion of children with intakes >UL. However, if the different groups of New Zealand children had different bread consumption patterns it may do so.

There is evidence from the dietary modelling conducted by FSANZ using the 1995 and 1997 NNSs that New Zealand estimated dietary folic acid intakes for adults were lower than those for Australia. This difference could be due to different food consumption patterns, seasonality of consumption and/or lower levels of uptake of voluntary fortification permissions. It would be expected that similar food consumption patterns to adults would be found for the younger children in New Zealand, however it is possible that changes in food consumption in the 7 year period from 1995 through to 2002 may account for some differences in the estimated folic acid intakes. FSANZ will be in a position to use the 2002 CNS data in DIAMOND later in 2007, so can rerun these estimates at that time.

Table 12: Comparison between proportion of Australian children aged 4-8 years and New Zealand children aged 5-8 years exceeding the UL using different dietary intake methodologies (single day unadjusted versus two day adjusted models) for the FAR Mandatory fortification scenario of 135 µg folic acid /100 g bread

Gender	% above UL		
	New Zealand (LINZ data)	Australia (FSANZ FAR)	Australia (FSANZ FAR)
	Single day un-adjusted model 5-8 yrs	Two day adjusted model 4-8 yrs	Single day un-adjusted model 4-8 yrs
All		3	9
Males	13.8	5	7
Females	8.2	<1	2

FSANZ has used the best available food consumption data available for the folic acid intake assessments (1995 and 1997 NNSs) and validated these with more up-to-date studies that assessed bread consumption in the Australian and New Zealand populations. Results were published in the FAR.

7.2 Mandatory fortification and the national nutrition guidelines

7.2.1 Contributions of high fat and/or high sugar breads to estimated folic acid intakes

The First Review request indicated that the mandatory fortification of all bread products with folic acid may contravene national nutrition policies as the definition of bread included sweet buns and other bread products to which fat and/or sugar may be added pre-baking. Also, breads to which fat and/or sugar are added after baking would also be fortified with folic acid i.e. buns filled or topped with cream and jam and coffee scrolls topped with icing. The First Review request questioned whether it would be appropriate to apply qualifying or disqualifying criteria for bread to be fortified.

To determine the impact of fortifying breads with added fat and/or sugar with folic acid, the proportion of fat and sugar in bread products and their contribution to folic acid intakes was investigated as follows:

- Determining the proportion of fat and sugar in sweet fancy buns and other bread products to which fat and/or sugar may be added pre- and post-baking was compared to 'standard' breads i.e. white, wholemeal, grain.
- Calculating the contribution of sweet fancy buns and other bread products to which fat and/or sugar may be added pre- and post-baking to total folic acid intakes was compared to 'standard' plain breads i.e. white, wholemeal, grain.

7.2.1.1 Proportion of fat and sugar in bread products

The proportion of fat and sugar in bread products is shown in Table 13. Bread products have been separated into three categories: (1) plain bread and rolls; (2) flat breads and English-style muffins; and (3) fancy breads with added fat and/or sugar. The latter category includes those products that conform to the criteria outlined in the First Review request i.e. fat and/or sugar added pre- or post-baking.

Table 13: Proportion of fat and sugar in bread products (%) in Australia and New Zealand (range)

	Proportion of fat in bread (% range)		Proportion of sugar in bread (% range)	
	Australia	**New Zealand**	**Australia**	**New Zealand**
Plain bread and rolls	1 – 5	<1 – 3	2 – 7	<1 – 6
White bread and rolls	1 – 5	<1 – 3	2 – 7	2 – 3
Fibre-increased bread and rolls	3 – 4	<1	2 – 4	2 - 4
Wholemeal bread and rolls	1 – 5	1 – 2	2 – 6	1 – 2
Mixed grain bread and rolls	3 – 4	<1 – 2	2 – 4	1 – 2
Rye bread and rolls	1 – 4	<1 – 3	3 – 5	<1 – 6
Flat breads and English-style muffins	1 – 12	<1 – 8	<1 – 8	<1 – 14
Flat breads	2 – 12[2]	<1 – 8[3]	3 – 8[4]	<1 – 6[5]
English-style muffins	1 – 4	2 – 8	<1 – 2	2 – 14[6]
Fancy breads with added fat and/or sugar	3 – 14	<1 – 28	2 – 22	1 – 28
Fruit	3 – 5	3 – 6	2 – 21	11 – 19
Garlic	13 – 14	28	4	2
Cheese topped	3 – 7	3 – 5	2 – 4	2
Flavoured[1]	3 – 6	<1 – 6	2 – 3	1 – 2
Buns and yeast-based products	4 – 14	<1 – 9	8 – 22	4 – 28

[1] Includes focaccia.
[2] Upper figure is for Naan. Next highest figure is 3% (wholemeal, toasted).
[3] Upper figure is for Naan. Next highest figures are 4% (Chinese bread); and 2% (wholemeal (toasted).
[4] Upper figure is for Naan. Next highest figure is 4% (white, toasted).
[5] Upper figure is for Chinese bread. Next highest figures are: 4% (Naan); 3% (takakau); and 2% (wholemeal, toasted).
[6] Upper figure is for muffin split, with fruit.

7.2.1.1.1 Proportion of fat in bread products

In Australia, the proportion of fat in plain bread and rolls ranged from 1% to 5%. The proportion of fat in fancy breads with added fat and/or sugar ranges from 3% to 14%. The breads containing the highest proportion of fat were garlic bread and buns and yeast-based products (up to 14%).

In New Zealand, the proportion of fat in plain bread and rolls ranged from less than 1% to 3%. The proportion of fat in fancy breads with added fat and/or sugar ranged from less than 1% to 28%. Garlic bread contained the highest proportion of fat at 28%.

7.2.1.1.2 Proportion of sugar in bread products

In Australia, the proportion of sugar in plain bread and rolls ranged from 2% to 7%. The proportion of fat in fancy breads with added fat and/or sugar ranged from 2% to 22%. The breads containing the highest proportion of sugar were fruit bread (up to 21%) and buns and yeast-based products (up to 22%).

In New Zealand, the proportion of sugar in plain bread and rolls ranged from less than 1% to 6%. The proportion of sugar in fancy breads with added fat and/or sugar ranged from 1% to 28%. The breads containing the highest proportion of sugar were buns and yeast-based products (up to 28%).

7.2.1.2 Contribution of bread products to folic acid intakes

The contribution of bread products to folic acid intakes for various Australian and New Zealand population groups is shown in Table 14. Bread products have been separated into three categories: (1) plain breads; (2) sweet breads; and (3) fancy breads with added fat and/or sugar.

7.2.1.3 Risk characterisation

In Australia, garlic bread and buns and yeast-based products were identified as containing the highest proportion of fat (14%), whilst fruit bread, and buns and yeast-based products were identified as containing the highest proportion of sugar (21% and 22% respectively). These products were included in the 'fancy breads with added fat and/or sugar' category that made a minor contribution to folic acid intakes (between 1% and 4% for the three population groups examined).

In New Zealand, garlic bread was identified as containing the highest proportion of fat (28%), whilst buns and yeast-based products were identified as containing the highest proportion of sugar (28%). These products were included in the 'fancy breads with added fat and/or sugar' category that made a minor contribution to folic acid intakes (approximately 6% for both population groups examined).

7.2.1.4 Conclusions

Whilst sweet buns and other fancy bread products to which fat and/or sugar may be added pre-baking and fancy breads to which fat and/or sugar are added after baking contain a varying proportions of fat and sugar, their contribution to folic acid intake for the target population group (Australian and New Zealand females aged 16-44 years), Australians aged 2-3 years and 2 years and above, and New Zealanders aged 15 years and above was minimal. The highest contribution of fancy breads with added fat and/or sugar to folic acid intakes was approximately 6% for the New Zealand population.

Table 14: Contribution of bread products to folic acid intakes (%) for various Australian and New Zealand population groups

	Contribution to folic acid intake (%)				
	Australia			New Zealand	
Bread product	**2-3 years**	**Females 16-44 years**	**2 years and above**	**Females 16-44 years**	**15 years and above**
Plain bread and rolls	41	44	45	56	57
White bread and rolls	28	29	29	33	29
Fibre-increased bread and rolls	4	2	2	3	3
Wholemeal bread and rolls	7	9	10	9	12
Mixed grain bread and rolls	2	4	4	7	9
Rye bread and rolls	<1	<1	<1	4	4
Flat breads and English-style muffins	<1	2	1	2	<1
Flat breads	<1	1	<1	<1	<1
English-style muffins	<1	<1	<1	<1	<1
Fancy breads with added fat and/or sugar	1	4	3	6	6
Fancy bread[1]	<1	3	2	4	4
Buns and yeast-based products	<1	1	1	2	2

[1] Fruit, garlic, cheese-topped, flavoured.

In Australia, plain bread and rolls contributed between 41% and 45% to folic acid intakes. White bread and rolls made the largest contribution to folic acid intakes (28% to 29%), followed by wholemeal bread and rolls (7% to 10%). Fancy breads with added fat and/or sugar contributed between 1% and 4% to folic acid intakes.

In New Zealand, plain bread and rolls contributed 56% and 57% to folic acid intakes. As with Australia, white bread and rolls made the largest contribution to folic acid intakes (29% to 33%), followed by wholemeal bread and rolls (9% to 12%). Fancy breads with added fat and/or sugar contributed approximately 6% to folic acid intakes.

8. Dietary folate intakes

Submissions to the DAR for P295 indicated confusion about the differences between dietary folate and folic acid intakes. As a result, FSANZ has estimated the intake of naturally occurring folate and dietary folate equivalents (expressed as DFEs)[2] by general population groups within Australia and New Zealand for the First Review, providing a full set of information on naturally occurring folate and dietary folate intakes for the first time.

Dietary intake assessments for naturally occurring folate and dietary folate for Australia and New Zealand were conducted separately. Age groups for both countries were based on age groups specified in the 2006 NHMRC Nutrient Reference Values document and incorporated women of child bearing age (16-44 years) as the primary target group.

Two scenarios were investigated for this dietary intake assessment and included:

i. **Baseline** –estimate of current naturally occurring folate and dietary folate intakes, based on current uptake of voluntary folic acid permissions by industry; and

ii. **Mandatory Fortification** –estimate of dietary folate intakes under a mandatory fortification scenario i.e. from current uptake by industry of voluntary folic acid permissions (except those for wheat flour for making bread (Australia only) and for bread (NZ only) plus the introduction of mandatory fortification of wheat flour for making bread at 200 µg/ 100 g flour (Australia only) and all bread at 135 µg folic acid per 100 g of bread (New Zealand only)).

Estimated naturally occurring folate intakes differ between genders and ages as well as between countries. Australia has higher estimated naturally occurring folate intakes than New Zealand for all population groups. Females in both countries were found to have lower naturally occurring folate intakes than males in each age group.

New Zealand, as a population, had lower estimated intakes of dietary folate in comparison to Australian both at *Baseline* and under *Mandatory Fortification*. This difference in dietary folate intakes between countries is likely due to the higher naturally occurring folate concentrations in similar foods reported from analysis in Australia in comparison to New Zealand and a lower uptake of voluntary folic acid fortification permissions in New Zealand compared to Australia.

Cereals and cereal products were the highest contributors to dietary folate intakes for the Australian population as a whole under both *Baseline* and *Mandatory Fortification* scenarios. Breads and breakfast cereals were the major food group contributors for New Zealand, however, breads contributed to a greater extent under the *Mandatory Fortification* scenario.

Dietary folate intakes were compared to the Estimated Average Requirement (EAR) for folate. In the absence of any folic acid fortification (i.e. intake of naturally occurring folate only), 31% Australians aged 2 years and over and 92% New Zealand population aged 15 years and over were estimated to have naturally occurring folate intakes below the EAR, with slightly higher proportions below the EAR for the target group, women of child bearing age (52% Australia, 97% New Zealand).

Under the current (*Baseline*) voluntary folic acid fortification situation, estimated dietary folate intakes increased compared to those from naturally occurring folate only as would be expected, resulting in lower proportions of the Australian and New Zealand populations with dietary folate intakes below the EAR (7% Australian population, 50% NZ population), thus indicating that current voluntary fortification with folic acid makes a significant contribution to dietary folate intakes. Under *Mandatory Fortification*, less than 10% of all population sub-groups were estimated to have dietary folate intakes below the EAR. This indicates that *Mandatory Fortification* has the potential to further reduce the proportion of the Australian and New Zealand population with dietary folate intakes below the EAR.

9. Limitations of the dietary intake assessments

The general limitations used in the dietary intake assessments for folic acid were provided in detail in Attachment 7 of the Final Assessment Report (FAR) for P295 – Consideration of Mandatory Fortification with Folic Acid. Those assumptions specific for the voluntary scenarios are in Attachment 7B and for dietary folate assessments in Attachment 7C.

Appendix 1: Summary *of concentration data used for various foods for dietary modelling purposes*

Table A1.1: Market share information used in the preparation of databases for folic acid modelling

Food group	Australian market share	New Zealand market share
Breads (all types)	Three different figures provided: 15%, 16% and 20% for different breads. **15% based on**: addition of folic acid to Bakers Delight Breads, which represented 14.6% of all bread sold in Australia in march 2006. **16% based on:** Bakers Delight March 2006, 14.6% of Australian market, allowance of 1.4% for Wonder Gold (note that Wonder White brand has 12% market share). **20% based on:** market share is for Bakers Delight and takes into account Tip Top 9 Grain and Noble Rise breads.	1997 NNS provided separate consumption amounts for some fortified vs. unfortified breads. Where fortification status was not specified, assumed no folic acid added. Note that *Bakers Delight* bread in NZ does not contain folic acid.
Breakfast cereals (all types)	1995 NNS provided separate consumption amounts for fortified vs. unfortified breakfast cereals. Modelling assumes that consumption patterns for breakfast cereals have not changed.	1997 NNS provided separate consumption amounts for fortified vs. unfortified breakfast cereals.
Juices	50% market share used for commercial orange juice. Based on both Berri and Golden Circle ambient juices being fortified with folic acid as well as use of folic acid fortified juice in McDonalds restaurants. Mixed fruit juices (Breakfast style) assumed to be 100% folic acid fortified.	25% market share used for commercial orange juice or orange and other fruit juice mixtures.

Food group	Australian market share	New Zealand market share
Soy beverages	Where the 1995 NNS indicated a product was fortified, a 100% market share weighting was used (i.e. assumed all products fortified with folic acid). Where fortification status was not specified, a 50% market share was used, based on approximately half the products available containing added folic acid.	Where there was some certainty from the 1997 NNS about the brand or beverage consumed, and this beverage is known to be folic acid fortified, 100% market share was used. Where fortification was not specified, 50% market share was used.
Other milk substitutes	100% market share	100% market share
Yeast spreads	Assumes 100% fortified (i.e. 100% Vegemite)	1997 NNS provided separate consumption amounts for fortified vs. unfortified yeast spreads.
Infant food	10% market share	1997 NNS provided a consumption amount for a high folate cereal that is assumed to be folic acid fortified. No other infant cereals were reported as consumed.
Meal replacement products	100% fortified	1997 NNS provided separate consumption amounts for fortified vs. unfortified
Flour	Self-raising and plain 5% market share. Based on the addition of folic acid to The Healthy Baker flour.	

Notes

- Folate values reported in the 1995 Australian and 1997 New Zealand National Nutrition Surveys have been updated to reflect recent analytical results (2004 onwards) or to reflect current label information.
- Where label information was used, no adjustment was made for possible over- or under-ages.

Appendix 2: Complete information on dietary intake assessment results

Table A2.1: Estimated mean and 95th percentile folic acid intakes from food for Australian and New Zealand women of child-bearing age (16-44 years)

Scenario	Mean dietary folic acid intake (µg/day)				95th percentile dietary folic acid intake (µg/day)			
	Market weighted		Consumer behaviour		Market weighted		Consumer behaviour	
	Australia[1]	New Zealand[2]	Australia[1]	New Zealand[2]	Australia[1]	New Zealand[2]	Australia[1]	New Zealand[2]
Baseline	108	62	83 – 243	60 – 69	283	190	192 – 219	181 – 196
Mandatory Fortification[3]	208	202	204 – 231	200 – 209	407	359	403 – 455	353 – 369
Lower voluntary	115	97	84 – 245	63 – 225	291	234	251 – 476	194 – 396
Moderate voluntary	136	119	86 – 313	64 – 304	319	260	251 – 606	194 – 519
Higher voluntary	153	136	95 – 315	73 – 304	351	296	271 – 606	218 – 519

[1] Number of Australian respondents aged 16-44 years = 3,178.
[2] Number of NZ respondents aged 16-44 years = 1,509.
[3] For Australia: mandatory folic acid fortification of bread-making flour. Folic acid concentration is 200 µg/100 g flour. For New Zealand: mandatory folic acid fortification of bread. Folic acid concentration is 135 µg/100 g bread.

Table A2.2: Estimated mean and 95th percentile dietary folic acid intakes from food for various Australian population non-target sub-groups

a. Mean

			Estimated mean dietary folic acid intake (µg/day)									
Pop. group	Gender	No. of respondents	*Baseline*		*Mandatory Fortification*[1]		*Lower* voluntary		*Moderate* voluntary		*Higher* voluntary	
			Market Weighted	Consumer Behaviour	Market Weighted	Consumer Behaviour	Market Weighted	Consumer Behaviour	Market Weighted	Consumer Behaviour	Market Weighted	Consumer Behaviour
2 yrs & above	All	13,858	129	100-285	244	241-268	137	102-287	158	103-350	175	111-353
2-3 yrs	All	383	128	106-237	217	215-225	133	106-238	153	108-289	167	112-290
	M	170	141	117-251	238	236-239	146	117-251	167	119-303	179	112-304
	F	213	118	97-227	200	198-214	123	97-227	143	99-277	155	104-278
4-8 yrs	All	977	140	115-270	241	238-258	147	116-271	168	118-328	182	123-331
	M	513	157	131-295	269	266-285	164	132-297	186	134-355	200	137-357
	F	464	121	99-242	210	208-228	127	99-243	148	101-299	162	107-302
9-13 yrs	All	913	162	134-320	275	271-309	169	135-321	192	137-384	210	144-388
	M	474	192	162-369	319	315-359	200	163-371	225	165-436	244	173-439
	F	439	128	104-266	227	224-255	135	104-268	156	106-328	172	113-333
14-18 yrs	All	734	161	129-329	293	289-320	169	130-330	194	132-407	213	140-410
	M	378	202	166-398	361	357-391	211	167-399	238	170-477	259	177-480
	F	356	117	90-256	222	217-246	124	90-257	147	92-334	164	101-335
19-29 yrs	All	2,203	146	115-309	278	273-303	154	116-311	177	118-387	195	124-389
	M	1,014	179	142-377	346	342-373	188	142-378	214	145-458	234	150-461
	F	1,189	118	93-252	219	215-243	125	94-253	146	95-325	163	103-327
30-49 yrs	All	4,397	119	90-280	238	235-262	127	91-282	148	92-348	166	100-350

Pop. group	Gender	No. of respondents	**Estimated mean dietary folic acid intake (µg/day)** *Baseline*		***Mandatory Fortification***[1]		***Lower* voluntary**		***Moderate* voluntary**		***Higher* voluntary**	
			Market Weighted	**Consumer Behaviour**	**Market Weighted**	**Consumer Behaviour**	**Market Weighted**	**Consumer Behaviour**	**Market Weighted**	**Consumer Behaviour**	**Market Weighted**	**Consumer Behaviour**
	M	2,080	140	105-330	283	280-309	150	107-333	172	109-401	190	113-404
	F	2,317	100	75-236	198	195-220	107	77-237	127	78-301	144	88-302
50-69 yrs	All	3,019	114	86-270	221	218-247	123	89-273	143	90-332	161	99-336
	M	1,442	131	98-313	256	253-284	141	100-315	160	101-373	178	107-377
	F	1,577	99	76-232	189	186-214	107	79-235	127	79-295	146	92-299
70 yrs & above	All	1,232	117	91-265	217	215-240	125	93-266	142	93-310	157	99-315
	M	545	126	97-293	241	239-267	134	98-294	152	99-277	167	103-342
	F	687	111	87-243	198	196-220	117	88-244	134	89-288	148	96-293

[1] Mandatory folic acid fortification of bread-making flour. Folic acid concentration is 200 µg/100 g flour.

b. 95th Percentile

Pop. group	Gender	No. of respondents	*Baseline*		*Mandatory Fortification*[1]		*Lower* voluntary		*Moderate* voluntary		*Higher* voluntary	
			Estimated 95th percentile dietary folic acid intake (µg/day)									
			Market Weighted	Consumer Behaviour	Market Weighted	Consumer Behaviour	Market Weighted	Market Weighted	Consumer Behaviour	Market Weighted	Consumer Behaviour	Market Weighted
2 yrs & above	All	13,858	346	306-590	507	503-554	364	324-598	391	324-705	420	340-711
2-3 yrs	All	383	232	209-412	338	334-384	238	210-413	263	212-506	293	218-513
	M	170	250	224-454	377	373-423	257	224-455	288	228-543	318	249-544
	F	213	210	195-408	308	306-372	215	196-408	237	197-490	264	207-497
4-8 yrs	All	977	282	256-481	388	383-464	290	256-486	316	259-588	341	266-591
	M	513	313	280-556	442	438-532	322	281-359	350	282-678	381	295-680
	F	464	246	230-406	328	326-379	252	231-406	278	232-507	300	234-518
9-13 yrs	All	913	367	341-613	495	487-588	375	342-615	403	346-760	441	362-768
	M	474	420	386-725	543	536-650	428	387-428	463	387-877	497	410-879
	F	439	291	257-463	392	390-461	299	258-463	332	261-587	371	284-598
14-18 yrs	All	734	378	342-659	566	564-634	389	344-659	426	348-781	451	351-782
	M	378	539	508-766	733	730-813	551	512-767	575	516-862	605	519-862
	F	356	273	239-477	407	392-447	280	237-474	308	241-582	328	243-581
19-29 yrs	All	2,203	365	329-644	585	577-629	375	336-648	402	338-757	430	338-767
	M	1,014	449	402-772	736	737-771	463	404-773	507	411-890	541	414-891
	F	1,189	286	244-469	420	416-455	290	242-474	307	245-612	329	257-611
30-49 yrs	All	4,397	342	302-602	516	513-552	361	324-612	392	324-712	422	340-717
	M	2,080	373	321-675	576	569-622	401	339-685	426	342-792	456	361-797
	F	2,317	299	274-488	409	405-467	309	274-488	343	274-605	380	325-604

Pop. group	Gender	No. of respondents	*Baseline*		*Mandatory Fortification*[1]		*Lower* voluntary		*Moderate* voluntary		*Higher* voluntary	
			Estimated 95th percentile dietary folic acid intake (µg/day)									
			Market Weighted	Consumer Behaviour	Market Weighted	Consumer Behaviour	Market Weighted	Market Weighted	Consumer Behaviour	Market Weighted	Consumer Behaviour	Market Weighted
50-69 yrs	All	3,019	368	341-574	480	477-533	384	349-597	410	351-682	439	362-697
	M	1,442	403	364-656	545	541-595	445	396-681	465	396-770	484	404-775
	F	1,577	325	304-494	415	414-454	336	311-494	368	311-591	398	347-598
70 yrs & above	All	1,232	357	306-530	456	454-495	373	332-540	384	332-607	402	346-610
	M	545	331	297-551	469	466-503	360	321-570	379	321-618	395	320-622
	F	687	369	350-498	441	437-464	375	349-498	394	349-584	413	361-592

[1] Mandatory folic acid fortification of bread-making flour. Folic acid concentration is 200 µg/100 g flour.

Table A2.3: Estimated mean and 95th percentile dietary folic acid intakes from food for various New Zealand population non-target sub-groups

a. Mean

			Estimated mean dietary folic acid intake (µg/day)									
			Baseline		*Mandatory Fortification*[1]		*Lower* voluntary		*Moderate* voluntary		*Higher* voluntary	
Pop. group	**Gender**	**No. of respondents**	**Market Weighted**	**Consumer Behaviour**	**Market Weighted**	**Consumer Behaviour**	**Market Weighted**	**Market Weighted**	**Consumer Behaviour**	**Market Weighted**	**Consumer Behaviour**	**Market Weighted**
15 yrs & above	All	4,636	75	73-81	236	234-241	114	76-260	136	77-337	154	85-337
15-18 yrs	All	246	81	77-90	255	252-264	122	79-284	148	80-371	169	90-371
	M	109	113	111-119	322	320-328	162	113-351	190	115-444	212	124-445
	F	137	54	51-67	201	197-212	90	51-231	115	53-312	135	64-312
19-29 yrs	All	804	76	74-84	239	237-247	115	76-263	139	78-348	158	87-348
	M	286	112	110-119	316	314-323	160	112-342	188	114-437	210	122-437
	F	518	56	54-65	197	194-205	90	56-219	112	58-299	130	68-299
30-49 yrs	All	1,883	75	73-80	241	240-246	116	76-266	138	77-344	156	85-344
	M	787	86	85-91	291	289-296	136	87-320	159	88-395	179	96-394
	F	1,096	67	65-72	206	204-211	102	68-228	122	69-306	140	78-307
50-69 yrs	All	1,147	76	74-81	231	229-236	114	78-255	133	78-328	151	85-328
	M	538	84	82-89	266	264-271	127	84-293	147	85-362	164	89-362
	F	609	69	68-73	200	199-205	102	72-221	121	72-297	139	81-297
70 yrs & above	All	556	70	69-73	214	213-218	105	72-236	123	72-305	140	80-305
	M	207	69	68-73	236	235-240	108	70-261	125	71-327	141	75-327
	F	349	70	69-73	201	200-204	103	72-221	121	73-292	139	83-292

[1] Mandatory folic acid fortification of bread. Folic acid concentration is 135 µg/100 g bread.

b. 95th Percentile

			Estimated 95th percentile dietary folic acid intake (µg/day)									
			Baseline		*Mandatory Fortification*[1]		*Lower* voluntary		*Moderate* voluntary		*Higher* voluntary	
Pop. group	Gender	No. of respondents	Market Weighted	Consumer Behaviour	Market Weighted	Consumer Behaviour	Market Weighted	Market Weighted	Consumer Behaviour	Market Weighted	Consumer Behaviour	Market Weighted
15 yrs & above	All	4,636	214	209-229	443	439-452	262	213-491	299	214-617	336	238 - 617
15-18 yrs	All	246	195	187-223	485	480-500	252	186-568	315	187-785	377	224 - 786
	M	109	225	213-260	560	554-580	301	211-654	357	213-949	410	247 - 950
	F	137	157	135-193	340	330-381	208	138-391	249	139-532	276	179 - 532
19-29 yrs	All	804	194	180-217	447	434-461	248	188-503	304	190-689	345	220 - 690
	M	286	221	205-255	543	529-592	279	204-629	353	205-900	411	242 - 900
	F	518	162	159-184	341	338-347	223	167-386	255	168-509	288	194 - 510
30-49 yrs	All	1,883	223	220-233	460	457-469	268	224-505	302	224-629	343	254 - 629
	M	787	246	230-268	540	532-548	301	244-577	341	244-698	378	281 - 697
	F	1,096	205	200-215	370	367-373	241	206-405	267	208-534	301	224 - 534
50-69 yrs	All	1,147	238	237-248	438	438-448	278	241-459	304	241-564	341	254 - 564
	M	538	262	260-271	489	486-491	316	267-514	350	266-624	387	282 - 624
	F	609	210	204-225	367	357-371	248	219-391	267	219-492	293	232 - 493
70 yrs & above	All	556	187	186-189	367	367-379	226	186-389	248	186-473	270	219 - 473
	M	207	188	186-191	392	391-394	231	188-427	250	189-488	276	219 - 488
	F	349	179	179-185	322	322-320	207	177-352	226	178-465	261	210 - 465

[1] Mandatory folic acid fortification of bread. Folic acid concentration is 135 µg/100 g bread.

Appendix 3 – Complete information on risk characterisation

Table A3.1: Proportion of respondents with folic acid intakes above the Upper Level for various Australian population non-target sub-groups

				% of respondents with folic acid intakes > UL[1]				
Pop. group	**Gender**	**Upper level (µg/day)**	**No. of respondents**	***Baseline***	***Mandatory Fortification***[2]	***Lower* voluntary**	***Moderate* voluntary**	***Higher* voluntary**
	All		383	2	9	2	2	4
2-3 yrs	M	300	170	3	13	4	4	7
	F		213	<1	6	<1	<1	3
	All		977	1	4	1	2	3
4-8 yrs	M	400	513	2	7	2	3	4
	F		464	<1	1	<1	<1	1
	All		913	1	2	1	1	2
9-13 yrs	M	600	474	2	4	2	2	3
	F		439	<1	<1	<1	<1	1
	All		734	<1	<1	<1	<1	<1
14-18 yrs	M	800	378	1	1	1	2	2
	F		356	0	0	0	0	0
	All		2,203	<1	<1	<1	<1	<1
19-29 yrs	M	1,000	1,014	<1	<1	<1	<1	<1
	F		1,189	<1	<1	<1	<1	<1
	All		4,397	<1	<1	<1	<1	<1
30-49 yrs	M	1,000	2,080	<1	<1	<1	<1	<1
	F		2,317	<1	<1	<1	<1	<1
	All		3,019	<1	<1	<1	<1	<1
50-69 yrs	M	1,000	1,442	<1	<1	<1	<1	<1
	F		1,577	<1	<1	<1	<1	<1
	All		1,232	0	0	0	0	0
70 yrs & above	M	1,000	545	0	0	0	0	0
	F		687	0	0	0	0	0

[1] Concentration of folic acid in foods is weighted according to the proportion of a food group that is fortified. This estimates dietary intakes over the long-term and across the population.
[2] Mandatory folic acid fortification of bread-making flour. Folic acid concentration is 200 µg/100 g flour.

Table A3.2: Proportion of respondents with folic acid intakes above the Upper Level for various New Zealand population non-target sub-groups

				% of respondents with folic acid intakes > UL[1]				
Pop. group	**Gender**	**Upper level (µg/day)**	**No. of respondents**	***Baseline***	***Mandatory Fortification*[2]**	***Lower* voluntary**	***Moderate* voluntary**	***Higher* voluntary**
	All		246	0	<1	0	0	0
15-18 yrs	M	800	109	0	2	0	0	0
	F		137	0	0	0	0	0
	All		804	0	<1	0	0	0
19-29 yrs	M	1,000	286	0	<1	0	0	0
	F		518	0	0	0	0	0
	All		1,883	<1	<1	<1	<1	<1
30-49 yrs	M	1,000	787	0	0	0	0	0
	F		1,096	<1	<1	<1	<1	<1
	All		1,147	0	<1	0	0	0
50-69 yrs	M	1,000	538	0	<1	0	0	0
	F		609	0	0	0	0	0
	All		556	0	0	0	0	0
70+ yrs	M	1,000	207	0	0	0	0	0
	F		349	0	0	0	0	0

[1] Concentration of folic acid in foods is weighted according to the proportion of a food group that is fortified. This estimates dietary intakes over the long-term and across the population.
[2] Mandatory folic acid fortification of bread. Folic acid concentration is 135 µg/100 g bread.

Appendix 4 – Complete information of folic acid intake from food and supplements

Table A4.1: Estimated mean and 95th percentile folic acid intakes from food and supplements for Australian women of child-bearing age (16-44 years)

	Folic acid intake from food and supplements (µg/day)[1, 2]			
Scenario	**Mean intake + 200 µg supplement**	**Mean intake + 500 µg supplement**	**95th percentile intake + 200 µg supplement**	**95th percentile intake + 500 µg supplement**
Baseline	308	608	483	783
Mandatory Fortification[3]	408	708	607	907
Lower voluntary	315	615	491	791
Moderate voluntary	336	736	519	819
Higher voluntary	353	753	551	851

[1] Concentration of folic acid in foods is weighted according to the proportion of a food group that is fortified. This estimates dietary intakes over the long-term and across the population.
[2] Number of respondents aged 16-44 years = 3,178.
[3] Mandatory folic acid fortification of bread-making flour. Folic acid concentration is 200 µg/100 g flour.

Table A4.2: Estimated mean and 95th percentile folic acid intakes from food and supplements for New Zealand women of child-bearing age (16-44 years)

	Folic acid intake from food and supplements (µg/day)[1, 2]			
Scenario	**Mean intake + 200 µg supplement**	**Mean intake + 500 µg supplement**	**95th percentile intake + 200 µg supplement**	**95th percentile intake + 500 µg supplement**
Baseline	262	862	390	990
Mandatory Fortification[3]	402	1,002	559	1,159
Lower voluntary	297	897	434	1,034
Moderate voluntary	319	919	460	1,060
Higher voluntary	336	936	496	1,096

[1] Concentration of folic acid in foods is weighted according to the proportion of a food group that is fortified. This estimates dietary intakes over the long-term and across the population.
[2] Number of respondents aged 16-44 years = 1,509.
[3] Mandatory folic acid fortification of bread. Folic acid concentration is 135 µg/100 g bread.

Attachment 7A

Dietary Intake Assessment Report – Mandatory Fortification with Folic Acid

Contents

EXECUTIVE SUMMARY 90

1. BACKGROUND 92

2. HOW DIETARY FOLIC ACID INTAKES WERE CALCULATED 92

3. ASSUMPTIONS USED IN THE DIETARY INTAKE ASSESSMENTS 101

4. ESTIMATED DIETARY FOLIC ACID INTAKES FROM FOLIC ACID ADDED TO FOODS ONLY 101

5. ADDITIONAL CALCULATIONS TO ESTIMATE FOLIC ACID INTAKES FROM FOOD AND SUPPLEMENTS 108

6. FOOD CONSUMPTION PATTERNS FOR WOMEN AGED 16-44 YEARS FOR RESPONDENTS WITH LOW AND HIGH QUINTILE INTAKES OF FOLIC ACID 111

7. LIMITATIONS OF THE DIETARY INTAKE ASSESSMENT 123

REFERENCES 123

APPENDIX 1: DETERMINATION OF THE FOOD VEHICLE FOR MANDATORY FORTIFICATION 124

APPENDIX 2: SUMMARY OF CONCENTRATION DATA USED FOR VARIOUS FOODS FOR DIETARY MODELLING PURPOSES 126

APPENDIX 3: COMPLETE INFORMATION ON DIETARY INTAKE ASSESSMENT RESULTS 135

APPENDIX 4: COMPLETE INFORMATION ON RISK CHARACTERISATION 139

APPENDIX 5: COMPLETE INFORMATION ON FOLIC ACID INTAKES FROM FOOD AND SUPPLEMENTS 142

APPENDIX 6: COMPLETE INFORMATION ON FOOD CONSUMPTION PATTERNS FOR AUSTRALIAN AND NEW ZEALAND WOMEN OF CHILD-BEARING AGE FOR CONSUMERS WITH LOW AND HIGH QUINTILE INTAKES OF FOLIC ACID 144

Executive Summary

In the Ministerial Council review request ('First Review'), a number of issues were raised that related to dietary intake assessments for folic acid. The dietary intake assessments undertaken for the First Review assumed that, as previously, the overall aim of any fortification program is to ensure that folic acid intakes are maximised for the target groups whilst minimising the proportion of all population groups that exceed the upper level of intake (UL).

In order for the issues raised in the First Review request for be addressed, a number of changes were made to the dietary intake assessments for both Australia and New Zealand. These changes were:

1. Review the **Fortification Vehicle** for Australia with a view to mandating 'wheat flour for making bread' at 200 μg of folic acid per 100 g of bread-making flour. For New Zealand, the mandatory fortification food vehicle remained unchanged from Final Assessment – 'all bread' fortified at 135 ug folic acid per 100 g of bread32.

2. **Baseline concentration** data for voluntarily fortified foods has been revised following Final Assessment for Australia and New Zealand based on new data collected in 2006 becoming available to FSANZ. The proportion of foods within each category that were fortified was also revised.

3. **Additional modelling** was undertaken to estimate dietary folic acid intakes for 'individuals' assuming that, where individuals have a choice between a fortified and non-fortified product they: (1) never choose the fortified food; and (2) they always choose the fortified food.

4. **Food consumption patterns** were assessed for Australian and New Zealand women aged 16-44 years who have low and high intakes of folic acid to identify whether women with low folic acid intakes have different food consumption patterns in comparison to those with high folic acid intakes.

The results of the dietary intake assessment for folic acid indicate that:

Estimated dietary folic acid intakes

- Current folic acid intakes from food by the target groups were low.

- New Zealand had lower baseline folic acid intakes from food for all age groups considered compared to Australian populations.

- By mandating or fixing the level of folic acid in 'wheat flour for making bread' in Australia, the choice for consumers is limited for that one type of food but the certainty of outcome of fortification increases considerably.

---

[32] Amounts of folic acid refer to the amounts of folic acid in the flour portion of the final food (Australia) or in bread (NZ); the Draft Standard refers to a range of folic acid permitted to be added to achieve this outcome.

- Mean folic acid intakes for the target group increased from *Baseline* to *Mandatory Fortification* by +100 µg/day and +140 µg/day for Australia and New Zealand, respectively.

- Despite these increases in folic acid intakes from food, the mean dietary folic acid intake from food alone for the women of child bearing age did not achieve the desired folic acid intake of 400 µg per day for either *Baseline* or *Mandatory Fortification*.

Risk characterisation

- The proportion of the target group exceeding the UL for Australia and New Zealand was <1% for both *Baseline* and *Mandatory Fortification*.

- Children aged 2-3 and 4-8 years are the most likely of the non-target groups to have intakes exceeding the upper level (UL) if mandatory fortification of 'wheat flour for making bread' or bread were to be introduced. Investigation of high consumer (95^{th} percentile) intakes of folic acid and the maximum estimated dietary folic acid intakes indicated that estimated dietary folic acid intakes for Australian children aged 2-3 years and 4-8 years were acceptable.

Dietary intakes from food and supplements

- Without the consumption of folic acid supplements, 5% of Australian and 3% of New Zealand women of child-bearing age were estimated to meet the recommended 'target intake' of 400 µg folic acid per day under the Mandatory Fortification scenarios.

- When a 200 µg per day folic acid supplement was considered in conjunction with Mandatory Fortification, approximately 40% of Australian and New Zealand women of child-bearing age were estimated to meet the target intake of folic acid.

- If a 500 µg or 800 µg folic acid supplement was consumed by all women of child-bearing age, 100% of women of child-bearing age would meet the target intake of folic acid.

- The proportion of Australian and New Zealand target population exceeding the UL with a folic acid supplement of 200 µg per day for *Baseline* and *Mandatory Fortification* scenarios was <1%.

- With a 500 µg supplement, the proportion of the Australian target population exceeding the UL increased slightly from 2% at *Baseline* to 4% under the *Mandatory Fortification* scenario.

- In New Zealand, supplements containing 800 µg of folic acid are available. With consumption of an 800 µg supplement, the proportion of the New Zealand target population exceeding the UL increased from 10% at *Baseline* to 46% under the *Mandatory Fortification* scenario.

Food Consumption Patterns

- There does not appear to be a single food or food group that is consumed preferentially and by a significant proportion of women of child bearing age in the low folic acid intake group that could be fortified to effectively target these women.

- Mandatory fortification of wheat flour for bread making in Australia and bread in New Zealand would effectively target women with low folic intakes without overly increasing intakes for women who currently have higher folic acid intakes.

- Mean folic acid intakes from food did not meet the NHMRC target for any of the women of child bearing age when grouped according to quintiles of folic acid intake; therefore, increasing the folic acid in the food supply would assist all these groups.

1. Background

In the Ministerial Council review request, a number of issues were raised that relate to dietary intake assessments for folic acid. The dietary intake assessments undertaken for the First Review assumed that, as previously, the overall aim of any fortification program is to ensure that folic acid intakes are maximised for the target group whilst minimising the proportion of all population groups that exceed the upper level of intake (UL).

In the First Review, FSANZ was asked to review the fortification vehicle selected for the addition of folic acid to the food supply by exploring the option of mandating bread-making flour as the food vehicle for Australia (to minimise the regulatory burden on industry and regulators) but retain the option of bread as the food vehicle in New Zealand. Therefore, the dietary intake assessments undertaken for the First Review reflect these options.

Baseline folic acid concentration data for voluntarily fortified foods have been revised following Final Assessment for Australia and New Zealand, based on new 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 used these new baseline values as a starting point.

2. How Dietary Folic Acid Intakes Were Calculated

For an overview of how dietary folic acid intakes were estimated and the population groups assessed refer to Attachment 7 of the P295 – Consideration of Mandatory Fortification with Folic Acid Final Assessment report.

2.1 Food vehicles for First Review

At Draft Assessment, 'all bread-making flour' was selected as a food vehicle for incorporating folic acid into foods due to the high consumption of products assumed to contain bread-making flour as an ingredient by the target group. Following consultations, the mandatory fortification of folic acid in 'bread', rather than bread-making flour, was proposed and modelled for Final Assessment.

At First Review, FSANZ was asked to review the fortification vehicle selected with a view to mandating flour for bread-making as the food vehicle for Australia to minimise the regulatory burden on industry and regulators. For New Zealand, the mandatory fortification food vehicle remained as 'all bread' in the First Review.

To determine the range of foods that would be likely to contain added folic acid, it was necessary to determine which foods contain 'wheat flour for making bread' (Australia only) and 'all bread' (New Zealand only). In Australia, flour for 'bread-making' must contain added thiamin. For the purposes of estimating folic acid intakes, foods were assumed to contain 'wheat flour for making bread' if Australian products were labelled as containing added thiamin. Following consultation with the food industry, it was also determined that croissants contain 'wheat flour for making bread'. For the purpose of estimating folic acid intakes for New Zealand, foods were assumed to be a 'bread' if they contain cereal flour, were yeast leavened and were baked (refer to Figure 1a and Figure 1b below).

Figure 1: Definition of folic acid fortified foods for dietary intake assessment purposes

a. Australia

Wheat flour for making bread:

Includes all white and wholemeal wheat flour used as an ingredient in commercially produced plain, fancy, sweet and flat breads and bread rolls, English-style muffins, crumpets, scones, pancakes, pikelets, crepes, yeast donuts, pizza bases, croissants and breadcrumb containing products.

b. New Zealand

***All Bread*:**

Includes all yeast-containing plain white, white high fibre, wholemeal, grain and rye bread loaves and rolls that are baked; yeast-containing flat breads that are baked (e.g. pita bread, naan bread); focaccia; bagels (white, wholemeal, sweet); topped breads and rolls (e.g. cheese and bacon rolls); English muffins (white, white high fibre, grain, wholemeal and fruit); sweet buns; fruit breads and rolls; and breadcrumbs.

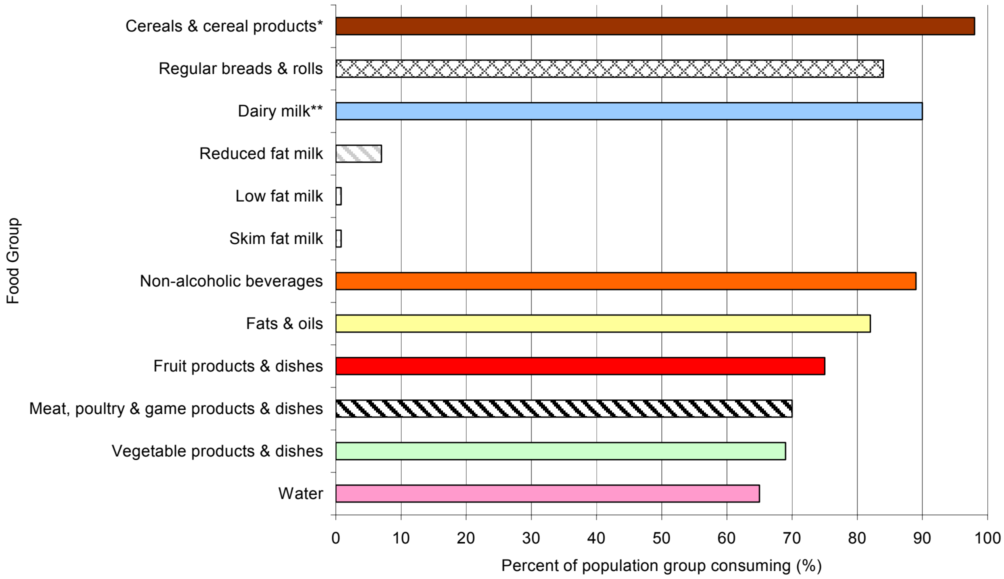
Excludes steamed breads; breads cooked by frying (e.g. puri/poori); yeast-free breads (e.g. chapatti, tortilla); gluten-free breads; doughnuts; pizzas and pizza bases; scones; pancakes, pikelets and crepes; crumpets; and bread mixes intended for home use.

2.1.1 Why breads/wheat flour for making bread?

At the start of the Proposal P295 – Consideration of Mandatory Fortification with Folic Acid, FSANZ considered suitable food vehicles for fortification; the initial criteria being that the food had to be consumed by a large proportion of the target group in all socio-economic groups and that is was technically feasible to fortify the food. The proportion of different population groups consuming milks (full and reduced fat), fruit juices, breakfast cereals, yoghurts and soy beverage were examined during the initial investigations as well as bread and bread products. There is no food that is consumed by the target group only and not by other population groups. From the data from the NNS publication *National Nutrition Survey Foods Eaten Australia 1995* (McLennan and Podger, 1999) indicate that those food groups consumed by a large proportion of women of child-bearing age are also those consumed by a large proportion of young children (aged 2-3 years). Figures 2a and b show the proportions of 2-3 year old Australian children and 16-44 year old Australian women that consume various foods/food groups.

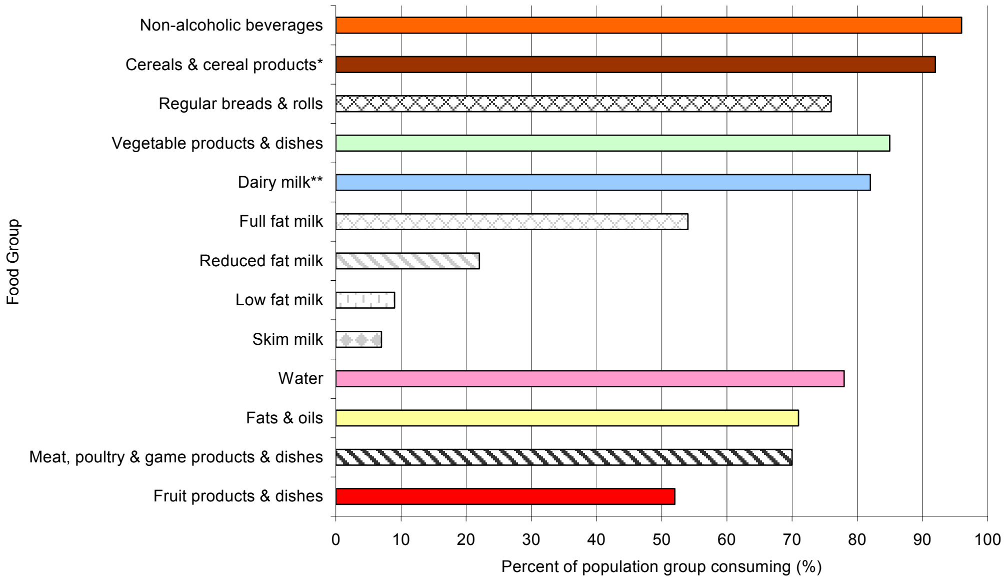
Figure 2: Percentage of Australian children aged 2-3 years and Australian women aged 16-44 year old consuming various food types

a. Australian children aged 2-3 years



* Cereal and cereal products includes regular breads and rolls
** Dairy milk includes full fat, reduced, low fat and skim milk
Note: These figures are for foods reported as consumed in the NNS and do not take account of consumption of these foods in recipes e.g. milk used in custard.

b. Australian women aged 16-44 years



* Cereal and cereal products includes regular breads and rolls
** Dairy milk includes full fat, reduced, low fat and skim milk
Note: These figures are for foods reported as consumed in the NNS and do not take account of consumption of these foods in recipes e.g. milk used in custard.

Some foods consumed by a large proportion of the target group were not suitable for fortification for technical reasons, for example fruit, vegetables, meat and their products. Foods such as fruit juices, yoghurts and soy beverages were not consumed by a high enough proportion of the target group to consider them as effective food vehicles for mandatory fortification. However, two food groups were further investigated: (1) bread and bread products; and (2) milk and milk products.

Fortifying flour with folic acid, in this case bread-making flour, is consistent with international experience of mandatory fortification to reduce the incidence of NTDs. Bread-making flour is an effective and technically feasible food vehicle for mandatory folic acid fortification and bread-making flour (as bread and bread products) is a staple food consumed widely, consistently and regularly by the target population of women of child-bearing age across different socio-economic sub groups (as discussed previously in the Draft Assessment report and the Final Assessment Report). In addition, Australia's experience with mandatory thiamin fortification provides an opportunity to extend the use of existing infrastructure to the mandatory addition of folic acid to bread-making flour. In the NNSs, approximately 85% of Australian and 83% of New Zealand women of child-bearing age consumed bread-based foods, as defined previously. Regular breads and rolls were consumed by approximately 76% of women of child-bearing age and by approximately 84% of young children (aged 2-3 years).

Dairy milk and products were originally identified as potential food vehicles as they were consumed by at least 50% of the target group (women of child-bearing age) and it was technically feasible to add folic acid. Approximately 82% of women of child-bearing age consumed dairy milk and 90% of children aged 2-3 years. The proportions of women of child-bearing age and children aged 2-3 years who consumed full fat and reduced/low fat milks and yoghurts were further investigated. In the 1995 NNS, a greater proportion of women aged 16-44 years (38%) consumed reduced/low fat milks in comparison to children aged 2-3 years (10%) while a greater proportion of children aged 2-3 years (84%) consumed full fat milk in comparison to women aged 16-44 years (58%). Further detail can be found in Figure 3 below. Reduced or low fat milks could be a more effective food vehicle for the target group than all milk or full fat milk. Full fat milks were consumed preferentially by young children and in larger relative amounts compared to other foods than for adults, so, were they mandated to be fortified, could potentially place young children at a higher risk of excessive folic acid intake than adults.

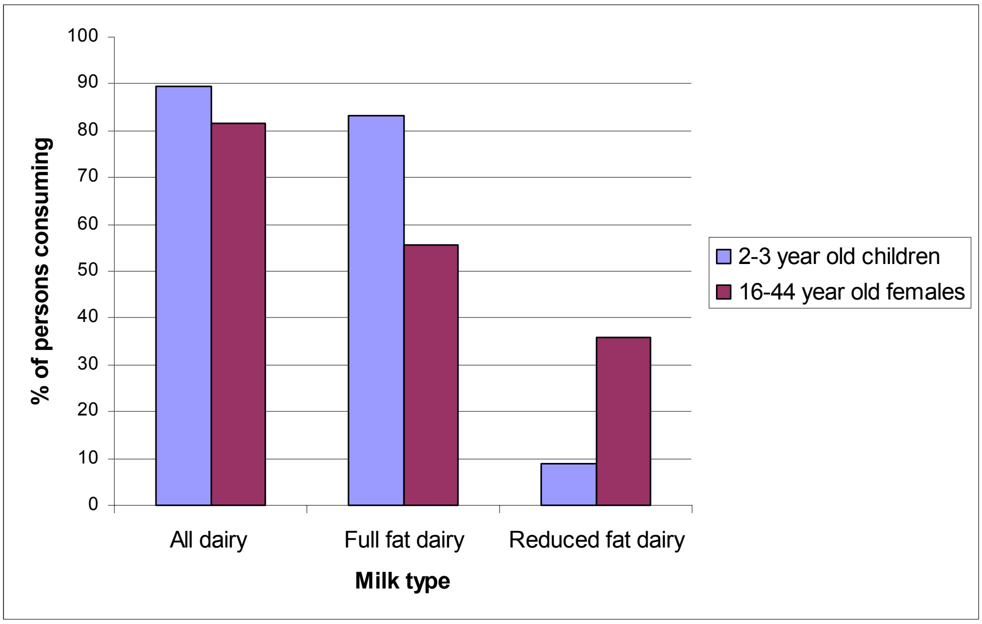


Figure 3: Proportion of Australian children aged 2-3 years and Australian women aged 16-44 years consuming different types of milks (1995 NNS)

More recent data from the Australian Dairy Corporation (ADC) on milk production and sales, the ADC Food Consumption Survey and the Roy Morgan Single Source Survey were also assessed as the retail data on milk sales indicated that there had been a trend towards a decrease in full fat milk sales and an increase in reduced fat/low fat milk sales since 1995 (Australian Dairy Corporation, 2003) (Roy Morgan, 2006a; Roy Morgan, 2006b). The ADC Survey (all ages) data confirm that, for all age groups, a higher proportion of people reported consuming low /reduced fat milk (Australian Dairy Corporation, 2003) than reported in the 1995 NNS. This trend is continuing as indicated by the Roy Morgan Survey data for 2001-2006 (respondents aged 14 years and over) (Roy Morgan, 2006a). FSANZ is also aware that, in the light of concerns about obesity, the current dietary advice for children aged 2 years and over is that reduced fat milks are suitable for these younger children (National Health and Medical Research Council, 2003). Based on this more recent information, FSANZ considered that reduced fat/low fat milk was not suitable as a food vehicle because it appears these milks are as likely as full fat milk to form a higher proportion of a young child's diet than an adult's given the trend toward consuming reduced fat milk at a younger age and would increase the potential risk of excessive folic acid intakes for the 2-3 year and 4-8 year age groups were these milks to be mandatorily fortified with folic acid.

In the 1995 NNS, less than 20% of women aged 16-44 years and children aged 2-3 years reported consuming yoghurts, irrespective of the fat content of the yoghurt. Similar proportions of these two population groups consumed reduced/low fat yoghurts, while a greater proportion of children aged 2-3 years consumed full fat yoghurt in comparison to women aged 16-44 years. Although more recent retail sales data and that from the ADC (Australian Dairy Corporation, 2003) and Roy Morgan (Roy Morgan, 2006a; Roy Morgan, 2006b) surveys indicate the proportion of people consuming yogurt has increased since 1995, it is still less than 40% for the target group but higher for the young children (up to 70%) so that again there would be a risk of excessive folic acid intakes for these latter age groups were full fat yoghurt to be mandatorily fortified with folic acid.

2.2 Scenarios and Folic acid concentration data

To ensure that the estimated dietary folic acid intakes at First Review gave equivalent outcomes to those at Final Assessment and Draft Assessment, that is maximising folic acid intakes for the target group whilst minimising intakes that exceed the UL, a number of fortification scenarios were examined. The final scenarios that were investigated for First Review are as follows:

1. ***Baseline***: to estimate current folic acid intakes from food alone based on current uptake of voluntary folic acid permissions by industry; and
2. ***Mandatory Fortification***: to estimate folic acid intakes based on current uptake by industry of voluntary folic acid permissions (excluding bread) and the introduction of mandatory fortification.

    a. For **Australia**, 'wheat flour for making bread' as the food vehicle, fortified at 200 µg of folic acid per 100 g of bread-making flour.
    b. For **New Zealand**, the food vehicle remained unchanged from Final Assessment – 'all bread' at 135 µg folic acid per 100 g of bread.

Within each of these scenarios, two different model types were assessed:

(a) market share model; and
(b) consumer behaviour models.

The market share and consumer behaviour model types are discussed in detail in the main dietary intake assessment report (for the first review).

An overview of the dietary modelling approach used for the First Review can be found in Figure 4.

2.2.1 Baseline'

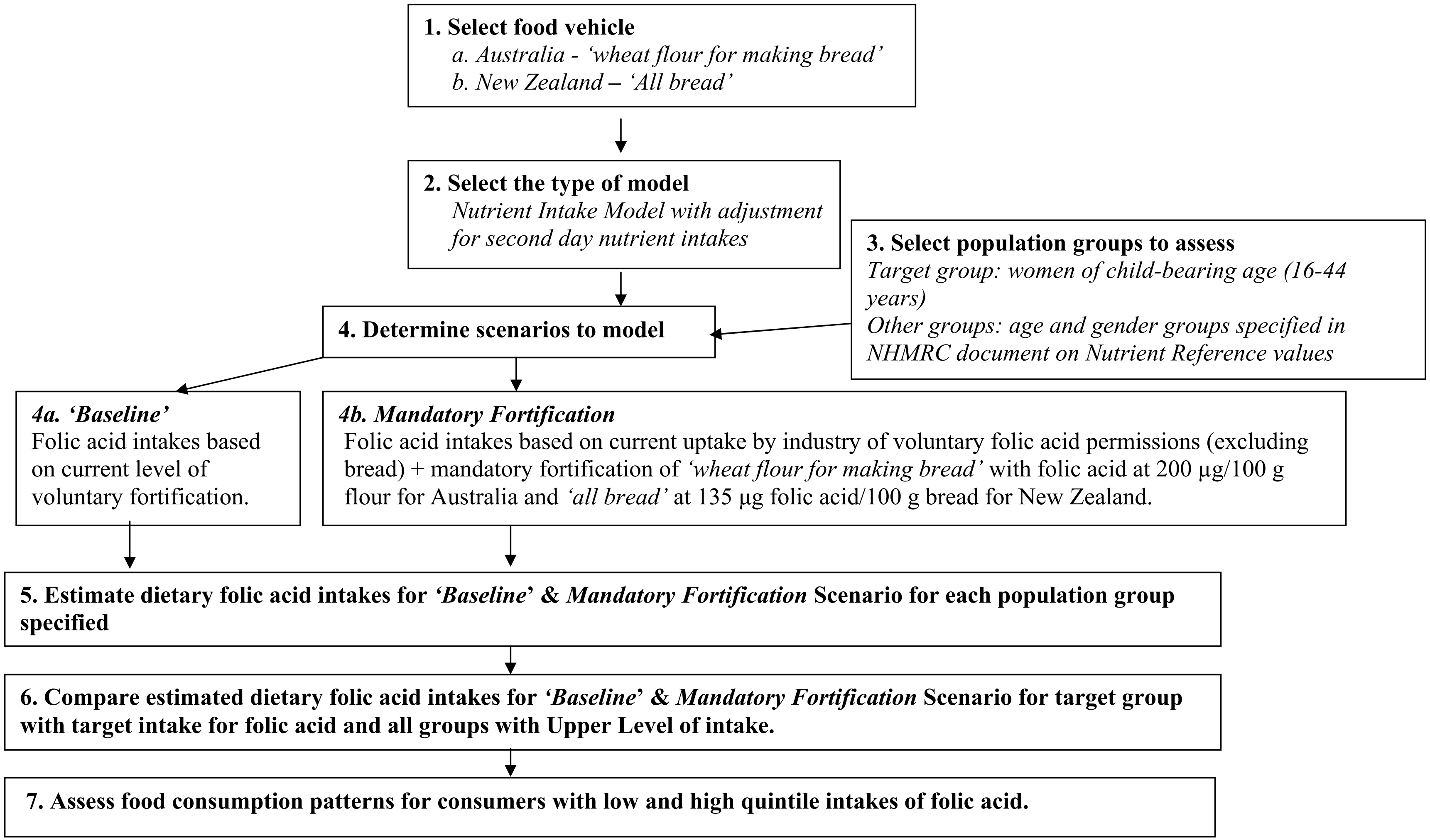
This scenario represents current estimated folic acid intakes for each population group assessed before mandatory folic acid fortification permissions are given in Australia and New Zealand. This scenario only considers those voluntary folic acid permissions outlined in Standard 1.3.2 of the Code that have been taken up by industry, as evidenced by products available on the supermarket shelves. It does not include foods or food groups where voluntary fortification of folic acid is permitted in the Code but has not been taken up by industry. It does not take into account naturally occurring folates in food or folic acid from the use of folic acid supplements or multi-vitamin supplements containing folic acid.

Baseline concentrations for foods voluntarily fortified with folic acid were derived from four major sources:

- unpublished FSANZ analytical data for samples purchased in Australia in 1997, 2005 and 2006; samples included in these analyses included a number of different types of common breakfast cereals, fortified breakfast juice and white bread;

- analytical data for samples purchased in New Zealand in 2003 and 2004 (Thomson, 2005); samples included in these analyses included breakfast cereals, juice, bread and food drinks;

Figure 4: Dietary modelling approach used for the First Review for Australia and New Zealand for mandatory fortification



- current label data for foods where no analytical values were available, without adjustment for potential under- or overages of folic acid; and
- recipe calculation for foods that contain a folic acid fortified food as one of their ingredients (e.g. chocolate crackles that contain fortified puffed rice breakfast cereal).

The effect of cooking foods was also taken into account when constructing the folic acid concentration database. For example, when cooking bread to make toast, both losses in folic acid from heat and weight change factors due to moisture losses when making bread into toast were taken into account.

Concentration data used for various foods for dietary modelling purposes were mainly based on the analytical data. The Australian NNS does not distinguish between the consumption of folic acid fortified white bread from unfortified white bread. The market share for folic acid fortified bread in Australia was estimated at 15% of all breads, based on sales information for a major bakery retail chain (Bakers Delight, 2006). A value representing 15% of the analysed or labelled concentration of folic acid in fortified breads was assigned to all white breads. New Zealand 1997 NNS provided separate consumption amounts for some fortified versus unfortified breads. Where fortification status was specified, folic acid concentrations were assumed only for those foods. Based on available information, fortification of breads with folic acid does not appear to be as common in New Zealand as in Australia. Note that *Bakers Delight* bread in NZ does not contain folic acid.

Information from the above mentioned four sources was matched against the 1995 Australian and 1997 New Zealand NNS food codes for all those foods identified as being fortified with folic acid (149/4,550 foods in Australia and 101/4,950 foods in New Zealand). All other foods recorded as being consumed were assumed not to contain added folic acid. The lists of foods assumed to currently contain added folic acid are detailed in Appendix 2 (Table A2.1 for Australia and Table A2.2 for New Zealand).

Baseline concentration data for foods voluntarily fortified with folic acid were revised following the Final Assessment for Australia and New Zealand due to new data collected in 2006 becoming available to FSANZ. The results showed an increase in mean folic acid intakes for the revised *Baseline* for each population group assessed by FSANZ at FAR. The increase in estimated mean *Baseline* dietary folic acid intakes for the target group was +13 µg/day and +4 µg/day for Australia and New Zealand, respectively.

2.2.2 Mandatory Fortification

<u>2.2.2.1 Australia – mandatory folic acid fortification of 'wheat flour for making bread'</u>

This model was conducted to estimate dietary folic acid intakes where mandatory folic acid fortification of 'wheat flour for making bread' is permitted in Australia at 200 µg folic acid per 100 g of bread-making flour.

This model assumes that the introduction of mandatory folic acid fortification of 'wheat flour for making bread' will have no impact on the current uptake of voluntary folic acid permissions by industry, with the exception of existing voluntary folic acid permissions for all breads. The *Baseline* folic acid concentrations in foods were revised for the First Review.

The *Mandatory Fortification* model includes *Baseline* folic acid concentrations for all foods other than breads and other foods assumed to contain 'wheat flour for making bread' as a result of mandatory folic acid fortification of all wheat bread-making flour at 200 µg per 100 g of bread-making flour.

It does not take into account naturally occurring folates in food or folic acid from the use of folic acid supplements or multi-vitamin supplements containing folic acid.

Folic acid concentrations were estimated based on the proportion of 'wheat flour for making bread' that a food contains and on the final concentration of folic acid assumed to be delivered in the 'wheat flour for making bread'. For example for white bread, the folic acid concentrations were calculated as follows:

Proportion of 'wheat flour for making bread' in white bread	=	60%
Final concentration of folic acid in flour after baking	=	200 µg folic acid/100 g
Folic acid concentration in white bread	=	0.6 x 200 µg folic acid/ 100 g bread
	=	120 µg folic acid/ 100 g bread

These estimates do not take into account potential losses of folic acid during storage. The proportions of 'wheat flour for making bread' in foods were estimated based on recipe information from the 1997 New Zealand NNS or from recipe information in the FSANZ dietary modelling computer program, DIAMOND.

Figure 1a outlines the foods that were deemed to contain 'wheat flour for making bread' for the purposes of the dietary intake assessment. For a summary of folic acid concentration data used for *Mandatory Fortification*, see Appendix 2 (Table A2.1).

2.2.2.2 New Zealand – mandatory folic acid fortification of 'all breads'

The *Mandatory Fortification* model estimated dietary folic acid intakes for each population group resulting from mandatory folic acid fortification of 'all bread' in New Zealand at 135 µg folic acid per 100 g of bread. Figure 1b outlines the foods that were deemed to be 'bread' for the purposes of the dietary intake assessment.

This model assumes that the introduction of mandatory folic acid fortification of 'all bread' will have no impact on the current uptake of voluntary folic acid permissions by industry, with the exception of existing voluntary folic acid permissions for white, brown, wholemeal, grain and rye breads. Therefore, this model includes *Baseline* folic acid concentrations for all foods other than bread, and folic acid concentrations for bread as a result of mandatory folic acid fortification at 135 µg folic acid per 100 g of bread.

It does not take into account naturally occurring folates in food or folic acid from the use of folic acid supplements or multi-vitamin supplements containing folic acid.

For a summary of folic acid concentration data used for *Mandatory Fortification* see Appendix 2 (Table A2.2).

3. Assumptions Used In The Dietary Intake Assessments

The assumptions used in the dietary intake assessments for folic acid were provided in detail in Attachment 7 of the P295 – Consideration of Mandatory Fortification with Folic Acid Final Assessment report.

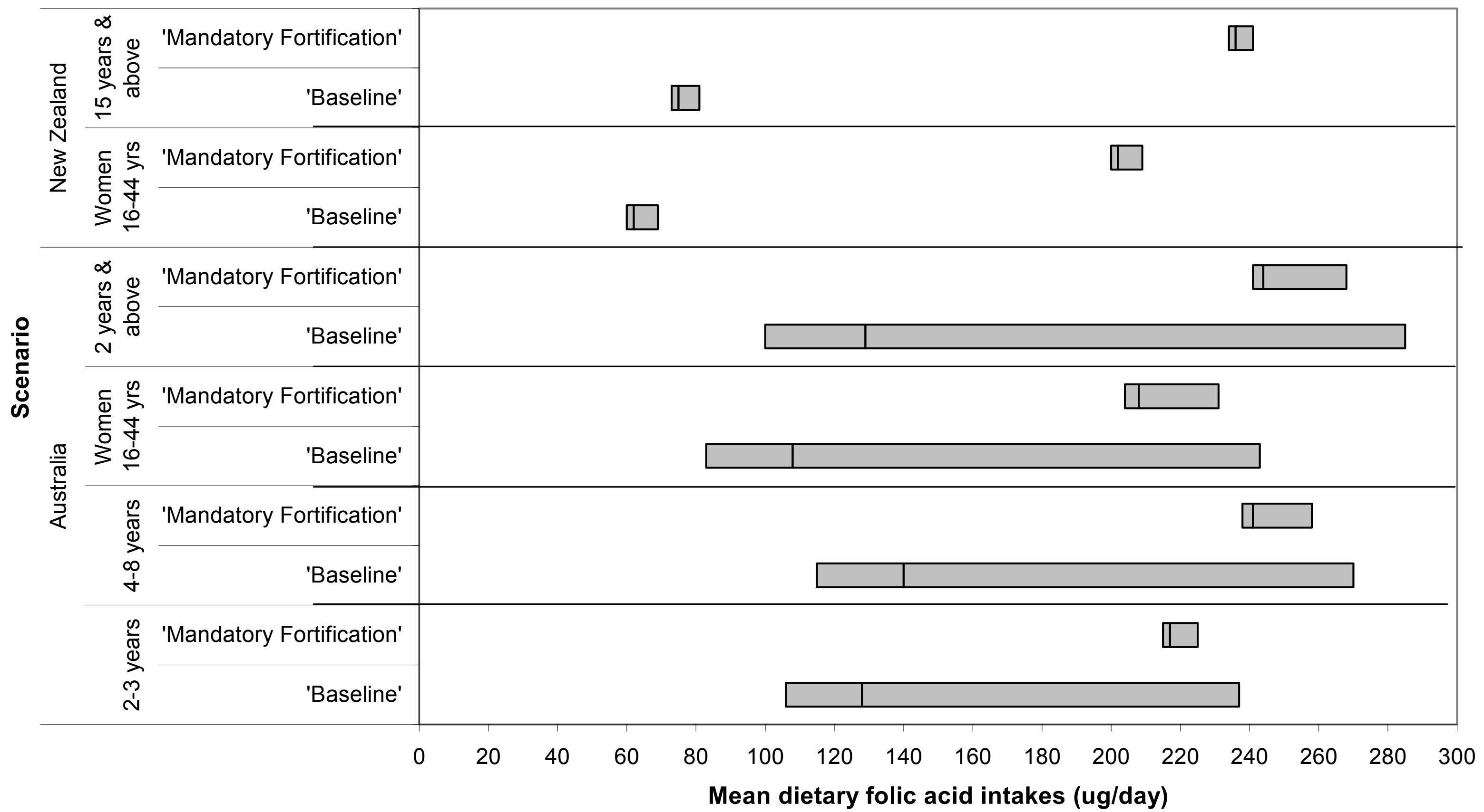
4. Estimated Dietary Folic Acid Intakes From Folic Acid Added To Foods Only

Dietary folic acid intakes were estimated for Australian and New Zealand population sub-groups using 2 different model types: (1) market share model; and (2) consumer behaviour models. These models are discussed in detail in Section 7 of the main report. Comparisons between estimated mean folic acid intakes under *Baseline* and *Mandatory Fortification* scenarios are presented in Figure 5; the lower and upper ends of the range of mean folic acid intakes represent the results from the 'consumer behaviour' model – the lower bound indicates folic acid intakes for individuals who always avoid the products that contain folic acid; the upper bound indicates folic acid intakes for individuals who always select the products that contain folic acid. The results from the 'market share' model are indicated by the black line within the range of estimated folic acid intakes, and are representative of mean **population** intakes over a period of time. Generally, the results presented in this section refer to the 'market share' model results.

The 'consumer behaviour' model range of results gives an indication of the uncertainty of the outcome of the current (*Baseline*) voluntary fortification approach for estimating folic acid intakes compared to the outcome for the *Mandatory Fortification* scenario. The differences in potential ranges of intakes between *Baseline* and *Mandatory Fortification* scenarios indicate that bread and bread products make a significant contribution to total folic acid intakes. By mandating or fixing the level of folic acid in wheat flour for making bread in Australia, the choice for consumers is limited for that one type of food but the certainty of outcome of fortification increases considerably. The estimated mean dietary folic acid intakes for New Zealand did not show as large a range as for Australia. This could be due to differences in the uptake of voluntary folic acid fortification between the two countries, being lower in New Zealand.

The 'consumer behaviour' model results indicate that, for an individual who eats large amounts of the fortified foods and goes out of their way to select the fortified version wherever there is a choice, then higher folic acid intakes can be achieved. However, it is considered that the number of consumers who would actually behave in this way on a regular basis is likely to be small.

Figure 5: Comparison between estimated mean dietary folic acid intakes at Baseline and Mandatory Fortification for Australian and New Zealand population groups.



4.1 Estimated dietary folic acid intakes for women of child-bearing age

The estimated mean dietary folic acid intakes for Australian and New Zealand women of child-bearing age are shown in Table 1 and Figure 6 for *Baseline* and *Mandatory Fortification* scenarios. There was an incremental increase in folic acid intakes for women of child-bearing age from *Baseline* to *Mandatory Fortification*: +100 µg/day for Australia and +140 µg/day for New Zealand. While the estimated mean dietary folic acid intakes showed a higher increase from *Baseline* to *Mandatory Fortification* for New Zealand than Australia, New Zealand women aged 16-44 years had a lower *Baseline* estimated mean folic acid intakes (62 µg/day) in comparison to Australian women (108 µg/day). The introduction of mandatory folic acid fortification of 'wheat flour for making bread' for Australia and 'all breads' for New Zealand would result in women aged 16-44 years in both Australia and New Zealand having similar estimated mean dietary folic acid intakes – 208 µg/day for Australia and 202 µg/day for New Zealand. Full results can be found in Appendix 3, Tables A3.1.a and b for Australia and New Zealand, respectively.

Estimated mean dietary folic acid intakes from food alone for women of child bearing age did not achieve the desired folic acid intake of 400 µg/day for any of the scenarios examined (i.e. *Baseline* voluntary fortification v/s *Mandatory Fortification*). Further details on the proportion of the target group whose estimated dietary folic acid intakes met the 400 µg/day folic acid target can be found in Table 5.

These results also indicate that New Zealand women of child-bearing age have lower *Baseline* folic acid intakes than Australian women. This is because there appears to be lesser uptake of voluntarily folic acid permissions in New Zealand. One of the major areas of difference is that Bakers Delight bread, which represents approximately 15% of the bread market in Australia (Bakers Delight 2006), is not fortified with folic acid in New Zealand, but is fortified in Australia.

Table 1: Estimated mean folic acid intakes from food and increase in folic acid intake from *Baseline* for women of child-bearing age (16-44 years) #

a. Australia

Scenario	**Mean dietary folic acid intake (Increase in folic acid intake from *Baseline*) µg/day**	
	Market weighted	**Consumer behaviour**
Baseline	108	83 – 243
Mandatory Fortification♦	208 (+100)	204 – 231

Number of respondents aged 16-44 years: Australia = 3,178

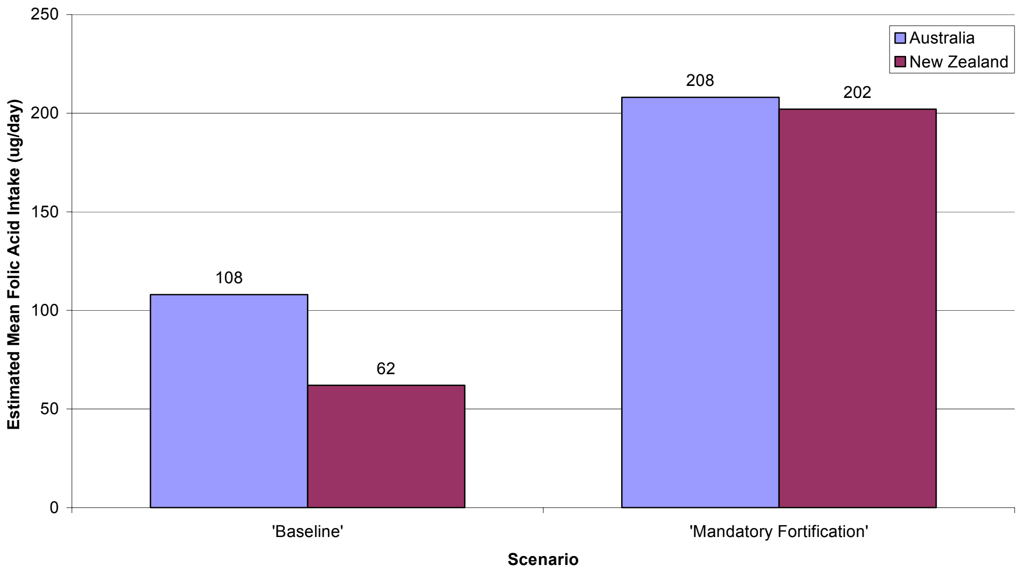
♦ Mandatory folic acid fortification of 'wheat flour for making bread' for Australia

b. New Zealand

Scenario	Mean dietary folic acid intake (Increase in folic acid intake from *Baseline*) µg/day	
	Market weighted	**Consumer behaviour**
Baseline	62	60 – 69
Mandatory Fortification♦	202 (+140)	200 – 209

\# Number of respondents aged 16-44 years: New Zealand = 1,509
♦ Mandatory folic acid fortification of 'all bread' for New Zealand

Figure 6: Estimated mean dietary folic acid intakes for Baseline and Mandatory Fortification scenarios for Australian and New Zealand women of child-bearing age (16-44 years)



4.2 Estimated dietary folic acid intakes for the non-target groups

Dietary folic acid intakes were estimated for the non-target groups to assess the impact that *Mandatory Fortification* would have on public health and safety. Figure 5 shows the estimated mean dietary folic acid intakes for the target group (women aged 16-44 years) and various other non-target groups. The results show an increase in estimated mean dietary folic acid intakes from *Baseline* to the *Mandatory Fortification* scenario for all non-target groups. As for women of child-bearing age, non-target groups in New Zealand also have lower *Baseline* folic acid intakes compared to Australia, with similar estimated mean dietary folic acid intakes for New Zealanders aged 15 years and above (236 µg/day) and Australians aged 2 years and above (244 µg/day) under *Mandatory Fortification*. Full results for the estimated dietary folic acid intakes for the non-target groups are in Appendix 3: Table A3.2 for Australia and Table A3.3 for New Zealand.

4.3 Major contributors to estimated folic acid intakes

The major food contributors for both Australia and New Zealand to total folic acid intake (≥5%) were calculated for women of child bearing age and the general population for both *Baseline* and *Mandatory Fortification* scenarios. The major contributing foods to folic acid intakes for Australian children aged 2-3 years and 4-8 years were also analysed. The results are shown in Table 2.

At *Baseline*, breakfast cereals were the major contributors to folic acid intakes for both the Australian and New Zealand populations. Yeast extracts and breads were also major contributors to the Australian population's intakes of folic acid. For New Zealand, yeast extracts were a major contributor at *Baseline* but breads were not.

For the *Mandatory Fortification* scenarios, bread was the major contributor to folic acid intakes for both Australia and New Zealand. Breakfast cereals and yeast extracts were the other major contributors to folic acid intakes for Australia and New Zealand for the *Mandatory Fortification* scenarios. While breakfast cereals were a major contributor to the folic acid intakes of the target group under current voluntary fortification levels (*Baseline*), they were not consumed by as large a proportion of the target group as breads.

Table 23: Major contributors (>5%) to folic acid intakes at *Baseline* and *Mandatory Fortification* scenarios for Australia and New Zealand

Country	Population group	Scenario	Major contributors (%)		
			Breads	Breakfast cereals	Yeast extracts
Australia	2 years and above	*Baseline*	19	51	24
		Mandatory Fortification♦	55	27	13
	2-3 years	*Baseline*	15	45	28
		Mandatory Fortification♦	46	28	17
	4-8 years	*Baseline*	16	48	31
		Mandatory Fortification♦	49	28	18
	Females 16-44 years	*Baseline*	20	47	28
		Mandatory Fortification♦	56	24	14
New Zealand	15 years and above	*Baseline*	<1	61	35
		Mandatory Fortification♦	69	19	11
	Females 16-44 years	*Baseline*	1	58	37
		Mandatory Fortification♦	70	18	11

♦ Mandatory folic acid fortification of 'wheat flour for making bread' for Australia and mandatory folic acid fortification of 'all bread' for New Zealand

Note: the shaded cells indicate that the food is not a major contributor to folic acid intakes

4.4 Risk characterisation

The estimated folic acid dietary intakes were compared with the Nutrient Reference Value (NRV) called an Upper Level (UL) to determine if the proposed level of addition of folic acid to 'wheat flour for making bread' (Australia only) or bread (New Zealand only) might be a concern to public health and safety. The UL is 'the highest average daily nutrient intake level likely to pose adverse health effects to almost all individuals in the general population' (National Health and Medical Research Council, 2006). The ULs for folic acid for pregnant and lactating women are 800 µg/day for 16-18 year old women and 1,000 µg/day for 19-44 year old women. The ULs for other population groups are given in Table 4.

The estimated dietary intakes for folic acid were determined for each individual and were compared to the relevant UL for the individual's age group and gender. The proportion of the target group exceeding the UL is shown in Tables 3a and b for Australia and New Zealand, respectively. The tables illustrate that less than 1% of women aged 16-44 years exceed the UL at *Baseline* and *Mandatory Fortification*.

Table 3: Proportion of respondents with folic acid intakes above the Upper Level for women of child-bearing age (16-44 years)#

a. Australia

Scenario	% of respondents with folic acid intakes >UL
Baseline	<1
Mandatory Fortification♦	<1

Number of respondents aged 16-44 years: Australia = 3,178
♦ Mandatory folic acid fortification of 'wheat flour for making bread' for Australia

b. New Zealand

Scenario	% of respondents with folic acid intakes >UL
Baseline	<1
Mandatory Fortification♦	<1

Number of respondents aged 16-44 years: New Zealand = 1,509
♦ Mandatory folic acid fortification of 'all bread' for New Zealand

The proportion of each non-target population group exceeding the UL is shown in **Table** for *Baseline* and *Mandatory Fortification* scenarios for the Australian and New Zealand populations.

For Australia, the results indicate that children aged 2-3 years and 4-8 years are the most likely of the non-target groups to have intakes exceeding the UL if mandatory folic acid fortification of 'wheat flour for making bread' were to be introduced (refer to Table 4 for details). In order for the risk to Australian children aged 2-3 years and 4-8 years to be characterised further, high consumer (95^{th} percentile) intakes of folic acid were investigated and compared to the UL.

Additionally, the maximum estimated dietary folic acid intakes for the 'consumer behaviour' model were investigated – i.e. for individual consumer behaviour. The results indicated that the estimated dietary folic acid intakes for Australian children aged 2-3 years and 4-8 years were acceptable.

Full results can be found in Appendix 4, Table A4.1 for Australia and Table A4.2 for New Zealand).

Table 4: Proportion of non-target group respondents with folic acid intakes above the Upper Level

a. Australia

Population Group	Upper Level (µg/day)	No. of respondents	% respondents with dietary folic acid intakes >UL		95th percentile dietary folic acid intakes µg/day (%UL)	
			Baseline	*Mandatory Fortification♦*	*Baseline*	*Mandatory Fortification♦*
2-3 years	300	383	2	9	232 (75%)	338 (110%)
4-8 years	400	977	1	4	282 (70%)	388 (95%)
9-13 years	600	913	1	2		
14-18 years	800	734	<1	2		
19-29 years	1,000	2,203	<1	<1		
30-49 years	1,000	4,397	<1	<1		
50-69 years	1,000	3,019	<1	<1		
70 years & above	1,000	1,232	0	0		

♦ Mandatory folic acid fortification of all bread making flour for Australia

b. New Zealand

Population Group	Upper Level (µg/day)	No. of respondents	% respondents with dietary folic acid intakes >UL	
			Baseline	*Mandatory Fortification♦*
15-18 years	800	246	0	<1
19-29 years	1,000	804	0	<1
30-49 years	1,000	1,883	<1	<1
50-69 years	1,000	1,147	0	<1
70 years & above	1,000	556	0	0

♦ Mandatory folic acid fortification of all bread for New Zealand

5. Additional Calculations To Estimate Folic Acid Intakes From Food And Supplements

Currently, women planning pregnancy and pregnant women are advised to take folic acid supplements (Food Standards Australia New Zealand, 2006). Consequently, additional calculations were undertaken by FSANZ to estimate folic acid intakes assuming women of child-bearing age received folic acid from folic acid supplements in addition to receiving folic acid via voluntary and mandatory fortification of foods.

Additional calculations were not conducted for each of the non-target groups due to limited information available on supplement use. Also, there are no specific nutrition policies that specify that members of the population other than the target group should take folic acid supplements.

5.1 How were the folic acid intakes from food and supplements calculated?

The methodology used to estimated dietary folic acid intakes from food and supplements is discussed in Attachment 7 of the P295 – Consideration of Mandatory Fortification with Folic Acid Final Assessment report.

5.2 Estimated dietary intakes of folic acid from food and supplements for women of child-bearing age

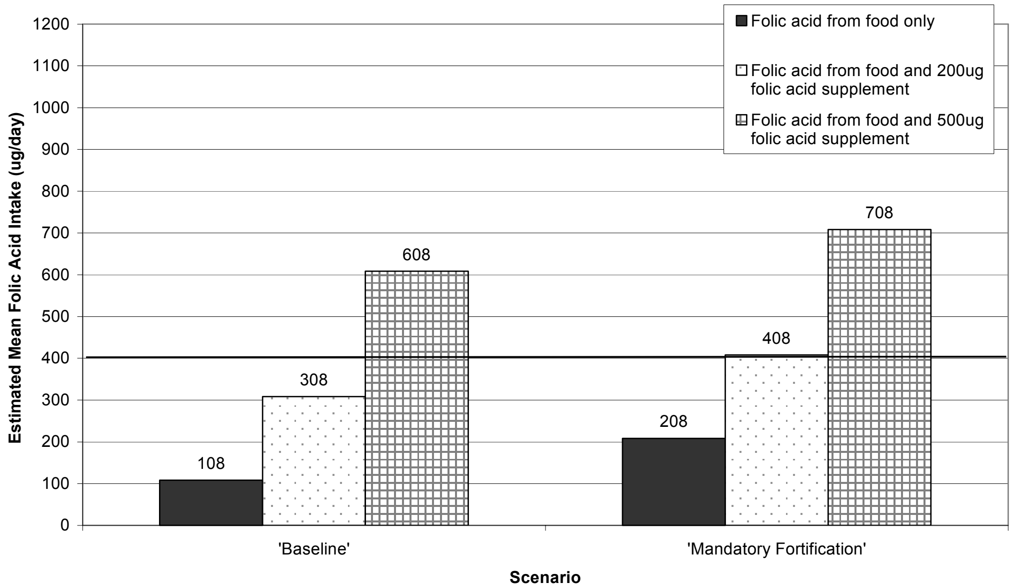
The results indicate that 5% of Australian and 3% of New Zealand women of child-bearing age met the recommended 400 µg of folic acid per day for *Mandatory Fortification* scenarios from food alone. The estimated dietary folic acid intakes for *Baseline* and *Mandatory Fortification* scenarios from food and folic acid supplements for Australian and New Zealand women of child-bearing age were compared with the 'target intake' (400 µg folic acid per day). The results show an increase in estimated dietary folic acid intakes for *Baseline* and *Mandatory Fortification* when additional folic acid is consumed from supplements. These results are also shown in Figures 7a and b.

When a 200 µg per day folic acid supplement is considered in conjunction with *Mandatory Fortification*, approximately 40% of Australian and New Zealand women of child-bearing age are estimated to meet the recommended amount of folic acid. If a 500 µg or 800 µg folic acid supplement is consumed by all women of child-bearing age, 100% of women of child-bearing age would meet the recommended daily amount of folic acid. Full details can be found in Table 5.

Full results on folic acid intakes from both food and supplements can be found in Appendix 5, table A5.1 for Australia and Table A5.2 for New Zealand).

Figure 7: Estimated mean dietary folic acid intakes from food and folic acid supplements for Baseline and Mandatory Fortification scenarios for Australian and New Zealand women of child-bearing age (16-44 years)

a: Australia



b: New Zealand

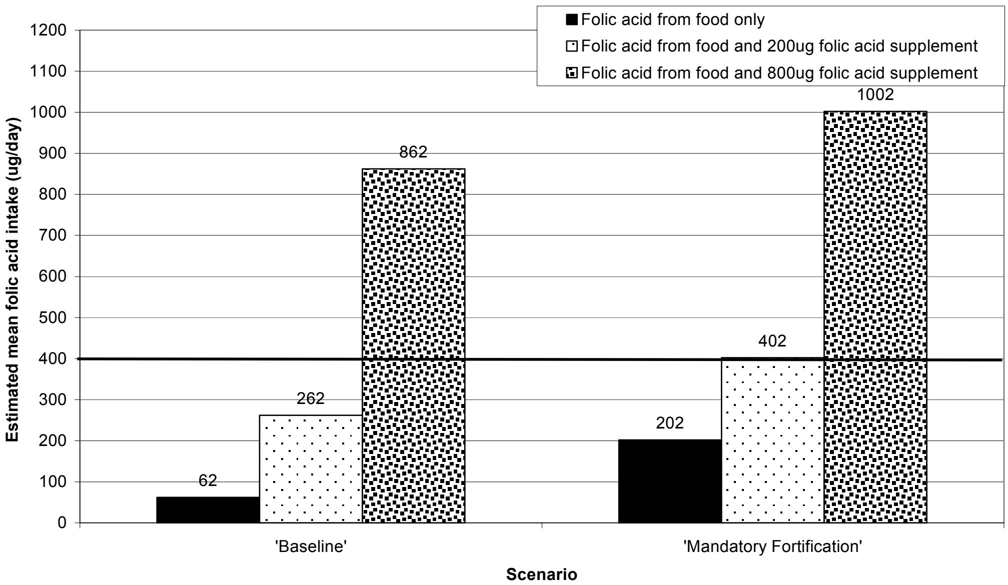


Table 5: Proportion of respondents with folic acid intakes of at least 400 µg/day from food with and without supplements for Australian and New Zealand women of child-bearing age (16-44 years)#

Scenario	% of respondents with folic acid intakes of at least 400 µg/day from food ± supplements					
	Australia			New Zealand		
	No Supplement	200µg Supplement	500µg Supplement	No Supplement	200µg Supplement	800µg Supplement
Baseline	2	11	100	<1	4	100
Mandatory Fortification♦	5	42	100	3	42	100

\# Number of respondents aged 16-44 years: Australia = 3,178; New Zealand = 1,509

♦ Mandatory folic acid fortification of 'wheat flour for making bread, for Australia and mandatory folic acid fortification of 'all bread' for New Zealand

5.3 Comparison of the estimated dietary intakes from food and supplements with the Upper Level

The results indicate that when Australian and New Zealand women of child-bearing age consume additional folic acid from a supplement, there is likely to be an increase in the proportion of the target group exceeding the UL of 800 µg of folic acid per day for women aged 16-18 years and 1,000 µg of folic acid per day for women aged 19-44 years (see Table 6 for a summary of results). Full results can be found in Table A5.3 and Table A5.4 of Appendix 5.

When consumption of supplements was considered for the target group, the proportion of respondents aged 16-44 years exceeding the UL increased as the concentration of folic acid in the supplement increased. There was no change in the proportion of the Australian target population exceeding the UL with a folic acid supplement of 200 µg per day from *Baseline* to *Mandatory Fortification*. With a 500 µg supplement, the proportion of the Australian target population exceeding the UL increases slightly from 2% at *Baseline* to 4% under the *Mandatory Fortification* scenario.

There was minimal change in the proportion of the New Zealand target population exceeding the UL with a folic acid supplement of 200 µg per day for all scenarios assessed. In New Zealand, supplements containing 800 µg of folic acid are available. If all New Zealand women of child-bearing age consumed this supplement, a high proportion (46%) would be likely to exceed the UL under the *Mandatory Fortification* scenario. With an 800 µg supplement, the proportion of the New Zealand target population exceeding the UL increases from 10% at *Baseline* to 46% under the *Mandatory Fortification* scenario.

Table 6: Proportion of respondents with folic acid intakes from food and supplements above the Upper Level for Australian and New Zealand women of child-bearing age (16-44 years)#

Scenario	% of respondents with folic acid intakes from food and supplements > UL			
	Australia		**New Zealand**	
	200µg Supplement	500µg Supplement	200µg Supplement	800µg Supplement
Baseline	<1	2	<1	10
Mandatory Fortification♦	<1	4	<1	46

Number of respondents aged 16-44 years: Australia = 3,178; New Zealand = 1,509

♦ Mandatory folic acid fortification of 'wheat flour for making bread' for Australia and mandatory folic acid fortification of 'all bread' for New Zealand

6. Food Consumption Patterns For Women Aged 16-44 Years For Respondents With Low and High Quintile Intakes of Folic Acid

During consultations with the food industry, one issue raised was that of exploring the potential for identifying food vehicles that would more effectively target women of child bearing age who currently have low folic acid intakes. The 1995 NNS and 1997 NZ NNS survey respondents were divided into five groups or 'quintiles of folic acid intake' for each country, quintile 1 being the low folic acid intake group (bottom 20% of folic acid intakes for women of child bearing age), quintile 5 being the high folic acid intake group (top 20% of folic acid intakes for women of child bearing age) and the food consumption patterns of each group assessed.

It should be noted that the folate status (blood levels of folate) for women in different quintiles cannot be assumed from their estimated folic acid intakes alone i.e. women in the lowest quintile for folic acid intakes are not necessarily those who would be in the lowest quintile for blood folate levels.

Food consumption patterns are complex, the proportion of people consuming and the amount of food they consume have an impact on both the total amount of folic acid consumed and the relative contribution each food makes to that folic acid intake. Food groups other than those currently permitted to add folic acid were also investigated as potential food vehicles that would better target the low folic acid intake group. The methodology used to investigate these potential differences is summarised in detail in Figure 8 below. Differences in folic acid intakes, major contributors to folic acid and in general food consumption patterns were found between quintile 1 and 5 groups.

Figure 8: Methodology for investigating differences in food consumption patterns for low and high folic acid consumers.

Population group to investigate:

- Females 16-44 years

Using 2nd day nutrient adjustment methodology:
Derive folic acid intakes for each individual in the population group for *'Baseline'*.

↓

For women of child bearing age:
Divide folic acid intakes into quintiles of intake.

↓

Identify the individual women of child bearing age with folic acid intakes in:

- Quintile 1 or bottom 20% (low folic acid intake); and
- Quintile 5 or top 20% (high folic acid intake).

↓

What were the mean *'Baseline'* and *Mandatory Fortification* intakes of folic acid for:

- Quintile 1; and
- Quintile 5 respondents?

↓

Using food consumption patterns from Day 1 of the NNSs:
Determine & compare the major food contributors to folic acid intakes for *'Baseline'* and *Mandatory Fortification* for:

- Quintile 1; and
- Quintile 5 respondents.

↓

Using food consumption patterns from Day 1 of the NNSs:
Determine & compare the proportion of women of child bearing age consuming specific foods and beverages for:

- Quintile 1; and
- Quintile 5.

↓

Using food consumption patterns from Day 1 of the NNSs:
Determine & compare the mean amount of specific foods and beverages eaten by women of child bearing age in:

- Quintile 1; and
- Quintile 5.

6.1 Mean folic acid intakes

For women of child bearing age with low and high folic acid intakes, the introduction of mandatory fortification of 'wheat flour for making bread' (Australia only) and 'all breads' (New Zealand only) increases the mean intake of folic acid (see Figure 9 for details).

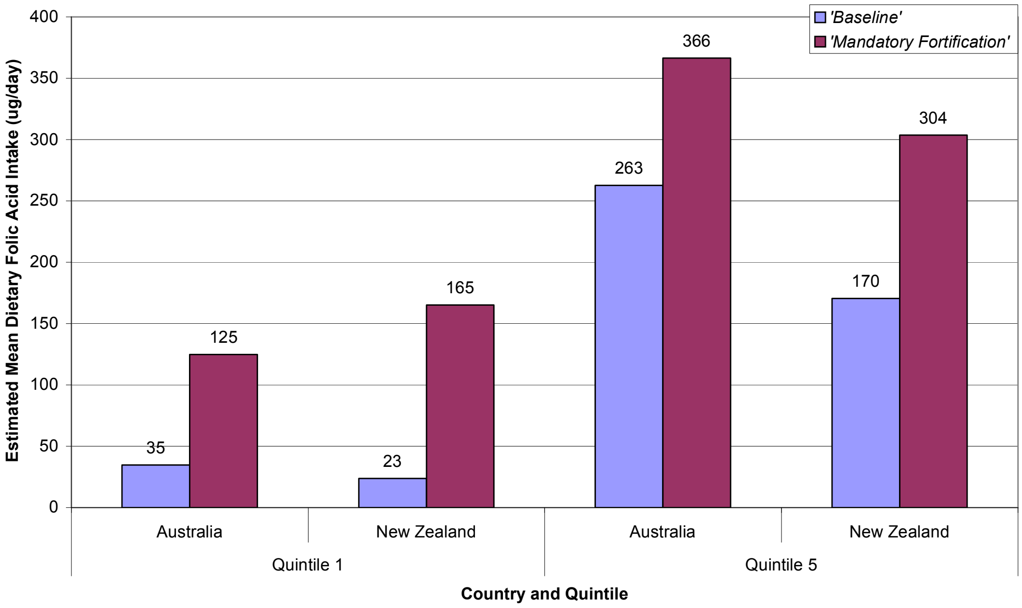


Figure 9: Mean intakes of folic acid for respondents with low and high Baseline intakes of folic acid and the effects of Mandatory Fortification on mean folic acid intakes

For both groups in Australia, mean folic acid intakes would increase by ~ 100 µg folic acid/day. However the impact of a mandatory fortification program would be much greater for the low folic acid intake group as their folic acid intakes would increase by a greater proportional amount (Australia: increase of 260% for low folic acid intake group from 35 µg folic acid /day; increase of 39% for the high intake group from 263 µg folic acid /day).

For the New Zealand women of child bearing age who currently have very low folic acid intakes, mandatory fortification has a bigger impact then that it does for the Australian women with an overall increase of ~ 130-140 µg folic acid /day for both groups (New Zealand: increase of 602% for low folic acid intake group from 23 µg folic acid /day; increase of 78% for the high intake group from 170 µg folic acid /day).

6.2 Major contributors to folic acid intakes

For the population groups outlined in Figure 8 above, the percentage contribution of various food groups to estimated dietary folic acid intakes was examined to determine whether respondents with low *Baseline* folic acid intakes (Quintile 1) have different major contributors to folic acid intakes in comparison to respondents with high *Baseline* folic acid intakes (Quintile 5). It is important to note that the percent contribution of each food group is based on total folic acid intakes for all consumers in the population groups assessed.

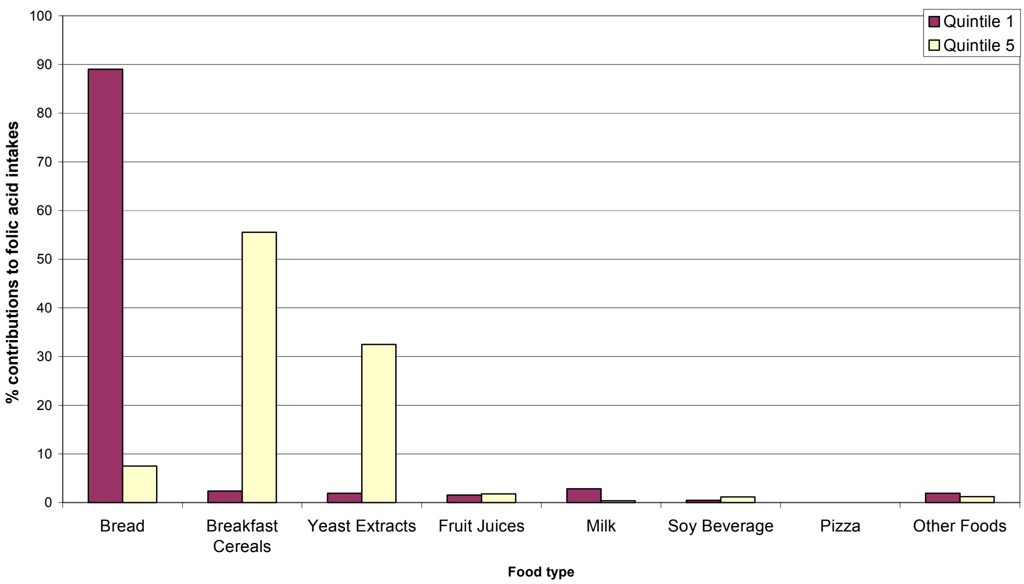
Therefore, the folic acid intakes differ for Quintile 1 and Quintile 5 and for *Baseline* and *Mandatory Fortification*.

6.2.1 Australia

For those respondents with low *Baseline* folic acid intakes (Quintile 1), breads were the major contributor to folic acid intakes for both *Baseline* (48 µg folic acid /day or 89%) and *Mandatory Fortification* (128 µg folic acid /day or 85%) scenarios. For those with high folic acid intakes (Quintile 5) breakfast cereals and yeast extracts were the major contributors for *Baseline* (breakfast cereals 155 µg folic acid /day or 56% total; yeast extracts 89µg folic acid /day or 32% total; bread 19 µg folic acid /day or 7% total) and mandatory fortification (breakfast cereals 41% total; yeast extracts 24% total; bread 110 µg folic acid /day or 29% total)[33]. For both groups in Australia the relative contribution from 'other foods' increased under the mandatory fortification scenario and that for bread decreased slightly because other bread products, such as croissants and English muffins, were also assumed to contain fortified flour. Refer Figure 10a and b below and Table A6.2a in Appendix 6 for further details.

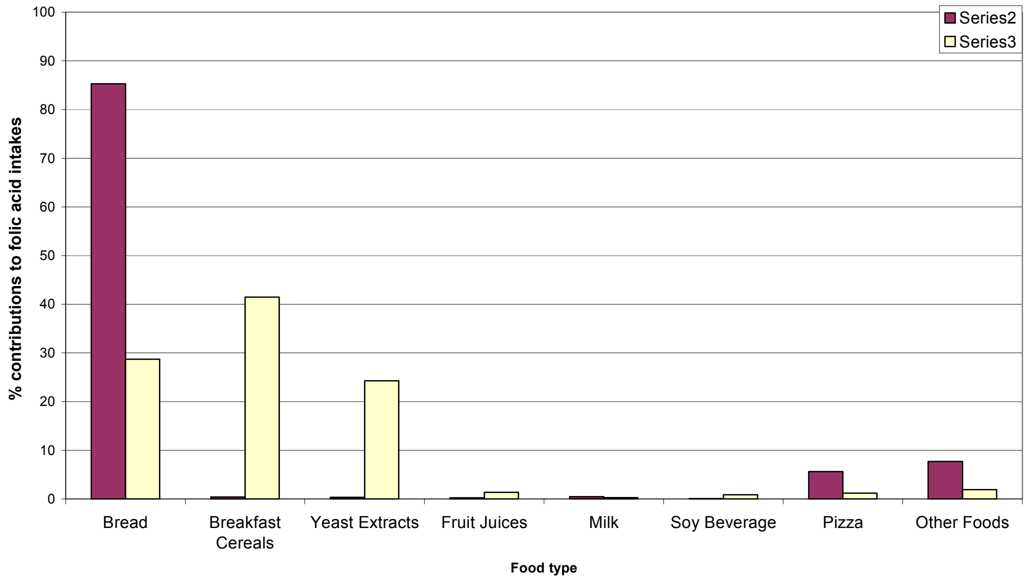
Figure 10: Contribution of various foods to folic acid intakes for Australian women aged 16-44 years, for low and high consumers of folic acid

a. *Baseline*



[33] The intake of folic acid in micrograms for each food group are derived manually, for the purposes of illustration here, using the percent contribution of the food group to total folic acid intakes and the mean folic acid intakes for the population group of interest. However, the calculation of the percent contribution in DIAMOND uses the total folic acid intake from all foods from all respondents and the total folic acid intake from all respondents from the food group in question. The total folic acid intakes differ for each sub-population group and each scenario.

b. *Mandatory Fortification*



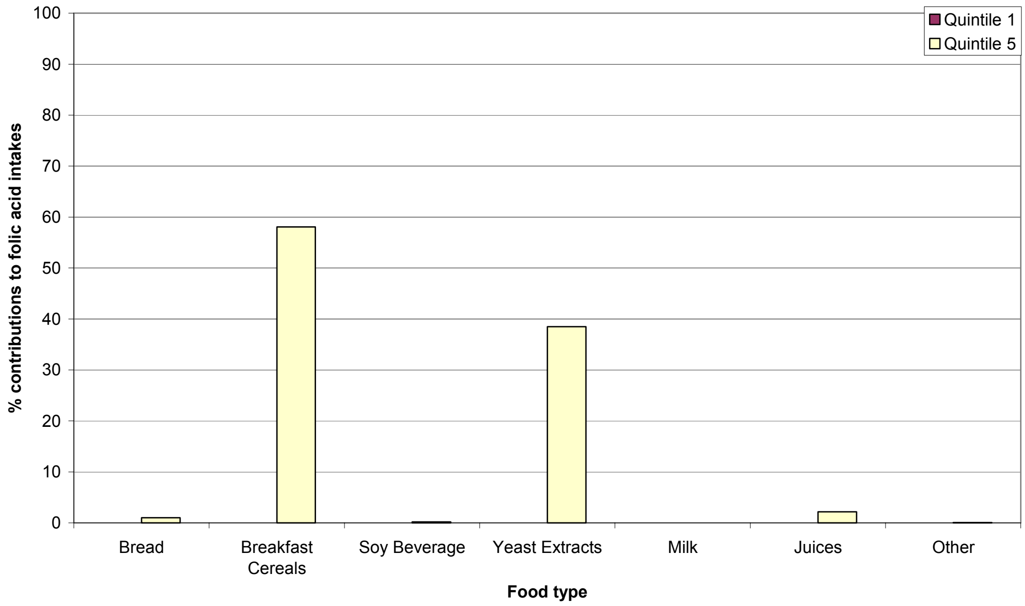
6.2.2 New Zealand

Unlike the Australian women, there were no consumers of foods containing folic acid in the low folic acid intake group of women of child bearing age in New Zealand in the day 1 records due to the fact that fewer fortified foods are currently available in New Zealand. For *Mandatory Fortification*, the major contributor to folic acid intakes for those with low folic acid intakes was breads. No other foods contributed to folic acid intakes for this group, thereby highlighted the importance of breads to folic acid intakes for women who currently have low intakes of folic acid. For those with high folic acid intakes, the major contributors to folic acid intakes for the *Baseline* scenario were breakfast cereals (58% total folic acid intakes), yeast extracts (38% total folic acid intakes) whereas for *Mandatory Fortification* the major contributors were breads, followed by breakfast cereals and yeast extracts (41%, 35% and 23% of folic acid intakes, respectively)[34]. Refer to Figure 11a and b below and Table A6.2 b in Appendix 6 for further details.

[34] The intake of folic acid in micrograms for each food group are derived manually, for the purposes of illustration here, using the percent contribution of the food group to total folic acid intakes and the mean folic acid intakes for the population group of interest. However, to calculation the percent contribution initially, DIAMOND uses the total folic acid intake from all foods from all respondents and the total folic acid intake from all respondents from the food group in question. The total folic acid intakes differ for each sub-population group and each scenario.

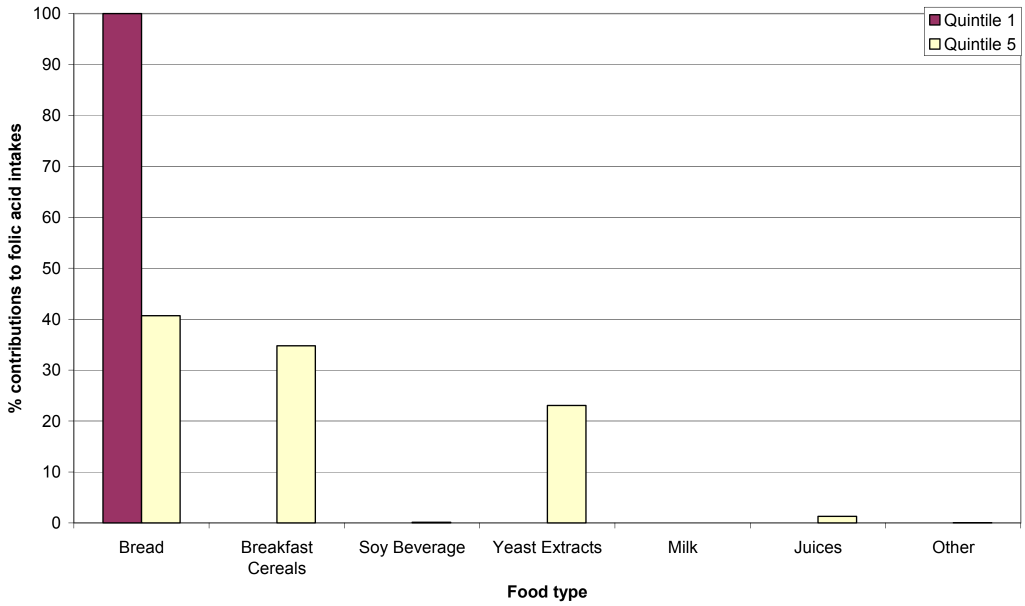
Figure 11: Contribution of various foods to folic acid intakes for New Zealand women aged 16-44 years, for low and high consumers of folic acid

a. Baseline



Note: The percent contribution of various foods to folic acid intakes is derived using Day 1 of the NNS only. For Day 1 of the NNS, the respondents in Quintile 1 (low folic acid intakes) did not have folic acid intakes greater than zero, therefore no contributing foods are presented.

b. Mandatory Fortification



6.2.3 Summary

For all population groups assessed, the major contributing foods to folic acid intakes were different between those with low folic acid intakes (Quintile 1) and those with high folic acid intakes (Quintile 5). Mandatory fortification of wheat flour for bread making in Australia and bread in New Zealand would effectively target women with low folic intakes without overly increasing intakes for women who currently have higher folic acid intakes in relation to increasing total folic acid intakes. Educational messages could highlight that fortified breakfast cereals and yeast extracts are also good sources of folic acid that are currently available.

6.3 Food consumption patterns

Food consumption patterns **were** investigated to check if there was a food(s) that women of child bearing age who currently have low folic acid intakes consumed in greater quantities than those with high folic acid intakes that could be targeted for folic acid fortification by:

1. examining whether similar proportions of respondents[35] in Quintile 1 (low intakes of folic acid) consumed specific foods in comparison to respondents in Quintile 5 (high intakes of folic acid); and
2. investigating whether the amounts of food eaten by consumers[36] of the specific foods were different between Quintile 1 and Quintile 5.

6.3.1 Australia

As shown in Figure 12a, a greater proportion of respondents in Quintile 5 (high folic acid intakes) consumed breads, breakfast cereals and yeast extract spreads than in Quintile 1 (low folic acid intakes). Similar proportions consumed the various types of yoghurts. There were no beverages that would be suitable for fortification that were consumed by a higher proportions of respondents in Quintile 1 than Quintile 5 (refer to Figure 12b).

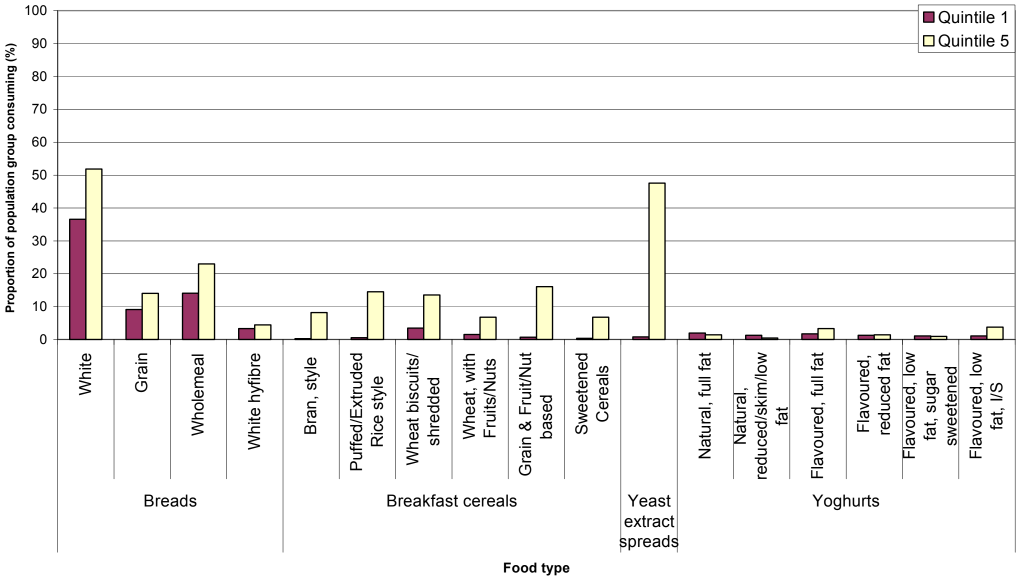
The proportion of Australian women aged 16-44 years consuming a range of other foods was also investigated. The data show that a slightly greater proportion of women in Quintile 1 consumed white wine, cola soft drinks, coffees and teas than those in Quintile 5. However, these types of food products are not appropriate food vehicles for mandatory fortification. The data are presented in detail in Table 6.4a in Appendix 6.

---

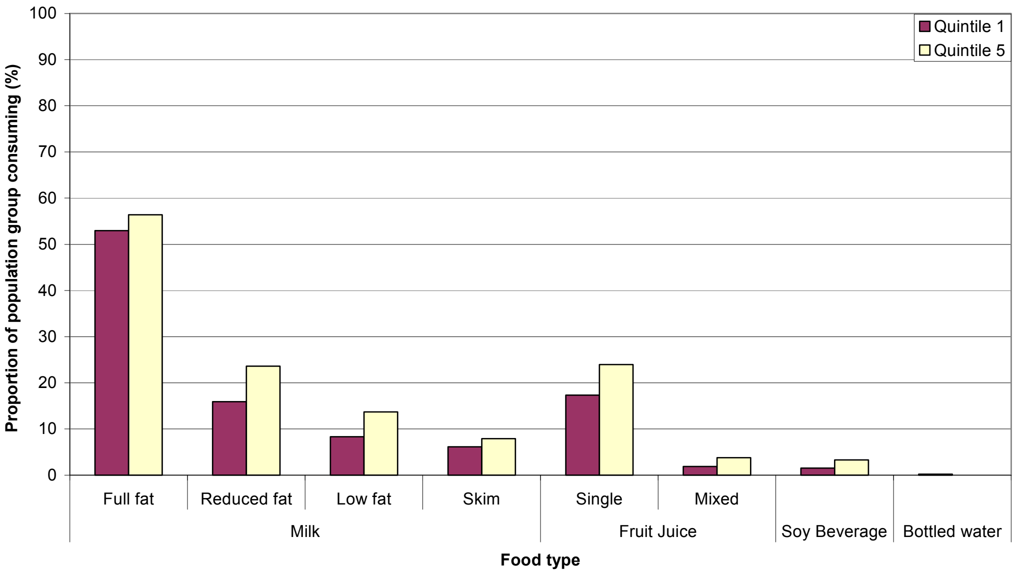
[35] 'Respondents' include all members of the survey population whether or not they consumed the food of interest.
[36] 'Consumers' only includes the people who have consumed the food of interest.

Figure 12: Proportion of Australian women aged 16-44 years that consume various foods and beverages

a. Foods



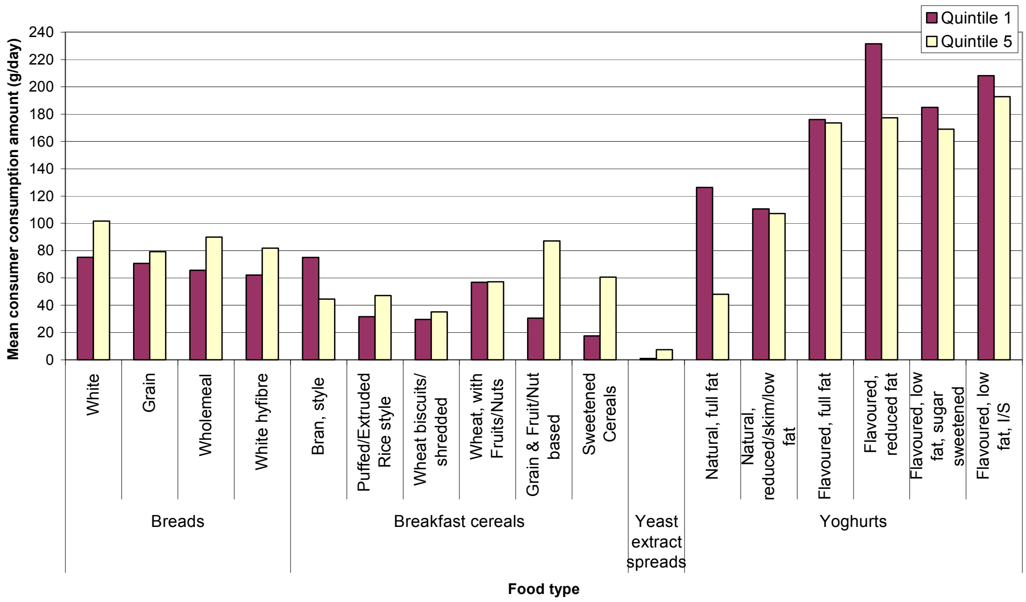
b. Beverages



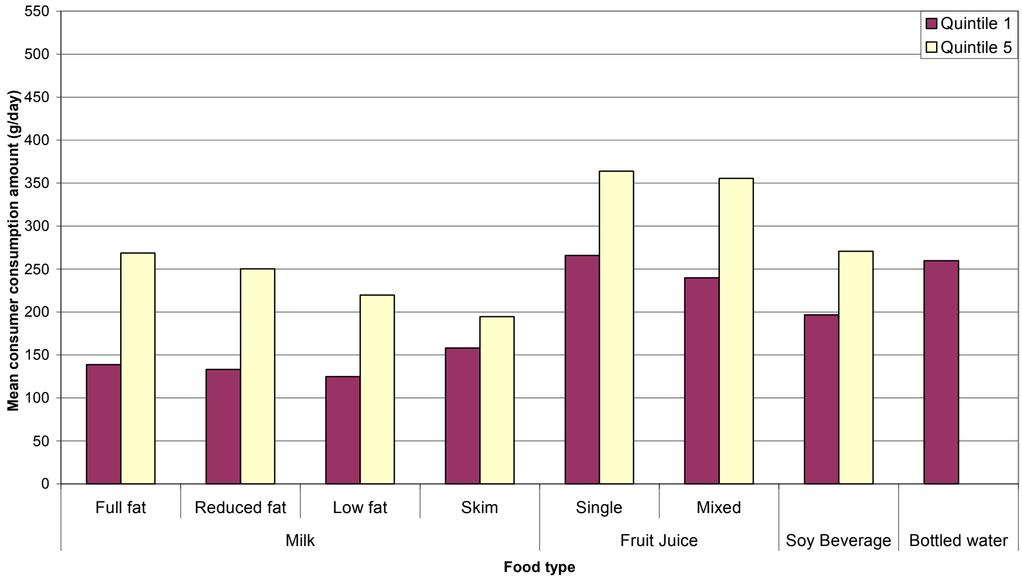
In terms of the actual amount of foods eaten, consumers in Quintile 5 (high folic acid intakes) ate breads, breakfast cereals, yeast extract spreads, milks, juices and soy beverage, on average, in larger amounts than those in Quintile 1 (low folic acid intakes). Refer to Figure 13a and b below and table A6.3a in Appendix 6 for further details. Exceptions were bran based cereals and yoghurts; cereals already have voluntary permission to fortify with folic acid; the potential to fortify low and reduced fat yoghurts is discussed below.

Figure 13: Mean amounts of various foods and beverages eaten by Australian female consumers aged 16-44 years

a. Foods



b. Beverages



6.3.2 New Zealand

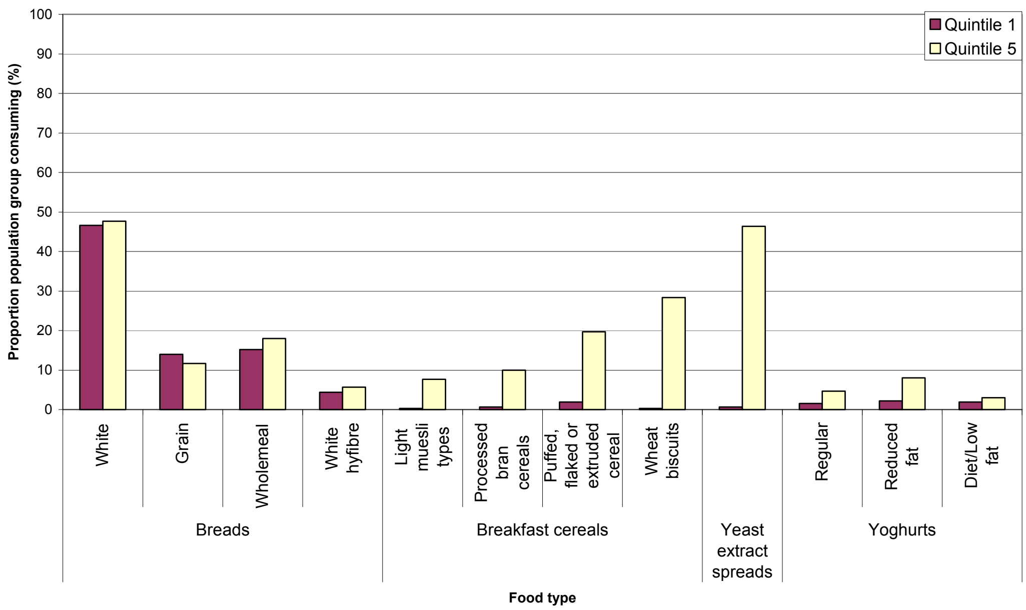
Generally, a greater proportion of respondents in Quintile 5 (high folic acid intakes) consumed breads, breakfast cereals, yeast extract spreads, yoghurts, milks, fruit juices, cordials and juice drinks and soy beverage than in Quintile 1 (low folic acid intakes).

Similar proportions of respondents in Quintile 1 and Quintile 5 consumed diet/low fat yoghurts, whole milk, calcium enriched milks and soy beverages. Refer to Figures 14a and b for details.

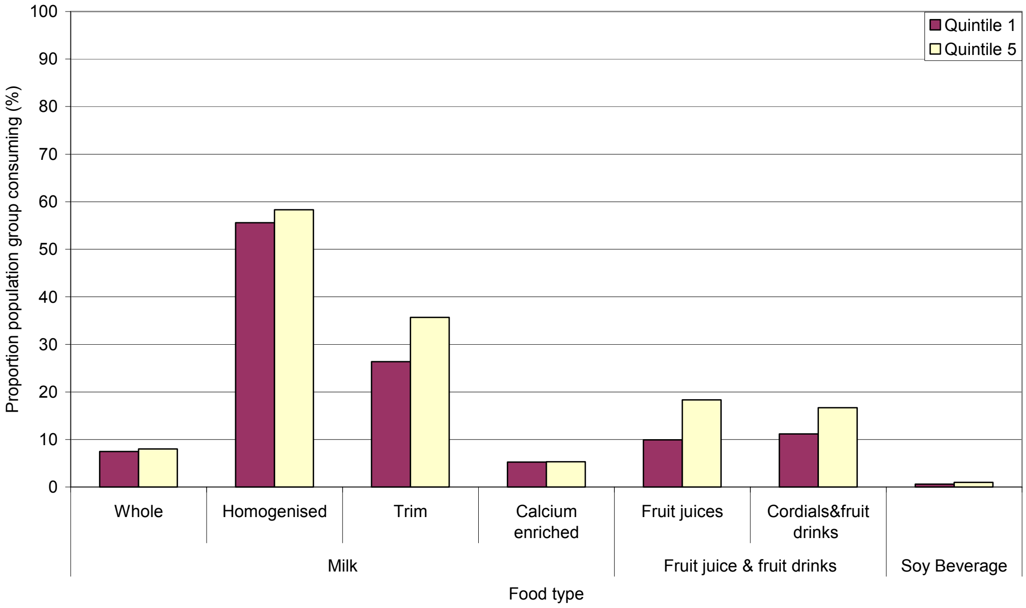
The proportion of New Zealand women aged 16-44 years consuming a range of other foods was also investigated. The data show that a slightly greater proportion of women in Quintile 1 consumed coffees, teas, sweet spreads (jam/marmalade/honey), chocolate biscuits, mixed grain bread and than those in Quintile 5. However, many of these types of food products are not appropriate food vehicles for fortification. Mixed grain bread is already included in the consideration of mandatory fortification with folic acid. The data are presented in detail in Table A6.4b in Appendix 6.

Figure 14: Proportion of New Zealand women aged 16-44 years that consume various foods and beverages

a. Foods



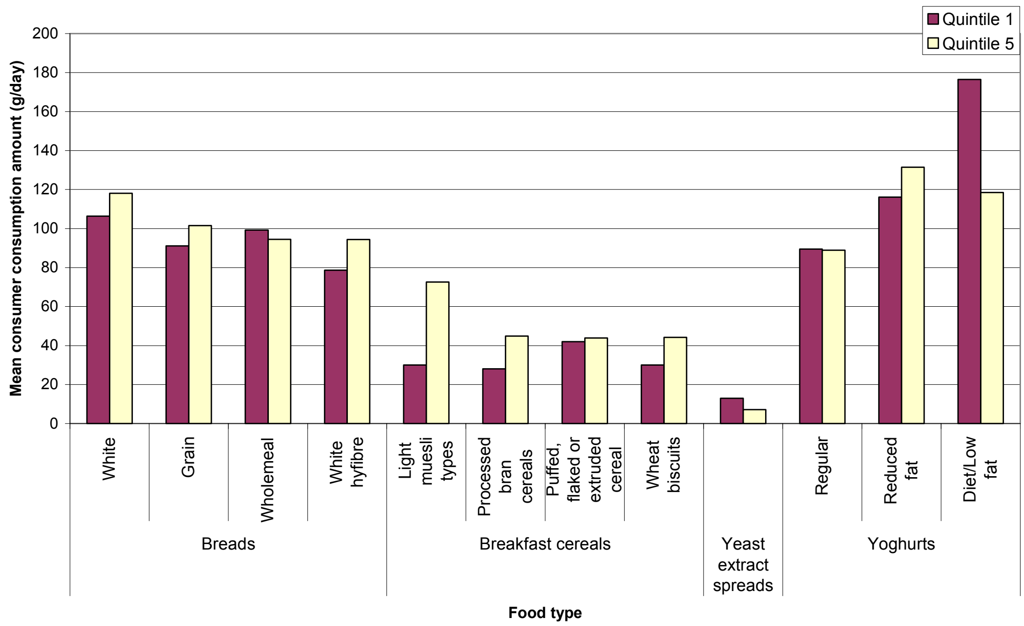
b. Beverages



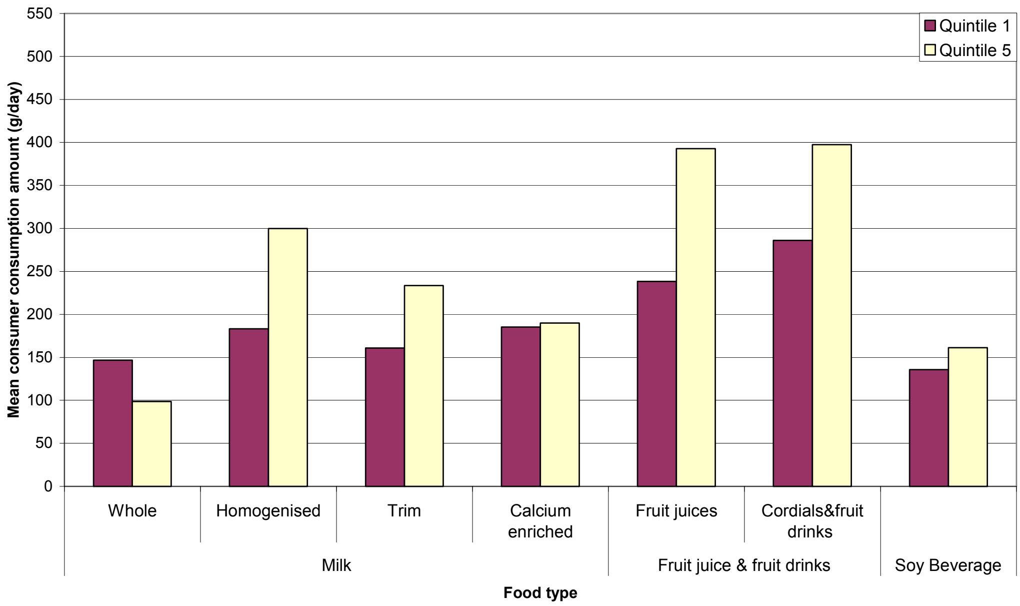
When consumers in Quintile 5 (high folic acid intakes) ate breads, breakfast cereals, milks, soy beverages, yoghurts and fruit juice and fruit drinks they ate, on average, larger amounts than those in Quintile 1 (low folic acid intakes). The exceptions were for wholemeal breads, diet/low fat yoghurts, yeast extract spreads and whole milks. Refer to Figures 15a and b below and b in Appendix 6 for further details.

Figure 15: Mean amounts of various foods and beverages eaten by New Zealand female consumers aged 16-44 years

a. Foods



b. Beverages



6.3.3 Summary

There were differences in the food consumption patterns between those with low folic acid intakes and those with high folic acid intakes. Generally, lower proportions of women of child bearing age with low folic acid intakes consumed breads, breakfast cereals, yeast extract spreads, milks, fruit juices and soy beverage than those with high folic acid intakes.

Additionally, women of child bearing age with low folic acid intakes, on average, consumed lower amounts of these foods than those with high folic acid intakes. There did not appear to be a 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 so did not meet the criteria for a suitable mandatory fortification vehicle[37]. However these 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.

7. Limitations Of The Dietary Intake Assessment

The limitations of dietary intake assessments for folic acid were discussed in Attachment 7 of the P295 – Consideration of Mandatory Fortification with Folic Acid Final Assessment report.

References

Australian Dairy Corporation. (2003) Australian Dairy Corporation Survey 2002-2003.

Bakers Delight (2006) *Company Profile*. 21 August 2006.

Food Standards Australia New Zealand. (2006) Folic Acid & Pregnancy. http://www.foodstandards.gov.au/_srcfiles/FSANZ%20Folic%20Acid.pdf.

McLennan, W. and Podger, A. (1999) National Nutrition Survey Foods Eaten Australia 1995. Australian Bureau of Statistics.

National Health and Medical Research Council (2003) *Food for health: Dietary guidelines for Australians*. http://nhmrc.gov.au/publications/synopses/_files/n31.pdf.

National Health and Medical Research Council (2006) *Nutrient Reference Values for Australia and New Zealand Including Recommended Dietary Intakes*. http://www.nhmrc.gov.au/publications/_files/n35.pdf. Accessed on 9 June 2006.

Roy Morgan. (2006a) Single Source Data 2001-2006.

Roy Morgan. (2006b) Young Australians Survey 2005-2006.

Thomson, B. (2005) *Fortification overages of the food supply. Folate and iron. Report to the New Zealand Food Safety Authority. New Zealand Environmental and Scientific Research.*

[37] See Sec 4.2, p72 FSANZ Issues Paper for criteria. Full fat yoghurt was also consumed in larger amounts by the low folic acid intake group but this is not considered a suitable vehicle for fortification as a greater proportion of children consume yoghurt than women of child bearing age and they are more likely to consume full fat yoghurt than reduced or low fat yoghurt (see Sec 4.2, p75 FSANZ Issues Paper)

Appendix 1 – Determination Of The Food Vehicle For Mandatory Fortification

Using data from the publication '*National Nutrition Survey Foods Eaten Australia 1995*' (McLennan and Podger, 1999), an assessment of the food categories eaten by a large proportion (≥50%) of women of child-bearing age (aged 16-44 years) was conducted. Details on the food categories that were consumed by at least 20% of women of child-bearing age are listed in Table A1.1 below.

Table A1.1: Major food categories consumed in the 1995 Australian NNS (g/day)

Food Group	Population Group			
	2-3 year old children	**16-18 years females**	**19-24 years females**	**25-44 years females**
CEREALS AND CEREAL PRODUCTS	**99.1**	**93.0**	**90.2**	**93.8**
Regular breads and rolls	**84.6**	**80.6**	**70.3**	**77.8**
CEREAL BASED PRODUCTS AND DISHES	**76.1**	**71.2**	**62.0**	**69.8**
Sweet biscuits	37.0	16.9	17.1	23.7
Cakes, buns, muffins, scones, cake-type desserts	20.1	18.4	18.5	24.5
Pastries	11.7	21.1	14.9	16.4
Mixed dishes where cereal is the major ingredient	21.0	30.7	22.9	21.1
FRUIT PRODUCTS AND DISHES	**76.5**	**41.1**	**41.4**	**55.0**
VEGETABLE PRODUCTS AND DISHES	**73.5**	**85.8**	**86.5**	**88.0**
MILK PRODUCTS AND DISHES	**98.2**	**87.3**	**90.1**	**94.3**
Dairy milk	**90.0**	**63.4**	**76.6**	**84.4**
Cheese	41.8	44.5	40.3	42.9
Frozen milk products	24.2	20.4	15.1	13.9
MEAT, POULTRY AND GAME PRODUCTS AND DISHES	**74.3**	**74.5**	**74.0**	**76.9**
SUGAR PRODUCTS AND DISHES	**62.5**	**44.9**	**59.4**	**61.4**
Sugar, honey and syrups	48.2	33.5	**52.5**	**53.4**
CONFECTIONERY	48.4	39.9	32.4	24.2
Chocolate and chocolate based confectionery	26.9	29.9	21.3	16.4

Food Group	Population Group			
	2-3 year old children	**16-18 years females**	**19-24 years females**	**25-44 years females**
FATS AND OILS	**83.2**	**66.9**	**63.7**	**72.3**
Dairy fats	16.8	17.5	19.0	25.1
Margarine	**66.2**	46.8	44.6	47.8
SAVOURY SAUCES AND CONDIMENTS	42.0	**63.0**	**51.7**	**52.0**
Gravies and savoury sauces	36.7	49.6	40.2	36.4
NON-ALCOHOLIC BEVERAGES	**98.8**	**100.0**	**99.7**	**100.0**
Tea	6.7	17.7	37.9	**54.3**
Coffee and coffee substitutes	-	19.4	36.9	**61.1**
Fruit and vegetable juices and drinks	**81.5**	**52.1**	46.6	35.6
Soft drinks, flavoured mineral waters and electrolyte drinks	25.8	**54.2**	47.7	29.2
Mineral waters and water	**83.1**	**85.1**	**84.6**	**82.0**
MISCELLANEOUS	48.4	33.4	32.9	29.9
Beverage flavourings	24.8	12.8	11.7	8.2
Yeast; yeast, vegetable and meat extracts	30.2	20.2	20.0	17.3

Note: the numbers in **bold** indicate that ≥50% of the population group consume this food group.
Source: (McLennan and Podger, 1999)

Appendix 2 – Summary of concentration data used for various foods for dietary modelling purposes

Table A2.1: Folic acid concentration data for main Australian products assumed to contain folic acid

Food		**Origin of baseline concentration data**	**Baseline folic acid concentration data (µg/100 g)**	**Bread making flour content (%)**	***Mandatory Fortification* folic acid concentration data (200 µg/100g of bread making flour)**
Breads	White bread	Label and analytical, with 15-16% market share weighting.	0-200^	52-71	104-142^
	Multigrain bread	Label and analytical, with 15-20% market share weighting.	0-133^	41-52	82-104^
	Wholemeal bread	Label and analytical, market share weighted.	0-187^	49-69	98-138^
	Rye bread and rolls	Label, with 15% market share weighting.	0-140^	21-45	42-90^
	Fibre-increased bread and rolls	Label, with 15% market share weighting.	0-180^	61-66	122-132^
	Savoury breads (Fancy Breads)	Label, with 15% market share weighting.	0-200^	40-74	80-148^
	Fruit breads	Label, with 15% market share weighting.	0-153^	34-68	68-136^
	Bun, sweet, various types	Label, with 15% market share weighting.	0-147^	38-56	76-112^
	Sandwiches, various	Market share updated as for white bread	0-99^	15 – 40 depending on type	30-80^
	Hamburger with meat, bread, other ingredients		0	20-30	40-60^

Food		**Origin of baseline concentration data**	**Baseline folic acid concentration data (µg/100 g)**	**Bread making flour content (%)**	***Mandatory Fortification* folic acid concentration data (200 µg/100g of bread making flour)**
Breads	Hot dog in bun		0	30	60
	Crumbed meat, chicken and fish	Market share updated as for flour	0	7-25 depending on type	14-50^
	Stuffing, bread based	Market share updated as for bread	0	4-35	10-70^
White flour	White flour	5% market share. Based on the addition of folic acid to The Healthy Baker flour.	0-250	0	0
	Pizza	Market share updated as for flour	0	15-55 depending on the type of crust and topping	30-110^ depending on the type of crust and topping
	Pizza base		0	69	138
	Scone, various types	Market share - assumes made with 40% flour	0-100^	37-65	74-130^
	Pancakes and pikelets	Market share updated as for flour	0	10-25	20-50^
	Doughnuts, yeast type	Market share updated as for flour	0	40	80

Food		Origin of baseline concentration data	Baseline folic acid concentration data (µg/100 g)	Bread making flour content (%)	*Mandatory Fortification* folic acid concentration data (200 µg/100g of bread making flour)
White flour	Croissants	Label and market share updated as for flour	0	38-67	76-134^
Yeast extracts	Yeast-based spreads	Label and analytical	3,250	0	3,250
Breakfast cereals	Bran flakes	Label and analytical depending on brand	330-770^	0	330-770^
	Puffed rice-style	Analytical	157-415^	0	157-415^
	Wheat biscuits	Analytical	108-411^	0	108-411^
	Muesli	Analytical	223	0	223
	Grain cereal, with or w/o fruit/nuts	Analytical	108-680^	0	108-680^
	Sweetened cereal	Label and analytical depending on brand	140-442^	0	140-442^
	Breakfast bars		270	0	270

Food		Origin of baseline concentration data	Baseline folic acid concentration data (µg/100 g)	Bread making flour content (%)	*Mandatory Fortification* folic acid concentration data (200 µg/100g of bread making flour)
Juice	Orange juice	Analytical with 50% market share weighting used for commercial orange juice.	0-30^	0	0-30^
	Breakfast juice	Mixed fruit juices (breakfast style) assumed to be 100% folic acid fortified.	30	0	30
	Fruit juice		0	0	0
Soy beverages	Soy beverage, fortified	Analytical, 100% Market share weighting	39-61^	0	39-61^
	Soy beverage, fortification not specified	50% Market share weighting	0-60	0	0-60
Other milk substitutes	Infant formula (fortified)		5	0	5
Infant food	Infant food		0-75	0	0-75

Food		**Origin of baseline concentration data**	**Baseline folic acid concentration data (µg/100 g)**	**Bread making flour content (%)**	***Mandatory Fortification* folic acid concentration data (200 µg/100g of bread making flour)**
Meal replacement products	Liquid meal replacements	Label and analytical depending on brand.	20	0	20
	Biscuit and bar meal replacements		82	0	82
	Supplement powders		117-667^	0	117-667^
	Energy drinks		1	0	1

^ Denotes range of values for category - individual products within these broad food categories were assigned a single folic acid concentration
Note: This is not a complete list of folic acid concentrations used in the dietary modelling to assess folic acid intakes.

Table A2.2: Folic acid concentration data for main New Zealand products assumed to contain folic acid

Food		**Origin of baseline concentration data**	**Baseline folic acid concentration data (µg/100 g)**	***Mandatory Fortification* folic acid concentration data (135 µg/100g of bread)**
Bread	White bread and rolls	Label and analytical, depending on type recorded in NNS	0	135
	Mixed grain bread and rolls	Analytical depending on type recorded in NNS	0 – 120^	135
	Wholemeal bread and rolls	Analytical depending on type recorded in NNS	0 – 120^	135
	Rye bread and rolls	Label and analytical, depending on type recorded in NNS	0	135
	Fibre-increased bread and rolls	Label and analytical, depending on type recorded in NNS	0 – 120^	135
	Savoury breads (Fancy Breads)		0	135
	Fruit breads	Label, with 15% market share weighting	0	135
	Buns and yeast-based products		0	135
	Sandwiches, filled rolls		0	135
Bread	Hamburger with meat, bread, other ingredients		0	135

Food		Origin of baseline concentration data	Baseline folic acid concentration data (µg/100 g)	*Mandatory Fortification* folic acid concentration data (135 µg/100g of bread)
	Crumbed meat, chicken and fish		0	9-31^
	Croutons		0	135
	Stuffing, bread based		0	86
Other 'wheat flour for making bread' containing foods	Pizza		0	0
	Scone, various types		0	0
	Pancakes and pikelets		0	0
	Doughnuts, yeast type		0	0
Yeast extract	Yeast extract	Label and analytical, depending on type recorded in NNS	2,200 – 3,250^	2,200 – 3,250^

Food		Origin of baseline concentration data	Baseline folic acid concentration data (µg/100 g)	*Mandatory Fortification* folic acid concentration data (135 µg/100g of bread)
Breakfast cereal	Bran flakes	Analytical depending on type recorded in NNS	69-770	69-770
	Wheat biscuits	Analytical	313-450	313-450
	Muesli	Analytical	140-680	140-680
	Single cereal, puffed flakes or extruded	Label and analytical, depending on type recorded in NNS	157-530	157-530
Juices	Orange juice	Analytical with 25% market share weighting	0-44	0-44
	Fruit juice		0	0
Soy beverages	Soy beverage	Analytical	30-85	30-85
Other milk substitutes	Rice milk	Analytical	40	40
Infant food	Infant food		90	90

Food		Origin of baseline concentration data	Baseline folic acid concentration data (µg/100 g)	*Mandatory Fortification* folic acid concentration data (135 µg/100g of bread)
Meal replacement products	Liquid meal replacements	Label and analytical depending on brand	40	40
	Biscuit and bar meal replacements		82	82
	Supplement powders		40-160	40-160

^ Denotes range of values for category - individual products within these broad food categories were assigned a single folic acid concentration
Note: This is not a complete list of folic acid concentrations used in the dietary modelling to assess folic acid intakes.

Appendix 3 –Complete information on dietary intake assessment results

Table A3.1: Estimated mean and 95th percentile dietary folic acid intakes for women of child-bearing age

a. Australia

Target Group	No. of respondents	Mean Folic Acid Intake (µg/day)				95th Percentile Folic Acid Intake (µg/day)			
		Baseline		*Mandatory Fortification* ♦ 200 µg/100 g flour		*Baseline*		*Mandatory Fortification* ♦ 200 µg/100 g flour	
		Market weighted	Consumer behaviour	Market weighted	Consumer behaviour	Market weighted	Consumer behaviour	Market weighted	Consumer behaviour
16-44 years	3,178	108	83 – 243	208	204 – 231	283	249 – 477	407	403 – 455

b. New Zealand

Target Group	No. of respondents	Mean Folic Acid Intake (µg/day)				95th Percentile Folic Acid Intake (µg/day)			
		Baseline		*Mandatory Fortification* ♦ 135 µg/100g bread		*Baseline*		*Mandatory Fortification* ♦ 135 µg/100 g bread	
		Market weighted	Consumer behaviour	Market weighted	Consumer behaviour	Market weighted	Consumer behaviour	Market weighted	Consumer behaviour
16-44 years	1,509	62	60 – 69	202	200 – 209	190	181 – 196	359	353 – 369

♦ Mandatory folic acid fortification of 'wheat flour for making bread' for Australia and mandatory folic acid fortification of 'all bread' for New Zealand

Table A3.2: Estimated mean and 95th percentile dietary folic acid intakes for various non-target Australian population sub-groups

Target Group	Gender	No. of respondents	Mean Folic Acid Intake (µg/day)				95th Percentile Folic Acid Intake (µg/day)			
			Baseline		*Mandatory Fortification* ♦ 200 µg/100g flour		*Baseline*		*Mandatory Fortification* ♦ 200 µg/100g flour	
			Market weighted	**Consumer behaviour**	**Market weighted**	**Consumer behaviour**	**Market weighted**	**Consumer behaviour**	**Market weighted**	**Consumer behaviour**
2 years & above	All	13,858	129	100 – 285	244	241 – 268	346	306 – 590	507	503 – 554
2-3 years	All	383	128	106 – 237	217	215 – 225	232	209 – 412	338	334 – 384
	M	170	141	117 – 251	238	236 – 239	250	224 – 454	377	373 – 423
	F	213	118	97 – 227	200	198 – 214	210	195 – 408	308	306 – 372
4-8 years	All	977	140	115 – 270	241	238 – 258	282	256 – 481	388	383 – 464
	M	513	157	131 – 295	269	266 – 285	313	280 – 556	442	438 – 532
	F	464	121	99 – 242	210	208 – 228	246	230 – 406	328	326 – 379
9-13 years	All	913	162	134 – 320	275	271 – 309	367	341 – 613	495	487 – 588
	M	474	192	162 – 369	319	315 – 359	420	386 - 725	543	536 – 650
	F	439	128	104 – 266	227	224 – 255	291	257 – 463	392	390 – 461
14-18 years	All	734	161	129 – 329	293	289 – 320	378	342 – 659	566	564 – 634
	M	378	202	166 – 398	361	357 – 391	539	508 – 766	733	730 – 813
	F	356	117	90 – 256	222	217 – 246	273	239 – 477	407	392 – 447

Target Group	Gender	No. of respondents	Mean Folic Acid Intake (µg/day)				95th Percentile Folic Acid Intake (µg/day)			
			Baseline		*Mandatory Fortification* ♦ 200 µg/100g flour		*Baseline*		*Mandatory Fortification* ♦ 200 µg/100g flour	
			Market weighted	**Consumer behaviour**	**Market weighted**	**Consumer behaviour**	**Market weighted**	**Consumer behaviour**	**Market weighted**	**Consumer behaviour**
19-29 years	All	2,203	146	115 – 309	278	273 – 303	365	329 – 644	585	577 – 629
	M	1,014	179	142 – 377	346	342 – 373	449	402- 772	736	737 – 771
	F	1,189	118	93 – 252	219	215 – 243	286	244 – 469	420	416 – 455
30-49 years	All	4,397	119	90 – 280	238	235 – 262	342	302 – 602	516	513 – 552
	M	2,080	140	105 – 330	283	280 – 309	373	321 – 675	576	569 – 622
	F	2,317	100	75 – 236	198	195 – 220	299	274 – 488	409	405 – 467
50-69 years	All	3,019	114	86 – 270	221	218 – 247	368	341 – 574	480	477 – 533
	M	1,442	131	98 – 313	256	253 – 284	403	364 – 656	545	541 – 595
	F	1,577	99	76 – 232	189	186 – 214	325	304 – 494	415	414 – 454
70 years & above	All	1,232	117	91 – 265	217	215 – 240	357	306 – 530	456	454 – 495
	M	545	126	97 – 293	241	239 – 267	331	297 – 551	469	466 – 503
	F	687	111	87 – 243	198	196 – 220	369	350 – 498	441	437 – 464

♦ Mandatory folic acid fortification of ‘wheat flour for making bread’ for Australia

Table A3.3: Estimated mean and 95th percentile dietary folic acid intakes for various New Zealand population sub-groups

Country	Target Group	Gender	No. of respondents	Mean Folic Acid Intake (µg/day)				95th Percentile Folic Acid Intake (µg/day)			
				Baseline		*Mandatory Fortification* ♦ 135 µg/100g bread		*Baseline*		*Mandatory Fortification* ♦ 135 µg/100g bread	
				Market weighted	**Consumer behaviour**	**Market weighted**	**Consumer behaviour**	**Market weighted**	**Consumer behaviour**	**Market weighted**	**Consumer behaviour**
New Zealand	15 years & above	All	4,636	75	73 – 81	236	234 – 241	214	209 – 229	443	439 – 452
	15-18 years	All	246	81	77 – 90	255	252 – 264	195	187 – 223	485	480 – 500
		M	109	113	111 – 119	322	320 – 328	225	213 – 260	560	554 – 580
		F	137	54	51 – 67	201	197 – 212	157	135 – 193	340	330 – 381
	19-29 years	All	804	76	74 – 84	239	237 – 247	194	180 – 217	447	434 – 461
		M	286	112	110 – 119	316	314 – 323	221	205 – 255	543	529 – 592
		F	518	56	54 – 65	197	194 – 205	162	159 – 184	341	338 – 347
	30-49 years	All	1,883	75	73 – 80	241	240 – 246	223	220 – 233	460	457 – 469
		M	787	86	85 – 91	291	289 – 296	246	230 – 268	540	532 – 548
		F	1,096	67	65 – 72	206	204 – 211	205	200 – 215	370	367 – 373
	50-69 years	All	1,147	76	74 – 81	231	229 – 236	238	237 – 248	438	438 – 448
		M	538	84	82 – 89	266	264 – 271	262	260 – 271	489	486 – 491
		F	609	69	68 – 73	200	199 – 205	210	204 – 225	367	357 – 371
	70 years & above	All	556	70	69 – 73	214	213 – 218	187	186 – 189	367	367 – 379
		M	207	69	68 – 73	236	235 – 240	188	186 – 191	392	391 – 394
		F	349	70	69 – 73	201	200 – 204	179	179 – 185	322	322 – 320

♦ Mandatory folic acid fortification of 'all bread' for New Zealand

Appendix 4 – Complete information on risk characterisation

Table A4.1: Proportion of respondents with folic acid intakes above the Upper Level for Baseline and Mandatory Fortification scenarios for various Australian population sub-groups

Population Group	Gender	No. of respondents	% respondents with dietary folic acid intakes > Upper Level	
			Baseline	***Mandatory Fortification*** ♦ **200 µg/100g bread making flour**
2-3 years	All	383	2	9
	M	170	3	13
	F	213	<1	6
4-8 years	All	977	1	4
	M	513	2	7
	F	464	<1	1
9-13 years	All	913	1	2
	M	474	2	4
	F	439	<1	<1
14-18 years	All	734	<1	2
	M	378	1	4
	F	356	0	<1

Population Group	Gender	No. of respondents	% respondents with dietary folic acid intakes > Upper Level	
			Baseline	*Mandatory Fortification* ♦ **200 µg/100g bread making flour**
19-29 years	All	2,203	<1	<1
	M	1,014	<1	2
	F	1,189	<1	<1
30-49 years	All	4,397	<1	<1
	M	2,080	<1	<1
	F	2,317	<1	<1
50-69 years	All	3,019	<1	<1
	M	1,442	<1	<1
	F	1,577	<1	<1
70 years & above	All	1,232	0	0
	M	545	0	0
	F	687	0	0

♦ Mandatory folic acid fortification of 'wheat flour for making bread' for Australia

Table A4.2: Proportion of respondents with folic acid intakes above the Upper Level for Baseline and Mandatory Fortification scenarios for various New Zealand population sub-groups

Population Group	Gender	No. of respondents	% respondents with dietary folic acid intakes > Upper Level	% respondents with dietary folic acid intakes > Upper Level
			Baseline	*Mandatory Fortification*♦ 135 µg/100g bread
15-18 yrs	All	246	0	<1
	M	109	0	2
	F	137	0	0
19-29 yrs	All	804	0	<1
	M	286	0	<1
	F	518	0	0
30-49 yrs	All	1,883	<1	<1
	M	787	0	0
	F	1,096	<1	<1
50-69 yrs	All	1,147	0	<1
	M	538	0	<1
	F	609	0	0
70+ yrs	All	556	0	0
	M	207	0	0
	F	349	0	0

♦ Mandatory folic acid fortification of 'all bread' for New Zealand.

Appendix 5 – Complete information on folic acid intakes from food and supplements

Table A5.1: Estimated folic acid intakes from folic acid added to food and supplements for Australian women of child-bearing age (16-44 years)#

Scenario	Mean Intake + 200 µg	Mean Intake + 500 µg	95th %tile + 200 µg	95th %tile + 500 µg
Baseline	308	608	483	783
Mandatory Fortification ♦	408	708	607	907

Number of respondents aged 16-44 years: Australia = 3,178
♦ Mandatory folic acid fortification of 'wheat flour for making bread' for Australia

Table A5.2: Estimated folic acid intakes from folic acid added to food and supplements for New Zealand women of child-bearing age (16-44 years)#

Scenario	Mean Intake + 200 µg	Mean Intake + 800 µg	95th %tile + 200 µg	95th %tile + 800 µg
Baseline	262	862	390	990
Mandatory Fortification ♦	402	1,002	559	1,159

Number of respondents aged 16-44 years: New Zealand = 1,509
♦ Mandatory folic acid fortification of 'all bread' for New Zealand

Table A5.3: Proportion of respondents with folic acid intakes above the Upper Level from folic acid added to food and supplements for Australian women of child-bearing age (16-44 years)#

Scenario	Individual's mean intake + 200 μg	Individual's mean intake + 500 μg
Baseline	<1	2
Mandatory Fortification ♦	<1	4

Number of respondents aged 16-44 years: Australia = 3,178
♦ Mandatory folic acid fortification of 'wheat flour for making bread' for Australia

Table A5.4: Proportion of respondents with folic acid intakes above the Upper Level from folic acid added to food and supplements for New Zealand women of child-bearing age (16 - 44 years)#

Scenario	**% of respondents with folic acid intakes from diet and supplements > UL**	
	Individual's mean intake + 200 μg	**Individual's mean intake + 800 μg**
Baseline	<1	10
Mandatory Fortification ♦	<1	46

Number of respondents aged 16-44 years: New Zealand = 1,509
♦ Mandatory folic acid fortification of 'all bread' for New Zealand

Appendix 6 – Complete information on food consumption patterns for Australian and New Zealand women of child-bearing age for consumers with low and high quintile intakes of folic acid

Table A6.1: Mean folic acid intakes for Australian and New Zealand women aged 16-44 years for low (Quintile 1) and high (Quintile 5) consumers of folic acid

Country	Mean folic acid intake (µg/day)			
	Low Folic Acid Intakes (Quintile 1)		High Folic Acid Intakes (Quintile 5)	
	Baseline	*Mandatory Fortification*♦	*Baseline*	*Mandatory Fortification*♦
Australia	35	125	263	366
New Zealand	23	165	170	304

♦ Mandatory folic acid fortification of 'wheat flour for making bread' for Australia and mandatory folic acid fortification of 'all bread' for New Zealand

Table A6.2: Major contributors to folic acid intakes for Australian and New Zealand women aged 16-44 years

Country		Contributors to folic acid intakes (%)			
		Baseline		*Mandatory Fortification*	
		Quintile 1	Quintile 5	Quintile 1	Quintile 5
Australia	Breads	89	7	85	29
	Breakfast cereals	2	56	<1	41
	Yeast extracts	2	32	<1	24
	Fruit juices	2	2	<1	1
	Milk	3	<1	<1	<1
	Soy beverage	<1	1	<1	<1
	Pizza	0	0	6	1
	Other	2	1	8	2
New Zealand	Bread	0	1	100	41
	Breakfast cereals	0	58	0	35
	Soy beverage	0	<1	0	<1
	Yeast extracts	0	38	0	23
	Milk	0	0	0	0
	Juices	0	2	0	1
	Other foods	0	<1	0	<1

Table A6.3: Proportion of Australian and New Zealand women aged 16-44 years that consume various foods and the mean amounts eaten by consumers of these foods

a. Australian women aged 16-44 years

		% consuming		**Mean consumer consumption amount (g/day)**	
		Quintile 1	Quintile 5	Quintile 1	Quintile 5
Breads	White	37	52	75	102
	Grain	9	14	71	79
	Wholemeal	14	23	66	90
	White hyfibre	3	4	62	82
Breakfast cereals	Bran, processed	<1	8	75	45
	Puffed/Extruded Rice style	<1	14	32	47
	Wheat biscuits/ shredded	3	14	30	35
	Wheat, with Fruits/Nuts	1	7	57	57
	Grain & Fruit/Nut based	<1	16	31	87
Yoghurts	Natural, full fat	2	1	126	48
	Natural, reduced/skim/low fat	1	<1	111	107
	Flavoured, full fat	2	3	176	174
	Flavoured, reduced fat	1	1	231	177
	Flavoured, low fat, sugar sweetened	1	<1	185	169
	Flavoured, low fat, I/S	1	4	208	193

		% consuming		Mean consumer consumption amount (g/day)	
		Quintile 1	Quintile 5	Quintile 1	Quintile 5
Yeast extract spreads		<1	48	1	7
Milk	Full fat	53	56	139	269
	Reduced fat	16	24	133	250
	Low fat	8	14	125	220
	Skim	6	8	158	195
Fruit Juice	Single	17	24	266	364
	Mixed	2	4	240	355
Soy Beverage		1	3	196	271
Bottled water		<1	0	260	0

b. New Zealand women aged 16-44 years

		% consuming		Mean consumer consumption amount (g/day)	
		Quintile 1	Quintile 5	Quintile 1	Quintile 5
Breads	White	47	48	106	118
	Grain	14	12	91	102
	Wholemeal	15	18	99	94
	White hyfibre	4	6	79	94
Breakfast cereals	Light muesli types	<1	8	30	73
	Processed bran cereals	<1	10	28	45
	Puffed, flaked or extruded cereal	2	20	42	44
	Wheat biscuits	<1	28	30	44
Yoghurts	Regular	2	5	90	89
	Reduced fat	2	8	116	132
	Diet/Low fat	2	3	176	119
Yeast extract spreads		<1	46	13	7
Milk	Whole	7	8	147	99
	Homogenised	56	58	183	300
	Trim	26	36	161	233
	Calcium enriched	5	5	185	190

		% consuming		Mean consumer consumption amount (g/day)	
		Quintile 1	**Quintile 5**	**Quintile 1**	**Quintile 5**
Fruit juice & fruit drinks	Fruit juices	10	18	238	393
	Cordials & fruit drinks	11	17	286	397
Soy Beverage		<1	1	136	161

Table A6.4: Food groups consumed by ≥ 10% of Australian and New Zealand women aged 16-44 the mean amounts eaten by consumers of these foods

a. Australia

Food Group	% consuming		Mean consumer consumption amount (g/day)	
	Quintile 1	Quintile 5	Quintile 1	Quintile 5
Plain drinking water	77	79	1,077	1,120
Coffee beverage	58	46	750	723
Milk, fluid, regular whole, full fat	53	56	139	269
Tea	47	45	671	691
Sugar	43	48	16	16
Breads, rolls, white	37	52	75	102
Savoury sauces	25	26	29	28
Cheese, natural, traditional	24	35	30	31
Polyunsat. margarine & spreads	24	34	10	13
Single fruit juices	17	24	266	364
Milk, fluid, reduced fat, < 2%	16	24	133	250
Butter	16	17	12	12
Soft drinks, cola	14	13	508	458
Breads, rolls, wholemeal	14	23	66	90
Domestic water	13	17	402	393
Wines, white	12	10	406	332
Jams and conserves	12	12	13	14
Soft drinks, non-cola	11	12	399	420
Sweet biscuits, plain or flavoured	11	12	22	25

Food Group	% consuming		Mean consumer consumption amount (g/day)	
	Quintile 1	Quintile 5	Quintile 1	Quintile 5
Ham	10	13	39	35
Chocolate-based confectionery	10	16	51	49
Breads, rolls, mixed grain	9	14	71	79
Ice cream, tub varieties	9	10	78	90
Cakes, cake mixes	8	11	81	82
Milk, fluid, low fat,< 1%	8	14	125	220
Monounsat. Margarine & spreads	6	11	9	10
B'fast cereal, wheat-based biscuits & shredded wheat	3	14	30	35
Yeast, vegetable and meat extracts	<1	48	1	7
Breakfast cereal, grain and fruit/nut mixtures	<1	16	31	87
Breakfast cereal, low added sugar, puffed/flake/extruded. Single cereal	<1	14	32	47

b. New Zealand

Food Group	Proportion of Population Group Consuming (%)		Mean consumer amount (g/day)	
	Quintile 1	Quintile 5	Quintile 1	Quintile 5
Water incl. mineral/soda/tap/filtered	86	88	1,139	1,099
Coffee & coffee substitutes	62	51	98	99
Tea	61	56	730	720
Milk, homog. fluid (blue)	56	58	183	300
Sugar	52	60	18	19
Bread and rolls, white	47	48	106	118
Polyunsat. margarine	37	39	18	21
Butter	35	43	20	19
Jam/marmalade/honey	35	19	17	19
Milk, trim (green)	26	36	161	233
Sauces incl. tomato/steak/fruit	26	23	20	26
High fat cheese (>30g fat/100g)	19	28	28	36
Regular soft drinks	18	21	393	451
Bread & rolls, wholemeal	15	18	99	94
Oil blends	15	15	8	8
Bread & rolls, mixed grain	14	12	91	102
Wine	13	13	323	373
Biscuit, chocolate or chocolate chip	13	9	28	27
Mayonnaise & cream style dressings, full fat	12	15	19	16
Hot drinks includes Milo, hot chocolate	12	17	13	16
Biscuit, sweet, plain	11	13	27	25
Cordials & fruit drinks	11	17	286	397
Medium fat cheese (20-30g fat/100g)	11	13	30	32
Ice cream-regular	10	12	79	88

Food Group	Proportion of Population Group Consuming (%)		Mean consumer amount (g/day)	
	Quintile 1	Quintile 5	Quintile 1	Quintile 5
Fruit Juices	10	18	238	393
Chocolate & chocolate based confectionery	10	12	40	45
Olive oil	8	10	15	11
Bread, rye & heavy types	8	11	90	90
Ham	7	10	36	29
Sausages	5	10	103	101
Single cereal; puffed/flakes/extruded	2	20	42	44
Processed bran cereals	<1	10	28	45
Yeast & vege extracts	<1	46	13	7
Wheat based biscuits & shredded wheat	<1	28	30	44

Attachment 7B

Dietary Intake Assessment Report – Extended Voluntary Fortification with Folic Acid

Contents

EXECUTIVE SUMMARY 154

1. BACKGROUND 156

2. HOW DIETARY FOLIC ACID INTAKES WERE CALCULATED 156

3. ASSUMPTIONS USED IN THE DIETARY EXPOSURE ASSESSMENT 161

4. ESTIMATED DIETARY FOLIC ACID INTAKES FROM FOLIC ACID ADDED TO FOOD 161

5. ESTIMATES OF FOLIC ACID INTAKES FROM FOOD AND SUPPLEMENTS 172

6. REFERENCES 177

APPENDIX 1: EXTENDED VOLUNTARY FOLIC ACID FORTIFICATION SCENARIOS 178

APPENDIX 2: SUMMARY OF CONCENTRATION DATA USED FOR VARIOUS DIETARY MODELLING PURPOSES 188

APPENDIX 3: COMPLETE INFORMATION ON DIETARY INTAKE ASSESSMENT RESULTS . 193

APPENDIX 4: COMPLETE INFORMATION ON RISK CHARACTERISATION 200

APPENDIX 5: PROPORTION OF CONSUMERS OF FOODS UNDER THE VOLUNTARY FORTIFICATION SCENARIOS 202

APPENDIX 6: COMPLETE INFORMATION OF FOLIC ACID INTAKE FROM FOOD AND SUPPLEMENTS 204

Executive Summary

In order to present a comprehensive review to the Ministerial Council in response to their First Review request, FSANZ investigated the potential impact of extending voluntary fortification at higher levels of uptake (i.e. higher market share) of current permissions and across a broader range of food groups. Impact was measured by determining folic acid intakes among the target group (women of child-bearing age), and the general population.

The aim was to determine whether an extension of voluntary fortification would assist the target group achieve their recommended intake of 400 µg of folic acid per day, whilst minimising the proportion of people in the target and non-target groups exceeding upper levels (UL) of intake.

The dietary intake assessment was conducted for females aged 16-44 years who were assumed to represent the target group of women of child-bearing age and also for the age and gender groups specified in the National Health and Medical Research Councils (NHMRC) Nutrient Reference Values for Australia and New Zealand document. Two dietary exposure assessments for women of child-bearing age were considered: (1) folic acid intakes from food alone; and (2) folic acids intake from food and supplement use.

Dietary modelling was conducted for Australian and New Zealand populations to estimate:

- current folic acid intakes from food alone based on current uptake of voluntary folic acid permissions by industry **(*Baseline*)**;
- folic acid intakes based on current uptake of voluntary folic acid permissions by industry with an additional 'low' extension in voluntary folic acid fortification as proposed by industry at Final Assessment **(*Lower*)**;
- folic acid intakes based on current uptake of voluntary folic acid permissions by industry with an additional Moderate extension in voluntary folic acid fortification as proposed by industry **(*Moderate*)**; and
- folic acid intakes based on current uptake of voluntary folic acid permissions by industry with an additional Higher extension in voluntary folic acid fortification as proposed by industry **(*Higher*)**.

The foods selected for fortification in each of the scenarios were based on:

- food groups with current uptake of voluntary permissions in the Code;
- food groups with voluntary permissions in the Code; however with no uptake; and
- food groups for which there are no current permissions in the Code; however there is a possibility that folic acid could be added in the future.

Results indicate that, from *Baseline* to the various voluntary scenarios, there was an increase in mean folic acid intakes of between 7-45 µg per day for Australia and 35-74 µg per day for New Zealand women aged 16-44 years, depending on the degree of extension of voluntary folic acid fortification permissions and uptake of permissions. The higher the extension in voluntary fortification, the greater the increase in mean folic acid intakes for the target group. Under the *Higher* voluntary fortification scenario, estimated mean dietary folic acid intakes increased by 45 µg per day from *Baseline* for Australia and 74 µg per day for New Zealand. This scenario was designed to include a wide range of foods and market share weighting. However it was not perceived to be likely given current market trends for fortification.

Estimated mean folic acid intakes from food alone for women of child-bearing age did not achieve the desired folic acid intake of 400 µg per day under any of the extended voluntary folic acid fortification scenarios examined.

Less than 1% of women of child-bearing age exceeded the UL under *Baseline* and for all three extended voluntary fortification scenarios (*Lower*, *Moderate* and *Higher*). For the Australian non-target groups, respondents aged 2-3 years and 4-8 years were the most likely to have estimated dietary folic acid intakes that exceeded the UL under the *Baseline* and extended voluntary fortification scenarios (*Lower*, *Moderate* and *Higher*). For New Zealand, no non-target population group exceeded the UL, with the exception of the population aged 30-49 years (<1%).

Breakfast cereal, bread and yeast extract were major contributors (≥5%) to folic acid intakes for the population groups assessed under all scenarios (with the exception of bread at *Baseline* for New Zealand). Under the *Higher* proposed extension in voluntary fortification, low and reduced fat yoghurt (plain and fruit or flavoured) and fruit juice were also major contributors.

As expected, there was an increase in estimated dietary folic acid intakes from *Baseline* under all three extended voluntary fortification scenarios (*Lower*, *Moderate* and *Higher*) when additional folic acid was consumed from supplements. The results indicate that, without the consumption of folic acid supplements, <1% to 3% of Australian and New Zealand women of child-bearing age met the recommended 400 µg folic acid per day under all scenarios. When a 200 µg folic acid per day supplement was considered, between 4% and 21% of Australian and New Zealand women of child-bearing age were estimated to meet the recommended intake of folic acid. If 500 µg (Australia) or 800 µg (New Zealand[38]) folic acid supplements were consumed by all women of child-bearing age per day, 100% would meet the recommended intake.

When women of child-bearing age consume additional folic acid from a supplement, there is likely to be an increase in the proportion of the population group exceeding the UL, which increases as the concentration of folic acid in the supplement increases. There was no change in the proportion of the Australian target group exceeding the UL with a folic acid supplement of 200 µg per day under all scenarios. If Australian women of child-bearing age consume a 500 µg supplement, there was no increase in the proportion of the population with estimated folic acid intakes that exceed the UL between *Baseline* and the *Higher* extended voluntary fortification scenario. Due to the high folic acid content of the supplement at 800 µg, a large proportion of New Zealand women are likely to exceed the UL, particularly under the *Higher* proposed extension in voluntary fortification.

[38] New Zealand Ministry of Health advises women capable of planning a pregnancy to take a folic acid supplement of 800 µg/day for at least 4 weeks before and 12 weeks after conception.

1. Background

In order to present a comprehensive review to the Ministerial Council in response to their First Review request, FSANZ investigated the potential impact of extending voluntary fortification at higher levels of uptake (i.e. higher market share) of current permissions and across a broader range of food groups. Discussions with the Australian Food and Grocery Council (AFGC) resulted in two scenarios being developed with input obtained from relevant AFGC members on the foods to be included and predicted proportion of each food category that could be fortified in the future. At Final Assessment (FAR), a more limited extension in voluntary fortification was assessed. This industry proposed scenario was reassessed for the First Review for comparative purposes.

2. How Dietary Folic Acid Intakes were Calculated

For a detailed description of what dietary modelling is, how dietary intakes were calculated, the dietary survey data used, population groups assessed, the assumptions used and the limitations of this assessment, please refer to Attachment 7 of the Final Assessment Report (FAR) for P295 – Consideration of Mandatory Fortification with Folic Acid.

2.1 Scenarios assessed.

Four scenarios were assessed as part of the dietary intake assessment for extended voluntary folic acid fortification:

1. ***Baseline* -** to estimate current folic acid intakes from food alone based on current uptake of voluntary folic acid permissions by industry.
2. ***Lower*** proposed extension in voluntary fortification presented at FAR– to estimate folic acid intakes based on *Baseline* with an additional Lower extension in voluntary fortification as proposed by industry.
3. ***Moderate*** proposed extension in voluntary fortification – to estimate folic acid intakes based on *Baseline* with an additional Moderate extension in voluntary folic acid fortification as agreed to by industry.
4. ***Higher*** proposed extension in voluntary fortification – to estimate folic acid intakes based on *Baseline* with an additional Higher extension in voluntary folic acid fortification as agreed to by industry.

The foods selected for fortification in each of the scenarios were based on:

- food groups with current uptake of voluntary permissions in the Code;
- food groups with voluntary permissions in the Code; however with no uptake; and
- food groups for which there are no current permission in the Code; however there is a possibility that folic acid could be added in the future.

In each of the three extended voluntary fortification scenarios (*Lower*, *Moderate* and *Higher*), either a new food group was added to the list of foods to be fortified or there was an increase in the proportion of foods within the group to be fortified (i.e. increased market share). The differences between the *Baseline*, *Lower*, *Moderate* and *Higher* voluntary fortification scenarios are outlined in Table 1 for Australia and Table 2 for New Zealand. They are discussed in detail below.

The foods fortified and their market share for Australia and New Zealand are presented in Appendix 1 (Table A1.1 for Australia and table A1.2 for New Zealand).

Table 1: Summary in the changes to foods fortified and market share of fortification between scenarios for Australia

	Scenario		
Food	**Baseline to Lower proposal**	**Lower proposal to Moderate proposal**	**Moderate proposal to Higher proposal**
Bread	Increased market share to 20%	Increased market share to 25%	Increased market share to 30%
Flour (white)	No change	No change	No change
Flour (wholemeal)	No change	Added food with a market share of 5%	No change
Yeast extract	No change	No change	No change
Pasta	No change	Added food with a market share of 2.5%	Increased market share to 5%
Breakfast cereal	No change	No change	No change
Low/reduced fat milk	No change	Increased market share to 10%	Increased market share to 20%
Low/reduced fat fruit/flavoured yoghurt	No change	Added food with a market share of 50%	Increased market share to 100%
Low/reduced fat plain yoghurt	Added food with a market share of 100%	No change	No change
Diet ready-to-eat meals	Added food with a market share of 100%	No change	No change
Fruit juice	No change	Extended to include all single and mixed fruit juice with a market share of 40%. No change for breakfast juice.	Increased market share to 50% for single and mixed fruit juice. No change for breakfast juice.
Soy beverages	No change	No change	No change
Other milk substitutes	No change	No change	No change
Infant food	No change	No change	No change
Meal replacement products	No change	No change	No change
Formulated beverages	No change	Added food with a market share of 100%	No change
Ready-to-drink tea	No change	Added food with a market share of 50%	Increased market share to 100%
Low fat, low sugar biscuits	No change	Added food with a market share of 5%	Increased market share to 10%

Table 2: Change in foods fortified and market share of fortification between scenarios for New Zealand

Food	Scenario: Baseline to Lower proposal	Lower proposal to Moderate proposal	Moderate proposal to Higher proposal
Bread	Those with individual concentrations, keep as for *Baseline*. Market share of 20% for other breads.	Those with individual concentrations, keep as for *Baseline*. Market share of 25% for other breads.	Those with individual concentrations, keep as for *Baseline*. Market share of 30% for other breads.
Flour (white)	No change	Added food with a market share of 5%	No change
Flour (wholemeal)	No change	Added food with a market share of 5%	No change
Yeast extract	No change	No change	No change
Pasta	No change	Added food with a market share of 2.5%	Increased market share to 5%
Breakfast cereal	No change	No change	No change
Low/reduced fat milk	No change	Added food with a market share of 10%	Increased market share to 20%
Low/reduced fat fruit/flavoured yoghurt	No change	Added food with a market share of 50%	Increased market share to 100%
Low/reduced fat plain yoghurt	Market share of 100%	No change	No change
Fruit juice	No change	Extended to include all single and mixed fruit juice with a market share of 40%	Increased market share to 50% for single and mixed fruit juice
Soy beverages	No change	No change	No change
Other milk substitutes	No change	No change	No change
Infant food	No change	No change	No change
Meal replacement products	No change	No change	No change
Formulated beverages	No change	Added food with a market share of 100%	No change
Ready-to-drink tea	No change	Added food with a market share of 50%	Increased market share to 100%
Low fat, low sugar biscuits	No change	Added food with a market share of 5%	Increased market share to 10%

The Lower scenario, proposed by the food industry previously, was presented in the FAR, The *Moderate* scenario was based on an extension in voluntary folic acid fortification considered feasible by industry. The *Higher* scenario is not considered likely based on current market trends. Each of the extended voluntary folic acid fortification scenarios were presented to the AFGC and input obtained on the foods included and market share percentages used.

Within each of the scenarios investigated, two different model types were assessed:

a) market share model; and
b) consumer behaviour models.

The 'market share' model estimates intakes on a population basis; whereas the 'consumer behaviour' model estimates intakes on an individual basis. The market share and consumer behaviour model types are discussed in detail in the main dietary intake assessment report (for the First Review).

An overview of the dietary intake assessments conducted for the extended voluntary fortification scenarios is shown in Figure 1.

2.2 Folic acid concentration data

2.2.1 Baseline

Baseline folic acid concentration data for voluntarily fortified foods have been updated following Final Assessment for Australia and New Zealand, based on new data recently becoming available to FSANZ. Refer to Section 2.2.1 of Attachment A of this Dietary Intake Assessment report for further details on baseline folic acid concentration data.

2.2.2 Extended voluntary fortification

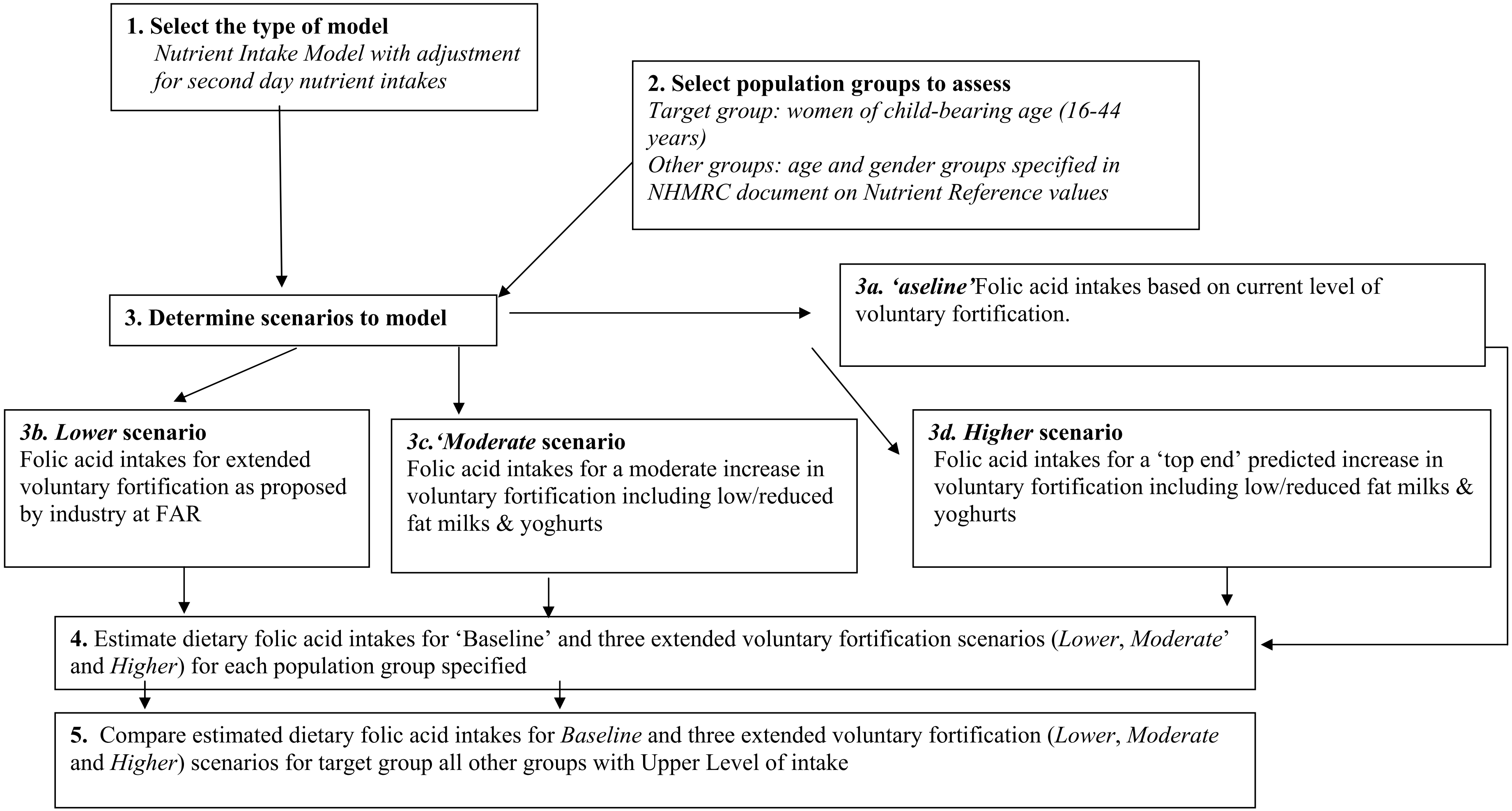
Under the extended voluntary fortification scenarios (*Lower*, *Moderate* and *Higher*), folic acid concentrations were assigned to foods based on either:

- their current level of fortification; or
- the level of fortification permitted in the Code; or
- where there is no current permission in the Code, the level proposed by the food industry.

The Baseline and voluntary fortification scenarios do not take into account naturally occurring folate in food or folic acid from the use of folic acid supplements or multi-vitamin supplements containing folic acid. The estimates of dietary folic acid intake do not take into account potential losses of folic acid during storage.

The folic acid concentration in food for each of the scenarios is shown in Appendix 2 (Table A2.1 for Australia and table A2.2 for New Zealand.

Figure 1: Dietary intake assessment approach used for the First Review for Australia and New Zealand for extended voluntary fortification



3. Assumptions Used in the Dietary Exposure Assessment

The assumptions used in the dietary intake assessments for folic acid were provided in detail in Attachment 7 of the P295 – Consideration of Mandatory Fortification with Folic Acid Final Assessment report.

4. Estimated Dietary Folic Acid Intakes from Folic Acid Added to Food

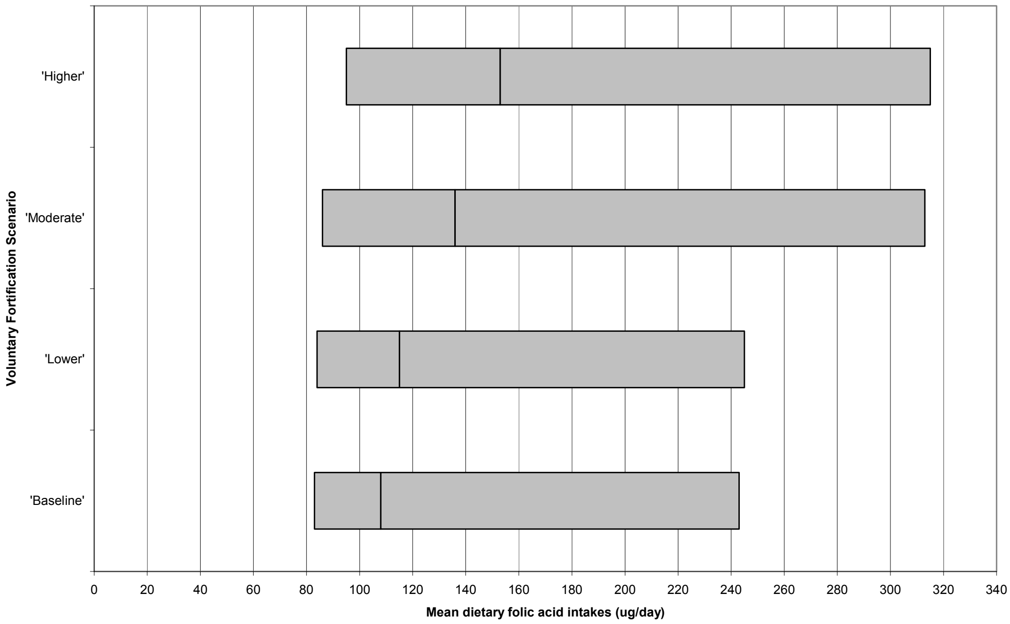
While folic acid intakes were estimated for a broad range of population sub-groups, the focus of the risk assessment was women of child-bearing age. Therefore, the results section of this report is primarily focussed on this population sub-group.

4.1 Estimated dietary folic acid intakes for the target group (women aged 16-44 years)

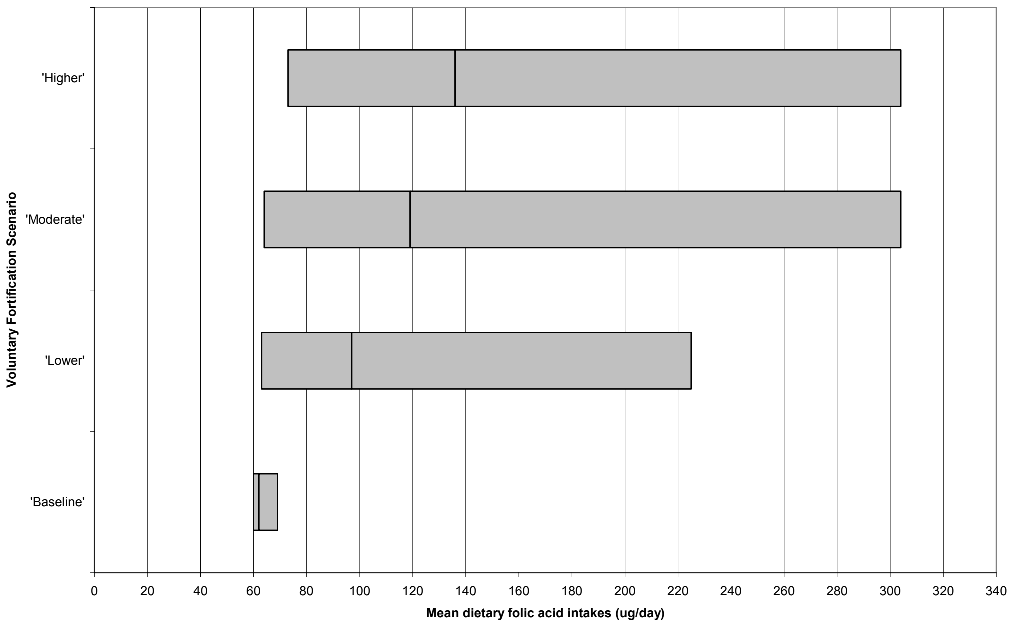
Comparisons between estimated mean folic acid intakes under the *Baseline* and *Lower*, *Moderate* and *Higher* extended voluntary fortification scenarios are presented in Figure 2a for Australian and New Zealand women aged 16-44 years; the lower and upper ends of the range of mean folic acid intakes represent the results from the ‘consumer behaviour’ model – the lower bound indicates mean folic acid intakes for individuals who always avoid the products that contain folic acid; the upper bound indicates mean folic acid intakes for individuals who always select the products that contain folic acid. The results from the ‘market share’ model are indicated by the black line within the range of estimated folic acid intakes, and are representative of mean **population** intakes over a period of time. Generally, the results presented in this section refer to the ‘market share’ model results.

Figure 2: Range in estimated mean dietary folic acid intakes for women aged 16-44 years

a. Australia



b. New Zealand



The ‘consumer behaviour’ model range of results gives an indication of the uncertainty of the outcome of the different voluntary fortification approaches. At *Baseline*, the estimated mean dietary folic acid intakes for New Zealand did not show as large a range as for Australia.

This could be due to differences in the uptake of voluntary folic acid fortification between the two countries.

The 'consumer behaviour' model results indicate that, for an individual who eats large amounts of the fortified foods and goes out of their way to select the fortified version wherever there is a choice, then higher folic acid intakes can be achieved. However, it is considered that the number of consumers who would actually behave in this way on a regular basis is likely to be small.

The 'market share' estimated mean dietary folic acid intakes for Australian and New Zealand women of child-bearing age are shown in Figure 3 and Table 3 for *Baseline* and the *Lower*, *Moderate* and *Higher* extended voluntary fortification scenarios.

Table 3: Estimated mean folic acid intakes from food, and increase in folic acid intake from Baseline, for Australian and New Zealand women of child-bearing age (16-44 years)

	Mean dietary folic acid intake (increase in folic acid intake from *Baseline*) [µg/day][1]	
Scenario	**Australia[2]**	**New Zealand[3]**
Baseline voluntary fortification	108	62
Lower voluntary fortification	115	97
	(+7)	(+35)
Moderate voluntary fortification	136	119
	(+28)	(+57)
Higher voluntary fortification	153	136
	(+45)	(+74)

[1] Concentration of folic acid in foods is weighted according to the proportion of a food group that is fortified. This estimates dietary intakes over the long-term and across the population.
[2] Number of Australian respondents aged 16-44 years = 3,178.
[3] Number of NZ respondents aged 16-44 years = 1,509.

From *Baseline*, there was an increase in mean folic acid intakes of between 7-45 µg per day for Australia and 35-74 µg per day for New Zealand, depending on the degree of extension of voluntary folic acid fortification. The higher the extension in voluntary fortification, the greater the increase in mean folic acid intakes for the target group of women aged 16-44 years.

Under the *Higher* voluntary fortification scenario, the mean intake increased by 45 µg per day from *Baseline* for Australia and 74 µg per day for New Zealand. This scenario was designed to include a wide range of foods and market share weighting; however it was not considered likely to occur by the food industry, given current market trends for fortification. Mean estimated folic acid intakes from food alone for women of child-bearing age did not achieve the desired folic acid intake of 400 µg per day for any of the extended voluntary folic acid fortification scenarios examined. Full results can be found in Appendix 3 (Table A3.1).

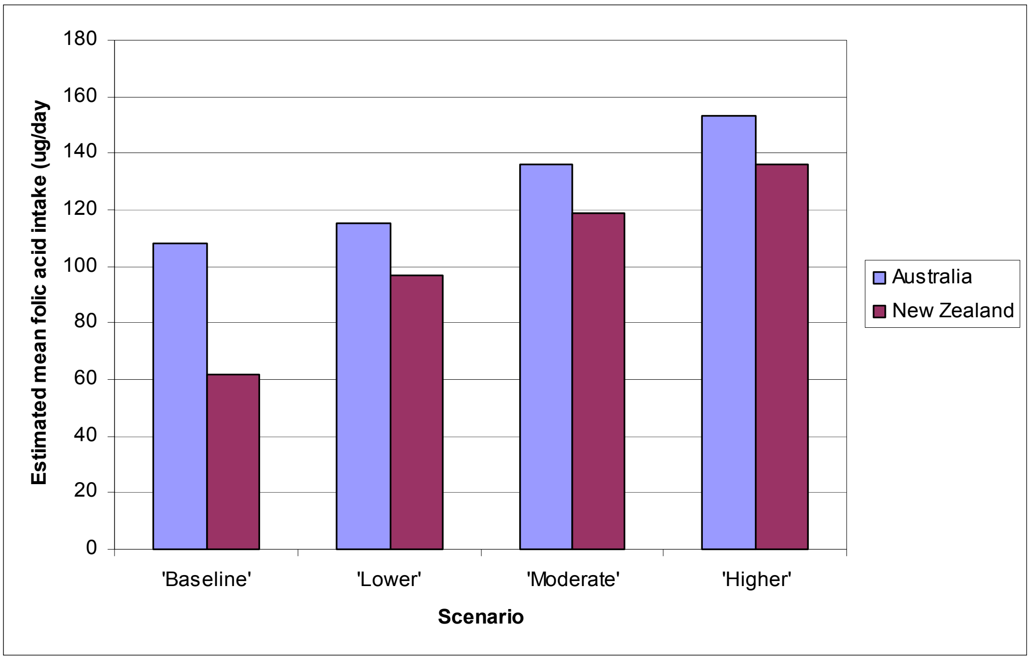


Figure 3: Estimated mean folic acid intakes from food for Baseline and Lower, Moderate and Higher extended voluntary fortification scenarios, for Australian and New Zealand women of child-bearing age (16-44 years)

These results also indicate that New Zealand women of child-bearing age have larger incremental increases in folic acid intake from *Baseline* under the *Lower*, *Moderate* and *Higher* extension of voluntary fortification scenarios in comparison to the same population group for Australia. This is due to fewer voluntary folic acid permissions being taken up by industry in New Zealand at *Baseline*.

4.1.1 Differences in estimated mean folic acid intakes between Baseline *and* Lower *voluntary fortification scenarios*

<u>4.1.1.1 Australian women aged 16-44 years</u>

For Australia, there was an increase in mean folic acid intake of 7 µg per day from *Baseline* to the *Lower* proposed extension in voluntary fortification at FAR. Two foods were added to the list of foods fortified (low or reduced fat plain yoghurt and diet ready-to-eat meals) for the *Lower* scenario. Bread was assigned a higher market share for fortification of 20%.

From the 1995 NNS, only 1% of Australian women aged 16-44 years consumed low and reduced fat plain yoghurt and less than 1% consumed diet-ready-to-eat meals. While 78% of the population consumed bread, the increase in market share of the fortified product to 20% and minor proportion of the population consuming low and reduced fat plain yoghurt and diet ready-to-eat meals, did not increase mean folic acid intakes to a large extent. For details of the proportion of Australian women aged 16-44 years consuming various foods, refer to Table 4 below. Details for other, non-target population groups, can be found in Appendix 5, Table A5.1.

Table 4: Proportion of population consuming certain foods under voluntary fortification scenarios for Australian women of child-bearing age (16-44 years)

	Scenario		
Food	***Baseline***	***Lower***	***Moderate & Higher***
Bread	78	78	78
Flour (white)	6	6	6
Flour (wholemeal)	-	-	0
Yeast extract	19	19	19
Pasta	-	-	15
Breakfast cereal	12	12	12
Low/reduced fat milk	21	21	38
Low/reduced fat fruit/flavoured yoghurt	-	-	5
Low/reduced fat plain yoghurt	-	1	1
Diet ready-to-eat meals	-	<1	<1
Fruit juice	5	5	21
Soy beverages	1	1	1
Other milk substitutes	0	0	0
Infant food	0	0	0
Meal replacement products	<1	<1	<1
Formulated beverages	-	-	45
Ready-to-drink tea	-	-	45
Low fat, low sugar biscuits	-	-	1

Note: Where there is no figure, the food was not included in the scenario

4.1.1.2 New Zealand women aged 16-44 years

For New Zealand, there was an increase in mean folic acid intake of 35 µg per day from *Baseline* to the *Lower* proposed extension in voluntary fortification at FAR. One food was added to the list of foods fortified (low and reduced fat yoghurt) for the *Lower* scenario. The breads with individual folic acid concentrations at *Baseline* remained the same; however other breads were included with a market share for fortification of 20%. Diet ready-to-eat meals were included in the proposal from industry; however they were not able to be identified in the New Zealand NNS. Only 2% of the population consumed low and reduced fat yoghurt and the proportion of consumers of breads potentially fortified with folic acid increased to 80% from <1%.

For details of the proportion of New Zealand women aged 16-44 years consuming various foods, refer to Table 5 below. Details for other, non-target population groups, can be found in Appendix 5, Table A5.1.

Table 5: Proportion of population consuming certain foods under voluntary fortification scenarios for various New Zealand women of child-bearing age

	Scenario		
Food	***Baseline***	***Lower***	***Moderate & Higher***
Bread	<1	80	80
Flour (white)	-	-	3
Flour (wholemeal)	-	-	0
Yeast extract	15	15	15
Pasta	-	-	14
Breakfast cereal	24	24	24
Low/reduced fat milk	-	-	33
Low/reduced fat fruit/flavoured yoghurt	-	-	6
Low/reduced fat plain yoghurt	-	2	2
Fruit juice	5	5	12
Soy beverages	<1	<1	<1
Other milk substitutes	0	0	0
Infant food	<1	<1	<1
Meal replacement products	<1	<1	<1
Formulated beverages	-	-	91
Ready-to-drink tea	-	-	91
Low fat, low sugar biscuits	-	-	5

Note: Where there is no figure, the food was not included in the scenario

4.1.2 Differences in estimated mean folic acid intakes between Lower *and* Moderate *voluntary fortification scenarios*

4.1.2.1 Australia women aged 16-44 years

For Australian women aged 16-44 years, there was an increase in mean folic acid intake of 21 µg per day from the *Lower* to *Moderate* proposed extension in voluntary fortification. Seven foods were added to the list of foods fortified for the *Moderate* scenario. There was an increase in the market share for folic acid fortification for bread and low and reduced fat milk. There were no consumers of wholemeal flour (this excludes wholemeal flour used in recipes); 15% of the population consumed pasta; 5% consumed low or reduced fat fruit or flavoured yoghurt; 21% consumed single or mixed fruit juice; 45% consumed foods that were assumed to be consumed as a formulated beverage or ready-to-drink tea; and 1% consumed low fat, low sugar biscuits (refer to Table 4 above).

4.1.2.2 New Zealand women aged 16-44 years

For New Zealand, there was an increase in mean folic acid intake of 22 µg per day from the *Lower* to *Moderate* proposed extension in voluntary fortification. Nine foods were added to the list of foods fortified between the *Lower* to *Moderate* scenarios. There was an increase in the market share for fortification for bread. Only 3% of the population consumed white flour and there were no consumers of wholemeal flour (this excludes wholemeal flour used in recipes).

Fourteen percent of the population consumed pasta; 33% consumed low or reduced fat milk; 6% consumed low or reduced fat fruit or flavoured yoghurt; 12% consumed single or mixed fruit juice; 91% consumed foods that were assumed to be consumed as a formulated beverage or ready-to-drink tea; and 5% consumed low fat, low sugar biscuits (refer to Table 5 above).

While the proportion of the Australian and New Zealand populations consuming some foods was high, either the folic acid concentration, market share, or the amount of the food consumed resulted in only a small increase in folic acid intakes from *Lower* to *Moderate* voluntary fortification scenarios in comparison to the target intake of 400 µg/day. Details for other, non-target population groups, can be found in Appendix 5, Table A5.1 and Table A5.2.

4.1.3 Differences in estimated mean folic acid intakes between Moderate *and* Higher *voluntary fortification scenarios*

For Australian and New Zealand women aged 16-44 years, there was a further increase in mean folic acid intake of 17 µg per day from the *Moderate* to the *Higher* proposed extensions in voluntary fortification. No foods were added to the list of foods fortified. However, the market share for fortification was increased for seven foods. This increase in market share did not increase folic acid intakes to a large extent in comparison to the target intake of 400 µg/day.

4.2 Estimated dietary folic acid intakes for the non-target groups

Dietary folic acid intakes were estimated for non-target groups to assess the impact that extended voluntary fortification would have on public health and safety. The results show an increase in estimated dietary folic acid intakes from *Baseline* for the *Lower*, *Moderate* and *Higher* extended voluntary fortification scenarios. As for women of child-bearing age, non-target groups in New Zealand have larger incremental increases in folic acid intakes than Australia due to fewer voluntary folic acid permissions being taken up by industry in New Zealand at *Baseline*. Full results for the estimated dietary folic acid intakes for the non-target groups can be found in Appendix 3 (Table A3.2 for Australia and Table A3.3 for New Zealand).

4.3 Major contributors to estimated dietary folic acid intakes

The major contributors to folic acid intakes (≥5%) were estimated for women of child-bearing age and the general population. Percent contributors were calculated from data from a single 24-hour recall. The results are shown in Table 6.

Breakfast cereal, bread and yeast extract were major contributors to folic acid intakes for the population groups assessed under all scenarios. The contribution of bread increases as the market share of the fortified product increases under each of the proposed extension in voluntary fortification scenarios (*Lower*, *Moderate*, and *Higher*). Under the *Higher* proposed extension in voluntary fortification, low and reduced fat yoghurt (plain and fruit or flavoured) and fruit juice were also major contributors.

Table 64: Major contributors (≥5%) to folic acid intakes for Australia and New Zealand population sub-groups

Country	Population group	Scenario	Major contributors (%)				
			Breads	**Breakfast cereals**	**Yeast extracts**	**Low/Red. fat yoghurt**	**Fruit juice**
Australia	2 years and above	*Baseline*	19	51	24		
		Lower	23	48	22		
		Moderate	23	48	22		
		Higher	27	38	17	5	5
	Females 16-44 years	*Baseline*	20	47	28		
		Lower	23	44	26		
		Moderate	23	44	26		
		Higher	26	33	19	6	7
New Zealand	15 years and above	*Baseline*		61	35		
		Lower	33	40	23		
		Moderate	33	40	23		
		Higher	36	29	17	7	5

Country	Population group	Scenario	Major contributors (%)				
			Breads	Breakfast cereals	Yeast extracts	Low/Red. fat yoghurt	Fruit juice
	Females 16-44 years	*Baseline*		58	37		
		Lower	34	36	23		
		Moderate	34	37	23		
		Higher	35	26	17	8	7

Note: the shaded areas indicate that the food was not a major contributor to folic acid intakes for the population group.

4.4 Comparison of estimated dietary folic acid intakes with the Upper Level

In order to determine if the proposed levels of increased uptake of voluntary folic acid fortification (*Lower*, *Moderate* and *Higher*) might be a concern to public health and safety, the estimated folic acid dietary intakes were compared with the Upper Level (UL). The UL is 'the highest average daily nutrient intake level likely to pose adverse health effects to almost all individuals in the general population'(National Health and Medical Research Council).

The estimated dietary intakes for folic acid were determined for each individual and were compared to the relevant UL for the individual's age group and gender.

4.4.1 Proportion of the target group exceeding the Upper Level

The proportion of Australian and New Zealand women of child-bearing age exceeding the UL is shown in Table 7. Less than 1% of women aged 16-44 years exceeded the UL under *Baseline* and for all extended voluntary fortification scenarios (*Lower*, *Moderate* and *Higher*).

Table 7: Proportion of respondents with folic acid intakes above the Upper Level for Australian and New Zealand women of child-bearing age (16-44 years)

	% of respondents with folic acid intakes > UL[1]	
Voluntary Fortification Scenario	**Australia[2]**	**New Zealand[3]**
Baseline	<1	<1
Lower	<1	<1
Moderate	<1	<1
Higher	<1	<1

[1] Concentration of folic acid in foods is weighted according to the proportion of a food group that is fortified. This estimates dietary intakes over the long-term and across the population.
[2] Number of Australian respondents aged 16-44 years = 3,178.
[3] Number of NZ respondents aged 16-44 years = 1,509.

4.4.1 Proportion of the non-target population exceeding the Upper Level

The proportion of each non-target population group exceeding the UL is shown in Table 8 for Australia and Table 9 for New Zealand. Results on gender differences can be found in Appendix 4 (Table A4.1 for Australia and Table A4.2 for New Zealand).

For Australia, the results indicate that respondents aged 2-3 years and 4-8 years were the most likely of the non-target groups to have intakes exceeding the UL for both the *Baseline* and *Lower*, *Moderate* and *Higher* extended voluntary fortification scenarios, with 4% of 2-3 year old children and 3% of 4-8 year old children exceeding the UL under the *Higher* extended voluntary fortification scenario. As discussed previously, the *Higher* scenario was not considered by the food industry to be likely, given current market trends for fortification.

For New Zealand no population sub-group exceeded the UL, with the exception of the population group aged 30-49 years (less than 1%).

Table 8: Proportion of respondents with folic acid intakes above the Upper Level for various Australian population non-target sub-groups

			% of respondents with folic acid intakes > UL[1]			
Pop. group	**UL (µg/day)**	**No. of respondents**	***Baseline***	***Lower***	***Moderate***	***Higher***
2-3 yrs	300	383	2	2	2	4
4-8 yrs	400	977	1	1	2	3
9-13 yrs	600	913	1	1	1	2
14-18 yrs	800	734	<1	<1	<1	<1
19-29 yrs	1,000	2,203	<1	<1	<1	<1
30-49 yrs	1,000	4,397	<1	<1	<1	<1
50-69 yrs	1,000	3,019	<1	<1	<1	<1
70 yrs & above	1,000	1,232	0	0	0	0

[1] Concentration of folic acid in foods is weighted according to the proportion of a food group that is fortified. This estimates dietary intakes over the long-term and across the population.

Table 9: Proportion of respondents with folic acid intakes above the Upper Level for various New Zealand population non-target sub-groups

			% of respondents with folic acid intakes > UL[1]			
Pop. group	**UL (µg/day)**	**No. of respondents**	***Baseline***	***Lower***	***Moderate***	***Higher***
15-18 yrs	800	246	0	0	0	0
19-29 yrs	1,000	804	0	0	0	0
30-49 yrs	1,000	1,883	<1	<1	<1	<1
50-69 yrs	1,000	1,147	0	0	0	0
70 yrs & above	1,000	556	0	0	0	0

[1] Concentration of folic acid in foods is weighted according to the proportion of a food group that is fortified. This estimates dietary intakes over the long-term and across the population.

4.4.2 Estimated 95th percentile folic acid intakes as a proportion of the Upper Level

An assessment was made of 95th percentile folic acid intakes as a proportion of the UL under the 'consumer behaviour' model to provide an indication of the level of risk **for an individual** who eats large amounts of the fortified foods and goes out of their way to select the fortified version wherever there is a choice. This is not a prediction of expected 95th percentile intakes for the population as a whole.

Estimated 95th percentile folic acid intakes from food, as a proportion of the UL, for various Australian population sub-groups is shown in Table 10 and in Table 11 for New Zealand. The results show that high consumer (95th percentile) intakes of folic acid for the Australian population aged 2 years and above and the New Zealand population aged 15 years and above were either at or below the UL. For Australian children aged 2-3 years and 4-8 years, high consumer intakes of folic acid were estimated to exceed the UL at *Baseline* and under the three extended voluntary fortification scenarios (*Lower*, *Moderate*, and *Higher*). However, it is considered very unlikely that young children would always be given the fortified version wherever there is a choice on a regular basis, as these products are not targeted at this age group.

Table 10: Estimated 95th percentile folic acid intakes from food as a proportion of the Upper Level for various Australian population sub-groups

		95th percentile folic acid intake from food as a proportion of the UL (%)			
Population group	**No. of respondents**	***Baseline***	***Lower***	***Moderate***	***Higher***
Females 16-44 years	3,178	50	50	60	60
2-3 years	383	140	140	170	170
4-8 years	977	120	120	150	150
2 years and above	13,858	80	80	100	100

Table 11: Estimated 95th percentile folic acid intakes from food as a proportion of the Upper Level for various New Zealand population sub-groups

		95th percentile folic acid intake from food as a proportion of the UL (%)			
Population group	**No. of respondents**	***Baseline***	***Lower***	***Moderate***	***Higher***
Females 16-44 years	1,509	20	40	55	55
15 years and above	4,636	25	50	65	65

5. Estimates of Folic Acid Intakes from Food and Supplements

Currently women planning pregnancy are advised to take folic acid supplements (Food Standards Australia New Zealand, 2006). Consequently, additional calculations were undertaken by FSANZ to estimate folic acid intakes assuming women of child-bearing age received folic acid from folic acid supplements in addition to receiving folic acid via voluntary and mandatory fortification of foods.

Additional calculations were not conducted for each of the non-target groups due to limited information available on supplement use. Also, there are no specific nutrition policies that specify that members of the population other than the target group should take folic acid supplements.

5.1 Calculation of estimated folic acid intakes from food and supplements

For an overview of methods used to calculate folic acid intakes from food and supplements, refer to Attachment 7 of the Final Assessment Report (FAR) for P295 – Consideration of Mandatory Fortification with Folic Acid.

5.2 Estimated mean dietary intakes of folic acid from food and supplements for the target group

The estimated mean dietary folic acid intakes for *Baseline* and the extended voluntary fortification scenarios (*Lower*, *Moderate*, and *Higher*) from food and folic acid supplements for Australian and New Zealand women of child-bearing age were compared with the 'target intake' (400 µg folic acid per day). The results show an increase in estimated dietary folic acid intakes from *Baseline* for all three extended voluntary fortification scenarios (*Lower*, *Moderate*, and *Higher*) when additional folic acid is consumed from supplements.

For all voluntary fortification scenarios examined, the mean folic acid intakes for women aged 16-44 years only reach the 400 µg/day target with consumption of a 500 µg folic acid supplement (for Australia) or an 800 µg folic acid supplement (for New Zealand). Refer to Table 12, Figure 4, and Figure 5 below for further details. Full results can be found in Appendix 6 (Table A6.1 for Australia and table A6.2 for New Zealand).

Table 12: Estimated mean folic acid intakes from food and supplements for Australian and New Zealand women of child-bearing age (16-44 years)

	Mean folic acid intake from food and supplements (µg/day)[1]			
	Australia[2]		New Zealand[3]	
Scenario	**Mean intake with 200 µg supplement**	**Mean intake with 500 µg supplement**	**Mean intake with 200 µg supplement**	**Mean intake with 800 µg supplement**
Baseline	308	608	262	862
Lower	315	615	297	897
Moderate	336	636	319	919
Higher	353	653	336	936

[1] Concentration of folic acid in foods is weighted according to the proportion of a food group that is fortified. This estimates dietary intakes over the long-term and across the population.
[2] Number of Australian respondents aged 16-44 years = 3,178.
[3] Number of NZ respondents aged 16-44 years = 1,509.

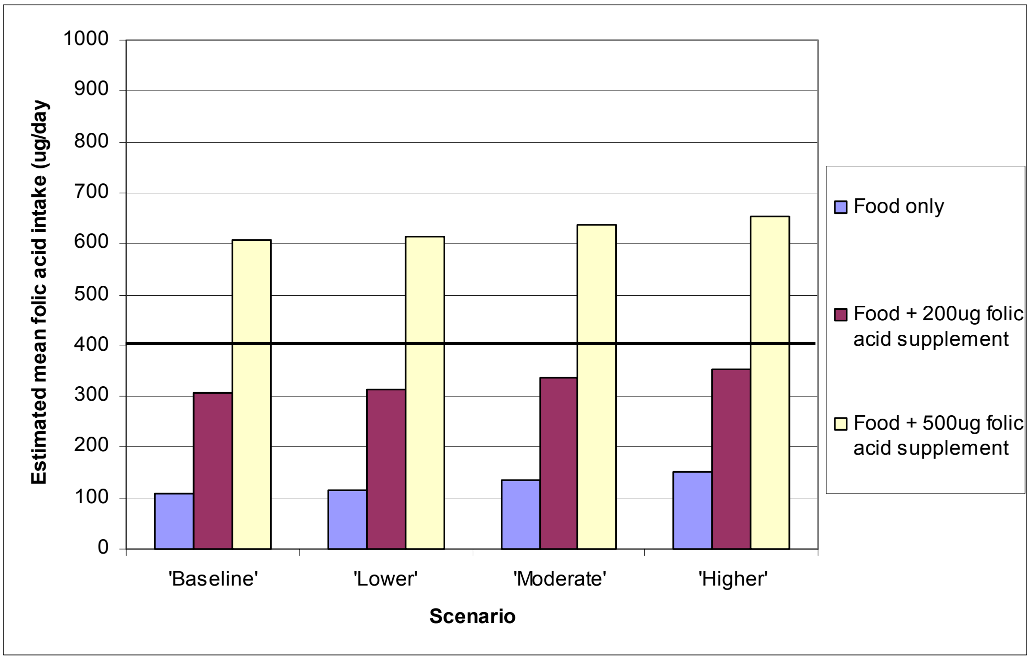


Figure 4: Estimated mean folic acid intakes from food and supplements for Australian women of child-bearing age (16-44 years)

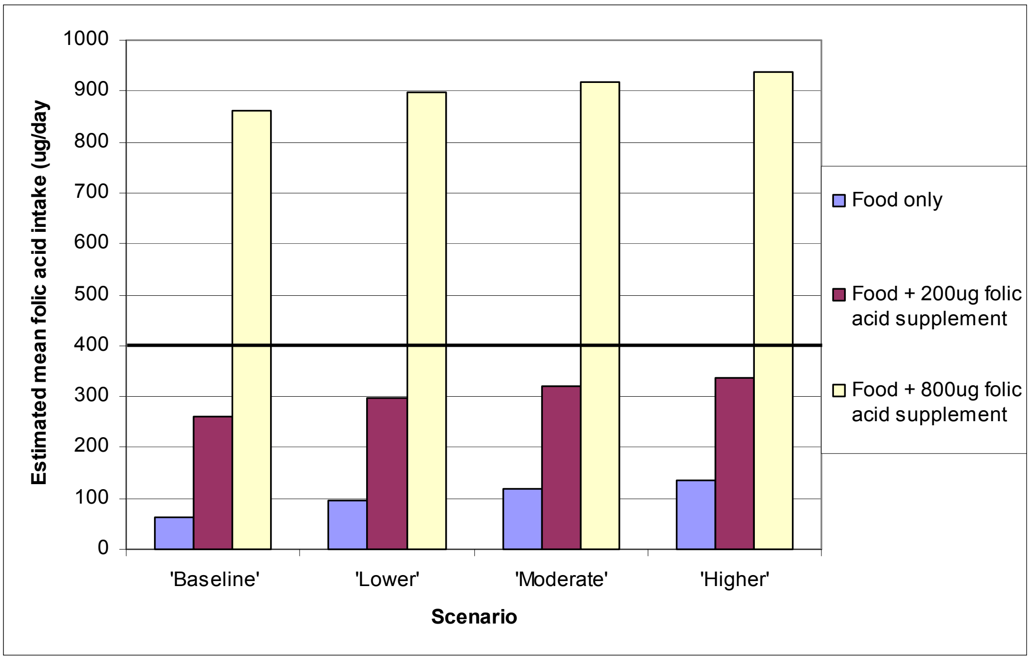


Figure 5: Estimated mean folic acid intakes from food and supplements for New Zealand women of child-bearing age

The proportion of Australian and New Zealand women aged 16-44 years with folic acid intakes (from food and supplements) of at least 400 µg per day are shown in Table 13. The results indicate that, without the consumption of folic acid supplements, <1% to 3% of Australian and New Zealand women of child-bearing age met the recommended 400 µg folic acid per day under all scenarios. When a 200 µg folic acid per day supplement was considered, between 4% and 21% of Australian and New Zealand women of child-bearing age were estimated to meet the recommended intake of folic acid. If 500 µg (Australia) or 800 µg (New Zealand) folic acid supplements were consumed by all women of child-bearing age, 100% would meet the recommended intake. Refer to Table 13 for further detail.

Table 13: Proportion of respondents with folic acid intakes of at least 400 µg/day from food and supplements for Australian and New Zealand women of child-bearing age (16-44 years)

Scenario	% respondents with folic acid intakes from food and supplements ≥ 400 µg[1]					
	Australia[2]			New Zealand[3]		
	Food + No supplement	Food + 200 µg folic acid supplement	Food + 500 µg folic acid supplement	No supplement	Food + 200 µg folic acid supplement	Food + 800 µg folic acid supplement
Baseline	2	11	100	<1	4	100
Lower	3	12	100	<1	8	100
Moderate	3	16	100	1	12	100
Higher	3	21	100	2	17	100

[1] Concentration of folic acid in foods is weighted according to the proportion of a food group that is fortified. This estimates dietary intakes over the long-term and across the population.
[2] Number of Australian respondents aged 16-44 years = 3,178.
[3] Number of NZ respondents aged 16-44 years = 1,509.

5.3 Comparison of the estimated dietary intakes from food and supplements with the Upper Level

The proportion of the Australian and New Zealand target groups exceeding the UL when supplements are taken into account is shown in Table 14. The results indicate that when Australian and New Zealand women of child-bearing age consumed additional folic acid from supplements, there was likely to be an increase in the proportion of the target group exceeding the UL of 800 µg of folic acid per day for women aged 16-18 years and 1,000 µg of folic acid per day from women aged 19-44 years.

The proportion of respondents exceeding the UL increases as the concentration of folic acid in the supplement increases. There was no change in the proportion of the Australian target group exceeding the UL with a folic acid supplement of 200 µg per day under all scenarios. If Australian women of child-bearing age consume a 500 µg supplement, there was no increase in the proportion of the population with estimated folic acid intakes that exceed the UL between *Baseline* and the *Higher* extended voluntary fortification scenario.

Due to the high folic acid content of the supplement at 800 µg, a large proportion of New Zealand women were likely to exceed the UL, particularly under the *Higher* proposed extension in voluntary fortification.

Table 14: Proportion of respondents with folic acid intakes from food and supplements above the Upper Level for Australian and New Zealand women of child-bearing age (16-44 years)

Scenario	% respondents with folic acid intakes from food and supplements > UL[1]			
	Australia[2]		New Zealand[3]	
	Food + 200 µg folic acid supplement	Food + 500 µg folic acid supplement	Food + 200 µg folic acid supplement	Food + 800 µg folic acid supplement
Baseline	<1	2	<1	10
Lower	<1	2	<1	14
Moderate	<1	2	<1	18
Higher	<1	2	<1	22

[1] Concentration of folic acid in foods is weighted according to the proportion of a food group that is fortified. This estimates dietary intakes over the long-term and across the population.
[2] Number of Australian respondents aged 16-44 years = 3,178.
[3] Number of NZ respondents aged 16-44 years = 1,509.

References

Reference List

Food Standards Australia New Zealand. Folic Acid & Pregnancy. 2006.
Ref Type: Pamphlet
National Health and Medical Research Council. 'Nutrient Reference Values for Australia and New Zealand Including Recommended Dietary Intakes.' June 9, 2006. 2006. http://www.nhmrc.gov.au/publications/_files/n35.pdf.

Appendix 1 – Extended voluntary folic acid fortification scenarios

Table A1.1: Extended voluntary folic acid fortification scenarios for Australia

Food	*Baseline*	*Lower**	*Moderate*	*Higher*	Rationale/Notes
Bread	Market share based on four figures for different breads, either 15%, 16%, 20% or 100%	20% market share	25% market share	30% market share	Industry information indicates not a large uptake proposed in future, and will mostly be in products marketed to target population. Folic acid concentrations were based on analysed values.
Flour (white)	5% market share	Same as *Baseline*	Same as *Baseline*	Same as *Baseline*	Industry information indicates not targeting this food for fortification given small consumption and not specifically used by target group. Folic acid concentrations were based on analysed values.
Flour (wholemeal)	Not fortified	Not fortified	5% market share	5% market share	To be the same as for white flour.
Yeast extract	Assumes 100% fortified (i.e. 100% vegemite)	Same as *Baseline*	Same as *Baseline*	Same as *Baseline*	The folic acid concentration was based on analysed values.
Pasta	Not fortified	Not fortified	2.5% market share	5% market share	Industry information indicates not targeting this food for fortification given not specifically used by target group and large volume of imported products. A pasta product was recently identified as being fortified with folic acid, therefore this concentration was used in the scenarios.
Breakfast cereal	Folic acid concentrations assigned to individual breakfast cereals i.e. no market share weighting.	Same as *Baseline*	Same as *Baseline*	Same as *Baseline*	Assumed no further uptake of voluntary fortification. Most of the breakfast cereal market is fortified and it may not be realistic to assume 100%. Folic acid concentrations were based on analysed values.

Food	*Baseline*	*Lower**	*Moderate*	*Higher*	Rationale/Notes
Low/reduced fat milk	5% market share	5% market share	10% market share	20% market share	Industry information used to determine *Moderate* and *Higher* market shares based on major brands in the low/reduced fat milk market adding folic acid. There is no current fortification permission; however, the one currently fortified milk is labelled as a 'Formulated supplementary food'. It is assumed that whole/'full cream' milk would not be fortified. The concentration of the identified fortified milk was used in the scenarios.
Low/reduced fat flavoured/fruit yoghurt	Not fortified	Not fortified	50% market share	100% market share	Industry information indicates the potential for high uptake in this category due to its high consumption by the target group. There is no current fortification permission. The folic acid concentration was based on that provided in the submission by industry at DAR for voluntary fortification for low/reduced fat plain yoghurt.
Low/reduced fat plain yoghurt	Not fortified	Folic acid concentrations assigned to individual low/reduced fat yoghurt (assumed 100% market share)	Same as *Lower* voluntary proposal	Same as Lower voluntary proposal	Not many individual food codes in the NNS relating to this food therefore assumed 100% market share. There is no current fortification permission. The folic acid concentration was based on that provided in the submission by industry at DAR for voluntary fortification for this food group.
Diet ready-to-eat meals	Not fortified	Folic acid concentrations assigned to individual diet ready-to-eat meals (assumed 100% market share)	Same as Lower voluntary proposal	Same as Lower voluntary proposal	Not many individual food codes in the NNS relating to this food therefore assumed 100% market share. There is no current fortification permission. The folic acid concentration was based on that provided in the industry proposal.

Food	*Baseline*	*Lower**	*Moderate*	*Higher*	Rationale/Notes
Juices	50% market share used for commercial orange juice. Mixed fruit juices (breakfast style) assumed to be 100% folic acid fortified.	Same as *Baseline*	40% market share which extends to other single and mixed juices Mixed fruit juices (breakfast style) assumed to be 100% folic acid fortified.	50% market share which extends to other single and mixed juices Mixed fruit juices (breakfast style) assumed to be 100% folic acid fortified.	The market share (based, in this case, on the proportion of the category consumed in the NNS) for orange juice as a proportion of all juice available is 60%. At *Baseline*, 50% of those were fortified (i.e. 30% of the fruit juice market). This has been increased slightly for *Moderate* and *Higher* models to a small degree given this food may be consumed by all family members. The folic acid concentration was based on the level as analysed in orange juice in Australia (30 µg/100 ml).
Soy beverages	NNS specified whether fortified. Others assigned 50% market share weighting.	Same as *Baseline*	Same as *Baseline*	Same as *Baseline*	
Other milk substitutes	100% market share	Same as *Baseline*	Same as *Baseline*	Same as *Baseline*	Folic acid concentrations were based on analysed values.
Infant food	10% market share	Same as *Baseline*	Same as *Baseline*	Same as *Baseline*	Folic acid concentrations were based on analysed values.
Meal replacement products	100% fortified	Same as *Baseline*	Same as *Baseline*	Same as *Baseline*	Folic acid concentrations were based on analysed values.

Food	*Baseline*	*Lower**	*Moderate*	*Higher*	Rationale/Notes
Formulated beverages	Not fortified	Same as *Baseline*	Fortified*	Fortified*	Because there is no current data on the consumption of formulated beverages in Australia, a different approach was taken to assign a folic acid concentration. A concentration was assigned to soft drinks that were assumed to be replaced with formulated beverages in the diet (data generated from a previous FSANZ application – A470 Formulated Beverages). The concentration was based on that currently permitted in the Code. A market share weighting of 5% was applied to these soft drinks, which represents the proportion of formulated beverages in the total soft drink market (provided by industry). * The industry proposed that for the *Moderate* and *Higher* scenarios, 100% of formulated beverages would be fortified.

Food	*Baseline*	*Lower**	*Moderate*	*Higher*	Rationale/Notes
Ready to drink tea	Not fortified	Same as *Baseline*	Fortified*	Fortified*	Because there is no current data on the consumption of ready to drink tea in Australia, a different approach was taken to assign a folic acid concentration. A concentration was assigned to soft drinks that were assumed to be replaced with ready to drink tea in the diet (data generated from a previous FSANZ application – A470 Formulated Beverages). The concentration was based on that currently permitted in the Code. A market share weighting of 2% was applied to these soft drinks, which represents the proportion of ready to drink teas in the total soft drink market (provided by industry). * The industry proposed that for the *Moderate* scenario, 50% of ready to drink teas would be fortified and 100% in the *Higher* scenario.
Low fat, low sugar biscuits (containing <200 g/kg fat and <50 g/kg sugar)	Not fortified	Not fortified	5% market share	10% market share	Currently permitted to be fortified however there is no current uptake. Industry information indicates the potential for some products in this market (savoury biscuits) to be fortified. The folic acid concentration was based on that currently permitted in the code.

* As presented in the FAR. Assumed to be equivalent to a 'low' voluntary uptake.

Table A1.2: Extended voluntary folic acid fortification scenarios for New Zealand

Commodity	***Baseline***	***Lower****	***Moderate***	***Higher***	**Rationale/Notes**
Bread	Folic acid concentrations assigned to individual breads i.e. no market share weighting.	Those with individual concentrations, keep as for *Baseline*. Market share set at 20% for other breads.	Those with individual concentrations, keep as for *Baseline*. Market share to increase to 25% for other breads.	Those with individual concentrations, keep as for *Baseline*. Market share to increase to 30% for other breads.	General assumption of increase. Market share for *Lower* proposal the same as for Australia. Folic acid concentrations were based on analysed values.
Flour (white)	Not fortified	Not fortified	5% market share	5% market share	*Baseline* based on no current voluntary fortification of flour in New Zealand. Moderate and higher models based on Australian data. The folic acid concentration was based on that analysed in Australia.
Flour (wholemeal)	Not fortified	Not fortified	5% market share	5% market share	*Baseline* based on no current voluntary fortification of flour in New Zealand. *Moderate* and *Higher* models based on Australian data. The folic acid concentration was based on that analysed in Australia.
Yeast extract	Folic acid concentrations assigned to individual yeast extracts i.e. no market share weighting.	Same as *Baseline*	Same as *Baseline*	Same as *Baseline*	Folic acid concentrations were based on analysed values.

Commodity	*Baseline*	*Lower**	*Moderate*	*Higher*	Rationale/Notes
Pasta	Not fortified	Not fortified	2.5% market share	5% market share	Australian industry information indicates that industry are not targeting this food for fortification given it isn't specifically used by target group and the large volume of imported products. A pasta product was recently identified in Australia as being fortified with folic acid, therefore this concentration was used in the scenarios.
Breakfast cereal	Folic acid concentrations assigned to individual breakfast cereals i.e. no market share weighting	Same as *Baseline*	Same as *Baseline*	Same as *Baseline*	Assumed no further uptake of voluntary fortification. Most of the breakfast cereal market is fortified and it may not be realistic to assume 100%. Folic acid concentrations were based on analysed values.
Low/reduced fat milk	Not fortified	Not fortified	10% market share	20% market share	Industry information used to determine *Moderate* and *Higher* market shares based on major brands in the low/reduced fat milk market adding folic acid. There is no current fortification permission; however, the one currently fortified milk is available in Australia and is labelled as a 'Formulated supplementary food'. It is assumed that whole/'full cream' milk would not be fortified. The concentration of the identified fortified milk was used in the scenarios.

Commodity	***Baseline***	***Lower****	***Moderate***	***Higher***	**Rationale/Notes**
Low/reduced fat flavoured/fruit yoghurt	Not fortified	Not fortified	50% market share	100% market share	Australian industry information indicates the potential for high uptake in this category due to its high consumption by the target group. There is no current fortification permission. The concentration was based on that provided in the submission by Australian industry at DAR for voluntary fortification for low/reduced fat plain yoghurt.
Low/reduced fat plain yoghurt	Not fortified	Folic acid concentrations assigned to individual low/reduced fat yoghurt (assumed 100% market share)	Same as Lower voluntary proposal	Same as Lower voluntary proposal	Not many individual food codes in the NNS relating to this food therefore assumed 100% market share. There is no current fortification permission. The concentration was based on that provided in the *Lower* proposal (100 µg/100 g).
Diet ready-to-eat meals	Not included in NNS	Not included in NNS	Not included in NNS	Not included in NNS	
Juices	25% market share used for commercial orange juice or orange and other fruit juice mixtures	Same as *Baseline*	40% market share, which extends to other juices	50% market share, which extends to others juices	The market share for orange juice and orange and other fruit juice (based, in this case, on the proportion of the category consumed in the NNS) as a proportion of all juice available is 60%. At *Baseline*, 25% of those were fortified (i.e. 15% of the fruit juice market). This has been increased based on market share data from Australian industry. The concentration was based on the level as analysed in orange juice in New Zealand (44 µg/100 ml).
Soy beverages	100% market share	Same as *Baseline*	Same as *Baseline*	Same as *Baseline*	Folic acid concentrations were based on

Commodity	*Baseline*	*Lower**	*Moderate*	*Higher*	Rationale/Notes
					analysed values.
Other milk substitutes	100% market share	Same as *Baseline*	Same as *Baseline*	Same as *Baseline*	Folic acid concentrations were based on analysed values.
Infant food	Folic acid concentration assigned to one cereal. No others reported to be fortified.	Same as *Baseline*	Same as *Baseline*	Same as *Baseline*	Folic acid concentrations were based on analysed values.
Meal replacement products	Folic acid concentrations assigned to individual products i.e. no market share weighting.	Same as *Baseline*	Same as *Baseline*	Same as *Baseline*	Folic acid concentrations were based on analysed values.
Formulated beverages	Not included	Same as *Baseline*	Fortified*	Fortified*	Because there is no current data on the consumption of formulated beverages in New Zealand, a different approach was taken to assign a folic acid concentration. A concentration was assigned to soft drinks that were assumed to be replaced with formulated beverages in the diet (data generated from a previous FSANZ application: A470 – Formulated Beverages). The concentration was based on that currently permitted in the Code. A market share weighting of 5% was applied to these soft drinks, which represents the proportion of formulated beverages in the total soft drink market (provided by industry). *The Industry proposed that for the *Moderate* and *Higher* scenarios, 100% of formulated beverages would be fortified.

Commodity	*Baseline*	*Lower**	*Moderate*	*Higher*	Rationale/Notes
Ready to drink tea	Not fortified	Same as *Baseline*	Fortified*	Fortified*	Because there is no current data on the consumption of ready to drink tea in New Zealand, a different approach was taken to assign a folic acid concentration. A concentration was assigned to soft drinks that were assumed to be replaced with ready to drink tea in the diet (data generated from a previous FSANZ application: A470 – Formulated Beverages). The concentration was based on that currently permitted in the Code. A market share weighting of 2% was applied to these soft drinks, which represents the proportion of ready to drink teas in the total soft drink market (provided by industry). * The Industry proposed that for the *Moderate* scenario, 50% of ready to drink teas would be fortified and 100% in the *Higher* scenario.
Low fat, low sugar biscuits (containing <200 g/kg fat and <50 g/kg sugar)	Not fortified	Not fortified	5% market share	10% market share	Currently permitted to be fortified however there is no current uptake. Industry information indicates the potential for some products in this market (savoury biscuits) to be fortified. The folic acid concentration was based on that currently permitted in the Code.

* Assumed to be equivalent of a 'low' voluntary uptake.

Appendix 2 – Summary of concentration data used for various dietary modelling purposes

Table A2.1: Concentration data for Australian foods assumed to contain folic acid (range) (µg/100 g) for each of the voluntary fortification scenarios

Food (main category)	Food (sub category)	Range of folic acid concentrations (µg/100g)			
		Baseline	*Lower*	*Moderate*	*Higher*
Bread	White bread and rolls	0-200	0-200	0-200	0-200
	Mixed grain bread and rolls	0-133	0-133	0-133	0-133
	Wholemeal bread and rolls	0-187	0-187	0-187	0-187
	Rye bread and rolls	0-140	0-140	0-140	0-140
	Fibre-increased bread and rolls	0-180	0-180	0-180	0-180
	Savoury bread	0-200	0-200	0-200	0-200
	Fruit bread	0-153	0-153	0-153	0-153
	Buns and yeast-based products	0-147	0-147	0-147	0-147
	Sandwiches	0-99	0-99	0-99	0-99
White flour	White flour	0-250	0-250	0-250	0-250
Wholemeal flour	Wholemeal flour	0	0	0-250	0-250
Yeast extract	Vegemite	3,250	3,250	3,250	3,250
Pasta	Dry pasta	0	0	0-200	0-200
	Cooked pasta	0	0	0-66	0-66
Breakfast cereal	Bran flakes	330-370	330-370	330-370	330-370
	Puffed rice-style	157-415	157-415	157-415	157-415
	Wheat biscuits	108-411	108-411	108-411	108-411
	Muesli	223	223	223	223
	Grain cereal, with or w/o fruit/nuts	108-680	108-680	108-680	108-680
	Sweetened cereal	140-442	140-442	140-442	140-442
	Breakfast bars	270	270	270	270
Low/reduced fat milk	Reduced fat, calcium increased milk	0-40	0-40	0-40	0-40

Food (main category)	Food (sub category)	Range of folic acid concentrations (µg/100g)			
		Baseline	*Lower*	*Moderate*	*Higher*
	Low/reduced fat milk	0	0	0-40	0-40
Low/reduced fat fruit/flavoured yoghurt	Low/reduced fat fruit/flavoured yoghurt	0	0	0-100	0-100
Low/reduced fat plain yoghurt	Low/reduced fat plain yoghurt	0	100	100	100
Diet ready-to-eat meals	Diet ready-to-eat meals	0	67	67	67
Fruit juice	Orange juice	0-30	0-30	0-30	0-30
	Fruit juice	0	0	0-30	0-30
	Breakfast juice	30	30	30	30
Soy beverages	Soy beverage, fortified	39-61	39-61	39-61	39-61
	Soy beverage, fortification not specified	0-60	0-60	0-60	0-60
Other milk substitutes	Infant formula	5	5	5	5
Infant food	Infant food	0-75	0-75	0-75	0-75
Meal replacement products	Liquid meal replacements	20	20	20	20
	Biscuit and bar meal replacements	82	82	82	82
	Supplement powders	117-667	117-667	117-667	117-667
	Energy drinks	1	1	1	1
Formulated beverages	Fruit drink - regular dilution	0	0	0.4	0.4
	Fruit drink - concentrate	0	0	1.6	1.6
	Cordial - regular dilution	0	0	0.4	0.4
	Cordial - concentrate	0	0	2	2
	Soft drink	0	0	0.4	0.4
	Flavoured and plain mineral/soda water	0	0	0.4	0.4
	Electrolyte drinks	0	0	0.4	0.4
	Electrolyte drink base	0	0	4.2	4.2
	Bottled water	0	0	0.4	0.4

Food (main category)	Food (sub category)	Range of folic acid concentrations (µg/100g)			
		Baseline	***Lower***	***Moderate***	***Higher***
Ready to drink tea	Fruit drink - regular dilution	0	0	0.1	0.2
	Fruit drink - concentrate	0	0	0.4	0.8
	Cordial - regular dilution	0	0	0.1	0.2
	Cordial - concentrate	0	0	0.5	1
	Soft drink	0	0	0.1	0.2
	Flavoured and plain mineral/soda water	0	0	0.1	0.2
	Electrolyte drinks	0	0	0.1	0.2
	Electrolyte drink base	0	0	1.1	2.2
	Bottled water	0	0	0.1	0.2
Low fat/low sugar biscuits	Low fat/low sugar biscuits	0	0	0-285	0-285

Note: A range in folic acid concentrations is presented for most foods. The range represents the folic acid concentration in foods where consumers have a choice as to whether they choose a food that is folic acid fortified within the category. For example, in Australia not all bread is fortified, therefore the lower bound concentration is zero. The upper bound represents that folic acid concentration in breads that are folic acid fortified. However, for meal replacement products, all foods within the category are fortified therefore the actual folic acid concentration was used.

Table A2.2: Concentration data for New Zealand foods assumed to contain folic acid (range) (µg/100g) for each of the voluntary fortification scenarios

Food (main category)	Food (sub category)	Range of folic acid concentration (µg/100 g)			
		Baseline	***Lower***	***Moderate***	***Higher***
Bread	White bread and rolls	0	0-198	0-198	0-198
	Mixed grain bread and rolls[1]	0-120	0-140	0-140	0-140
	Wholemeal bread and rolls[2]	0-120	0-187	0-187	0-187
	Rye bread and rolls	0	0-140	0-140	0-140
	Fibre-increased bread and rolls[3]	0-120	0-180	0-180	0-180
	Savoury bread	0	0-200	0-200	0-200
	Fruit bread	0	0-153	0-153	0-153
	Buns and yeast-based products	0	0-147	0-147	0-147
	Sandwiches, filled rolls	0	0-100	0-100	0-100
White flour	White flour	0	0	0-250	0-250
Wholemeal flour	Wholemeal flour	0	0	0-250	0-250
Yeast extract	Yeast extract	2200-3250	2200-3250	2200-3250	2200-3250
Pasta	Dry pasta	0	0	0-200	0-200
	Cooked pasta	0	0	0-66	0-66
Breakfast cereal	Bran flakes	69-770	69-770	69-770	69-770
	Wheat biscuits	313-450	313-450	313-450	313-450
	Muesli	140-680	140-680	140-680	140-680
	Single cereal, puffed flakes or extruded	157-530	157-530	157-530	157-530
Low/reduced fat milk	Low/reduced fat milk	0	0	0-40	0-40
Low/reduced fat fruit/flavoured yoghurt	Low/reduced fat fruit/flavoured yoghurt	0	0	0-100	0-100
Low/reduced fat plain yoghurt	Low/reduced fat plain yoghurt	0	100	100	100
Diet ready-to-eat meals	Diet ready-to-eat meals	0	0	0	0
Juices	Orange juice	0-44	0-44	0-44	0-44

Food (main category)	Food (sub category)	Range of folic acid concentration (µg/100 g)			
		Baseline	***Lower***	***Moderate***	***Higher***
	Fruit juice	0	0	0-44	0-44
Soy beverages	Soy beverage	30-85	30-85	30-85	30-85
Other milk substitutes	Rice milk	40	40	40	40
Infant food	Infant food	90	90	90	90
Meal replacement products	Liquid meal replacements	40	40	40	40
	Biscuit and bar meal replacements	82	82	82	82
	Supplement powders	40-160	40-160	40-160	40-160
Formulated beverages	Cordial and fruit drink - regular dilution	0	0	0.4	0.4
	Cordial and fruit drink - concentrate	0	0	2	2
	Soft drink	0	0	0.4	0.4
	Flavoured and plain mineral/soda water	0	0	0.4	0.4
	Electrolyte drinks	0	0	0.4	0.4
	Electrolyte drink powder	0	0	2	2
Ready to drink tea	Cordial and fruit drink - regular dilution	0	0	0.1	0.2
	Cordial and fruit drink - concentrate	0	0	0.5	1
	Soft drink	0	0	0.1	0.2
	Flavoured and plain mineral/soda water	0	0	0.1	0.2
	Electrolyte drinks	0	0	0.1	0.2
	Electrolyte drink powder	0	0	0.5	1
Low fat/low sugar biscuits	Low fat/low sugar biscuits	0	0	0-285	0-285

Note: A range in folic acid concentrations is presented for most foods. The range represents the folic acid concentration in foods where consumers have a choice as to whether they choose a food that is folic acid fortified within the category. For example, in New Zealand not all bread is fortified, therefore the lower bound concentration is zero. The upper bound represents that folic acid concentration in breads that are folic acid fortified. However, for meal replacement products, all foods within the category are fortified therefore the actual folic acid concentration was used.

[1] 1 bread only assigned a concentration at *Baseline*
[2] 3 breads only assigned a concentration at *Baseline*
[3] 4 breads only assigned a concentration at *Baseline*

Appendix 3 – Complete information on dietary intake assessment results

Table A3.1: Estimated mean and 95th percentile folic acid intakes from food for Australian and New Zealand women of child-bearing age (16-44 years)

Scenario	Mean dietary folic acid intake (µg/day)				95th percentile dietary folic acid intake (µg/day)			
	Market weighted		Consumer behaviour[1]		Market weighted		Consumer behaviour[1]	
	Australia[2]	New Zealand[3]	Australia[2]	New Zealand[3]	Australia[2]	New Zealand[3]	Australia[2]	New Zealand[3]
Baseline	108	62	83-243	60-69	283	190	249-477	181-196
Lower	115	97	84-245	63-225	291	234	251-476	194-396
Moderate	136	119	86-313	64-304	319	260	251-606	194-519
Higher	153	136	95-315	73-304	351	296	271-606	218-519

[1] Not a population estimate, intended to be an indication of the range of possible folic acid intakes for individuals who either avoid or always select the fortified product, where there is a choice.
[2] Number of Australian respondents aged 16-44 years = 3,178.
[3] Number of NZ respondents aged 16-44 years = 1,509

Table A3.2: Estimated mean and 95th percentile dietary folic acid intakes from food for various Australian population non-target sub-groups

a. Mean

Pop. group	Gender	No. of respondents	Mean dietary folic acid intake (µg/day)							
			'Baseline		*Lower**		*Moderate*		*Higher*	
			Market Weighted	Consumer Behaviour[1]	Market Weighted	Consumer Behaviour[1]	Market Weighted	Consumer Behaviour[1]	Market Weighted	Consumer Behaviour[1]
2 yrs & above	All	13,858	129	100-285	137	102-287	158	103-350	175	111-353
2-3 yrs	All	383	128	106-237	133	106-238	153	108-289	166	112-290
	M	170	141	117-251	146	117-251	167	119-303	179	122-304
	F	213	118	97-227	123	97-227	143	99-277	155	104-278
4-8 yrs	All	977	140	115-270	147	116-271	168	118-328	182	123-331
	M	513	157	131-295	164	132-297	186	134-355	200	137-357
	F	464	121	99-242	127	99-243	148	101-299	162	107-302
9-13 yrs	All	913	162	134-320	169	135-321	192	137-384	210	144-388
	M	474	192	162-369	200	163-371	225	165-436	244	173-439
	F	439	128	104-266	135	104-268	156	106-328	172	113-333
14-18 yrs	All	734	161	129-329	169	130-330	194	132-407	213	140-410
	M	378	202	166-398	211	167-399	238	170-477	259	177-480
	F	356	117	90-256	124	90-257	147	92-334	164	101-335
19-29 yrs	All	2,203	146	115-309	154	116-311	177	118-387	195	124-389
	M	1,014	179	142-377	188	142-378	214	145-458	234	150-461
	F	1,189	118	93-252	125	94-253	146	95-325	163	103-327
30-49 yrs	All	4,397	119	90-280	127	91-282	148	92-348	166	100-350
	M	2,080	140	105-330	150	107-333	172	109-401	190	113-404
	F	2,317	100	75-236	107	77-237	127	78-301	144	88-302

Pop. group	Gender	No. of respondents	Mean dietary folic acid intake (µg/day)							
			'Baseline		*Lower**		*Moderate*		*Higher*	
50-69 yrs	All	3,019	114	86-270	123	89-273	143	90-332	161	99-336
	M	1,442	131	98-313	141	100-315	160	101-373	178	107-377
	F	1,577	99	76-232	107	79-235	127	79-295	146	92-299
70 yrs & above	All	1,232	117	91-265	125	93-266	142	93-310	157	99-315
	M	545	126	97-293	134	98-294	152	99-338	167	103-342
	F	687	111	87-243	117	88-244	134	89-288	148	96-293

[1] Not a population estimate; intended to be an indication of the range of possible folic acid intakes for individuals who either avoid or always select the fortified product, where there is a choice.

b. 95th Percentile

Pop. group	Gender	No. of respondents	95th percentile dietary folic acid intake (µg/day)							
			'Baseline		*Lower*		*Moderate*		*Higher*	
			Market Weighted	**Consumer Behaviour[1]**	**Market Weighted**	**Consumer Behaviour[1]**	**Market Weighted**	**Consumer Behaviour[1]**	**Market Weighted**	**Consumer Behaviour[1]**
2 yrs & above	All	13,858	346	306-590	364	324-598	391	324-705	420	340-711
2-3 yrs	All	383	232	209-412	238	210-413	263	212-506	293	218-513
	M	170	250	224-454	257	224-455	288	228-543	318	249-544
	F	213	210	195-408	215	196-408	237	197-490	264	207-497
4-8 yrs	All	977	282	256-481	290	256-486	316	259-588	341	266-591
	M	513	313	280-556	322	281-559	350	282-678	381	295-680
	F	464	246	230-406	252	231-406	278	232-507	300	234-518
9-13 yrs	All	913	367	341-613	375	342-615	403	346-760	441	362-768
	M	474	420	386-725	428	387-728	463	387-877	497	410-879
	F	439	291	257-463	299	258-463	332	261-587	371	284-598
14-18 yrs	All	734	378	342-659	389	344-659	426	348-781	451	351-782
	M	378	539	508-766	551	512-767	575	516-862	605	519-862
	F	356	273	239-477	280	237-474	308	241-582	328	243-581
19-29 yrs	All	2,203	365	329-644	375	336-648	402	338-757	430	338-767
	M	1,014	449	402-772	463	404-773	507	411-890	541	414-891
	F	1,189	286	244-469	290	242-474	307	245-612	329	257-611
30-49 yrs	All	4,397	342	302-602	361	324-612	392	324-712	422	340-717
	M	2,080	373	321-675	401	339-685	426	342-792	456	361-797
	F	2,317	299	274-488	309	274-488	343	274-605	380	325-604
50-69 yrs	All	3,019	368	341-574	384	349-597	410	351-682	439	362-697
	M	1,442	403	364-656	445	396-681	465	396-770	484	404-775
	F	1,577	325	304-494	336	311-494	368	311-591	398	347-598

Pop. group	Gender	No. of respondents	95th percentile dietary folic acid intake (µg/day)							
			'Baseline		*Lower*		*Moderate*		*Higher*	
70 yrs & above	All	1,232	357	306-530	373	332-540	384	332-607	402	346-610
	M	545	331	297-551	360	321-570	379	321-618	395	320-622
	F	687	369	350-498	375	349-498	394	349-584	413	361-592

[1] Not a population estimate; intended to be an indication of the range of possible folic acid intakes for individuals who either avoid or always select the fortified product, where there is a choice.

Table A3.3: Estimated mean and 95th percentile dietary folic acid intakes from food for various New Zealand population non-target sub-groups

a. Mean

			Mean dietary folic acid intake (µg/day)							
			'Baseline		*Lower*		*Moderate*		*Higher*	
Pop. group	**Gender**	**No. of respondents**	**Market Weighted**	**Consumer Behaviour[1]**	**Market Weighted**	**Consumer Behaviour[1]**	**Market Weighted**	**Consumer Behaviour[1]**	**Market Weighted**	**Consumer Behaviour[1]**
15 yrs & above	All	4,636	75	73-81	114	76-260	136	77-337	154	85-337
15-18 yrs	All	246	81	77-90	122	79-284	148	80-371	169	90-371
	M	109	113	111-119	162	113-351	190	115-444	212	124-445
	F	137	54	51-67	90	51-231	115	53-312	135	64-312
19-29 yrs	All	804	76	74-84	115	76-263	139	78-348	158	87-348
	M	286	112	110-119	160	112-342	188	114-437	210	122-437
	F	518	56	54-65	90	56-219	112	58-299	130	68-299
30-49 yrs	All	1,883	75	73-80	116	76-266	138	77-344	156	85-344
	M	787	86	85-91	136	87-320	159	88-395	179	94-396
	F	1,096	67	65-72	102	68-228	122	69-306	140	78-307
50-69 yrs	All	1,147	76	74-81	114	78-255	133	78-328	151	85-328
	M	538	84	82-89	127	84-293	147	85-362	164	89-362
	F	609	69	68-73	102	72-221	121	72-297	139	81-297
70 yrs & above	All	556	70	69-73	105	72-236	123	72-305	140	80-305
	M	207	69	68-73	108	70-261	125	71-327	141	75-327
	F	349	70	69-73	103	72-221	121	73-292	139	83-292

[1] Not a population estimate; intended to be an indication of the range of possible folic acid intakes for individuals who either avoid or always select the fortified product, where there is a choice.

b. 95th Percentile

			95th percentile dietary folic acid intake (µg/day)							
			'Baseline		*Lower*		*Moderate*		*Higher*	
Pop. group	**Gender**	**No. of respondents**	**Market Weighted**	**Consumer Behaviour[1]**	**Market Weighted**	**Consumer Behaviour[1]**	**Market Weighted**	**Consumer Behaviour[1]**	**Market Weighted**	**Consumer Behaviour[1]**
15 yrs & above	All	4,636	214	209-229	262	213-491	299	214-617	336	238 - 617
15-18 yrs	All	246	195	187-223	252	186-568	315	187-785	377	224 - 786
	M	109	225	213-260	301	211-654	357	213-949	410	247 - 950
	F	137	157	135-193	208	138-391	249	139-532	276	179 - 532
19-29 yrs	All	804	194	180-217	248	188-503	304	190-689	345	220 - 690
	M	286	221	205-255	279	204-629	353	205-900	411	242 - 900
	F	518	162	159-184	223	167-386	255	168-509	288	194 - 510
30-49 yrs	All	1,883	223	220-233	268	224-505	302	224-629	343	254 - 629
	M	787	246	230-268	301	244-577	341	244-698	378	281 - 697
	F	1,096	205	200-215	241	206-405	267	208-534	301	227 - 534
50-69 yrs	All	1,147	238	237-248	278	241-459	304	241-564	341	254 - 564
	M	538	262	260-271	316	267-514	350	266-624	387	282 - 624
	F	609	210	204-225	248	219-391	267	219-492	293	232 - 493
70 yrs& above	All	556	187	186-189	226	186-389	248	186-473	270	219 - 473
	M	207	188	186-191	231	188-427	250	189-488	276	219 - 488
	F	349	179	179-185	207	177-352	226	178-465	261	210 - 465

[1] Not a population estimate; intended to be an indication of the range of possible folic acid intakes for individuals who either avoid or always select the fortified product, where there is a choice.

Appendix 4 – Complete information on risk characterisation

Table A4.1: Proportion of respondents with folic acid intakes above the Upper Level for various Australian population non-target sub-groups

Pop. group	Gender	UL (µg/day)	No. of respondents	% of respondents with folic acid intakes > UL[1]			
				'Baseline	*Lower*	*Moderate*	*Higher*
2-3 yrs	All	300	383	2	2	2	4
	M		170	3	4	4	7
	F		213	<1	<1	<1	3
4-8 yrs	All	400	977	1	1	2	3
	M		513	2	2	3	4
	F		464	<1	<1	<1	1
9-13 yrs	All	600	913	1	1	1	2
	M		474	2	2	2	3
	F		439	<1	<1	<1	<1
14-18 yrs	All	800	734	<1	<1	<1	<1
	M		378	1	1	2	2
	F		356	0	0	0	0
19-29 yrs	All	1,000	2,203	<1	<1	<1	<1
	M		1,014	<1	<1	<1	<1
	F		1,189	<1	<1	<1	<1
30-49 yrs	All	1,000	4,397	<1	<1	<1	<1
	M		2,080	<1	<1	<1	<1
	F		2,317	<1	<1	<1	<1
50-69 yrs	All	1,000	3,019	<1	<1	<1	<1
	M		1,442	<1	<1	<1	<1
	F		1,577	<1	<1	<1	<1
70 yrs & above	All	1,000	1,232	0	0	0	0
	M		545	0	0	0	0
	F		687	0	0	0	0

[1] Concentration of folic acid in foods is weighted according to the proportion of a food group that is fortified. This estimates dietary intakes over the long-term and across the population.

Table A4.2: Proportion of respondents with folic acid intakes above the Upper Level for various New Zealand population non-target sub-groups

Pop. group	Gender	UL (µg/day)	No. of respondents	% of respondents with folic acid intakes > UL[1]			
				'Baseline	*Lower*	*Moderate*	*Higher*
15-18 yrs	All	800	246	0	0	0	0
	M		109	0	0	0	0
	F		137	0	0	0	0
19-29 yrs	All	1,000	804	0	0	0	0
	M		286	0	0	0	0
	F		518	0	0	0	0
30-49 yrs	All	1,000	1,883	<1	<1	<1	<1
	M		787	0	0	0	0
	F		1,096	<1	<1	<1	<1
50-69 yrs	All	1,000	1,147	0	0	0	0
	M		538	0	0	0	0
	F		609	0	0	0	0
70+ yrs	All	1,000	556	0	0	0	0
	M		207	0	0	0	0
	F		349	0	0	0	0

[1] Concentration of folic acid in foods is weighted according to the proportion of a food group that is fortified. This estimates dietary intakes over the long-term and across the population.

Appendix 5 – Proportion of consumers of foods under the voluntary fortification scenarios

Table A5.1: Proportion of respondents who consumed various foods under the voluntary fortification scenarios, for various Australian population sub-groups

Food	Proportion of respondents who were consumers of various foods for the voluntary fortification scenarios								
	'Baseline			*Lower*			*Moderate/Higher*		
	2-3 yrs	**Females 16-44 yrs**	**2 years and above**	**2-3 yrs**	**Females 16-44 yrs**	**2 years and above**	**2-3 yrs**	**Females 16-44 yrs**	**2 years and above**
Bread	83	78	83	83	78	83	83	78	83
Flour (white)	5	6	6	5	6	6	5	6	6
Flour (wholemeal)	-	-	-	-	-	-	0	0	0
Yeast extract	32	19	19	32	19	19	32	19	19
Pasta	-	-	-	-	-	-	19	15	12
Breakfast cereal	23	12	14	23	12	14	23	12	14
Low/reduced fat milk	7	21	19	7	21	19	11	38	34
Low/reduced fat fruit/flavoured yoghurt	-	-	-	-	-	-	3	5	4
Low/reduced fat plain yoghurt	-	-	-	0	1	1	0	1	1
Diet ready-to-eat meals	-	-	-	0	<1	0	0	<1	0
Fruit juice	9	5	5	9	5	5	36	21	20
Soy beverages	4	1	2	4	1	2	4	1	2
Other milk substitutes	<1	0	<1	<1	0	<1	<1	0	<1
Infant food	0	0	0	0	0	0	0	0	0
Meal replacement products	1	<1	<1	1	<1	<1	1	<1	<1
Formulated beverages	-	-	-	-	-	-	54	45	44
Ready-to-drink tea	-	-	-	-	-	-	54	45	44
Low fat, low sugar biscuits	-	-	-	-	-	-	1	1	2

Note: Where there is no figure, the food was not included in the scenario

Table A5.2: Proportion of respondents who consumed various foods under the voluntary fortification scenarios, for various New Zealand population sub-groups

	Proportion of respondents who were consumers of various foods for the voluntary fortification scenarios					
	'Baseline		*Lower*		*Moderate/Higher*	
Food	**Females 16-44 yrs**	**15 years and above**	**Females 16-44 yrs**	**15 years and above**	**Females 16-44 yrs**	**15 years and above**
Bread	<1	<1	80	85	80	85
Flour (white)	-	-	-	-	3	3
Flour (wholemeal)	-	-	-	-	0	0.1
Yeast extract	15	16	15	16	15	16
Pasta	-	-	-	-	14	11
Breakfast cereal	24	31	24	31	24	31
Low/reduced fat milk	-	-	-	-	33	37
Low/reduced fat fruit/flavoured yoghurt	-	-	-	-	6	6
Low/reduced fat plain yoghurt	-	-	2	2	2	2
Fruit juice	5	5	5	5	12	11
Soy beverages	<1	<1	<1	<1	<1	<1
Other milk substitutes	0	0	0	0	0	0
Infant food	<1	0	<1	0	<1	0
Meal replacement products	<1	<1	<1	<1	<1	<1
Formulated beverages	-	-	-	-	91	88
Ready-to-drink tea	-	-	-	-	91	88
Low fat, low sugar biscuits	-	-	-	-	5	6

Note: Where there is no figure, the food was not included in the scenario

Appendix 6 – Complete information of folic acid intake from food and supplements

Table A6.1: Estimated mean and 95th percentile folic acid intakes from food and supplements for Australian women of child-bearing age (16-44 years)

	Folic acid intake from food and supplements (µg/day)[1, 2]			
Scenario	**Mean intake + 200 µg folic acid supplement**	**Mean intake + 500 µg folic acid supplement**	**95th percentile intake + 200 µg folic acid supplement**	**95th percentile intake + 500 µg folic acid supplement**
Baseline	308	608	483	783
Lower	315	615	491	791
Moderate	336	636	519	819
Higher	353	653	551	851

[1] Concentration of folic acid in foods is weighted according to the proportion of a food group that is fortified. This estimates dietary intakes over the long-term and across the population.
[2] Number of respondents aged 16-44 years = 3,178.

Table A6.2: Estimated mean and 95th percentile folic acid intakes from food and supplements for New Zealand women of child-bearing age (16-44 years)

	Folic acid intake from food and supplements (µg/day)[1, 2]			
Scenario	**Mean intake + 200 µg folic acid supplement**	**Mean intake + 800 µg folic acid supplement**	**95th percentile intake + 200 µg folic acid supplement**	**95th percentile intake + 800 µg folic acid supplement**
Baseline	262	862	390	990
Lower	297	897	434	1,034
Moderate	319	919	460	1,060
Higher	336	936	496	1,096

[1] Concentration of folic acid in foods is weighted according to the proportion of a food group that is fortified. This estimates dietary intakes over the long-term and across the population.
[2] Number of respondents aged 16-44 years = 1,509.

Attachment 7C

Dietary Intake Assessment Report – Dietary Folate

Contents

EXECUTIVE SUMMARY 206

1. BACKGROUND 207

2. HOW DIETARY FOLATE INTAKES WERE CALCULATED 210

3. ASSUMPTIONS USED IN THE DIETARY MODELLING 213

4. ESTIMATED INTAKES OF DIETARY FOLATE 214

5. RISK CHARACTERISATION 224

REFERENCES 233

APPENDIX 1 - SUMMARY OF CONCENTRATION DATA USED FOR VARIOUS FOODS FOR DIETARY MODELLING PURPOSES 234

APPENDIX 2- COMPLETE INFORMATION ON DIETARY INTAKE ASSESSMENT RESULTS 236

APPENDIX 3- COMPLETE RISK CHARACTERISATION INFORMATION 253

Executive Summary

Submissions to the DAR for P295 indicated confusion about the differences between dietary folate and folic acid intakes. As a result, FSANZ has estimated the intake of naturally occurring folate and dietary folate (expressed as Dietary Folate Equivalents, DFEs)[39] by general population groups within Australia and New Zealand for the 1st review, providing a full set of information on folate intakes for the first time.

Dietary intake assessments for dietary folate for Australia and New Zealand were conducted separately. Age groups for both countries were based on age groups specified in the 2006 NHMRC Nutrient Reference Values document and incorporated women of child bearing age (16-44 years) as the primary target group.

Two scenarios were investigated for this dietary intake assessment and included:

~~i.~~(a) **Baseline** –estimate of current dietary folate intakes, based on current uptake of voluntary folic acid permissions by industry; and

Formatted: Bullets and Numbering

~~ii.~~(b) **Mandatory fortification** –estimate of dietary folate intakes under a mandatory fortification scenario i.e. from current uptake by industry of voluntary folic acid permissions (except those for wheat flour for making bread (Australia only) and for bread (NZ only) plus the introduction of mandatory fortification of wheat flour for making bread at 200 µg/ 100 g flour (Australia only) and all bread at 135 µg folic acid per 100 g of bread (New Zealand only)).

Formatted: Bullets and Numbering

Estimated naturally occurring folate intakes differ between genders and ages as well as between countries. Australia has higher estimated naturally occurring folate intakes than New Zealand for all population groups. Females in both countries were found to have lower naturally occurring folate intakes than males in each age group.

New Zealand, as a population, has lower estimated intakes of dietary folate in comparison to Australian both at *Baseline* and under *Mandatory Fortification*. This difference in dietary folate intakes between countries is likely due to the higher naturally occurring folate concentrations levels in similar foods reported from analysis in Australia in comparison to New Zealand and a lower uptake of voluntary folic acid fortification permissions in New Zealand compared to Australia.

Cereals and cereal products were the highest contributors to dietary folate intakes for the Australian population as a whole under both *Baseline* and *Mandatory Fortification* scenarios. Breads and breakfast cereals were the major food group contributors for New Zealand, however, breads contributed to a greater extent under the *Mandatory Fortification* scenario.

[39] Dietary Folate Equivalent (DFE) = (naturally occurring food folate µg) + (folic acid µg x 1.67)

Dietary folate intakes were compared to the Estimated Average Requirement (EAR) for folate[40]. In the absence of any folic acid fortification (i.e. intake of dietary folate from naturally occurring folates only), 31% Australians aged 2 years and over and 92% New Zealand population aged 15 years and over were estimated to have dietary folate intakes below the EAR, with slightly higher proportions below the EAR for the target group, women of child bearing age (52% Australia, 97% New Zealand).

Under the current (*Baseline*) voluntary folic acid fortification situation, estimated dietary folate intakes increased compared to those from naturally occurring folate only as would be expected, resulting in lower proportions of the Australian and New Zealand populations with dietary folate intakes below the EAR (7% Australian population, 50% NZ population), indicating that current voluntary fortification with folic acid makes a significant contribution to dietary folate intakes. Under *Mandatory Fortification*, less than 10% of all population sub-groups were estimated to have dietary folate intakes below the EAR. This indicates that *Mandatory Fortification* has the potential to further reduce the proportion of the Australian and New Zealand population with dietary folate intakes below the EAR.

~~1.~~1. Background

Formatted: Bullets and Numbering

The first review request asked FSANZ to re-examine folic acid intakes across all population sub-groups and to assess these intakes in terms of excesses or imbalances. Submissions to the DAR for P295 indicated confusion about the differences between dietary folate and folic acid intakes. As a result, FSANZ has also estimated the intake of naturally occurring folate and dietary folate (expressed as DFEs) by general population groups within Australia and New Zealand for the 1st review, providing a full set of information on folate intakes for the first time. Specifically, FSANZ sought to establish which population groups were currently meeting their Estimated Average Requirement (EAR) for folate, and what impact mandatory fortification may have on dietary folate intakes.

1.1. Dietary Folate and Folic Acid

Folate is a generic term used to describe natural derivatives of pteroic acid (a water soluble B vitamin) showing metabolic activity within the human body. Folate acts as a coenzyme in single carbon transfers when metabolising amino acids and nucleotides and is also essential for DNA synthesis. In this respect, a folate deficiency can reduce the ability of cells in the body to divide (Vozenilek, 1999; Ball, 2004; National Health and Medical Research Council, 2005b). Dietary folate can be found in green leafy vegetables (spinach, broccoli and salad greens), legumes (kidney beans and chick peas), orange juice, some fruits and dried beans or peas (Griffith, 1995; West Suitor and Bailey, 2000; Ball, 2004).

Folic acid is the synthetic, oxidised form of folate and is used in supplements and fortification of products such as breakfast cereals, flours and pasta as it is the most stable folate derivative (West Suitor and Bailey 2000; French *et al*., 2003). More recently, folic acid has been implicated in the prevention and reoccurrence of neural tube defects (NTDs), a congenital abnormality where the spinal cord fails to develop (French *et al.,* 2003). Spina bifida is the most common form of NTD in Australia with one in 1,000 births being affected.

[40] The EAR for folate was set in 2006 by NHMRC, was higher than that set previously and was based on the effect of folate on lowering homocysteine levels, which was hypothesised to reduce the risk of heart disease (NHMRC, 2006).

The current recommendation for folic acid to reduce the risk of NTDs occurring is to have an additional 400 µg of folic acid per day approximately one month before pregnancy and for the first three months of pregnancy (Food Standards Australia New Zealand, 2006).

1.2. Dietary Folate Equivalents

Folate intakes are expressed in terms of Dietary Folate Equivalents (or DFEs) and are units that factor in differences in the bioavailability of food folate and of synthetic folic acid. Folic acid when consumed as a supplement on an empty stomach is almost 100% bioavailable, and is reduced to 85% absorption when consumed with food. Estimates of food folate's bioavailability are approximately 50-60% (West Suitor and Bailey 2000; National Health and Medical Research Council, 2005b).

DFEs are primarily used to compare information about physiologic requirements of folate on a common basis, thus accounting for differences in absorption between food folate and folic acid. Folate intakes, expressed as DFEs, are used for comparison with the Estimated Average Requirement (EAR) (West Suitor and Bailey 2000; National Health and Medical Research Council, 2005b).

1.2.1. How are dietary folate intakes calculated?

In 2006, 'Nutrient Reference Values for Use in Australia and New Zealand' replaced the 1991 NHMRC document 'Recommended Dietary Intakes in Australia'. An important change to the Nutrient Reference Values (NRVs) for folate was the change to the units in which the NRVs are expressed. Previously, the Recommended Dietary Intake (RDI) had been expressed in µg with the assumption that 1 µg dietary folate = 1 µg folic acid. However, this assumption is incorrect because supplemental folic acid has higher bioavailability than dietary folate. Following the American lead (Institute of Medicine, 1998), the difference in bioavailability was acknowledged and new units for folate were developed: micrograms of DFEs such that:

1 µg Dietary Folate Equivalent (DFE)	=	1 µg folate from dietary sources
	=	0.6 µg folic acid used to fortify food
	=	0.5 µg folic acid taken on an empty stomach

1 µg folic acid as a fortificant = 1.67 µg Dietary Folate Equivalent (DFE)
(Note: this makes the generalisation that folate from all dietary sources has the same bioavailability, which is probably not true).

Dietary Folate Equivalent (DFE) = (naturally occurring food folate µg) + (folic acid µg x 1.67)

1.3 Estimated average requirement for folate

The EAR is 'A daily nutrient level estimated to meet the requirements of half the healthy individuals in a particular life stage and gender group'. The EARs used in this assessment were set for folate by the NHMRC in 2006 for Australia and New Zealand (National Health and Medical Research Council 2006), and are shown in Table 1.

The EAR for folate for younger adults was set by reference to metabolic studies on erythrocyte folate and homocysteine levels, based on the effect of folate on lowering homocysteine levels, which was hypothesised to reduce the risk of heart disease. The EAR for children and adolescents was extrapolated on a body weight basis from the young adults value (National Health and Medical Research Council 2006). For older adults (51 years and over), the EAR was based on metabolic, observational and epidemiological studies (see Section 5 for further discussion).

Table 1: EARs used in the dietary modelling for folate

Age	Gender	EAR as DFEs (µg/day)
1-3 years	M/F	120
4-8 years	M/F	160
9-13 years	M	250
	F	250
14-18 years	M	330
	F	330
19-30 years	M	320
	F	320
31-50 years	M	320
	F	320
51-70 years	M	320
	F	320
>70 years	M	320
	F	320
Pregnancy		
14-18 years		520
19-30 years		520
31-50 years		520
Lactation		
14-18 years		450
19-30 years		450
31-50 years		450

It should be noted that the recommended target intake of 400 ug/day for folic acid to reduce NTDs is separate from the EAR for dietary folate. Folic acid can be obtained from foods that are mandatorily or voluntarily fortified and supplements but excludes naturally occurring folate. Folate can be derived from naturally occurring folate and folic acid. The recommended target intake for folic acid to reduce NTDs (400 µg/day) only applies to women of child bearing age whilst the EARs for folate apply to all population groups.

The current level of voluntary fortification already introduces some folic acid into the diet that has been taken into account both when assessing folate intakes and when assessing folic acid intakes for the target group of women of child bearing age. Hence it is incorrect to think of the recommended target intake of 400 ug/day for folic acid to reduce NTDs as an ‘addition’ or ‘top up’ to the EAR for folate.

Formatted: Bullets and Numbering

~~2.~~2. How dietary folate intakes were calculated

For a detailed description of what dietary modelling is, how dietary intakes are calculated, the dietary survey data used and the limitations of this assessment, please refer to Attachment 7 of the Final Assessment Report (FAR) for P295 – Consideration of Mandatory Fortification with Folic Acid.

~~2.1.~~2.1 Dietary intake assessment approach

Formatted: Bullets and Numbering

The dietary intake assessments discussed in this attachment were conducted using FSANZ's dietary modelling computer program, DIAMOND.

Dietary intake = nutrient concentration x food consumption amount

Naturally occurring and dietary folate intakes were estimated by combining usual patterns of food consumption, as derived from NNS data, with current levels of naturally occurring and dietary folate, and those proposed under the mandatory folic acid fortification option. All intake estimates were adjusted using second day records to better estimate 'usual' patterns of consumption (see Figure 1 for an overview of the dietary modelling approach that was used to assess the naturally occurring and dietary folate intakes).

~~2.2.~~2.2 Population groups assessed

Formatted: Bullets and Numbering

The dietary intake assessment was conducted separately for Australian and New Zealand population sub-groups.

Females aged 16-44 years were assessed for both Australia and New Zealand since this group is the target for folic acid fortification. The NHMRC NRVs (National Health and Medical Research Council, 2006) were used as a guide in selecting the other age groups to assess. As different NRVs are given to different age and gender groups for folate, conducting the dietary intake assessment based on the NRV age groups allows for easy comparison of the estimated intakes with the relevant NRV for risk assessment purposes.

As the Australian 1995 NNS was conducted on people aged 2 years and above, the following age groups were modelled:

- 2 years and above;
- 2-3 years;
- 4-8 years:
- 9-13 years;
- 14-18 years;
- 19-29 years:
- 30-49 years;
- 50-69 years; and
- 70 years and above.

The New Zealand 1997 NNS was conducted on people aged 15 years and above so the following age groups were assessed:

- 15 years and above;
- 15-18 years;
- 19-29 years;
- 30-49 years;
- 50-69 years; and
- 70 years and above.

~~2.3.~~1.3. Naturally occurring folate and dietary folate concentration data

Formatted: Bullets and Numbering

Naturally occurring folate and dietary folate concentration data was derived from the Australian Iodine Program (AIP) and the Key Foods Program (KFP). The AIP was conducted as an analytical program to investigate the current iodine levels in high consumption foods and those known or suspected to be major contributors to dietary intakes of iodine in Australia and New Zealand. As well as investigating iodine levels in these foods, analysis of nutrients such as folate, sodium, potassium and other food chemicals were assessed. The KFP generates up to date information on nutrient levels in the most significant foods in the diets of Australian children. Additionally, this program, where necessary, assesses variation in nutrient levels in these foods.

For further details on concentration data used for this dietary intake assessment and on the AIP and the KFP exposure assessment, see Appendix 1.

A discussion on the sources of folic acid concentration data for New Zealand can be found in Attachment 7 of the FAR for P295 – Consideration of Mandatory Fortification with Folic Acid. From the naturally occurring folate and folic acid concentration data, dietary folate concentrations were determined using the formula outlined in Section 1.2.1.

~~2.4.~~1.4. Models used for assessing intakes of dietary folate

Formatted: Bullets and Numbering

Two scenarios were investigated in the dietary intake assessment for dietary folate. These scenarios were:

~~i.~~(i) **Baseline** – estimate of current dietary folate intakes, based on current uptake of voluntary folic acid permissions by industry; and

Formatted: Bullets and Numbering

~~ii.~~(ii) **Mandatory Fortification** – estimate of dietary folate intakes under a mandatory fortification scenario i.e. from current uptake by industry of voluntary folic acid permissions (except those for wheat flour for making bread (Australia only) and for bread (NZ only)) plus the introduction of mandatory fortification of wheat flour for making bread at 200 µg/ 100 g flour (Australia only) and all bread at 135 µg folic acid per 100 g of bread (New Zealand only)).

Formatted: Bullets and Numbering

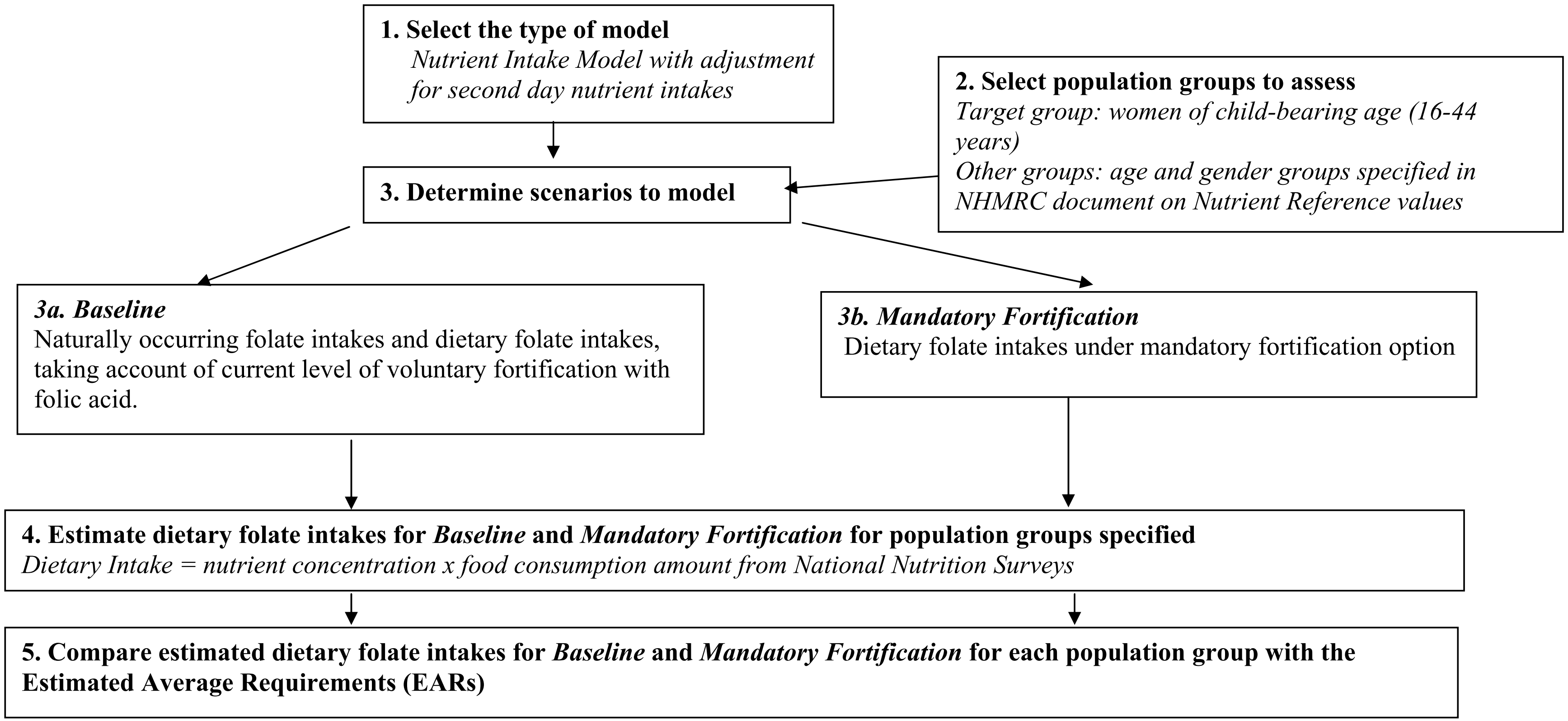
Within each of these scenarios, two different model types were assessed:

~~a)~~(a) market share model; and
~~b)~~(b) consumer behaviour models.

Formatted: Bullets and Numbering

The market share and consumer behaviour model types were discussed in detail in the main dietary intake assessment report.

Figure 1: Dietary modelling approach used for the first review for Australia and New Zealand for consideration of intakes of dietary folate



~~3.~~3. Assumptions used in the dietary modelling

Formatted: Bullets and Numbering

The aim of the dietary intake assessment is to make as realistic an estimate of dietary folate intakes as possible. However, where significant uncertainties in the data existed, conservative assumptions were generally used to ensure that the dietary intake assessment did not underestimate intake.

The assumptions made in the dietary intake assessment are listed below, broken down by category.

~~3.1.~~1.5. Consumer behaviour

Formatted: Bullets and Numbering

- people eat the same gram amount of bread today as they did when the 1995/1997 NNS data were collected;
- the dietary patterns for females aged 16-44 years are representative of the dietary patterns for pregnant women;
- consumers always select products containing naturally occurring folate and dietary folate at the concentrations specified; and
- current food consumption habits were reflected in the dietary intake assessment by weighting the dietary folate values for food groups identified as containing folic acid, according to market share data.

~~3.2.~~1.6. Concentration Data

Formatted: Bullets and Numbering

- if there were no Australian naturally occurring folate or dietary folate concentration data for specific foods, it was assumed that New Zealand data were representative of these food groups, and vice versa for New Zealand foods;
- if a food was not included in the intake assessment, it was assumed to contain a zero concentration of naturally occurring folate or dietary folate;
- a market share weighted dietary folate value was assigned to food categories that are voluntarily fortified with folic acid to reflect the proportion of products that have been fortified or, where possible, an analysis or label folic acid concentration was used to calculate dietary folate concentrations in individual foods using up to date food composition data; and
- there was no contribution to dietary folate intake through the use of complementary medicines (Australia) or dietary supplements (New Zealand).

~~3.3.~~1.7. General

Formatted: Bullets and Numbering

- there were no reductions in naturally occurring folate and dietary folate concentrations from storage; and
- for the purpose of this assessment, it was assumed that 1 millilitre is equal to 1 gram for all liquid and semi-liquid foods (e.g. orange juice).

Formatted: Bullets and Numbering

~~4.~~4. Estimated Intakes of Dietary Folate

~~4.1.~~4.1 Naturally Occurring Folate

Formatted: Bullets and Numbering

Naturally occurring folate intakes only take into account the folate present naturally in foods and exclude folic acid from food or supplements. Therefore, estimated naturally occurring folate intakes were the same for the *Baseline* and *Mandatory Fortification* scenarios.

~~4.1.1.~~4.1.1 Australian naturally occurring folate intakes

Formatted: Bullets and Numbering

The estimated intakes of naturally occurring folate for Australians are presented in Figure 2 and show that mean and 95th percentile naturally occurring folate intakes increased as age increases up until adulthood (19-29 year age group) is reached. Adults aged 19-69 years had similar mean and 95th percentile naturally occurring folate intakes, with respondents aged 70 years and above having slightly lower naturally occurring folate intakes in comparison to other adult population sub-groups. The estimated mean and 95th percentile naturally occurring folate intakes for the Australian population aged 2 years and above were 362 µg/day and 563 µg/day. Australian women aged 16-44 years had a mean estimated naturally occurring folate intake of 331 µg/day and a 95th percentile intake of 500 µg/day.

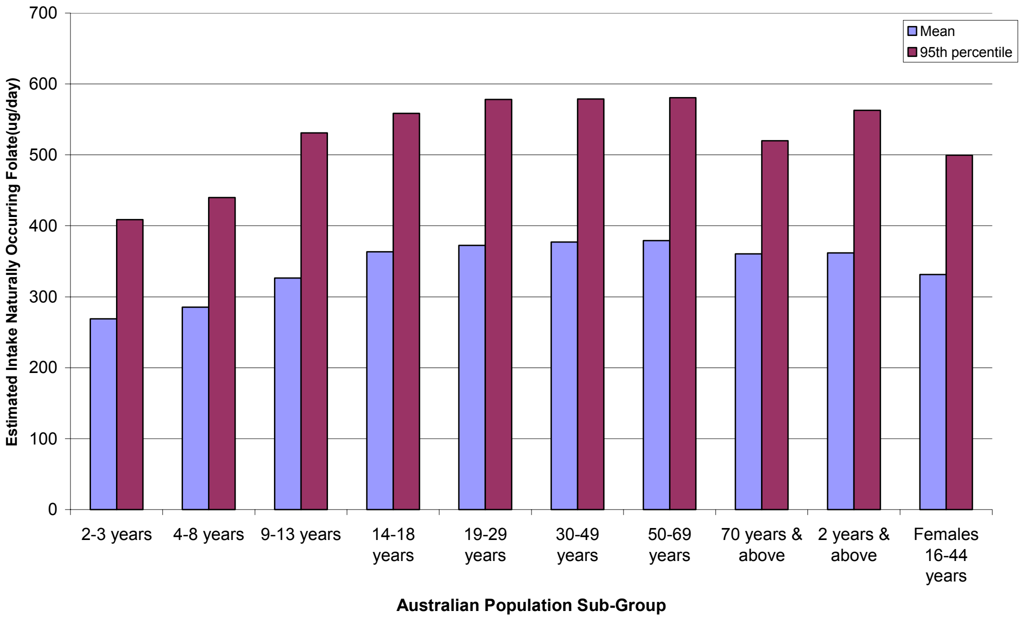


Figure 2: Estimated mean and 95th percentile naturally occurring folate intakes for Australian population sub-groups

As can be seen in Figure 3, mean naturally occurring folate intakes were lower for females than they were for males for each specified age group. Ninety-fifth percentile naturally occurring folate intakes were also lower for females than they were for males. Full results can be found in Table A2.1a in Appendix 2.

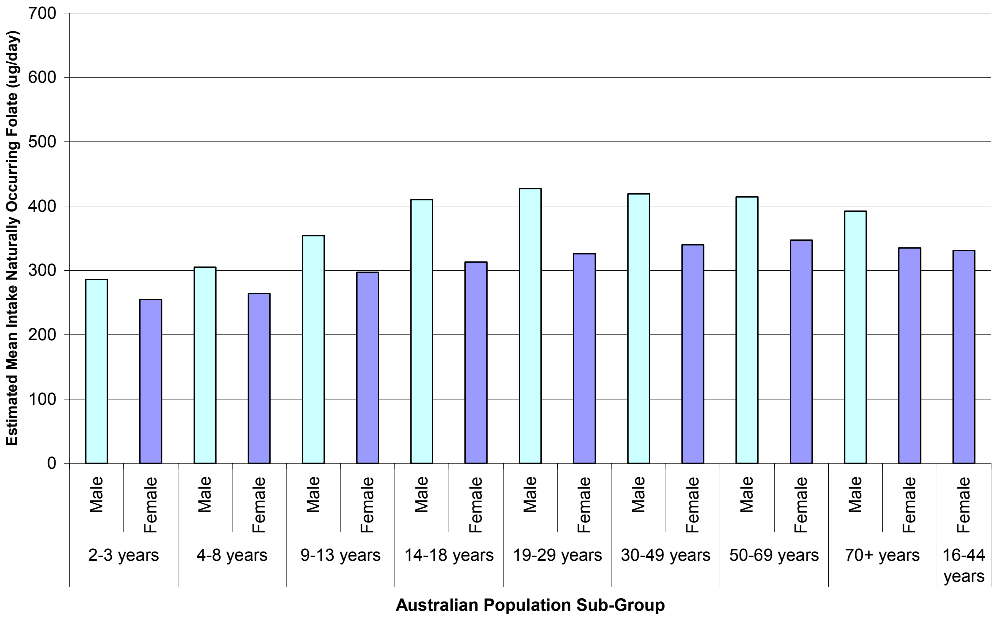


Figure 3: Estimated mean naturally occurring folate intakes for Australian population sub-groups, split by gender

~~4.1.2.~~ 4.1.2 *New Zealand naturally occurring folate intakes*

Formatted: Bullets and Numbering

The estimated intakes of naturally occurring folate for New Zealanders are presented in Figure 4 and show that mean and 95th percentile naturally occurring folate intakes were similar for New Zealanders aged 15 -69 years. Respondents aged 70 years and above had slightly lower naturally occurring folate intakes in comparison to the other adult population sub-groups. The estimated mean and 95th percentile naturally occurring folate intakes for the New Zealand population aged 15 years and above were 231 µg/day and 347 µg/day. New Zealand women aged 16-44 years had a mean estimated naturally occurring folate intake of 204 µg/day and a 95th percentile intake of 305 µg/day.

As can be seen in Figure 5, mean naturally occurring folate intakes in New Zealand were lower for females than they were for males for each specified age group. Ninety-fifth percentile naturally occurring folate intakes were also lower for females that they were for males. Full results can be found in Table A2.1b in Appendix 2.

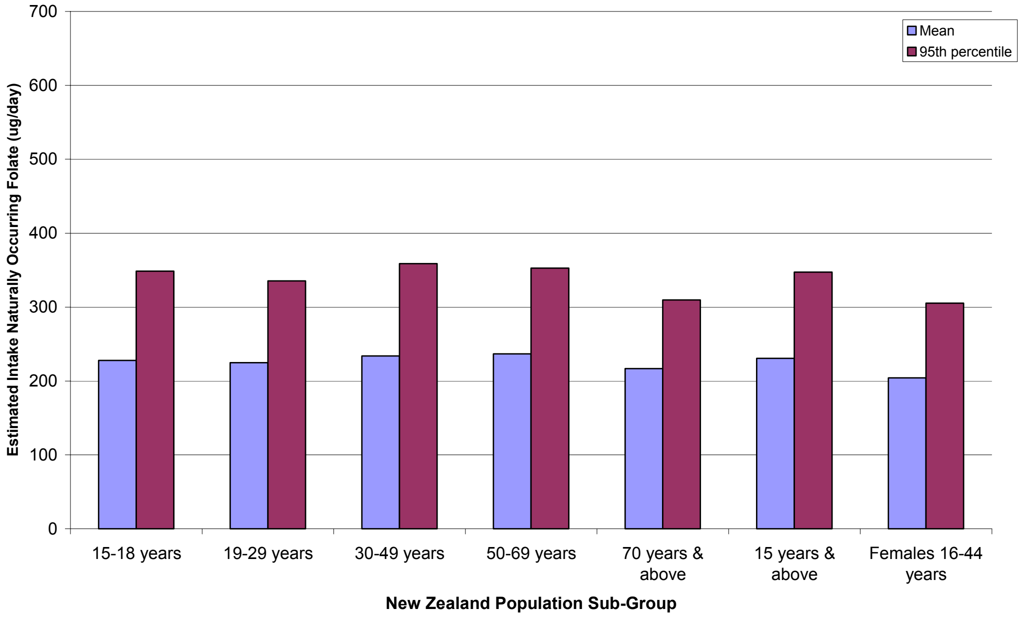


Figure4: Estimated mean and 95th percentile naturally occurring folate intakes for New Zealand population sub-groups

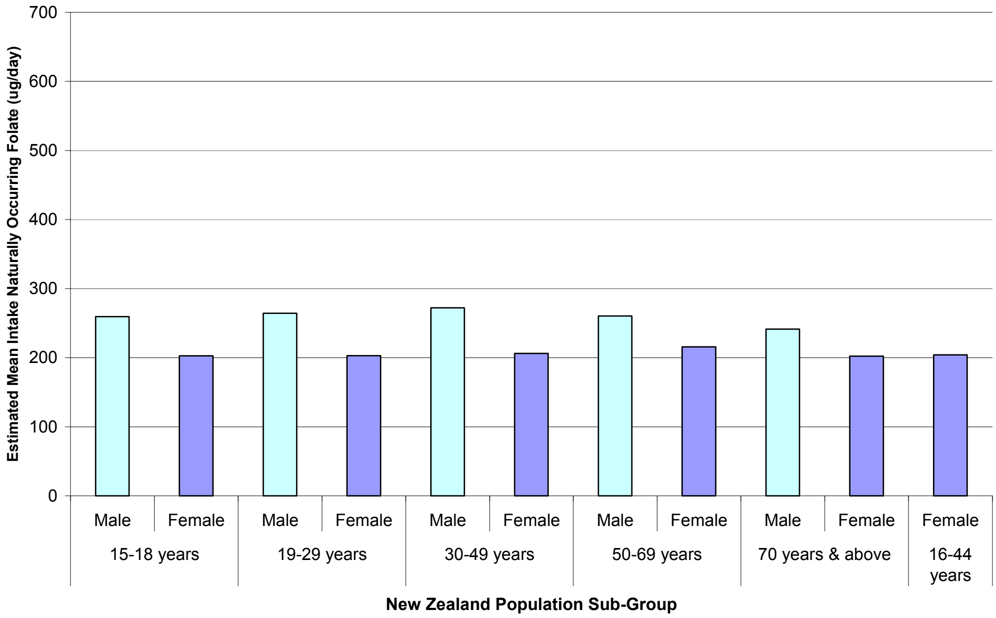


Figure 5: Estimated mean naturally occurring folate intakes for New Zealand population sub-groups split by gender

Formatted: Bullets and Numbering

~~4.1.3.~~4.1.3 Summary

New Zealanders had lower mean and 95th percentile intakes of naturally occurring folate in comparison to Australians. For example, Australian women aged 16-44 years had a mean naturally occurring folate intake (331 µg/day) that was higher than the 95th percentile naturally occurring folate intake (305 µg/day) for New Zealand women aged 16-44 years. This difference may be due, in general, to New Zealand foods containing lower amounts of naturally occurring folate in comparison to Australian foods. The New Zealand folate data were obtained from the NZFSA and differences may be due to differences in sampling and /or analytical methods, however in some cases there were significant differences in reported folate content of the same food. For example, the naturally occurring folate concentration for tea consumed in Australia was approximately 11 µg naturally occurring folate per 100 g whereas the naturally occurring folate concentration for tea consumed in New Zealand was approximately 3 µg naturally occurring folate per 100 g. As discussed in Section 4.3.1, non-alcoholic beverages are a major contributor to naturally occurring folate intakes for both Australia and New Zealand so this difference has an impact on calculated folate intakes.

~~4.2.~~4.2 Estimated Dietary Folate intakes

Formatted: Bullets and Numbering

Dietary folate intakes were estimated for Australia and New Zealand population sub-groups using the market share model and the consumer behaviour model. These models are discussed in detail in the main dietary intake assessment report. Full results for estimated dietary folate intakes for *Baseline* and *Mandatory Fortification* scenarios can be found in Table A2.2 and Table A2.3 in Appendix 2.

~~4.2.1.~~4.2.1 Australian dietary folate intakes

Formatted: Bullets and Numbering

Comparisons between estimated mean dietary folate intakes under *Baseline* and *Mandatory Fortification* scenarios are presented in Figure 6; the lower and upper ends of the range of mean dietary folate intakes represent the results from the 'consumer behaviour' model. The lower bound indicates dietary folate intakes for individuals who always avoid the products that contain folic acid, where a choice is possible. The upper bound indicates dietary folate intakes for individuals who always select the products that contain folic acid. The results from the 'market share' model are indicated by the black line within the range of estimated dietary folate intakes, and are representative of mean population intakes over a period of time.

Figure 6 shows that the estimated mean dietary folate intakes for the Australian population aged 2 years and above for the market share model were 577 µg/day and 769 µg/day for *Baseline* and *Mandatory Fortification* scenarios, respectively. Australian women aged 16-44 years had a mean estimated dietary folate intake of 511 µg/day and 678 µg/day for *Baseline* and *Mandatory Fortification* scenarios, respectively. The introduction of mandatory folic acid fortification of 'wheat flour for making bread' for Australia resulted in an increase in mean dietary folate intakes of 192 µg/day for Australians aged 2 years and above and 167 µg/day for women aged 16-44 years.

~~4.2.2.~~4.2.2 New Zealand dietary folate intakes

Formatted: Bullets and Numbering

Comparisons between estimated mean dietary folate intakes under *Baseline* and *Mandatory Fortification* scenarios are presented in Figure 7.

Figure 7 shows that the estimated mean dietary folate intakes for the New Zealand population aged 15 years and above for the market share model were 356 µg/day and 624 µg/day for *Baseline* and *Mandatory Fortification* scenarios, respectively. New Zealand women aged 16-44 years had a mean estimated dietary folate intakes of 308 µg/day and 542 µg/day for *Baseline* and *Mandatory Fortification* scenarios, respectively. The introduction of mandatory folic acid fortification of 'bread' for New Zealand resulted in an increase in mean dietary folate intakes of 268 µg/day for New Zealanders aged 15 years and above and 234 µg/day for women aged 16-44 years.

~~4.2.3.~~4.2.3 Comparison between Australian and New Zealand Dietary Folate Intakes

Formatted: Bullets and Numbering

New Zealanders have lower mean intakes of dietary folate in comparison to Australians for the market share model. For example, Australian women aged 16-44 years have mean dietary folate intakes of 511 µg/day and 678 µg/day for *Baseline* and *Mandatory Fortification* scenarios, respectively whereas New Zealand women aged 16-44 years have mean dietary folate intakes of 308 µg/day and 542 µg/day. However, under *Mandatory Fortification* New Zealand's mean dietary folate intakes increase by the greater amount. The difference between Australian and New Zealand estimated intakes of dietary folate may be due, in general, to New Zealand foods containing lower amounts of naturally occurring folate in comparison to Australian foods and to New Zealand having a lower uptake of voluntary folic acid fortification.

The 'consumer behaviour' model range of results give an indication of the uncertainty of the outcome of the mandatory or current voluntary approach for estimated dietary folate intakes. Predicted dietary folate intakes were more 'uncertain' for the voluntary fortification scenarios (*Baseline*) than the *Mandatory Fortification* scenario. The differences in potential ranges of intakes between *Baseline* and *Mandatory Fortification* scenarios indicate that bread and bread products made a significant contribution to total dietary folate intakes. By mandating or fixing the level of folic acid in wheat flour for bread making (Australia) or in bread (NZ), the choice for consumers is limited for that one type of food but the certainty of outcome of fortification increased considerably.

Figure 6: Comparison between estimated mean dietary folate intakes at Baseline and Mandatory Fortification for Australian population groups

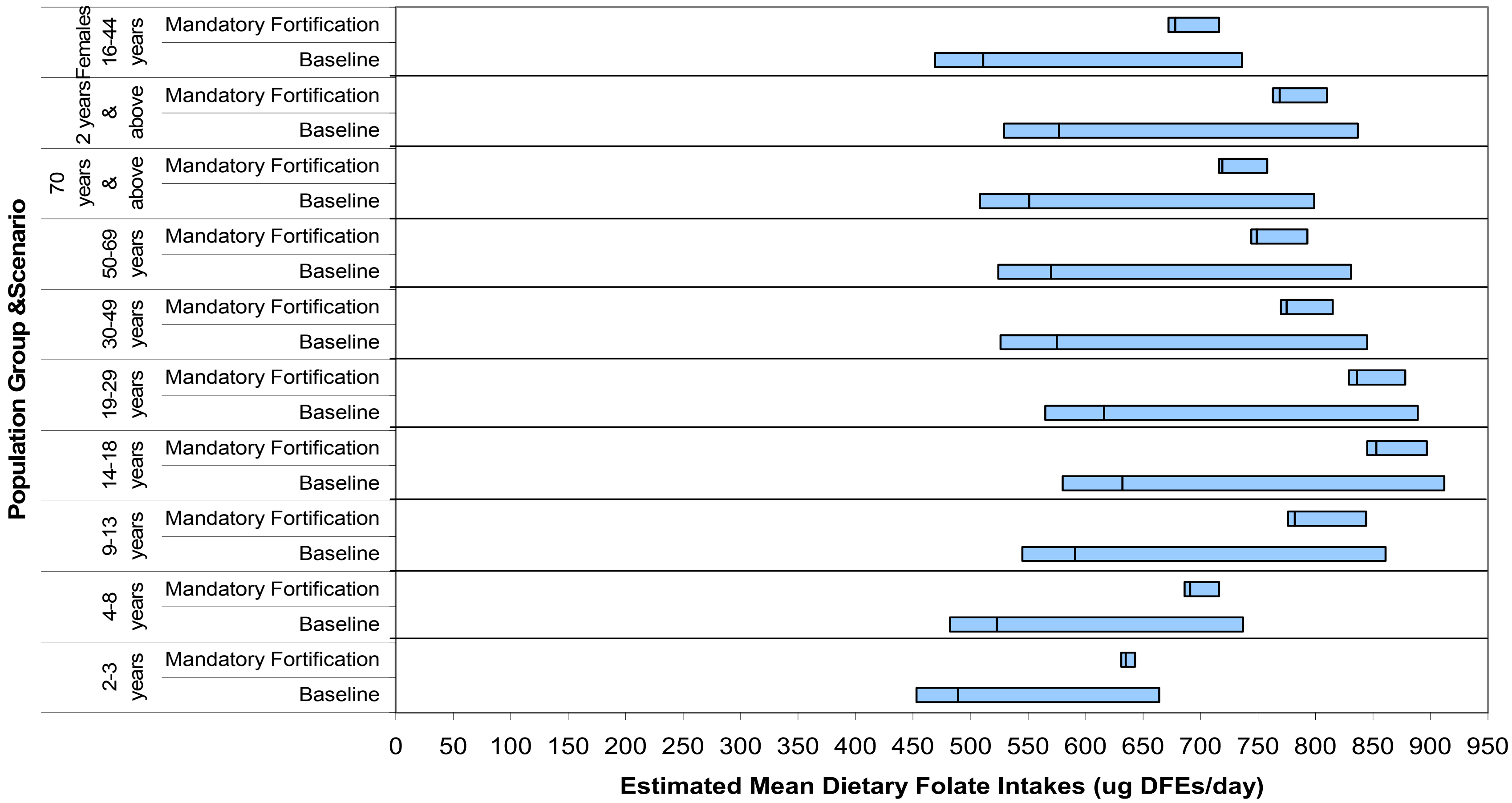
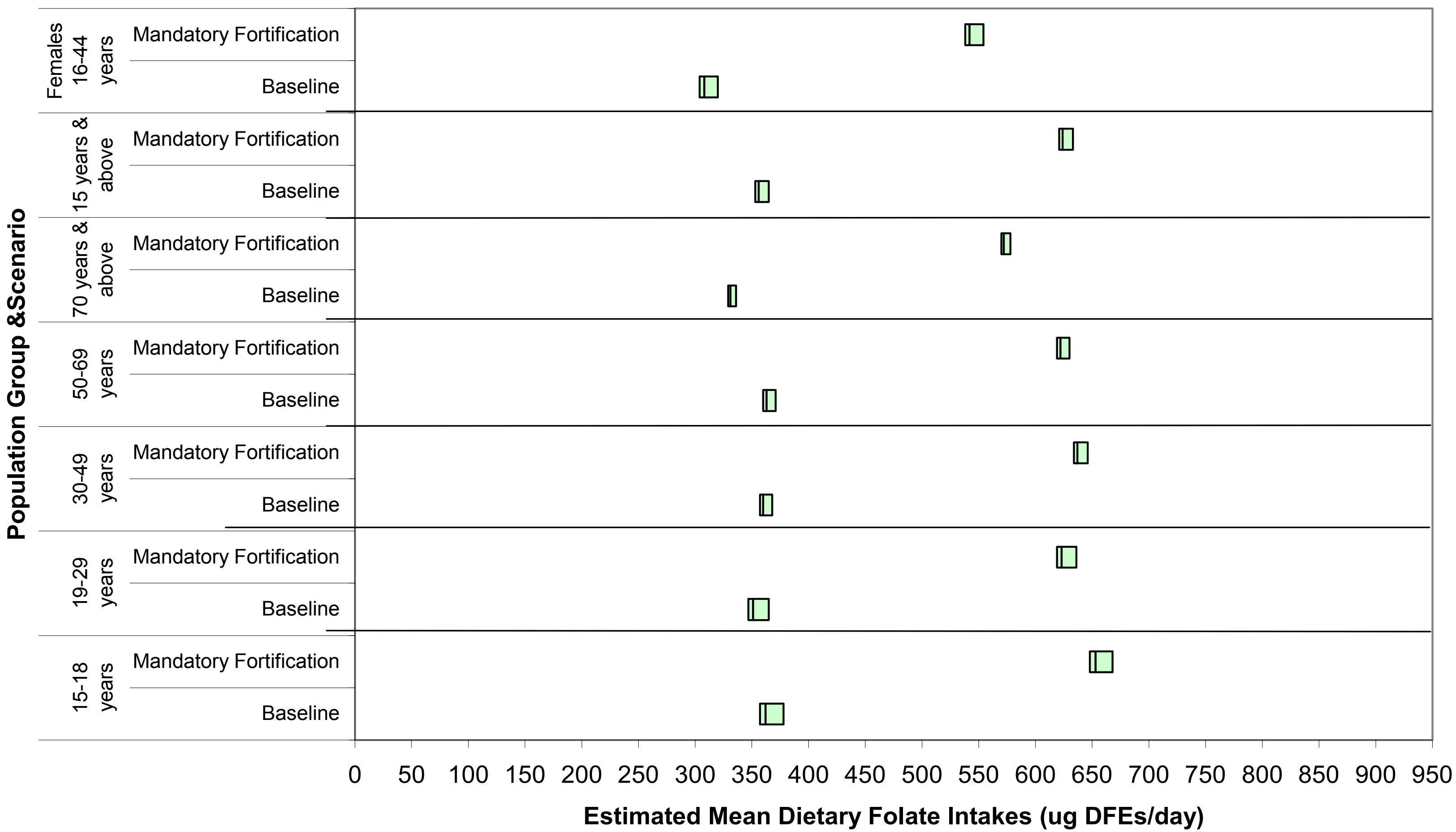


Figure 7: Comparison between estimated mean dietary folate intakes at Baseline and Mandatory Fortification for New Zealand population groups



~~4.3.~~4.3 Major Contributors to Naturally Occurring and Dietary Folate Intakes

Formatted: Bullets and Numbering

The foods contributing ≥5% to naturally occurring and dietary folate intakes are shown in Table A2.4 in Appendix 2. The calculations for major contributing foods were based on intakes derived from the first 24-hour recall data only.

~~4.3.1.~~4.3.1 Naturally occurring folate

Formatted: Bullets and Numbering

For Australian women aged 16-44 years, the major contributors to naturally occurring intakes for *Baseline* were cereals and cereal products and non-alcoholic beverages. Vegetable products and dishes, milk products and dishes, fruit products and dishes, cereal based products and dishes and meat, poultry and game products and dishes were other important contributors.

For New Zealand women aged 16-44 years, the major contributor to naturally occurring intakes for *Baseline* was vegetables. Bread (includes rolls and specialty breads), non-alcoholic beverages, fruit, potatoes and kumara, sauces and milk were other important contributors.

For Australians aged 2 years and above, the important contributors to naturally occurring intakes for *Baseline* were similar to those for women aged 16-44 years –i.e. cereals and cereal products, non-alcoholic beverages, vegetable products and dishes, milk products and dishes, fruit products and dishes, and meat and poultry and game products and dishes.

For New Zealanders aged 15 years and above, the important contributors to naturally occurring intakes for *Baseline* were similar to those for women aged 16-44 years and include, vegetables, bread (includes rolls and specialty breads), non-alcoholic beverages, fruit, potatoes and kumara, sauces and milk.

~~4.3.2.~~4.3.2 Dietary folate

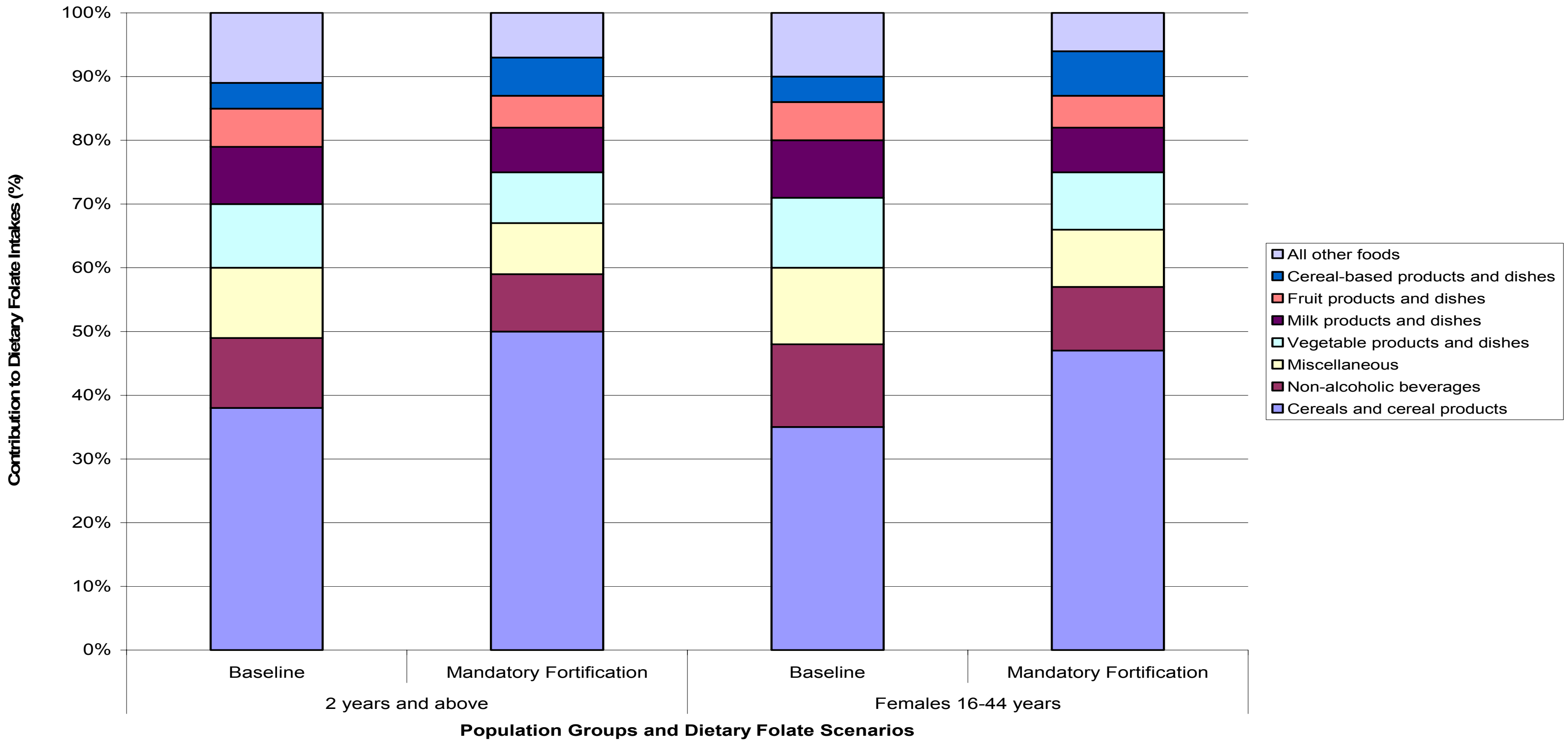
Formatted: Bullets and Numbering

For Australian women aged 16-44 years, the major contributor to dietary folate intakes for *Baseline* was cereals and cereal products, with non-alcoholic beverages and miscellaneous foods, vegetable products and dishes, milk products and dishes and fruit products and dishes being other important contributors to dietary folate intakes. For *Mandatory Fortification,* the major contributors to dietary folate intakes were the same as for *Baseline*, with cereals-based products and dishes also being an important contributor.

For New Zealand women aged 16-44 years, the major contributor to dietary folate intakes at *Baseline* was breakfast cereals, with sauces, vegetables, non-alcoholic beverages, fruit, potatoes and kumara being other important contributing foods. For *Mandatory Fortification*, breads, breakfast cereals, sauces and vegetables were important contributors dietary folate intakes for both scenarios.

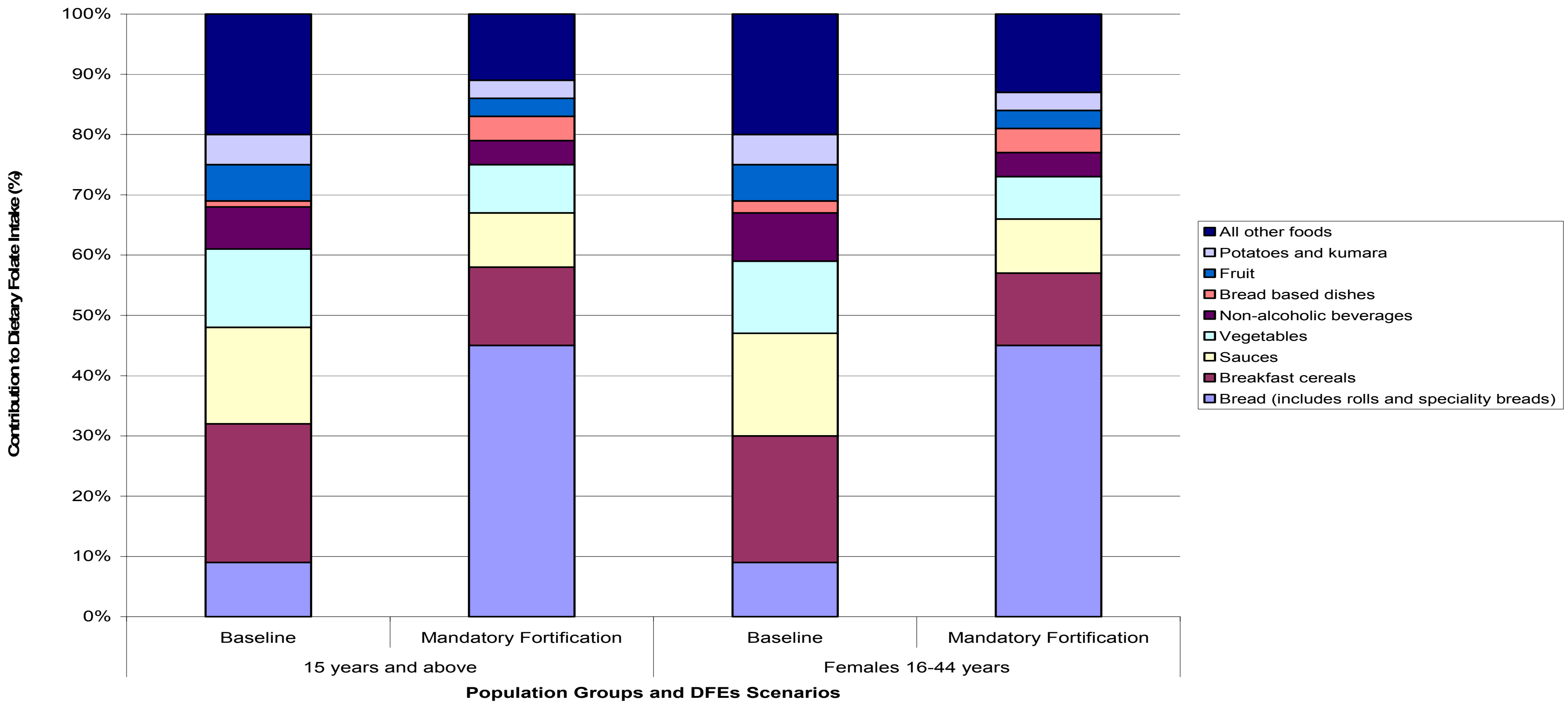
For Australians aged 2 years and above, the major contributor to dietary folate intakes for *Baseline* and *Mandatory Fortification* was cereals and cereal products, as it was for the target groups. Non-alcoholic beverages, miscellaneous foods, vegetable products and dishes, fruit products and dishes and milk products and dishes were also important contributors to dietary folate intakes. Cereal based products and dishes were also major contributors to dietary folate intakes for *Mandatory Fortification*.

Figure 8: Major food group contributors for Australians 2 years and above and women 16-44 years for dietary folate at Baseline and Mandatory Fortification1



[1] The percent contribution of each food group is based on total dietary folate intakes for all consumers in the population groups assessed. Therefore the total dietary folate intakes differ for each population group and each scenario. Only the major contributors for each scenario are shown separately.

Figure 9: Major food group contributors for New Zealand 15 years and above and women 16-44 years for dietary folate at Baseline and Mandatory Fortification1



[1] The percent contribution of each food group is based on total dietary folate intakes for all consumers in the population groups assessed. Therefore the total dietary folate intakes differ for each population group and each scenario. Only the major contributors for each scenario are shown separately.

For New Zealanders aged 15 years and above, the important contributors to dietary folate intakes for *Baseline* were breakfast cereals, sauces, vegetables, bread, non-alcoholic beverages, fruit, and potatoes and kumara. Bread was the overall highest contributor for *Mandatory Fortification* with breakfast cereals, sauces and vegetables being other important contributors to dietary folate intakes.

~~5.~~5. Risk Characterisation

Formatted: Bullets and Numbering

~~5.1.~~5.1 Naturally occurring folate intakes compared to EARs for Australia and New Zealand

Formatted: Bullets and Numbering

Estimated naturally occurring folate intakes were compared with the EAR relevant for each lifestage and age/gender group (see Section 1.2.3).

~~*5.1.1.*~~*5.1.1 Australia*

Formatted: Bullets and Numbering

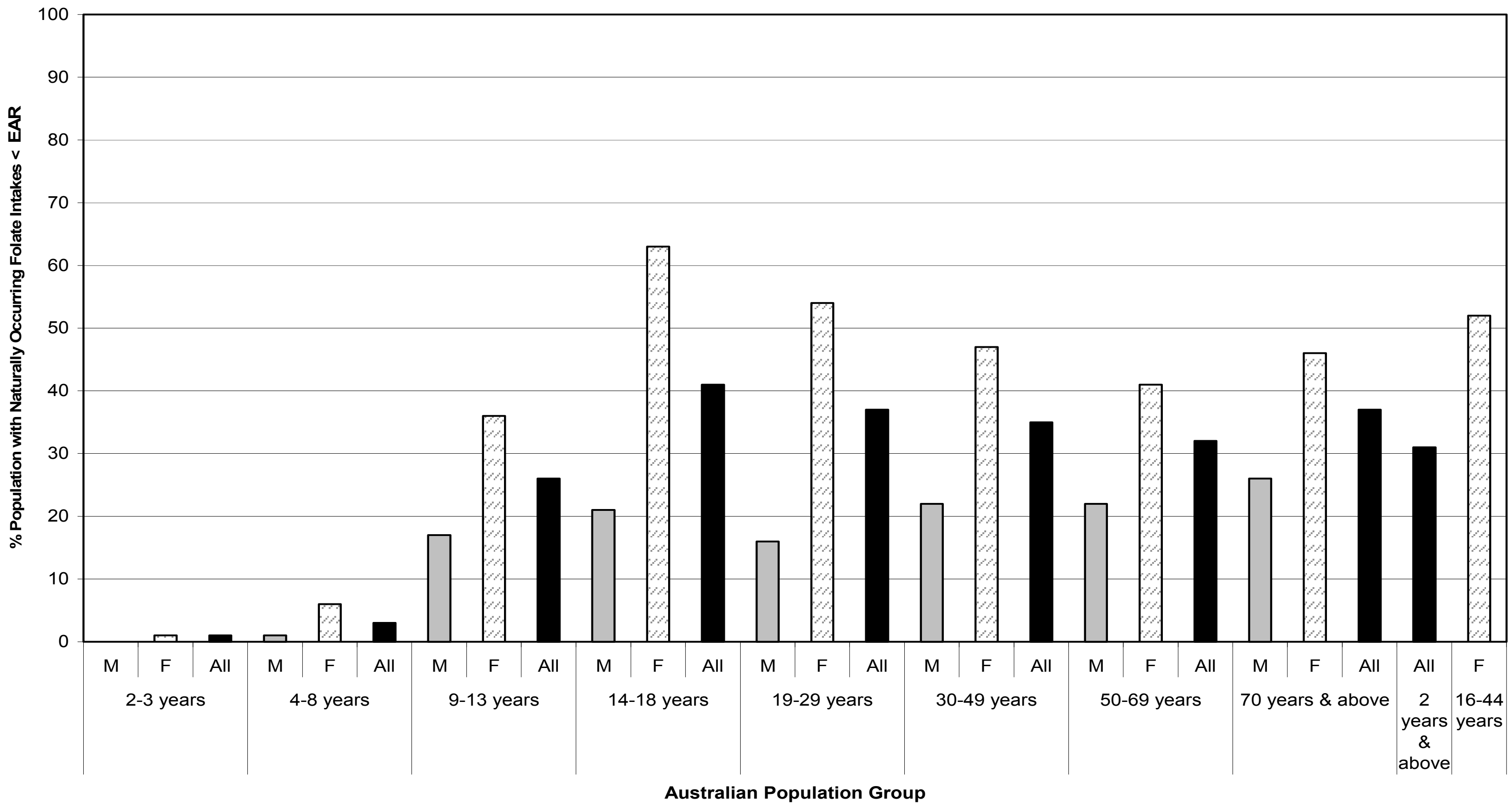
The Australian population group with the highest proportion of respondents with estimated naturally occurring intakes below the EAR was females aged 14-18 years (63%), followed by females aged 19-29 years (54%). For each population group, with the exception of children 2-3 years, a higher proportion of females with estimated naturally occurring intakes were below the EAR than males. The target group of women aged 16-44 years also had a high proportion of respondents with naturally occurring intakes below the EAR (52%). Overall, 30% of the Australian population 2 years and above had estimated naturally occurring intakes below the EAR. For further details, refer to Table 2.

Table 2: Proportion of the Australian population with estimated naturally occurring folate intakes below the EAR

Population Group	Gender	No. of Respondents	Proportion of population group with estimated naturally occurring folate intakes < EAR (%)
2-3 years	M	170	0
	F	213	<1
	All	383	<1
4-8 years	M	513	<1
	F	464	6
	All	977	3
9-13 years	M	474	17
	F	439	36
	All	913	26
14-18 years	M	378	21
	F	356	63
	All	734	41
19-29 years	M	1,014	16
	F	1,189	54
	All	2,203	37

Population Group	Gender	No. of Respondents	Proportion of population group with estimated naturally occurring folate intakes < EAR (%)
30-49 years	M	2,080	22
	F	2,317	47
	All	4,397	35
50-69 years	M	1,442	22
	F	1,577	41
	All	3,019	32
70 years & above	M	545	26
	F	687	46
	All	1,232	37
2 years & above	All	13,858	31
16-44 years	F	3,178	52

Figure 10: Proportion of the Australian population with naturally occurring folate intakes below the EAR



~~5.1.2.~~5.1.2 *New Zealand*

All New Zealand population groups (aged 15 years and above) had at least 82% or more of respondents with estimated naturally occurring intakes below the EAR. This was substantially higher than that for Australia for each specified population group. Females aged 15-18 years had the highest proportion of respondents below the EAR (99%) followed by females 19-29 years (98%). Similar to Australian women, a higher proportion of New Zealand females in each population group had estimated naturally occurring intakes below the EAR than males. Overall, 92% of the New Zealand population had estimated naturally occurring intakes below the EAR. For further details, refer to Table 3.

Table 3: Proportion of the New Zealand population with estimated naturally occurring folate intakes below the EAR

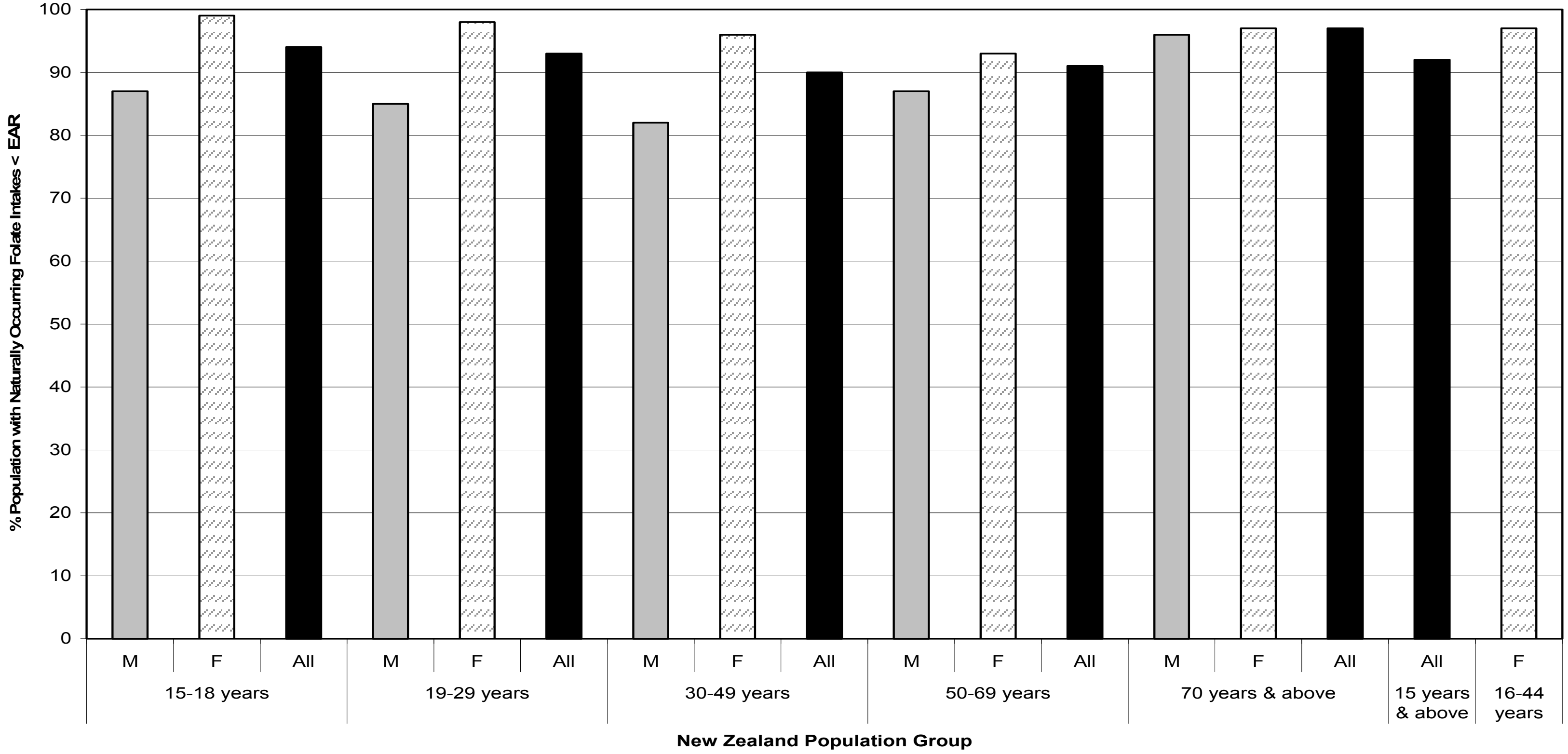
Population Group	Gender	No. of Respondents	Proportion of population group with naturally occurring folate intakes < EAR (%)
15-18 years	M	109	87
	F	137	99
	All	246	94
19-29 years	M	286	85
	F	518	98
	All	804	93
30-49 years	M	787	82
	F	1,096	96
	All	1,883	90
50-69 years	M	538	87
	F	609	93
	All	1,147	91
70 years & above	M	207	96
	F	349	97
	All	556	97
15 years & above	All	4,636	92
16-44 years	F	1,509	97

~~5.1.3.~~5.1.3 *Summary*

Formatted: Bullets and Numbering

In the absence of folic acid fortification (voluntary or mandatory), there is the potential for substantial proportions of the Australian and New Zealand populations to have estimated naturally occurring folate intakes (expressed as DFEs) below the EAR for folate.

Figure 11: Proportion of the New Zealand population with naturally occurring folate intakes below the EAR



~~5.2.~~5.2 Dietary folate intakes compared to EARs for Australia and New Zealand

Formatted: Bullets and Numbering

Estimated dietary folate intakes were compared to the EAR for various Australian and New Zealand population groups to investigate whether all population groups would be able to meet their EARs for folate in the presence of current voluntary and proposed mandatory folic acid fortification.

~~5.2.1.~~5.2.1 Australia

Formatted: Bullets and Numbering

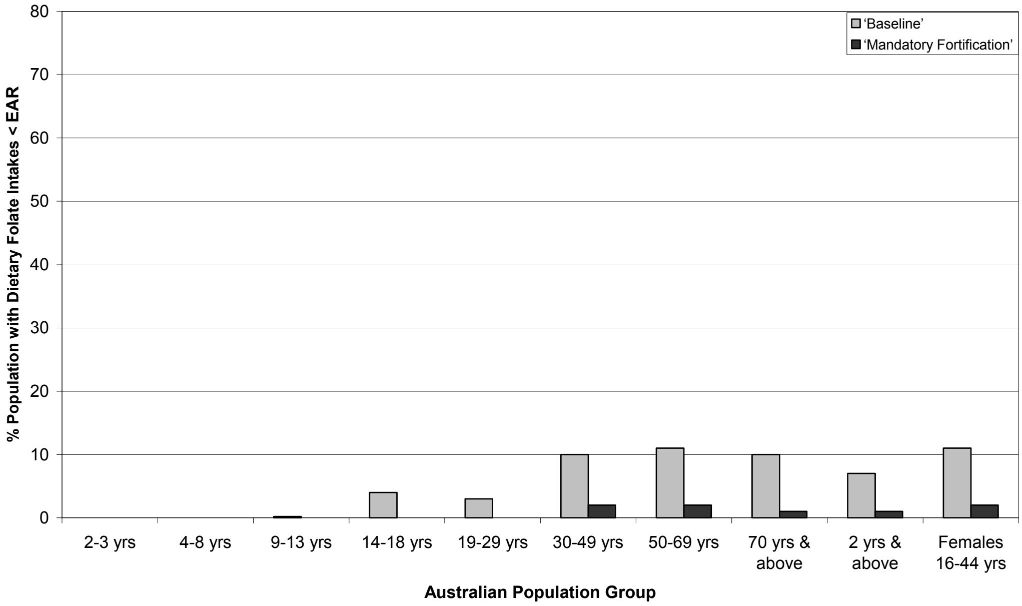
The estimated dietary intakes for dietary folate were determined for each individual and were compared to the relevant EAR for their age group and gender. The proportion of each population group with dietary folate intakes below the EAR is shown in Figure 12a and b for Australian population groups, with full details in Table A3.1 in Appendix 3.

At *Baseline*, 10-11% of Australians aged 30 years and above and women aged 16-44 years had estimated dietary folate intakes below the EAR. Additionally, 7% of Australians aged 2 years and above had estimated dietary folate intakes below the EAR. Females had higher proportions of the population with estimated intakes below the EAR than did males (refer to Figure 12b). This demonstrates that there are currently other 'non-target' groups (i.e. besides women aged 16-44 years) who potentially have inadequate intakes of dietary folate.

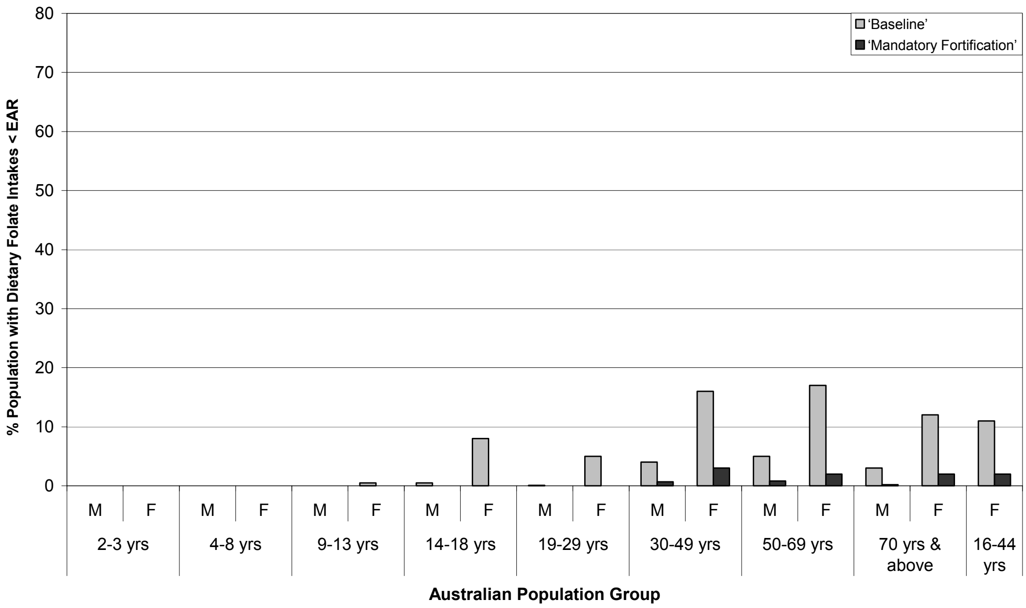
The proportion of the Australian population with dietary folate intakes below the EAR reduced from 7% at *Baseline* to 1% under the *Mandatory Fortification* scenario. For all population groups assessed, 3% or less had dietary folate intakes below the EAR for *Mandatory Fortification*.

Figure 12: Proportion of the Australian population with estimated dietary folate intakes less than the EAR at Baseline and Mandatory Fortification.

a. Both genders



b. Males and females



Formatted: Bullets and Numbering

~~5.2.2.~~5.2.2 *New Zealand*

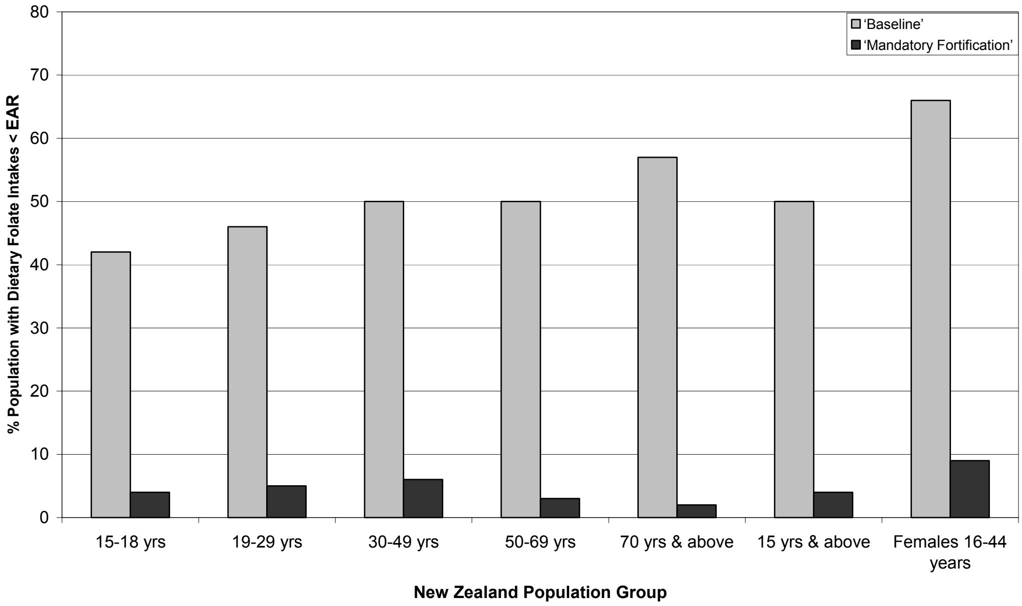
The estimated dietary intakes for dietary folate were determined for each individual and were compared to the relevant EAR for their age group and gender. The proportion of each population group with estimated dietary folate intakes below the EAR is shown in Figure 13a and b for New Zealand population groups and full details in Appendix 3.

At *Baseline*, 50% of the population 15 years and above had estimated dietary folate intakes below their EARs, with 66% of women aged 16-44 years having intakes below the EAR. In each age group, there were higher proportions of female with dietary folate intakes below the EARs in comparison to males. For example, 70% of women aged 19-29 years have estimated dietary folate intakes below the EAR, compared with 3% for males. Similar to Australia, other non-target groups have inadequate intakes of dietary folate.

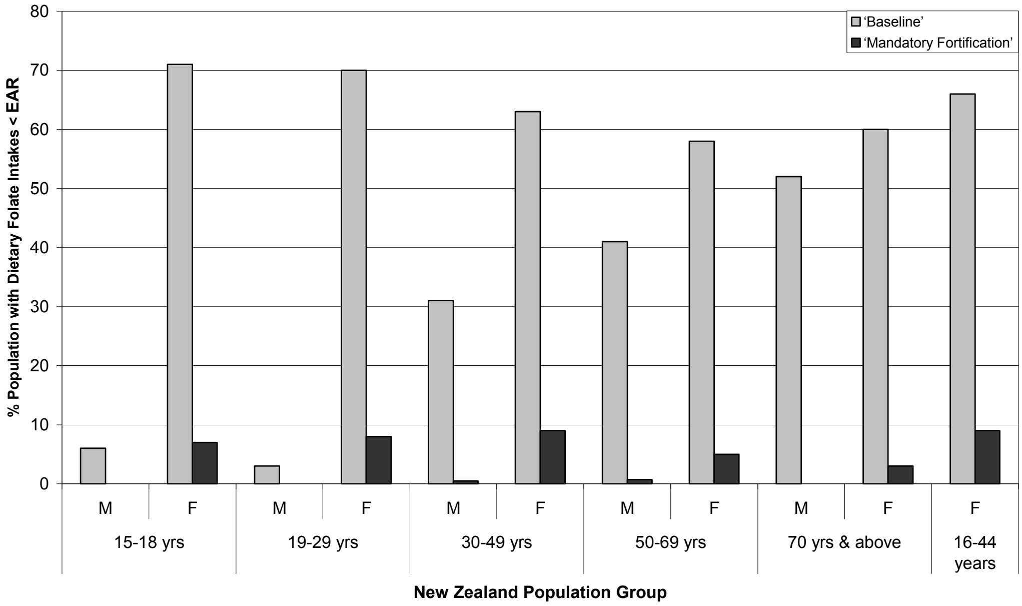
To investigate whether mandatory fortification of bread in New Zealand would assist population groups in meeting their EARs, the *Mandatory Fortification* scenario was also assessed. The proportion of the population 15 years and above with dietary folate intakes below the EAR was greatly reduced from *Baseline* (50%) to *Mandatory Fortification* (4%). The proportion of women aged 16-44 years with estimated dietary folate intakes below the EAR was reduced from 66% at *Baseline* to 9% under *Mandatory Fortification*. Under *Mandatory Fortification*, less than 10% of females and less than 1% of males have estimated dietary folate intakes below the EAR.

Figure 13: Proportion of the New Zealand population with estimated dietary folate intakes less than the EAR at Baseline and Mandatory Fortification.

a. Both genders



b. Males and females



5.2.3 Summary

Mandatory fortification of 'wheat flour for making bread' or bread with folic acid has the potential to address inadequate intakes of dietary folate in population groups that are not the 'target group' for folic acid fortification.

Potential reductions in the proportion of various population groups with estimated dietary folate intakes below the EAR are summarised below.

	No fortification		*Baseline*		*Mandatory Fortification*
Aust. women 16-44 yrs	52	→	11	→	2
Aust. 2 yrs & above	31	→	7	→	1
NZ women 16-44 yrs	97	→	66	→	9
NZ 15 yrs & above	92	→	50	→	4

References

Australian Bureau of Statistics. (1998) Technical Paper on the National Nutrition Survey: Confidentialised Unit Record File 1995. Australian Bureau of Statistics, Canberra.

Ball, G.F.M. (2004) Folate. In: *Vitamins: Their Role in the Human Body*. Chapter 17. Blackwell Publishing, Oxford, pp347-382.

French, M.R., Barr, S.I. and Levy-Milne, R. (2003) Folate intakes and awareness of folate to prevent neural tube defects: A survey of women living in Vancouver, Canada. *Journal of the American Dietetic Association* 103(2):181-185.

Griffith, H.W. (1995) The Vitamin Fact File. 2 ed, Diamond Books, Arizona, pp50-52.

Institute of Medicine, N.A.o.S. (2000) Dietary Reference Intakes: Applications in Dietary Assessment. National Academy Press, Washington DC.

National Health and Medical Research Council. (2001) Dietary Guidelines for Children and Adolescents In Australia Incorporating Infant Feeding Guidelines For Health Workers (Draft). (Unpublished Work).

National Health and Medical Research Council (2005a) *Nutrient Reference Values for Australia and New Zealand - Executive Summary*. Canberra. http://www.nhmrc.gov.au/publications/synopses/_files/n36.pdf.

National Health and Medical Research Council (2005b) *Nutrient Reference Values for Australia and New Zealand Including Recommended Dietary Intakes*. http://www.nhmrc.gov.au/publications/_files/n35.pdf.

National Health and Medical Research Council (2006) *Nutrient Reference Values for Australia and New Zealand Including Recommended Dietary Intakes*. http://www.nhmrc.gov.au/publications/_files/n35.pdf. Accessed on 9 June 2006.

Vozenilek, G.P. (1999) What they don't know could hurt them: Increasing public awareness of folic acid and neural tube defects. *Journal of the American Dietetic Association* 99(1):20-22.

West Suitor, C. and Bailey, L. (2000) Dietary folate equivalents: Interpretation and application. *Journal of the American Dietetic Association* 100(1):88-94.

Spina Bifida Explained – Victorian Government Better Health Website http://www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/(Pages)/Spina_bifida_explained?OpenDocument.

Appendix 1 – *Summary of concentration data used for various foods for dietary modelling purposes*

A1.1 Concentration data from the AIP and the KFP

Dietary folate data currently held by FSANZ were updated for the purposes of this assessment using new data provided by the Australian Iodine Program (AIP) and the Key Foods Program (KFP).

Data from chemical analysis between December 2005 and February 2006 to update Australian iodine information (AIP) as well as other key nutrients including folate were used to derive dietary folate and folic acid data used for this dietary exposure assessment.

The KFP analysed foods significant in Australian children's diets today for vitamins, minerals and proximates, with chemical analysis undertaken in August 2006. Foods were purchased nationally and also assessed for variation in nutrients across the country. Dietary folate and folic acid levels were then derived from this database and used for the current assessment.

Table A1.1: Foods analysed for naturally occurring folate, folic acid by the AIP and KFP

	Foods Analysed
Australian Iodine Program	Yoghurt, with fruit, low fat
	Yoghurt, low fat, flavoured
	Cheese, Brie
	Cheese, Camembert
	Juice, orange, shelf safe
	Fruit Juice cordial base, orange
	Extruded cheese snacks
	Tofu, Firm
	Sausage Roll
	Sponge Cake, commercial, cake only
	Bok Choy, raw
	Pizza, cheese and tomato topping
	Spinach and cheese pastry, baked
	Chicken, BBQ, including skin
	Tomatoes, canned
	Lobster
	Crab, Cooked
	Salmon, red, canned in brine, drained
	Processed chicken breast (presliced, low fat variety -4%)
	Vegetarian Sausage style products
	Muesli bars, without chocolate or nuts
	Muesli bars with nuts
	Lentil, red and brown, dry

	Foods Analysed
	Cocoa powder Chicken liver, raw Chicken liver, cooked Lambs Fry, cooked Bread, rye, light style Pastry, commercial, puff, raw, prepared with butter
Key Foods Program	Milk, fluid, regular whole, full fat Milk, fluid reduced fat Bread, white Bread, white, fortified with Iron & Folate Bread, white, toasted Bread roll, white Apple, red, raw, unpeeled Margarine, polyunsaturated Potato, boiled, without skin Chicken drumstick, baked Ice Cream, regular fat, vanilla Breakfast cereal, 'Nutrigrain' (Kellogg's) Breakfast cereal, 'Weet-Bix' type (Sanitarium) Pie, meat, 2 crusts, individual size Beef mince, regular mince, dry fried Pizza, meat (including chicken),vegetables Cheeseburger, with regular beef pattie on fortified bun Juice, orange, fresh Juice, orange, shelf Juice, apple, shelf Breakfast cereal, cornflakes, fortified (Kellogg's) Breakfast cereal, rice bubbles type, fortified (Kellogg's) Chicken nuggets Banana (cavendish)

Appendix 2 – Complete information on dietary intake assessment results

Table A2.1: Estimated naturally occurring folate intakes for the Australian and New Zealand populations for Baseline and Mandatory Fortification, split by gender and age.

a. Australia

Population Group	Gender	No. of Respondents	Estimated Folate Intakes (µg DFE/day)	
			Mean	95th percentile
2-3 years	M	170	286	426
	F	213	255	386
	All	383	269	409
4-8 years	M	513	305	455
	F	464	264	406
	All	977	286	440
9-13 years	M	474	354	566
	F	439	297	476
	All	913	326	531
14-18 years	M	378	410	585
	F	356	313	473
	All	734	363	559
19-29 years	M	1,014	427	637
	F	1,189	326	501
	All	2,203	372	578
30-49 years	M	2,080	419	637
	F	2,317	340	499
	All	4,397	377	579
50-69 years	M	1,442	414	638
	F	1,577	347	486
	All	3,019	379	581
70 years & above	M	545	392	578
	F	687	335	461
	All	1,232	360	520
2 years & above	All	13,858	362	563
16-44 years	F	3,178	331	500

b. New Zealand

Population Group	Gender	No. of Respondents	Estimated Folate Intakes (µg DFE/day)	
			Mean	**95th percentile**
15-18 years	M	109	259	381
	F	137	203	300
	All	246	228	349
19-29 years	M	286	264	396
	F	518	203	291
	All	804	225	336
30-49 years	M	787	272	382
	F	1,096	206	313
	All	1,883	234	359
50-69 years	M	538	260	365
	F	609	216	335
	All	1,147	237	353
70 years & above	M	207	242	318
	F	349	202	300
	All	556	217	310
15 years & above	All	4,636	231	347
16-44 years	F	1,509	204	305

Table A2.2: Estimated Dietary Folate Intakes at Baseline for the Australian and New Zealand populations.

a. Australia

Population Group	**Gender**	**No. of Respondents**	**Estimated dietary folate intakes (µg DFE/day)**							
			Mean				**95th percentile**			
			Market Weighted Model	**Consumer Behaviour Model**			**Market Weighted Model**	**Consumer Behaviour Model**		
2-3 years	M	170	529	492	–	703	770	713	–	1,054
	F	213	456	422	–	633	678	633	–	970
	All	383	489	453	–	664	735	687	–	1,020
4-8 years	M	513	572	529	–	798	903	835	–	1,357
	F	464	469	431	–	670	748	719	–	1,017
	All	977	523	482	–	737	820	768	–	1,213
9-13 years	M	474	668	618	–	971	1,132	1,058	–	1,795
	F	439	508	467	–	743	873	828	–	1,213
	All	913	591	545	–	861	1,038	970	–	1,515
14-18 years	M	378	747	688	–	1,073	1,400	1,315	–	1,820
	F	356	510	465	–	741	832	784	–	1214
	All	734	632	580	–	912	1,114	1,036	–	1,598
19-29 years	M	1,014	726	664	–	1,057	1,320	1,242	–	1,857
	F	1,189	523	480	–	746	882	832	–	1,229
	All	2,203	616	565	–	889	1,144	1,070	–	1,615
30-49 years	M	2,080	653	594	–	970	1,161	1,092	–	1,700
	F	2,317	506	465	–	733	960	912	–	1,255
	All	4,397	575	526	–	845	1,071	1,006	–	1,543

Population Group	Gender	No. of Respondents	Estimated dietary folate intakes (µg DFE/day)							
			Mean				95th percentile			
			Market Weighted Model	Consumer Behaviour Model			Market Weighted Model	Consumer Behaviour Model		
50-69 years	M	1,442	633	578	–	937	1,200	1,118	–	1,678
	F	1,577	513	474	–	735	966	926	–	1,244
	All	3,019	570	524	–	831	1,099	1,041	–	1,470
70 years & above	M	545	601	552	–	878	1,044	990	–	1,412
	F	687	513	473	–	736	1,029	983	–	1,263
	All	1,232	551	508	–	799	1,038	983	–	1,350
2 years & above	All	13,858	577	529	–	837	1,059	997	–	1,488
16-44 years	F	3,178	511	469	–	736	900	833	–	1,230

b. New Zealand

Population Group	Gender	No. of Respondents	Estimated Dietary Folate Intakes (µg DFE/day)						
			Mean				95th percentile		
			Market Weighted Model	Consumer Behaviour Model			Market Weighted Model	Consumer Behaviour Model	
15-18 years	M	109	451	448	–	460	674	659	–	716
	F	137	292	285	–	313	572	571	–	612
	All	246	362	357	–	378	665	651	–	706
19-29 years	M	286	452	449	–	463	697	681	–	801
	F	518	296	291	–	310	573	569	–	596
	All	804	351	347	–	365	629	616	–	663
30-49 years	M	787	417	414	–	425	762	755	–	795
	F	1,096	318	315	–	327	623	624	–	626
	All	1,883	360	357	–	368	701	695	–	705
50-69 years	M	538	398	395	–	407	742	740	–	800
	F	609	331	329	–	339	669	660	–	695
	All	1,147	363	360	–	371	713	711	–	740
70 years & above	M	207	350	349	–	357	574	557	–	600
	F	349	319	317	–	323	536	537	–	543
	All	556	331	329	–	336	559	555	–	581
15 years & above	All	4,636	356	353	–	365	670	660	–	695
16-44 years	F	1,509	308	304	–	320	598	589	–	613

Table A2.3: Estimated dietary folate intakes for Mandatory Fortification for the Australian and New Zealand populations split by age and gender.

a. Australia

Population Group	Gender	No. of Respondents	Estimated Intakes (µg DFE/day)			
			Mean		**95th percentile**	
			Market Weighted Model	**Consumer Behaviour Model**	**Market Weighted Model**	**Consumer Behaviour Model**
2-3 years	M	170	689	686 – 683	950	945 – 1,028
	F	213	592	588 – 611	829	825 – 927
	All	383	635	631 – 643	911	892 – 981
4-8 years	M	513	757	752 – 780	1,121	1,108 – 1,335
	F	464	618	614 – 645	893	890 – 977
	All	977	691	686 – 716	1,032	1,014 – 1,172
9-13 years	M	474	882	875 – 954	1,408	1,385 – 1,678
	F	439	674	669 – 724	1,031	1,014 – 1,193
		913	782	776 – 844	1,287	1,275 – 1,458
14-18 years	M	378	1,010	1,004 – 1,059	1,710	1,713 – 1,782
	F	356	685	677 – 725	1,064	1,048 – 1,195
	All	734	853	845 – 897	1,471	1,472 – 1,564
19-29 years	M	1,014	1,005	998 – 1,051	1,813	1,801 – 1,858
	F	1,189	691	684 – 730	1,105	1,087 – 1,192
	All	2,203	836	829 – 878	1,488	1,476 – 1,584
30-49 years	M	2,080	892	886 – 935	1,565	1,541 – 1,620
	F	2,317	670	665 – 707	1,122	1,117 – 1,230
	All	4,397	775	770 – 815	1,366	1,362 – 1,460

Population Group	Gender	No. of Respondents	Estimated Intakes (μg DFE/day)				
			Mean		95th percentile		
			Market Weighted Model	Consumer Behaviour Model		Market Weighted Model	Consumer Behaviour Model
50-69 years	M	1,442	842	837 – 889	1,470	1,465 – 1,562
	F	1,577	663	659 – 705	1,113	1,098 – 1,192
	All	3,019	749	744 – 793	1,300	1,294 – 1,396
70 years & above	M	545	792	788 – 834	1,266	1,264 – 1,335
	F	687	662	658 – 697	1,143	1,137 – 1,223
	All	1,232	719	716 – 758	1,218	1,214 – 1,297
2 years & above	All	13,858	769	763 – 810	1,336	1,326 – 1,429
16-44 years	F	3,178	678	672 – 716	1,097	1,093 – 1,192

b. New Zealand

Population Group	Gender	No. of Respondents	Estimated Dietary Folate Intakes (µg DFE/day)			
			Mean		95th percentile	
			Market Weighted Model	Consumer Behaviour Model	Market Weighted Model	Consumer Behaviour Model
15-18 years	M	109	798	794 – 808	1,285	1,275 – 1,313
	F	137	538	532 – 558	874	858 – 901
	All	246	653	648 – 668	1,168	1,161 – 1,223
19-29 years	M	286	792	789 – 803	1,290	1,263 – 1,391
	F	518	530	526 – 544	864	859 – 881
	All	804	623	619 – 636	1,065	1,058 – 1,094
30-49 years	M	787	758	755 – 767	1,221	1,216 – 1,236
	F	1,096	550	547 – 559	932	916 – 928
	All	1,883	637	634 – 646	1,108	1,102 – 1,130
50-69 years	M	538	703	700 – 712	1,135	1,133 – 1,170
	F	609	550	547 – 557	935	924 – 936
	All	1,147	622	619 – 630	1,016	1,009 – 1,048
70 years & above	M	207	631	629 – 638	939	938 – 962
	F	349	550	536 – 542	782	777 – 794
	All	556	572	570 – 578	881	879 – 898
15 years & above	All	4,636	624	621 – 633	1,051	1,044 – 1,078
16-44 years	F	1,509	542	538 – 554	899	887 – 914

Table A2.4: Food contributors to naturally occurring folate intakes for all Australians (aged 2 years and above), all New Zealanders (aged 15 years and above) and Australian and New Zealand women of child bearing age

a. Australia

Food Group	**% Contribution to naturally occurring folate intakes (%)**	
	2 years and above	**Females 16-44 years**
Cereals and cereal products[1]	**19**	**19**
Non-alcoholic beverages[2]	**17**	**19**
Vegetable products and dishes[3]	**16**	**17**
Milk products and dishes[4]	**13**	**13**
Fruit products and dishes[5]	**10**	**10**
Cereal-based products and dishes[6]	**6**	**6**
Meat, poultry and game products and dishes[7]	**6**	**5**
Miscellaneous	3	3
Egg products and dishes	2	1
Soup	1	1
Legume and pulse products and dishes	1	1
Fats and oils	1	<1
Alcoholic beverages	1	<1
Fish and seafood products and dishes	<1	<1
Seed and nut products and dishes	<1	<1
Savoury sauces and condiments	<1	<1
Snack foods	<1	<1
Sugar products and dishes	<1	<1
Confectionery and health bars	<1	<1
Special dietary foods	<1	<1
Infant formulae and foods	<1	<1
Water	0	0

Note: the contributions highlighted in **bold** are major contributors (≥ 5%) to naturally occurring folate intakes

1. **Cereals and cereal products** includes grains, cereal flours and starch powders, breads and rolls, breakfast cereals, English-style muffins, crumpets, tortillas, pastas, noodles and rice.
2. **Non-alcoholic beverages** includes teas, coffees, fruit and vegetable juices and drinks, cordials, soft drinks and mineral waters, electrolyte drinks, sports drinks, bottled water and tap water.
3. **Vegetable products and dishes** includes raw, cooked, canned, preserved, dried and frozen vegetables and vegetable dishes (e.g. vegetable patties, potato salad, vegetable curry etc.)
4. **Milk, milk products and dishes** includes milks (plain and flavoured), evaporated milk, condensed milk, milk powders, yoghurts (plain, flavoured and fruit), creams, cheeses, ice creams and ice confections (dairy and soy-based), frozen yoghurts, custards and other dairy-based desserts and soy-based beverages.
5. **Fruit products and dishes** includes fresh, canned, frozen, cooked, dried and preserved (e.g. glace) fruits.
6. **Cereal-based products and dishes** includes biscuits (sweet and savoury), cakes, buns, muffins (cake style), scones, slices, pastries and pastry products (sweet and savoury), pizzas, sandwiches, filled rolls and hamburgers, taco and tortilla-based dishes, savoury pasta and sauce dishes, dim sims, spring rolls, savoury rice-based dishes, pancakes, crepes, pikelets and doughnuts.
7. **Meat, poultry and game products and dishes** includes raw and cooked plain meat, poultry and game, cured meats (e.g. corned beef,), bacon, ham, offal, sausages, frankfurts, processed meats, and mixed dishes containing these foods (e.g. lamb curry, pork stir-fry).

b. New Zealand

Food Group	% Contribution to naturally occurring folate intakes (%)	
	15 years and above	Females 16-44 years
Vegetables[1]	**20**	**19**
Bread (includes rolls and speciality breads)[2]	**14**	**13**
Non-alcoholic beverages[3]	**9**	**10**
Fruit[4]	**9**	**9**
Potatoes and kumara[5]	**8**	**8**
Sauces[6]	**6**	**6**
Milk[7]	**5**	**5**
Breakfast cereals	3	3
Eggs and egg dishes	3	3
Beef and Veal	3	2
Fish/Seafood	3	2
Bread based dishes	2	2
Cakes and muffins	2	2
Poultry	2	2
Alcoholic beverages	2	>1
Grains and Pasta	1	2
Biscuits	1	1
Dairy products	1	1
Soups and stocks	1	>1
Nuts and Seeds	1	1
Pies and pasties	1	1
Puddings	<1	<1
Cheese	<1	<1
Butter and Margarine	<1	<1
Fats and oils	<1	<1
Lamb/Mutton	<1	<1
Pork	<1	<1
Other meat	<1	<1
Sausages and processed meats	<1	<1
Snack foods	<1	<1
Sugar/sweets	<1	<1

Food Group	% Contribution to naturally occurring folate intakes (%)	
	15 years and above	Females 16-44 years
Dietary supplements	<1	<1
Herbs & spices	0	0

Note: the contributions highlighted in **bold** are major contributors (≥ 5%) to naturally occurring folate intakes

1. **Vegetables** includes raw, frozen, canned, dried and cooked vegetables (excluding potatoes and kumara) and dishes made from these (e.g. stir-fry vegetables in sweet and sour sauce, vegetable fritters, coleslaw).
2. **Bread** includes white, wholemeal, multigrain, rye, fruit bread, flat breads, topped breads (e.g. cheese topped), bagels, English-style muffins, crumpets and buns
3. **Non-alcoholic beverages** includes teas, coffees, hot chocolate drinks, fruit juices, cordials, fruit drinks, soft drinks, waters (tap, mineral) and sports drinks
4. **Fruit** includes raw, cooked, canned, frozen and dried fruits, olives and avocadoes
5. **Potatoes and kumara** includes plain raw and cooked potatoes and kumara, mashed potato, mashed kumara, hot chips (potato and kumara), hash browns, potato wedges, potato croquettes, crisps (potato and kumara), stuffed potatoes
6. **Sauces** includes gravies, pasta sauces, commercially available sauces (e.g. tomato, tartare, worcestershire), mustard, curry pastes and powders, homemade sauces (e.g. cheese sauce, mushroom sauce), mayonnaise, dressings, relish, chutneys, vinegar, vegetable and yeast extract spreads and yeast
7. **Milk** includes cow's and goat's milks, evaporated milk, powdered milk, milkshakes, flavoured milk and soy beverages

Table A2.5: Food contributors to dietary folate intakes for Australian and New Zealand population groups at *Baseline* and *Mandatory Fortification*

a. Australia

Food Group	**% Contribution to Dietary Folate intakes (%)**			
	2 years and above		**Females 16-44 years**	
	Baseline	*Mandatory Fortification*	*Baseline*	*Mandatory Fortification*
Cereals and cereal products[1]	**38**	**50**	**35**	**47**
Non-alcoholic beverages[2]	**11**	**9**	**13**	**10**
Miscellaneous[3]	**11**	**8**	**12**	**9**
Vegetable products and dishes[4]	**10**	**8**	**11**	**9**
Milk products and dishes[5]	**9**	**7**	**9**	**7**
Fruit products and dishes[6]	**6**	**5**	**6**	**5**
Cereal-based products and dishes[7]	4	**6**	4	**7**
Meat, poultry and game products and dishes	4	3	3	3
Fats and oils	<1	<1	<1	<1
Fish and seafood products and dishes	<1	<1	<1	<1
Egg products and dishes	<1	<1	<1	<1
Soup	<1	<1	<1	<1
Seed and nut products and dishes	<1	<1	<1	<1
Savoury sauces and condiments	<1	<1	<1	<1
Legume and pulse products and dishes	<1	<1	<1	<1
Snack foods	<1	<1	<1	<1

Food Group	% Contribution to Dietary Folate intakes (%)			
	2 years and above		**Females 16-44 years**	
	Baseline	*Mandatory Fortification*	*Baseline*	*Mandatory Fortification*
Sugar products and dishes	<1	<1	<1	<1
Confectionery and health bars	<1	<1	<1	<1
Alcoholic beverages	<1	<1	<1	<1
Special dietary foods	<1	<1	<1	<1
Infant formulae and foods	<1	<1	<1	<1
Water	0	0	0	0

Note: the contributions highlighted in **bold** are major contributors (≥ 5%) to dietary folate intakes

1. **Cereals and cereal products** includes grains, cereal flours and starch powders, breads and rolls, breakfast cereals, English-style muffins, crumpets, tortillas, pastas, noodles and rice.
2. **Non-alcoholic beverages** includes teas, coffees, fruit and vegetable juices and drinks, cordials, soft drinks and mineral waters, electrolyte drinks, sports drinks, bottled water and tap water.
3. **Miscellaneous** includes dry beverage flavourings, yeast, yeast, vegetable and meat extracts, intense sweeteners, herbs and spices, stock cubes and seasonings, essences and chemical raising agents.
4. **Vegetable products and dishes** includes raw, cooked, canned, preserved, dried and frozen vegetables and vegetable dishes (e.g. vegetable patties, potato salad, vegetable curry etc.)
5. **Milk, milk products and dishes** includes milks (plain and flavoured), evaporated milk, condensed milk, milk powders, yoghurts (plain, flavoured and fruit), creams, cheeses, ice creams and ice confections (dairy and soy-based), frozen yoghurts, custards and other dairy-based desserts and soy-based beverages.
6. **Fruit products and dishes** includes fresh, canned, frozen, cooked, dried and preserved (e.g. glace) fruits.
7. **Cereal-based products and dishes** includes biscuits (sweet and savoury), cakes, buns, muffins (cake style), scones, slices, pastries and pastry products (sweet and savoury), pizzas, sandwiches, filled rolls and hamburgers, taco and tortilla-based dishes, savoury pasta and sauce dishes, dim sims, spring rolls, savoury rice-based dishes, pancakes, crepes, pikelets and doughnuts.

b. New Zealand

Food Group	**% Contribution to dietary folate intakes (%)**			
	15 years and above		**Females 16-44 years**	
	Baseline	*Mandatory Fortification*	*Baseline*	*Mandatory Fortification*
Bread (includes rolls and speciality breads)	**9**	**45**	**9**	**45**
Breakfast cereals	**23**	**13**	**21**	**12**
Sauces	**16**	**9**	**17**	**9**
Vegetables	**13**	**8**	**12**	**7**
Non-alcoholic beverages	**7**	4	**8**	4
Bread based dishes	1	4	2	4
Fruit	**6**	3	**6**	3
Potatoes and kumara	**5**	3	**5**	3
Milk	3	2	3	2
Fish/Seafood	2	1	2	1
Eggs and egg dishes	2	1	2	1
Cakes and muffins	1	1	2	1
Poultry	1	1	1	1
Beef and Veal	2	1	1	1
Grains and Pasta	1	1	1	1
Dairy products	1	1	1	1
Biscuits	1	1	1	<1
Soups and stocks	1	<1	1	<1
Cheese	1	<1	1	<1

Food Group	% Contribution to dietary folate intakes (%)			
	15 years and above		**Females 16-44 years**	
	Baseline	*Mandatory Fortification*	*Baseline*	*Mandatory Fortification*
Pies and pasties	1	<1	1	<1
Nuts and Seeds	1	<1	1	<1
Sausages and processed meats	<1	<1	<1	<1
Alcoholic beverages	1	1	<1	<1
Snack foods	<1	<1	<1	<1
Sugar/sweets	<1	<1	<1	<1
Puddings	<1	<1	<1	<1
Lamb/Mutton	<1	<1	<1	<1
Pork	<1	<1	<1	<1
Other meat	<1	<1	<1	<1
Butter and Margarine	<1	<1	<1	<1
Dietary supplements	<1	<1	<1	<1
Fats and oils	<1	<1	<1	<1
Herbs & spices	0	0	0	0

Note: the contributions highlighted in **bold** are major contributors (≥ 5%) to dietary folate intakes

1. **Vegetables** includes raw, frozen, canned, dried and cooked vegetables (excluding potatoes and kumara) and dishes made from these (e.g. stir-fry vegetables in sweet and sour sauce, vegetable fritters, coleslaw).
2. **Bread** includes white, wholemeal, multigrain, rye, fruit bread, flat breads, topped breads (e.g. cheese topped), bagels, English-style muffins, crumpets and buns
3. **Non-alcoholic beverages** includes teas, coffees, hot chocolate drinks, fruit juices, cordials, fruit drinks, soft drinks, waters (tap, mineral) and sports drinks
4. **Fruit** includes raw, cooked, canned, frozen and dried fruits, olives and avocadoes
5. **Potatoes and kumara** includes plain raw and cooked potatoes and kumara, mashed potato, mashed kumara, hot chips (potato and kumara), hash browns, potato wedges, potato croquettes, crisps (potato and kumara), stuffed potatoes
6. **Sauces** includes gravies, pasta sauces, commercially available sauces (e.g. tomato, tartare, worcestershire), mustard, curry pastes and powders, homemade sauces (e.g. cheese sauce, mushroom sauce), mayonnaise, dressings, relish, chutneys, vinegar, vegetable and yeast extract spreads and yeast
7. **Milk** includes cow's and goat's milks, evaporated milk, powdered milk, milkshakes, flavoured milk and soy beverages

Appendix 3 – Complete risk characterisation information

Table A3.1: Proportion of the Australian and New Zealand populations with estimated naturally occurring folate intakes below the EAR

a. Australia

Population Group	Gender	No. of Respondents	Proportion of population group with estimated naturally occurring folate intakes < EAR (%)
2-3 years	M	170	0
	F	213	<1
	All	383	<1
4-8 years	M	513	<1
	F	464	6
	All	977	3
9-13 years	M	474	17
	F	439	36
	All	913	26
14-18 years	M	378	21
	F	356	63
	All	734	41
19-29 years	M	1,014	16
	F	1,189	54
	All	2,203	37
30-49 years	M	2,080	22
	F	2,317	47
	All	4,397	35
50-69 years	M	1,442	22
	F	1,577	41
	All	3,019	32
70 years & above	M	545	26
	F	687	46
	All	1,232	37
2 years & above	All	13,858	31
16-44 years	F	3,178	52

b. New Zealand

Population Group	Gender	No. of Respondents	Proportion of population group with estimated naturally occurring folate intakes < EAR (%)
15-18 years	M	109	87
	F	137	99
	All	246	94
19-29 years	M	286	85
	F	518	98
	All	804	93
30-49 years	M	787	82
	F	1,096	96
	All	1,883	90
50-69 years	M	538	87
	F	609	93
	All	1,147	91
70 years & above	M	207	96
	F	349	97
	All	556	97
15 years & above	All	4,636	92
16-44 years	F	1,509	97

Table A3.2: Proportion of the Australian and New Zealand populations with estimated dietary folate intakes below the EAR at Baseline and Mandatory Fortification

a. Australia

Population Group	**Gender**	**No. of Respondents**	**Proportion of population group with estimated dietary folate intakes < EAR (%)**	
			Baseline	***Mandatory Fortification***
2-3 years	M	170	0	0
	F	213	0	0
	All	383	0	0
4-8 years	M	513	0	0
	F	464	0	0
	All	977	0	0
9-13 years	M	474	0	0
	F	439	<1	0
	All	913	<1	0
14-18 years	M	378	<1	0
	F	356	8	0
	All	734	4	0
19-29 years	M	1,014	<1	0
	F	1,189	5	0
	All	2,203	3	0
30-49 years	M	2,080	4	<1
	F	2,317	16	3
	All	4,397	10	2
50-69 years	M	1,442	5	<1
	F	1,577	17	2
	All	3,019	11	2
70 years & above	M	545	3	<1
	F	687	16	2
	All	1,232	10	1
2 years & above	All	13,858	7	1
16-44 years	F	3,178	11	2

b. New Zealand

Population Group	Gender	No. of Respondents	Proportion of population group with estimated dietary folate intakes < EAR (%)	
			Baseline	*Mandatory Fortification*
15-18 years	M	109	6	0
	F	137	71	7
	All	246	42	4
19-29 years	M	286	3	0
	F	518	70	8
	All	804	46	5
30-49 years	M	787	31	<1
	F	1,096	63	9
	All	1,883	50	6
50-69 years	M	538	41	<1
	F	609	58	5
	All	1,147	50	3
70 years & above	M	207	52	0
	F	349	60	3
	All	556	57	2
15 years & above	All	4,636	50	4
16-44 years	F	1,509	66	9

Attachment 8

MANDATORY FOLIC ACID FORTIFICATION

COMMUNICATION AND EDUCATION STRATEGY

April 2007

Introduction

Food Standards Australia New Zealand (FSANZ) has prepared this strategy, in consultation with the Government Food Communicators' Group, to guide our communication and education initiatives to raise awareness and understanding of the proposed standard for mandatory folic acid fortification and its implementation. The proposed standard aims to reduce the incidence of neural tube defects (NTDs) in Australia and New Zealand through mandatory fortification of the food supply with folic acid.

We recognise that optimal reduction in NTDs relies on implementation of a range of strategies which are beyond our regulatory role, including promotion of increased folic acid intakes in women of child-bearing age through education, voluntary fortification and supplement use.

To implement this strategy, we will collaborate with our State and Territory regulatory partners and other agencies to provide information and education to consumers, industry and other key stakeholders. This collaborative approach will increase public awareness of the proposed standard and fortification issues, ensure consistency of information, and maximise the effectiveness of available resources.

Low key campaigns such as this that have been carried out previously with our partners and other agencies have had considerable success in reaching audience, for example Listeria advice, Mercury in Fish advice and Food Safety Week activities.

Note that this communication strategy has been prepared to accompany the proposed mandatory fortification of bread in Australia and New Zealand. If mandatory fortification does proceed, health promotion and education strategies related to existing strategies to reduce NTDs, such as voluntary fortification and supplement use, will continue to be important.

Previous education and communication activity

In Australia, various education campaigns have been undertaken by a number of jurisdictions to encourage women of child-bearing age to increase their dietary folate and/or take folic acid supplements. Between 1994 and 1999, three national health promotion campaigns were implemented along with State-based campaigns in five jurisdictions. In New Zealand, there have been no publicly funded awareness campaigns regarding folate and women of child-bearing age (NZMoH 2003).

These health campaigns targeted women of child-bearing age and health professionals, and aimed to increase awareness of the association between folic acid and NTDs, promote dietary sources of naturally-occurring folate and folic acid supplements, and increase folate intake. Most of the campaigns promoted increased consumption of folate rich foods as well as folic acid supplementation.

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: a large percentage of pregnancies are unplanned (estimated to be more than 40-45% of all pregnancies); lack of knowledge among women about the benefits of folic acid; knowledge does not always equate to behavioural change; and there are many barriers to supplement usage, such as cost, access, and compliance issues.

Since 1995 in Australia and 1996 in New Zealand, certain foods have been able to be voluntarily fortified with folic acid. Despite this, total folic acid intakes in women of child-bearing age are still below recommended intakes of 400 micrograms per day.

Consumer research

In understanding the impacts on, and responses of, consumers regarding mandatory fortification, we have drawn upon relevant consumer studies and literature.

Some of the key issues are highlighted below:

- Consumer research has found varying levels of support for mandatory fortification.

- Previous exposure to mandatory fortification is also likely to impact on the level of support for such measures.

- Unlike some other nutrient disease relationships, awareness and understanding of the link between folic acid and NTDs among the general community is low.

- A range of psycho-social and demographic variables influence health-related attitudes to food. Accordingly the response to mandatory folic acid fortification is unlikely to be uniform, but rather will be mediated by the particular circumstances of individuals and the communities within which they live.

Strategic approach

Strategic Rationale

Mandatory folic acid fortification is a contentious issue, and views vary widely. While the scientific evidence linking folic acid to reduced incidence of NTDs is convincing, mandating fortification of the food supply has raised questions about the perceived risks versus the benefits.

Consumers need to know that the proposed standard is based on good science, and that the safety of the food supply is paramount. They need access to print and electronic education materials.

Consumer education activities should address the needs of Indigenous populations, people from non-English speaking backgrounds and those for health and cultural reasons do not consume bread.

Key stakeholders need to be informed about progress with development and implementation of the standard at regular intervals.

Health professionals need information to support consumers. They rely on a range of trusted sources, including medical/scientific journals, professional newsletters and electronic bulletin boards. They need access to print materials supplied for their dissemination, including consumer education materials.

The food industry needs information on the proposed standard to ensure compliance with the proposed standard, and access to timely, accurate advice, provided through jurisdictions and the FSANZ Advice Line.

Consumers and industry look to the media for responsible, accurate and reliable reporting of the facts. The media needs timely, accurate information about the proposed standard and its implementation.

Aim

This strategy aims to increase awareness among all target audiences of the proposed standard for mandatory folic acid fortification.

Target audiences

We have identified six target audiences for the strategy.

- Consumers, particularly women of child-bearing age and especially those who for health and cultural reasons may not consume bread.

- Industry, including the milling industry responsible for the mandatory fortification of bread making flour, manufacturers who currently have permissions to voluntarily fortify their product(s) with folic acid, manufacturers who wish to obtain further permissions to voluntarily fortify their product(s) with folic acid, importers and exporters.

- Health professionals, including those whose advice on dietary and nutrition issues is sought by consumers (obstetricians and gynaecologists, midwives, dietitians, nutritionists, general practitioners, complementary healthcare practitioners, pharmacists).

- The Governments of Australia and New Zealand, plus the State and Territory Governments who are responsible for monitoring, enforcement and education of the food standards.

- The media, which plays an important role in explaining complex regulatory issues through regular reports to consumers and industry.

- Internal stakeholders, including members of the Fortification Standards Development Advisory Committee and their networks, FSANZ staff involved in the development of the standard, and the FSANZ Board.

Key messages

For all target audiences, key messages must be recognisable as coming from a knowledgeable, authoritative source. The key messages must also reflect the needs and expectations of the different target audiences, present an accurate and balanced perspective on the issues, and avoid creating undue alarm.

<u>Main messages for all target audiences</u>

About mandatory folic acid fortification

- It is estimated that between 300 and 350 pregnancies in Australia and approximately 70-75 pregnancies in New Zealand year are affected by neural tube defects (NTDs) each year.
- The proposed standard mandates folic acid fortification of all wheat bread making flour to reduce NTDs.
- The proposed standard is based on the best available scientific evidence.
- NTDs are severe congenital malformations of the central nervous system and result from the failure of the neural tube to close during early embryonic development. The two major types of NTDs are anencephaly and spina bifida.
- Folic acid is a B group vitamin that is needed for healthy growth and development. This vitamin is known as folate when it is found naturally in food, such a green leafy vegetables, and as folic acid when it is added to food, such as bread and breakfast cereals, or used in dietary supplements.
- Folic acid is important for everyone but is especially important for women of child-bearing age particularly those planning a pregnancy. There is convincing evidence that folic acid taken at least one month before pregnancy and for the first three months of pregnancy will substantially reduce the risk of NTDs.
- Women of child bearing age are advised to take consume 400 micrograms of folic acid a day, as supplements and fortified foods to minimise the risk of their unborn child being affected by a NTD . These recommendations are in addition to the normal diet which contains naturally-occurring folate.
- Women who have a family history of NTDs like spina bifida should check with a health professional before becoming pregnant, as they may need even higher amounts of folic acid.
- Women who do not eat bread, for example because they are gluten intolerant or come for a culture where rice may be a staple, or who eat ‘organic’ bread (which is proposed to be exempted form mandatory fortification) must be particularly vigilant about taking folic acid supplements if there is a possibility they may become pregnant.

About FSANZ and its role

- We ensure safe food by developing effective food standards for Australia and New Zealand.
- We base our decisions on the rigorous scientific assessment of any risk to public health and safety.
- We are only one part of a strong food regulatory partnership between governments at all levels in Australia and New Zealand.

- We develop the food standards with advice from the jurisdictions, input from stakeholders and consistent with food regulatory policies endorsed by the Australia and New Zealand Food Regulation Ministerial Council.
- Our decisions are open and accountable and we welcome participation from consumers, the food industry, food producers, and health professionals about the most appropriate way to protect public health and safety and to provide consumers with accurate information about food.
- In Australia, we cover the whole food supply chain from primary production through to manufactured food and retail establishments.
- Other government agencies in the Australian states and territories, as well as in New Zealand, enforce these standards.

<u>Ancillary messages</u>

Consumers and the media

- The cost to consumers of mandatory folic acid fortification is likely to be small, probably up to 1% of the price of a loaf of bread.
- The presence of folic acid in bread and bread products must be identified in ingredient labelling.

Industry

- Industry has been consulted in developing the proposed standard.
- The proposed level of mandatory fortification is 200- 300 micrograms of folic acid per 100 grams of wheat bread-making flour, to achieve an average residual level of approximately 200 micrograms folic acid in the flour component of the final food. Or in New Zealand bread may be fortified at 80 – 180 micrograms per 100 grams of bread.
- Ingredient labelling will identify the presence of folic acid in bread and bread products.
- The approach maintains current voluntary folic acid fortification permissions.

Health professionals

- Consumers trust health professionals above all others for information about the health benefits of foods.
- Health professionals play an important role in communicating with and educating consumers about food issues.

Governments of Australia and New Zealand, and internal stakeholders

- Governments play a pivotal role in monitoring, enforcement and education of the food regulatory system.
- Consumers and industry need access to accurate, timely information about the proposed standard and its implementation.

Action plan

This strategy will be implemented on the anticipated gazettal of the proposed standard and finalisation of the transition arrangements for industry. FSANZ will work closely with the New Zealand Food Safety Authority to address specific communication needs in New Zealand.

1. Collaborate with other agencies responsible for education/health promotion initiatives relating to mandatory folic acid fortification.
2. Work with health and medical agencies to get advice about folic acid supplements on GP's lifestyle scripts for women planning pregnancy.
3. Update and launch our fact sheets and associated information materials for consumers and industry.
4. Develop and implement a consumer Quiz for access via the FSANZ website to promote awareness of the standard. Conduct this activity in association with our partners and with expert input. Review the quiz as necessary, in association with our partners and with expert input.
5. In collaboration with our partners, promote and disseminate our updated consumer education materials along with any new consumer education materials.
6. Maintain our website linkage strategy.
7. Continue to provide ongoing support to our key spokespeople.
8. Promote and disseminate information materials for use by industry, jurisdictions and the FSANZ Advice Line.
9. Continue to provide editorial and well-researched articles about the proposed standard for publication in key stakeholder publications.
10. Continue to conduct interviews with mainstream and specialist media.
11. Continue to promote discussion of the proposed standard and its implementation via talkback radio.
12. Implement display material at conferences, seminars and meetings.
13. Continue to participate in workshops, briefings, and other consultative as appropriate.
14. Prepare and submit final report on activities to the FSANZ Board.

Evaluation

We will monitor the implementation of this strategy as part of the overall monitoring and evaluation of the standard.

Responsibility for establishing and funding a monitoring system to assess the impact of mandatory fortification on the population is 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. Monitoring will provide a means of gauging both the ongoing effectiveness and safety of mandatory folic acid fortification, particularly in further reducing the incidence of NTDs.