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DRAFT ASSESSMENT REPORT

PROPOSAL P295

CONSIDERATION OF MANDATORY FORTIFICATION WITH FOLIC ACID

Attachments 7, 8, 9 10 and 12

Methodology and Results of Dietary Modelling

CONTENTS

EXECUTIVE SUMMARY

A dietary intake assessment was conducted to assess the potential impact the introduction of mandatory fortification of food with folic acid in Australia and New Zealand would have on:

- folic acid intakes among the target group, women of child-bearing age; and
- folic acid intakes among the general population

The aim was to determine a level of fortification that maximised folic acid intake for the target group to assist in achieving their recommended intake of 400 μg of folic acid a day, whilst preventing a significant proportion of people in the target and non-target groups exceeding upper safe levels 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 for easy comparison of estimated folic acid intakes against the upper levels of intake. Two dietary intake assessments for women of child bearing age were considered, folic acid intakes from food alone and folic acid intakes from food and supplement use.

In considering mandatory fortification of food with folic acid, bread making flour was selected as the food vehicle, based on a high percentage of women of child-bearing age consuming products containing bread-making flour and international experience. Bread-making flour was assumed to be 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 and crumbed products. Two scenarios were assessed as the potential vehicles for providing added folic acid from foods: all wheat bread-making flour (white and wholemeal) and white wheat bread-making flour only.

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

- current folic acid intakes from food alone (**Baseline**) based on the current uptake by industry of voluntary folic acid permissions outlined in Standard 1.3.2 of the *Australia New Zealand Food Standards Code* (the Code) for each relevant food category;
- folic acid intakes from food alone for 'Baseline' (except bread) and the introduction of mandatory fortification of all bread-making flour at 100 μg, 200 μg and 300 μg of folic acid per 100 g of bread-making flour (**Scenario 1**[1]); and
- folic acid intakes from 'Baseline' (except bread) and the introduction of mandatory fortification of white bread-making flour at 100 μg, 200 μg and 300 μg of folic acid per 100 g of bread-making flour (**Scenario 2**).

[1] All estimated dietary folic acid intakes reported are based on the assumption that the calculated folic acid concentration in the fortified product relates to a final folic acid concentration of 100 μg, 200 μg or 300 μg in the bread making flour component of each product. Losses in folic acid due to cooking and storage were not considered here but will be taken into account in setting the permission to add folic acid to bread making flour. For example, the permitted amount of folic acid in bread making flour may need to be higher than 200 μg/100g to allow for these losses and still achieve the desired folic acid level based on 200 μg/100g in the bread making flour component of the final product.

These dietary modelling scenarios did not take into account naturally occurring folates in food or folic acid from folic acid supplements or multivitamins containing folic acid.

The dietary modelling results indicated that fortification up to 200 µg folic acid/100g bread making flour maximised folic acid intakes from food for the target group without resulting in undesirably high levels of folic acid intake for the general population. Specifically it should be noted that:

- Current folic acid intake from food by the target group is low.
- New Zealand has lower baseline folic acid intakes from food for all age groups considered due to a lower level of uptake of voluntary folic acid permissions by industry.
- The introduction of mandatory fortification of all bread-making flour or white bread-making flour resulted in an increase in mean folic acid intakes for each population group assessed, which increased further as the amount of folic acid added to bread-making flour increased.
- Despite these increases folic acid intakes from food for the target group are still well below the recommended 400 µg per day.
- The selection of either all bread-making flour or white bread-making flour makes only a modest difference in mean folic acid intakes for the target group.
- Children aged 2-8 years are the most likely population group to exceed the upper level if mandatory fortification of either all bread-making flour or white bread-making flour were to be introduced, with the greatest number exceeding the UL when 300 µg of folic acid/100g is added to bread making flour.
- At the fortification levels modelled, only a small proportion of respondents exceeded the UL for all other Australian and New Zealand population groups assessed (including the target group).

The dietary modelling detailed above only considered folic acid added to food. Additional calculations were made to account for the possibility that both Australian and New Zealand women of child-bearing age may receive additional folic acid from supplements. These calculations assumed women of child-bearing age received an additional 200 µg or 500 µg of folic acid a day from supplements in Australia, and an additional 200 µg or 800 µg of folic acid a day from supplements in New Zealand, based on current supplement use and the recommended amount in each country.

Women of child-bearing age would receive the recommended 400 µg of folic acid a day when mandatory fortification of all bread-making flour occurs at 200 µg of folic acid per 100 g of bread-making flour and an additional 200 µg of folic acid from a supplement is taken. The additional folic acid from supplements does not result in intakes over the Upper Level, except for New Zealand women of child-bearing age who consumed an additional 800 µg of folic acid from supplements.

1. Dietary Modelling conducted to estimate folic acid intake from food only

1.1 What is dietary modelling?

Dietary modelling is a tool used to estimate intakes of food chemicals from the diet as part of the FSANZ risk assessment process. To estimate dietary intake of food chemicals records of what foods people have eaten are needed and reports of how much of the food chemical of interest is in each food. The accuracy of these intake estimates depend on the quality of the data used in the dietary models. Sometimes all the data needed are not available or the accuracy is uncertain so assumptions have to be made, either about the foods eaten or about chemical levels, based on previous knowledge and experience. The models are generally set up according to international conventions for food chemical intake estimates, however, each modelling process requires decisions to be made about how to set the model up and what assumptions to make; a different decision may result in a different answer. Therefore, FSANZ documents clearly all such decisions, model assumptions and data limitations to enable the results to be understood in the context of the data available and so that FSANZ risk managers can make informed decisions.

1.2 Dietary modelling approach

The dietary intake assessment discussed in this attachment was conducted using FSANZ's dietary modelling computer program, DIAMOND.

Dietary Intake = food chemical concentration x food consumption

The intake was estimated by combining usual patterns of food consumption, as derived from NNS data, with current levels of fortification based on the uptake of voluntary fortification permissions by industry and proposed levels of folic acid in foods if mandatory folic acid fortification is introduced (see Figure 1 for an overview of the dietary modelling approach). More details of each step in the process are given below.

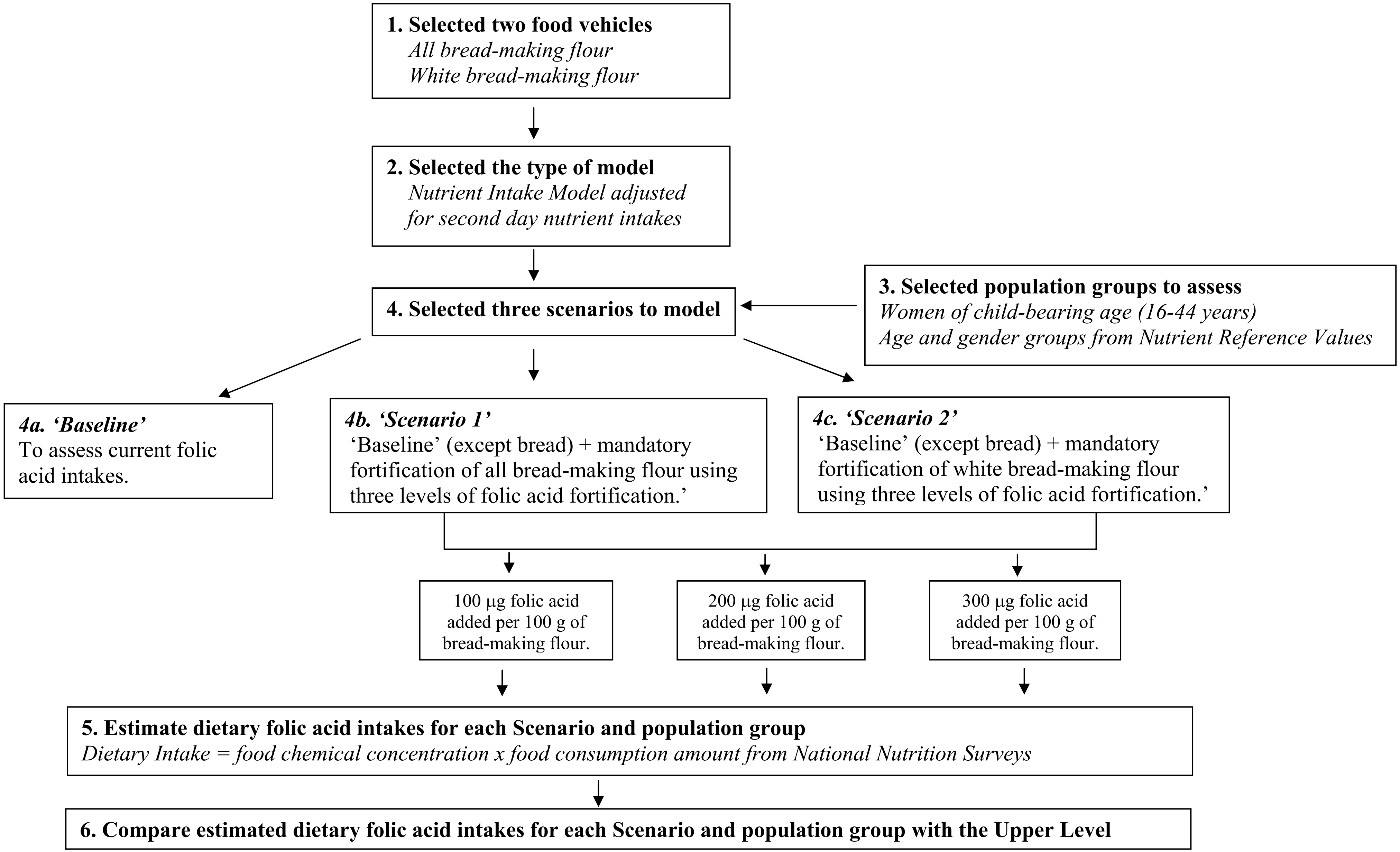
1.3 Dietary survey data

DIAMOND contains dietary survey data for both Australia and New Zealand; the 1995 NNS from Australia that surveyed 13,858 people aged 2 years and above, and the 1997 New Zealand NNS that surveyed 4,636 people aged 15 years and above.

Both of these surveys used a 24-hour food recall methodology. A second 24-hour recall was also collected on a subset of respondents in both surveys. Standard methodologies were used to estimate intake from a single 24 hour record (day one) and to adjust these records to estimate 'usual intake' by including information from a second 24 hour record (day two) (see Appendix 1*: How were the estimated dietary intakes estimated*).

It is recognised that these survey data have several limitations. For a complete list of limitations see section 5*: Limitations*.

Figure 1: Dietary Modelling approach used for assessing folic acid intakes from food for Australia and New Zealand



1.4 Population groups assessed

The dietary intake assessment was conducted separately for Australia and New Zealand population sub-groups.

Females 16-44 years were assessed for both Australia and New Zealand to determine the impact of mandatory fortification in the target group, women of child-bearing age. The NHMRC Nutrient Reference Values for Australia and New Zealand (NRVs) (NHMRC 2006) was used as a guide in selecting the other age groups to assess. As different NRVs were given to different age and gender groups for folate, conducting the dietary modelling 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: the whole population 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, all split by gender. The New Zealand NNS was conducted on people aged 15 years and above so the following age groups were also assessed: the whole population 15 years and above, 15-18 years 19-29 years, 30-49 years, 50-69 years and 70 years and above, all split by gender.

1.5 Food vehicle

In considering mandatory fortification with folic acid, all wheat bread-making flour and white wheat bread-making flour were selected as the potential 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. According to the NNSs, approximately 83% of Australian and 81% of New Zealand women of child-bearing age are likely to consume bread-based foods containing bread-making flour. White wheat bread-making flour was investigated to allow for consumer choice should they wish to avoid added folic acid in foods by selecting other types of products containing bread-making flour.

In practical terms, bread-making flour was also considered a feasible option due to the existing mandatory fortification permissions of these products with thiamin in Australia and it is consistent with international experience and the way mandatory folic acid fortification has been introduced in other countries, particularly the United States, Canada and more recently the United Kingdom.

To determine the range of foods that would be likely to contain added folic acid it was therefore necessary to determine which foods contain bread-making flour. In Australia, flour for 'bread-making' must contain added thiamin. For the purposes of dietary modelling, foods were assumed to contain bread-making flour if Australian products were labelled as containing added thiamin (see Figure 2). Breakfast cereals, although often contain added thiamin, were not considered to be made from bread-making flour.

Figure 2: Definition of all bread-making flour and white bread-making flour for dietary modelling purposes

All bread-making flour: 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 and crumbed products.

White bread-making flour: includes all white 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 and crumbed products.

1.6 Scenarios and folic acid concentration data

Three scenarios were modelled for the purpose of this Proposal.

1. '**Baseline**' to estimate current folic acid intakes from food alone based on current uptake of voluntary folic acid permissions by industry;
2. '**Scenario 1**' to estimate folic acid intakes from food alone from 'Baseline' (except bread) and the introduction of mandatory fortification of all bread-making flour at 100 μg, 200 μg and 300 μg of folic acid per 100 g of bread-making flour; and
3. '**Scenario 2**' to estimate folic acid intakes from food alone from 'Baseline' (except bread) and the introduction of mandatory fortification of white bread-making flour at 100 μg, 200 μg and 300 μg of folic acid per 100 g of bread-making flour.

The calculations based on these scenarios assume the introduction of mandatory folic acid fortification 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 and rye breads. These calculations do not take into account naturally occurring folates from the diet or folic acid from supplement intake.

All estimated dietary folic acid intakes reported are based on the assumption that the calculated folic acid concentration in the fortified product relates to a final folic acid concentration of 100 μg, 200 μg or 300 μg in the bread making flour component of each product. Losses in folic acid due to cooking and storage were not considered here but will be taken into account in setting the permission to add folic acid to bread making flour. For example, the permitted amount of folic acid in bread making flour may need to be higher than 200 μg/100g to allow for these losses and still achieve the desired folic acid level based on 200 μg/100g in the bread making flour component of the final product.

'Baseline'

This model 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 model only considers where voluntary folic acid permissions outlined in Standard 1.3.2 of the *Australia New Zealand Food Standards Code* (the Code) have been taken up by industry, as evidenced by products available on the supermarket shelves.

It does not include all 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;
- 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).

Information from these four sources was matched against the 1995 and 1997 Australian and New Zealand NNS food codes for all those foods identified as being fortified with folic acid (149/4550 foods in Australia and 101/4950 foods in New Zealand). All other foods recorded as being consumed were assumed not to contain added folic acid. For a list of foods assumed to currently contain added folic acid see Table 3A.1 for Australia and Table 3A.2 for New Zealand in Appendix 3.

For foods where a fortified version of the food was not specifically identified within the NNS, but where it is known that a significant proportion of the food category in the market place is now fortified, a folic acid concentration was assigned to the food, and weighted to reflect the proportion of the market for that food that is now believed to be fortified. For example, the Australian NNS does not distinguish consumption of folic acid fortified white bread from regular 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. A value representing 15% 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.

'Scenario 1 – mandatory folic acid fortification of all bread-making flour'

This model was conducted to estimate dietary folic acid intakes for each population group where mandatory folic acid fortification of all bread-making flour (wheat only) is permitted in Australia and New Zealand at 100 μg, 200 μg or 300 μg per 100 g of bread-making flour.

This model assumes that the introduction of mandatory folic acid fortification of all bread-making flour 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 and rye breads.

Therefore, this model includes 'Baseline' folic acid concentrations for all foods other than bread, and folic acid concentrations for bread and bread products assumed to contain bread-making flour as a result of mandatory folic acid fortification of all bread-making flour at 100 μg, 200 μg or 300 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 bread-making flour a food contains and on the final concentration of folic acid assumed to be delivered in the bread-making flour. For example for white bread, the folic acid concentrations were calculated as follows:

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

These estimates do not take into account potential losses of folic acid during cooking and storage[1]. Proportions of bread-making flour 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.

For a summary of folic acid concentration data used for 'Scenario 1' see Table 3A.1 for Australia and Table 3A.2 for New Zealand in Appendix 3.

'Scenario 2 – mandatory folic acid fortification of white bread-making flour'

This model was conducted to estimate dietary folic acid intakes for each population group where mandatory folic acid fortification of white bread-making flour (wheat only) is permitted in Australia and New Zealand at 100 μg, 200 μg or 300 μg per 100 g of white bread-making flour.

As for Scenario 1, this model assumes that the introduction of mandatory folic acid fortification of white bread-making flour 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 and rye breads.

Therefore, this model includes 'Baseline' folic acid concentrations for all foods other than bread, and folic acid concentrations for bread and bread products assumed to contain white bread-making flour as a result of mandatory folic acid fortification of white bread-making flour at 100 μg, 200 μg and 300 μg per 100 g of white bread-making flour[1].

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 as for 'Scenario 1' above.

1.7 How were the estimated dietary folic acid intakes calculated?

A detailed explanation of how the estimated dietary exposures are calculated can be found in Appendix 1.

2. Assumptions used in the dietary modelling

The aim of the dietary intake assessment is to make as realistic an estimate of dietary folic acid intake 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 modelling are listed below, broken down into several categories.

Consumer behaviour

- Consumption of foods as recorded in the NNS represent current food consumption amounts;
- the dietary patterns for females aged 16-44 years are representative of the dietary patterns for pregnant women;
- consumers always select products containing folic acid at the concentrations specified; and
- consumers have altered their food consumption habits compared to the NNS records to reflect the proportions of fortified and non-fortified products currently available within certain food categories.

Concentration Data

- Naturally occurring sources of folate have not been included in the dietary intake assessment;
- where there were no Australian folic acid concentration data for specific foods, it was assumed that New Zealand data were representative of these food groups, and vice versa for New Zealand;
- where a food was not included in the intake assessment, it was assumed to contain a zero concentration of folic acid;
- a market share weighted folic acid value is assigned to food categories with voluntarily permissions to fortify to reflect the proportion of products that have been fortified or where possible, a analyses or label folic acid concentration is assigned to individual foods using up to date food composition data; and
- there is no contribution to folic acid intake through the use of complementary medicines (Australia) or dietary supplements (New Zealand) for 'Baseline', 'Scenario 1' and 'Scenario 2' models.

Food Vehicles

- Bread-making flour was assumed to be used as an ingredient in all plain, fancy, sweet, and flat breads and bread rolls, English muffins, crumpets, scones, pancakes, pikelets, crepes, yeast donuts, pizza bases and crumbed products;

- bread-making flour was assumed not to include folic acid where the flour was used as a coating on food such as on the top of a take-away bun or to batter fish;
- only white bread-making flour was assumed to be used to make crumbed products;
- grain breads were assumed to contain white bread-making flour only (grains are added as a separate ingredient);
- sandwiches, hamburgers and pizzas were assumed to be made from white bread-making flour unless wholemeal was specifically stated;
- for Australia, wholemeal breads and bread rolls (including fruit and topped), wholemeal bagels, wholemeal muffins, wholemeal flat breads and wholemeal pancakes were assumed to contain wholemeal flour only and were therefore not assigned a folic acid concentration in Scenario 2 models;
- for Australia, rye, black and pumpernickel breads, wholemeal crumpets and wholemeal scones were assumed to contain both white and wholemeal flour and were therefore assigned a folic acid concentration for the white bread-making flour component only in Scenario 2 models;
- for New Zealand wholemeal pita bread and wholemeal scones were assumed to contain wholemeal flour only and these foods were therefore not assigned a folic acid concentration in Scenario 2 models; and
- for New Zealand wholemeal breads and bread rolls (including fruit and topped), rye and pumpernickel breads, wholemeal bagels, wholemeal muffins and wholemeal sandwiches were assumed to contain both white and wholemeal flour and were therefore assigned a folic acid concentration for the white bread-making flour component only in Scenario 2 models.

General

- All folic acid present in food is absorbed by the body;
- there are no reductions in folic acid concentrations from cooking and storage[1]; and
- for the purpose of this assessment, it is assumed that 1 millilitre is equal to 1 gram for all liquid and semi-liquid foods (e.g. orange juice).

3. Estimated dietary folic acid intakes from folic acid added to food only

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

All estimated dietary folic acid intakes in this Attachment are based on ‘residual’ folic acid, i.e. the amount consumed. The amount that must be added to the raw ingredients to allow for cooking and storage losses will be considered in a different part of the Draft Assessment Report (see Section 2).

3.1 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 3A for 'Baseline' and 'Scenario 1 – mandatory folic acid fortification of all bread-making flour' models and Figure 3B for 'Baseline' and 'Scenario 2 – mandatory folic acid fortification of white bread-making flour' models. The incremental increase in folic acid intake from 'Baseline' is also shown in Table 2. Full results can be found in Table A4.1 and Table A4.4 in Appendix 4.

These results show an increase in estimated dietary folic acid intakes from baseline for both 'Scenario 1- mandatory folic acid fortification of all bread-making flour' and 'Scenario 2 - mandatory folic acid fortification of white bread-making flour'. Further increases in estimated dietary folic acid intakes can be seen in each scenario model as the amount of folic acid added to all bread-making flour or white bread-making flour increases from 100 μg of folic acid per 100 g of bread-making flour to 300 μg of folic acid per 100 g of bread-making flour. The selection of either all bread-making flour or white bread-making flour makes only a modest difference in the overall increase in estimated mean folic acid intakes from 'Baseline' intakes. Estimated folic acid 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 models.

These results also indicate New Zealand women of child-bearing age have lower baseline folic acid intakes and therefore larger incremental increases in intake compared to the same population group for Australia. This is because of the lower baseline folic acid intakes in New Zealand due to fewer voluntary folic acid permissions take up by industry.

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

Model	Added Folic Acid in bread making flour (μg/100g)	Mean folic acid intake (μg/day)	
		Australia	New Zealand
'Baseline'		95	58
'Scenario 1'			
All bread making flour	100	135	123
	200	195	189
	300	254	254
'Scenario 2'			
All white bread making flour	100	125	115
	200	175	173
	300	225	231

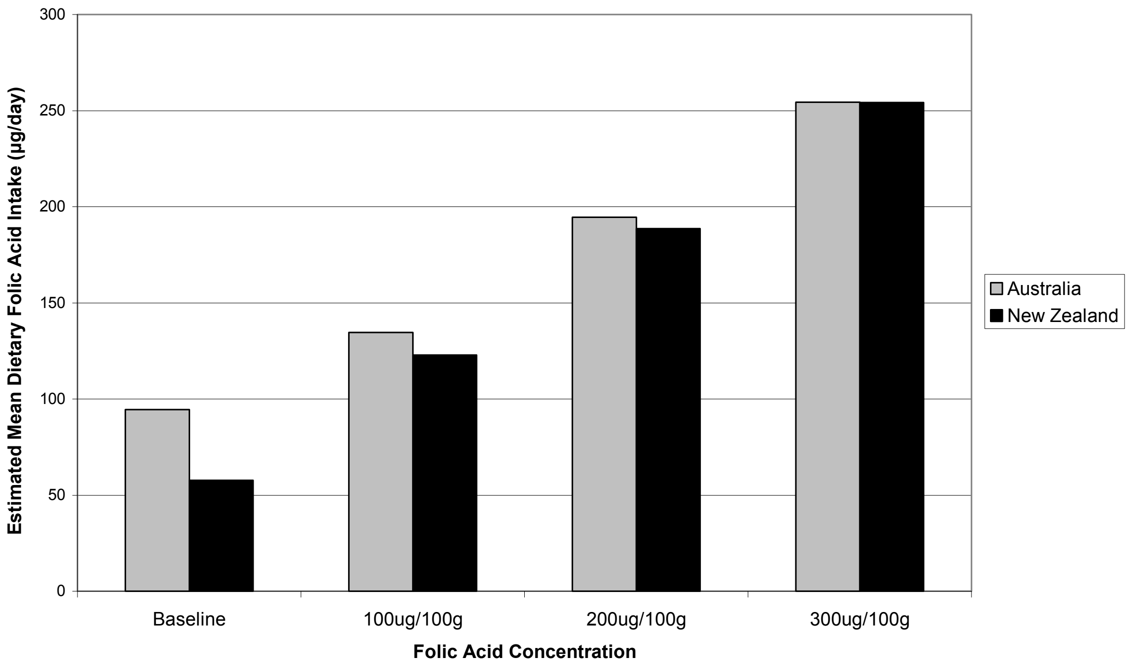
Table 2: Actual increase in folic acid intake for women of child-bearing age* due to the introduction of mandatory folic acid fortification of all bread-making flour and white bread-making flour

Model	Added Folic Acid in bread making flour (μg/100g)	Increase in folic acid intake from 'Baseline' (μg/day)	
		Australia	New Zealand
'Scenario 1'			
All bread making flour	100	+40	+65
	200	+100	+131
	300	+159	+196
'Scenario 2'			
All white bread making flour	100	+30	+57
	200	+80	+115
	300	+130	+173

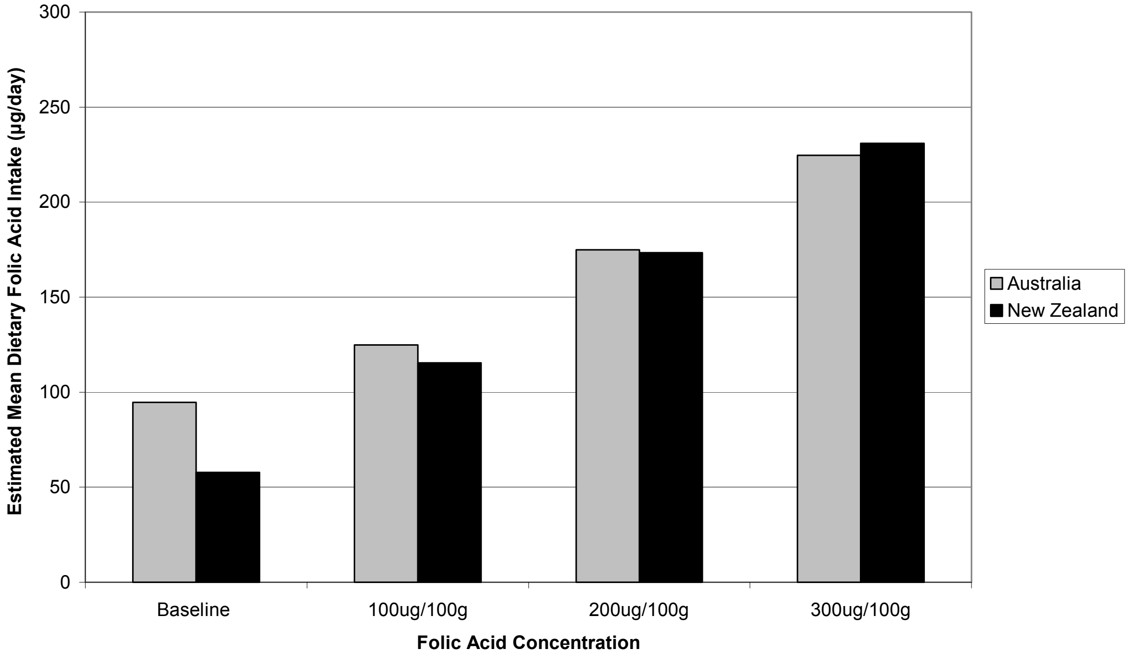
* All women aged 16-44 years

Figure 3: Estimated mean dietary folic acid intakes for 'Baseline' and both Scenario assessments for Australian and New Zealand women of child-bearing age (16-44 years)

A: 'Scenario 1 – mandatory fortification of all bread-making flour'



B: 'Scenario 2 – mandatory fortification of white bread-making flour'



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

Dietary folic acid intakes were estimated for the non-target groups to assess the impact 'Scenario 1 - mandatory folic acid fortification of all bread-making flour' and 'Scenario 2 – mandatory folic acid fortification of white bread-making flour' at various folic acid concentrations would have on public health and safety.

Full results for the estimated dietary folic acid intakes of these Australian and New Zealand non-target groups can be found in Table A4.2, Table A4.3, Table A4.5 and Table A4.6 in Appendix 4.

These results show an increase in estimated dietary folic acid intakes for both 'Scenario 1- mandatory folic acid fortification of all bread-making flour' and 'Scenario 2 - mandatory folic acid fortification of white bread-making flour'. As expected, increases in estimated dietary folic acid intakes can be seen for each scenario model as the amount of folic acid added to all bread-making flour and white bread-making flour increases from 100 µg to 300 µg of folic acid per 100 g or bread-making flour.

As for women of child-bearing age, non-target groups in New Zealand also have lower baseline folic acid intakes compared to Australia. This could by explained due to the assumption that voluntary folic acid fortification of breads is not as common in New Zealand as in Australia.

3.3 Comparison of the estimated dietary intakes with the Upper Level

In order to determine if the proposed level of addition of folic acid to bread making flour will be a public health and safety concern, the estimated folic acid dietary intakes were compared with the NRV called an Upper Level (UL).

The UL is 'the highest average daily intake level of a nutrient that is likely to pose no risk of adverse health effects to almost all individuals in the general population' (Institute of Medicine 1998).

The estimated dietary intakes for folic acid were determined for each individual and were compared to the relevant UL for their age group and gender. The proportion of each population group exceeding the UL are shown in Table 3A for 'Baseline' and 'Scenario 1 – mandatory folic acid fortification of all bread-making flour' and Table 3B for 'Baseline' and 'Scenario 2 – mandatory folic acid fortification of white bread-making flour' for the Australian and New Zealand non-target groups assessed. The proportion of the target group exceeding the UL is shown in Table 4. Full results can be found in Table A5.1 to Table A5.6 of Appendix 5.

Table 3: Per cent of Australian and New Zealand 'Baseline' and both Scenario respondents with folic acid intakes above the Upper Level

A: 'Baseline' and 'Scenario 1 – mandatory fortification of all bread-making flour'

Country	Population Group	Upper Level (μg/day)	No. of respondents	Baseline (% > UL)	Scenario 1: Mandatory folic acid fortification of all bread-making flour (% > UL)		
					100μg/100g	200μg/100g	300μg/100g
Australia	2-3 years	300	383	1	2	6	20
	4-8 years	400	977	0.6	1	3	9
	9-13 years	600	913	0.8	1	2	3
	14-18 years	800	734	0.5	0.8	2	3
	19-29 years	1000	2,203	0.2	0.4	0.6	1
	30-49 years	1000	4,397	0.3	0.3	0.3	0.5
	50-69 years	1000	3,019	0.1	0.2	0.2	0.3
	70+ years	1000	1,232	0	0	0	0.1
New Zealand*	15-18 years	800	246	0	0	0.4	0.8
	19-29 years	1000	804	0	0	0	0.1
	30-49 years	1000	1,883	0.1	0.1	0.1	0.3
	50-69 years	1000	1,147	0	0	0.1	0.3
	70+ years	1000	556	0	0	0	0

* Data for New Zealand children 2-14 years were not available

B: 'Baseline' and 'Scenario 2 – mandatory fortification of white bread-making flour'

	Population Group	Upper Level (μg/day)	No. of respondents	Baseline (% > UL)	Scenario 2: Mandatory folic acid fortification of white bread making flour (% > UL)		
					100μg/100g	200μg/100g	300μg/100g
Australia	2-3 yrs	300	383	1	2	5	15
	4-8 yrs	400	977	0.6	1	3	8
	9-13 yrs	600	913	0.8	1	2	3
	14-18 yrs	800	734	0.5	0.8	1	2
	19-29 yrs	1000	2,203	0.2	0.3	0.5	0.9
	30-49 yrs	1000	4,397	0.3	0.3	0.3	0.4
	50-69 yrs	1000	3,019	0.1	0.1	0.1	0.2
	70+ yrs	1000	1,232	0	0	0	0
New Zealand*	15-18 yrs	800	246	0	0	0	0.8
	19-29 yrs	1000	804	0	0	0	0
	30-49 yrs	1000	1,883	0.1	0.1	0.1	0.2
	50-69 yrs	1000	1,147	0	0	0.1	0.1
	70+ yrs	1000	556	0	0	0	0

* Data for New Zealand children 2-14 years were not available

Table 4: Per cent of respondents with folic acid intakes above the Upper Level for Australian and New Zealand women of child-bearing age

* All females aged 16-44 years

Model	Added Folic Acid in bread making flour (μg/100g)	Per cent above the UL	
		Australia	New Zealand
Baseline		0.2	0.1
'Scenario 1'			
All bread making flour	100	0.2	0.1
	200	0.2	0.1
	300	0.2	0.2
'Scenario 2'			
All white bread making flour	100	0.2	0.1
	200	0.1	0.1
	300	0.2	0.2

For Australia, the results indicate children 2-3 years and children 4-8 years are the most likely of the non-target groups to have people exceed the UL if mandatory folic acid fortification of either all bread-making flour or white bread-making flour were to be introduced (see Figures 4 and 5).

The number of respondents exceeding the UL increases as the amount of folic acid added to either all bread making flour or white bread-making flour increases, with the largest relative increase between the addition of 200 μg and 300 μg folic acid per 100 g of bread-making flour for both scenarios.

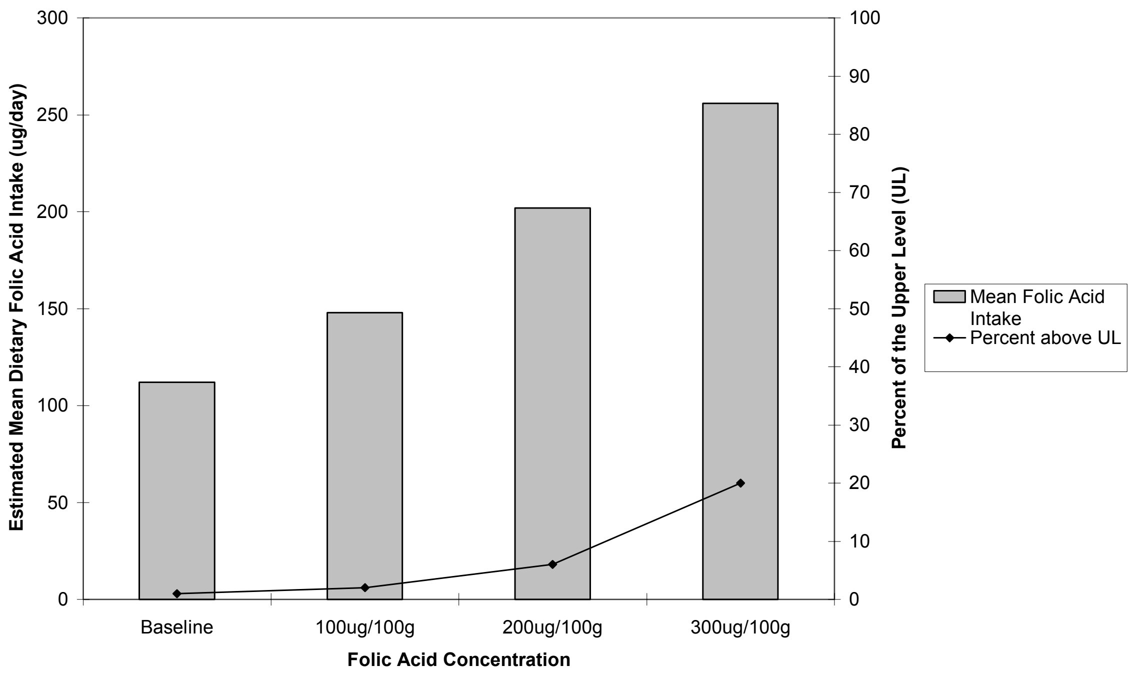
There appears to be a modest difference in the proportion of respondents exceeding the UL between 'Scenario 1 – mandatory folic acid fortification of all bread-making flour' and 'Scenario 2 – mandatory folic acid fortification of white bread-making flour'.

As FSANZ does not currently hold food consumption data for New Zealand children 2-14 years from the 2002 National Children's Nutrition Survey, the estimated dietary folic acid intakes for Australian children aged 2-14 were considered representative of this New Zealand age group. Therefore, it is assumed that New Zealand children 2-3 years and 4-8 years would show a similar proportion of respondents with folic acid intakes above the UL.

Only small proportions of respondents exceeding the UL can be seen for the other Australian and New Zealand non-target groups assessed at all levels of added folic acid considered.

Figure 4: Estimated mean dietary folic acid intakes and per cent of Australian children 2-3 years with 'Baseline' and both 'Scenario' folic acid intakes above the Upper Level

A: 'Scenario 1 – mandatory fortification of all bread-making flour'



B: 'Scenario 2 – mandatory fortification of white bread-making flour'

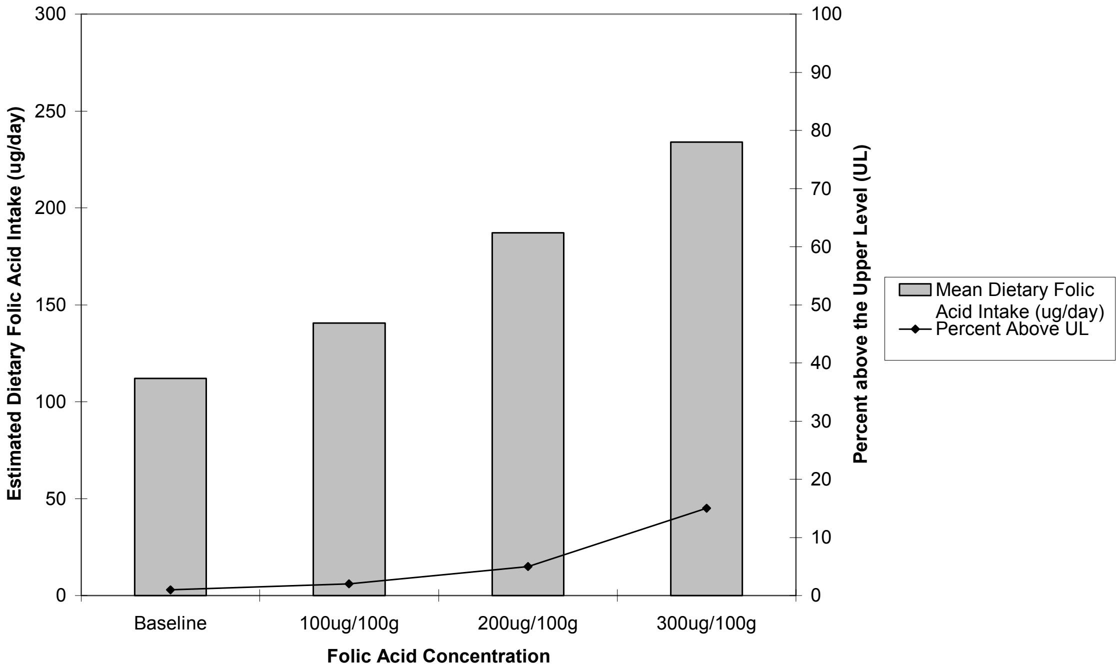
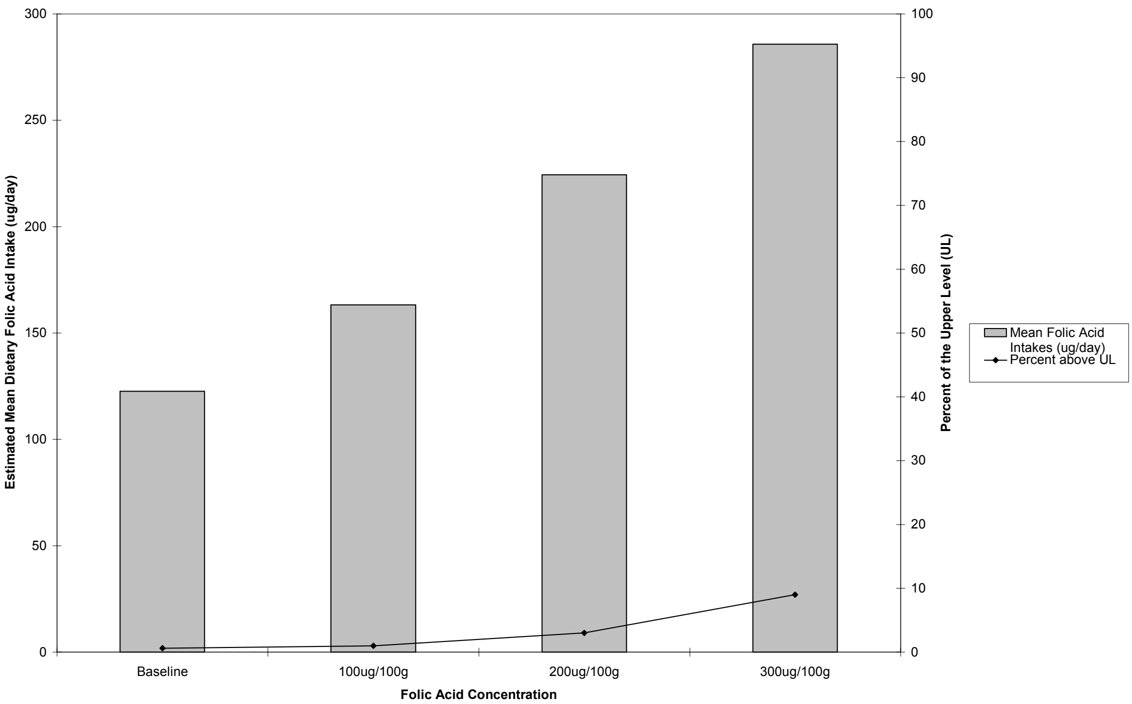
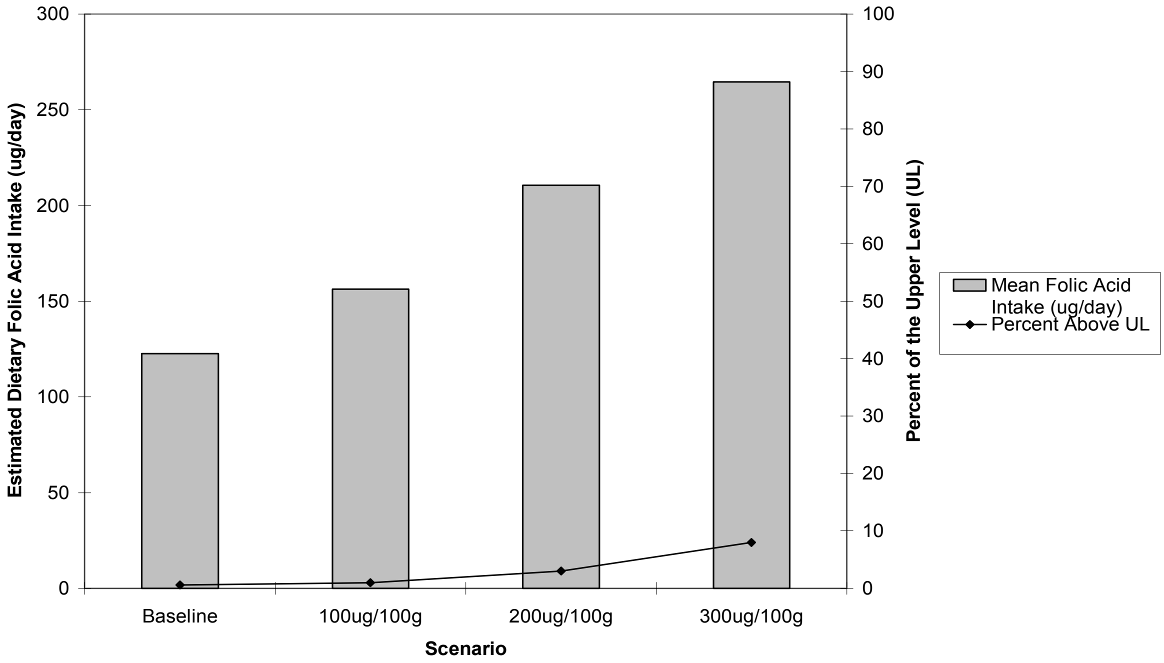


Figure 5: Estimated mean dietary folic acid intakes and per cent of Australian children 4-8 years with 'Baseline' and both 'Scenario' folic acid intakes above the Upper Level

'Scenario 1 – mandatory fortification of all bread-making flour'



'Scenario 2 – mandatory fortification of white bread-making flour'



4. 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. Consequently, additional calculations were made 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.

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

Two calculations were made for Australian and New Zealand women of child-bearing age. For Australia it was assumed 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. The lower concentration of 200 µg was based on recently published results by 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.

The intake of folic acid from supplements was added to the estimated mean folic acid intake from food for this population group at baseline, and for each scenario as outlined above to estimate total folic acid intake. It was assumed that all women aged 16-44 years consumed a folic acid supplement.

Although, 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.

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

The estimated total dietary folic acid intakes from food and folic acid supplements for Australian and New Zealand women of child-bearing age are shown in Figure 6A and Figure 6B respectively for 'Baseline' and 'Scenario 1 – mandatory folic acid fortification of all bread-making flour' models and Figure 7A and Figure 7B respectively for 'Baseline' and 'Scenario 2 – mandatory folic acid fortification of white bread-making flour' models.

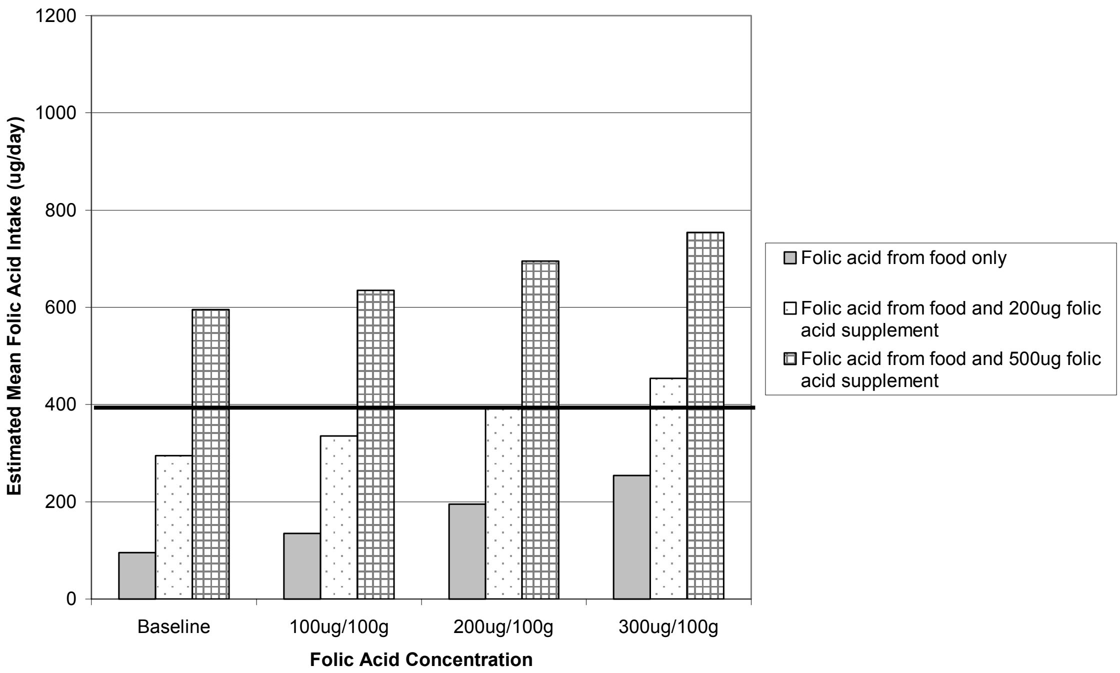
These results show an increase in estimated dietary folic acid intakes from baseline for both 'Scenario 1- mandatory folic acid fortification of all bread-making flour' and 'Scenario 2 - mandatory folic acid fortification of white bread-making flour' when additional folic acid is consumed from supplements. Further increases in estimated dietary folic acid intakes can be seen in each scenario model as the amount of folic acid added to all bread-making flour or white bread-making flour increases from 100 μg to 300 μg of folic acid per 100 g or bread-making flour.

The results indicate that an additional 200 μg of folic acid a day from folic acid supplements to mean folic acid intakes from food will result in women of child-bearing age having intakes just below the recommended 400 μg of folic acid a day, or just over if 300 μg of folic acid is added to all bread-making flour in 'Scenario 1' and white bread-making flour in 'Scenario 2' for both Australia and New Zealand.

Full results on folic acid intakes from both folic acid found in food and supplements can be found in Table A6.1 and Table A6.2 of Appendix 6.

Figure 6: Estimated mean dietary folic acid intakes from food and folic acid supplements for 'Baseline' and 'Scenario 1' (all bread-making flour) assessments for Australian and New Zealand women of child-bearing age (16-44 years)

A: Australia



B: New Zealand

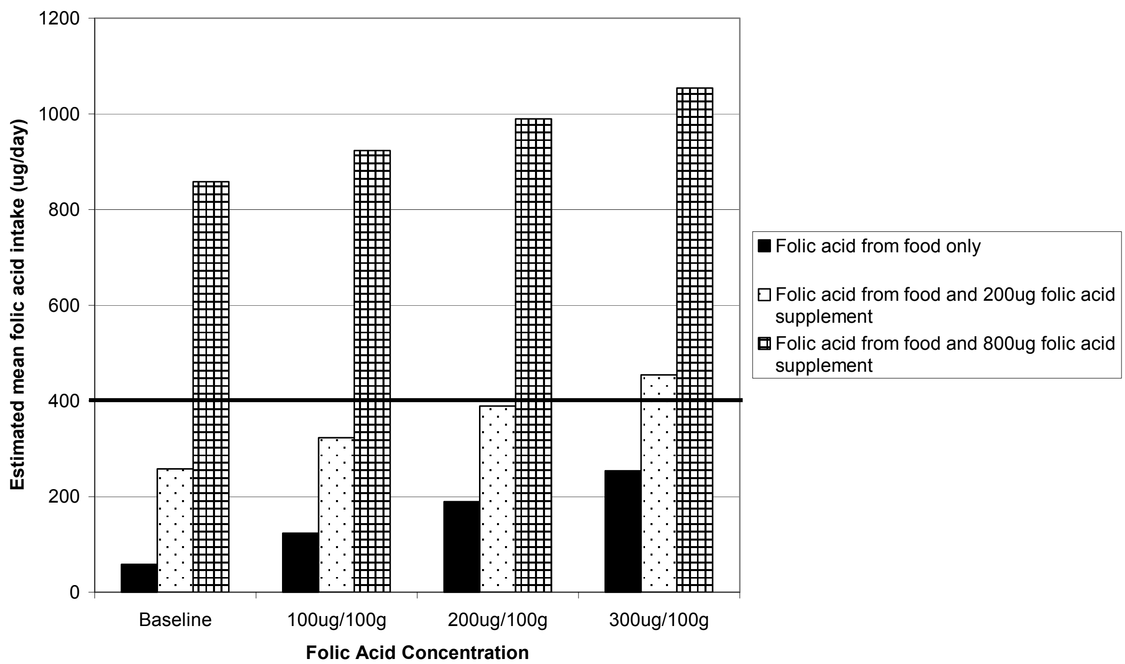
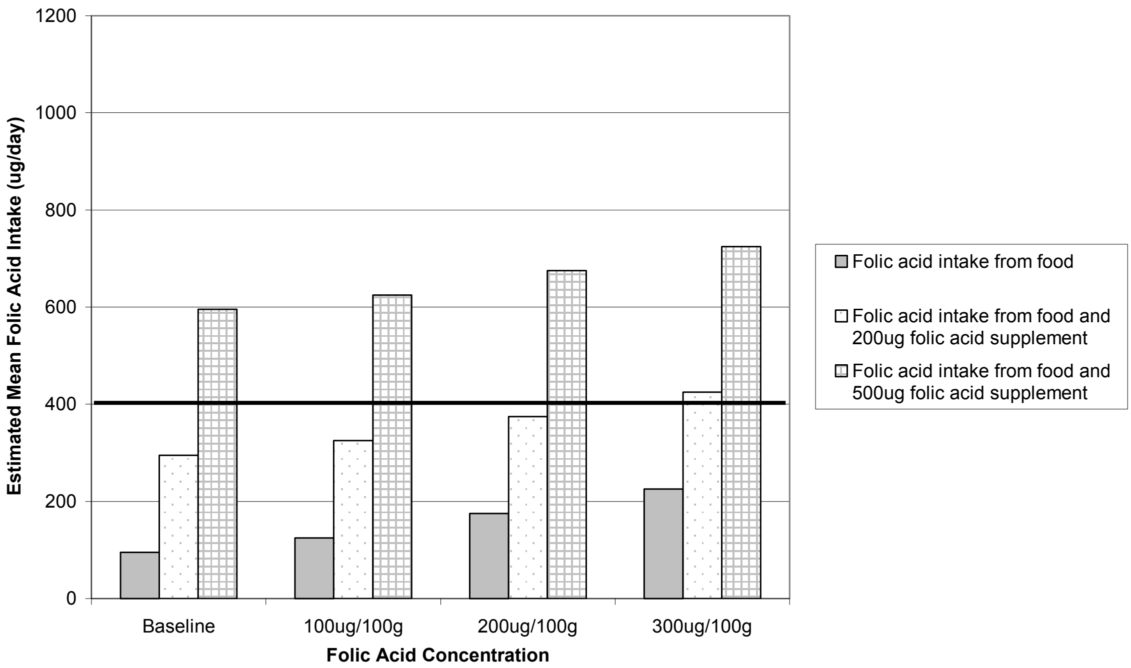
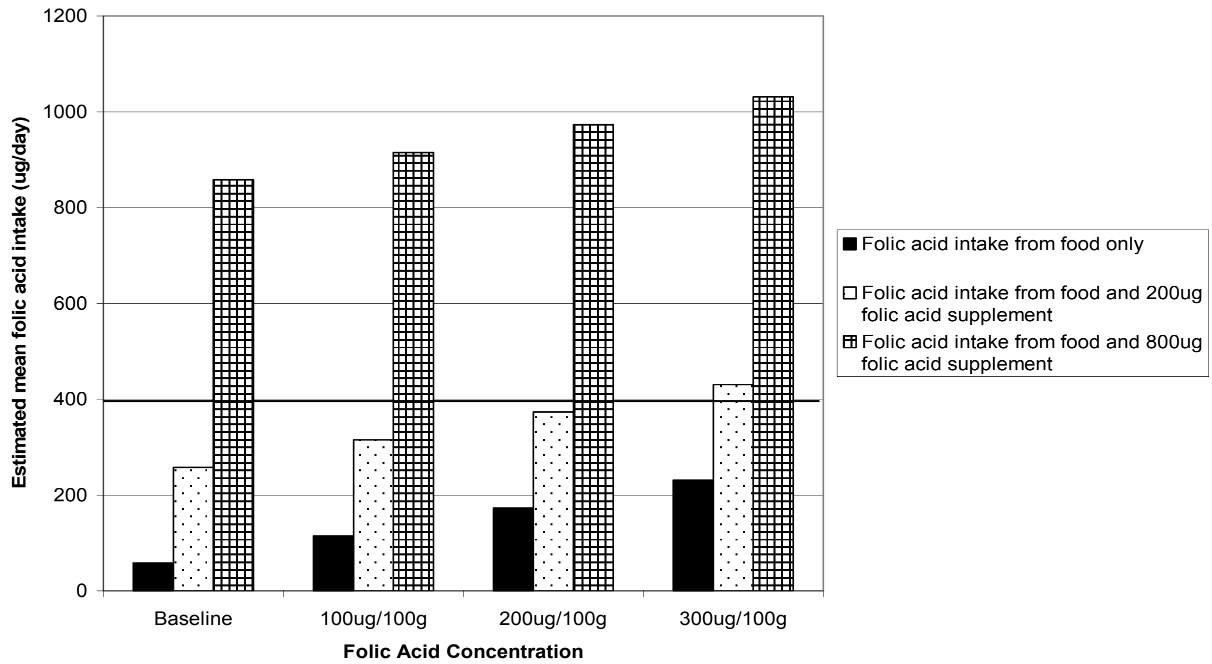


Figure 7: Estimated mean dietary folic acid intakes from food and folic acid supplements for 'Baseline' and 'Scenario 2' (white bread-making flour) assessments for Australian and New Zealand women of child-bearing age (16-44 years)

A: Australia



B: New Zealand



4.3 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 number of the target group exceeding the UL of 800 µg of folic acid a day for women 16-18 years and 1000 µg of folic acid a day for women 19-44 years.

Similar to above, the number of respondents exceeding the UL increases as the amount of folic acid added to either all bread-making flour or white bread-making flour increases and as the concentration of folic acid in the supplement increases.

There appears to be little difference in the per cent of respondents exceeding the UL between 'Scenario 1 – mandatory folic acid fortification of all bread-making flour' and 'Scenario 2 – mandatory folic acid fortification of white bread-making flour' when additional folic acid from supplements is consumed. However, due to the high folic acid content of the supplement at 800 µg of folic acid a day, a large proportion of New Zealand women are likely to exceed the UL if folic acid from food is taken into account.

The proportion of the target group exceeding the UL when supplements are taken is shown in Table 5 for Australia and New Zealand. Full results can be found in Table A6.3 and Table A6.4 of Appendix 6.

Table 5: Per cent of respondents with folic acid intakes from food and supplements above the Upper Level for Australian and New Zealand women of child-bearing age*

Model		Per cent of respondents with folic acid intakes from food and supplements above the UL (%)			
		Australia		New Zealand	
		200µg Supplement	500µg Supplement	200µg Supplement	800µg Supplement
Baseline		0.3	2	0.07	9
Scenario 1 All bread making flour	100	0.3	2	0.07	15
	200	0.4	4	0.2	40
	300	0.8	6	0.5	70
Scenario 2 White bread making flour	100	0.2	2	0.07	15
	200	0.3	3	0.2	35
	300	0.7	5	0.4	60

* All females aged 16-44 years.

5. Limitations of the dietary modelling

Dietary modelling based on 1995 or 1997 NNS food consumption data provides the best estimate of actual consumption of a food and the resulting estimated dietary intake of a nutrient for the population. However, it should be noted that the NNS data does have its limitations.

These limitations relate to the age of the data and the changes in eating patterns that may have occurred since the data were collected. Generally, consumption of 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). It is recognised while the overall amount of bread products people consume may not change over time, the type of bread products being consumed may vary. For example more focaccia may be consumed now than in the 1995 and 1997 NNS. However, despite these changes within the food category the overall consumption of bread products remains the same. The uncertainty is associated with the consumption of foods that may have changed in consumption since 1995/1997, or that have been introduced to the market since 1995/1997.

Over time, there may be changes to the ways in which manufacturers and retailers make and present foods for sale. Since the data were collected for the Australian and New Zealand NNSs, there have been significant changes to the Food Standards Code to allow more innovation in the food industry. As a consequence, a limitation of the dietary modelling is that some of the foods that are currently available in the food supply were either not available or were not as commonly available in 1995/1997. Additionally, since the data were collected for the NNSs, there has been an increase in the range of products that are fortified with nutrients. Therefore, the nutrient databases from the NNSs used for dietary modelling may not be entirely representative of the nutrient levels in some foods that are now on the market. FSANZ does update the food composition database through analytical programs, and scans of the market place. However, with the market place continually changing it is difficult to account for all fortified products. For the purposes of the dietary intake assessment for this Proposal, folic acid concentrations have been assigned to foods to take this into account and therefore should reflect current concentrations and foods fortified (e.g. to 15% of breads currently being fortified, as explained above).

A limitation of estimating dietary intake over a period time using food recalls is that people may over or under report food consumption, particularly for certain types of foods. Over and under-reporting of food consumption has not been accounted for in this dietary intake assessment. However, by adjusting intakes based on two days of food consumption data accounts for some variation both within individuals and between individuals.

FSANZ does not currently hold food consumption data for New Zealand children aged 2-14 years. Therefore, at the present time FSANZ can not assess current folic acid intakes for this group or the impact the introduction of mandatory fortification of either all bread-making flour or white bread-making flour with folic acid might have. For the purpose of this assessment it was assumed New Zealand children 2-14 years have similar intakes to Australian children the same age.

Although some data on the use of complementary medicines (Australia) or dietary supplements (New Zealand) was collected in the NNSs, it was either not in a robust enough format to include in DIAMOND or has simply not been included in the DIAMOND program to date. Consequently, intakes of substances consumed via complementary medicines or dietary supplements could not be included directly in the dietary intake assessment conducted using DIAMOND. Intake of folic acid from dietary supplements was considered for the target group using simple techniques to estimate the intake, as described previously.

While the results of national nutrition surveys can be used to describe the usual intake of groups of people, they cannot be used to describe the usual intake of an individual (Rutishauser, 2000). In addition, they cannot be used to predict how consumers will change their eating patterns as a result of an external influence such as the availability of a new type of food.

FSANZ does not apply statistical population weights to each individual in the NNSs in order to make the data representative of the population. Maori and Pacific Islanders were over-sampled in the 1997 New Zealand NNS so that statistically valid assessments could be made for these population groups. As a result, there may be bias towards these population groups in the dietary intake assessment because population weights were not used.

There are a number of limitations associated with the folic acid concentration data. Analytical values used may not fully reflect actual levels due to variation in folic acid concentrations between batches of foods and because the technique used to measure folic acid (microbiological assay) is subject to significant uncertainty (Thomson, 2005). Data generated from label values has not been adjusted to take into account potential extra addition of folic acid (overages). For baseline concentrations, a major limitation is that market share information, used to weight folic acid concentration in breads and juices according to the proportion of the category observed to be fortified, may not fully reflect actual fortification practices. For scenario concentrations, a major limitation of the study relates to the assumptions about the proportion of bread-making flour used in different foods.

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Appendix 1

How were the estimated dietary folic acid intakes from fortified food calculated?

Folic acid intakes were calculated for each individual in the NNSs using their individual food consumption records from the dietary survey. The DIAMOND program multiplies the specified concentration of folic acid for an individual food by the amount of the food that an individual consumed in order to estimate the intake of folic acid from each food. Once this has been completed for all of the foods specified to contain folic acid, the total amount of folic acid consumed from all foods is summed for each individual. Adjusted nutrient intakes are first calculated (see below) and population statistics (such as mean and high percentile intakes) are then derived from the individuals' ranked intakes.

Adjusted nutrient intakes, which better reflect 'usual' daily nutrient intakes, were calculated because NRVs such as the EAR and the UL are based on usual or long term intakes and it is therefore more appropriate to compare adjusted or 'usual' nutrient intakes with NRVs.

Calculating adjusted intakes
To calculate usual daily nutrient intakes more than one day of food consumption data are required. Information for a second (non-consecutive) day of food consumption was collected from approximately 10% of Australian NNS respondents and 15% of New Zealand NNS respondents. In order to calculate an estimate of more usual nutrient intakes using both days of food consumption data, an adjustment is made to each respondent's folic acid intake based on the first day of food consumption data from the NNS. The adjustment takes into account several pieces of data including each person's day one nutrient intake, the mean nutrient intake from the group on day one, the standard deviation from the day one sample and the between person standard deviation from the day two sample. This calculation is described in Figure A1.1 below. (For more information on the methodology of adjusting for second day intakes, see the Technical Paper on the National Nutrition Survey: Confidentialised Unit Record File (ABS, 1998).

Figure A1.1: Calculating adjusted nutrient intakes

$$\text{Adjusted value} = x + (x_1 - x) * (S_b/S_{obs})$$

Where: x is the group mean for the Day 1 sample
x_1 is the individual's day 1 intake
S_b is the between person standard deviation; and
S_{obs} is the group standard deviation for the Day 1 sample

Source: ABS, 1998

Not all foods consumed in the NNSs were assigned a folic acid concentration. Therefore not all NNS respondents are consumers of folic acid based on day one food consumption records only. However, after nutrient intake adjustments have been made based on a second day of food consumption data, all respondents have a folic acid intake as a function of how the adjusted intakes are calculated.

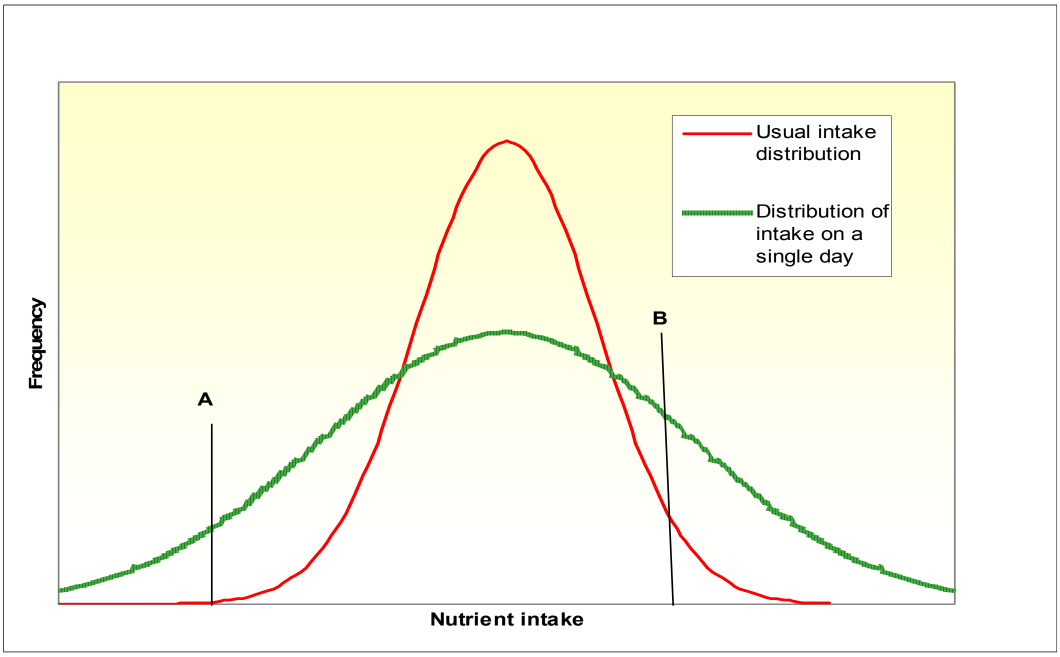
As a part of the two-day adjustment methodology, each individual below the mean in an intake distribution for day one will have an addition made to their folic acid intakes in order to calculate the adjusted intake over two days, as every individual's intakes are brought towards the mean. This applies to the intakes from respondents which are zero for day one.

Whilst this may not represent the correct usual intakes at the bottom end of the usual folic acid intake distribution, this is unlikely to be a major issue for the risk assessment because the proportion of the population below the EAR, which uses the lower end of the adjusted nutrient intake distribution, was not required to be determined. For this risk assessment, the concern is related to the proportion of respondents with intakes that exceed the upper safe reference health standard (the UL), which would be the intakes at the upper end of the intake distribution. The people in the upper end of the intake distribution would have consumed foods containing folic acid. Therefore the adjusted intakes in the upper end of the distribution accurately reflect the usual population intakes.

The benefit in being able to more accurately estimate their 'usual intake' by using the two day adjustment factor outweighs the possible over estimation of intakes for low consumers for risk assessment purposes.

Comparison of one day and usual intake distributions
The range of intakes from respondents is broader based on a single day of food consumption data than the range of usual intakes (Figure A1.2) as the latter takes into consideration the day-to-day variation in intakes within each person as well as the difference between each person.

Figure A1.2: Comparison of one day and usual intake distributions



Using adjusted intakes provides better information for risk characterisation purposes. Adjusted (or usual) nutrient intakes will have little or no impact on estimated mean nutrient intakes, but would result in an estimated 95th percentile intake that is lower than the 95th percentile intake from a single day only, or a 5th percentile intake that is higher than the 5th percentile intake based on day one intakes only.

Comparison of intakes with NRVs

Comparison of intakes based on a single day of food consumption data with NRVs such as EAR would result in a larger proportion of the population having intakes below a specified level (e.g. Figure A1.1, point A), which may overestimate the level of deficiency or inadequate intakes. A broader distribution from a single day of data also means a greater proportion of a population would exceed an upper cut off level, such as an upper level (e.g. Figure A1.1, point B), which overestimates the level of risk to this group of the population.

Note that where estimated intakes are expressed as a percentage of the Upper Level (UL), each individual's total adjusted intake is calculated as a percentage of the UL (using the total intakes in units per day) corresponding to their age and gender, the results are then ranked, and population statistics derived.

Appendix 2

Relationship between the dietary intake increments described in this document and the 2006 NHMRC/NZMoH 'Nutrient Reference Values for Use in Australia and New Zealand'

In 2006, 'Nutrient Reference Values for Use in Australia and New Zealand' replaced the 1991 NHMRC document 'Recommended Dietary Intakes in Australia'.

In addition to other changes, several NRVs are given for each nutrient (e.g. Estimated Average Requirement, Recommended Dietary Intake, Upper Level) for each physiological group (NHMRC 2006) whereas previously only the Recommended Dietary Intake had been defined (NHMRC 2001). The appropriate use of the various different levels is described elsewhere (Institute of Medicine, 2000b; 2003).

An additional important change for folate was the change in the units in which the levels are expressed. Previously, the Recommended Dietary Intake 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 does 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 Dietary Folate Equivalents (DFEs) such that

1 ug 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

(Note that this makes the generalisation that folate from all dietary sources has the same bioavailability, which is probably not true).

The recently released NHMRC publication indicates that the correct units for the UL for folate are μg supplementary or fortification folic acid, not μg DFE, because the UL is derived from studies using supplementary folic acid.

The dietary modelling work described in the current document therefore used concentrations in foods and supplements expressed as μg folic acid, not μg DFE, because all the studies examining the relationship of folic acid to the reduction of NTDs used supplemental folic acid and the UL is expressed in these units. It is not clear if enough dietary folate can be consumed to achieve the same outcomes.

From the above relationship, the change in total intake expressed as DFEs can be easily calculated from the described changes in folic acid intakes. For example, the uptake of the current voluntary fortification provisions is estimated to have increased folic acid intakes by 94 μg which means an increased total intake of 157 μg DFE (i.e. 94/0.6) over that obtainable from natural sources. Similarly, if folic acid intake in women aged 16-44 years would increase by an average of 100 μg under mandatory fortification of all bread-making flour to a residual level of 200 μg /100 g flour compared to the current voluntary fortification situation, then total folate intake will increase by a further 167 μg DFE on average.

Summary of Concentration data used for various foods for dietary modelling purposes

Table A3.1: Concentration data for main Australian products assumed to contain folic acid

Food	Baseline folic acid concentration data		Bread making flour content – (%)	Scenario: folic acid concentrations in food product (µg/100g)#		
	Folic acid concentration (µg/100 g)	Origin of baseline concentration data		100ug of folic acid added per 100g of BMF*	200ug of folic acid added per 100g of BMF*	300ug of folic acid added per 100g of BMF*
White bread	29	Label and analytical, with 15% market share weighting.	64	64	128	192
Multigrain bread	20	Label and analytical, market share weighted.	48	48	96	144
Wholemeal bread	27	Label and analytical, market share weighted.	'Scenario 1' - 64 'Scenario 2' - 0	'Scenario 1' - 64 'Scenario 2' - 0	'Scenario 1' - 128 'Scenario 2' - 0	'Scenario 1' - 192 'Scenario 2' - 0
Fruit breads	23	Label, with 15% market share weighting.	51	51	102	153
Maize flake style breakfast cereal	415	Analytical	0	415	415	415
Puffed rice style breakfast cereal	157	Analytical	0	157	157	157
Extruded & sweetened breakfast cereal	108 – 442^	Label and analytical depending on brand.	0	108 - 442	108 - 442	108 - 442
Bran & fruit style breakfast cereal	108 – 178^	Label and analytical depending on brand.	0	108 - 178	108 - 178	108 - 178
Wheat biscuit style breakfast cereal	333	Analytical	0	333	333	333
Nut-based breakfast cereal	167	Analytical	0	167	167	167
Orange juice	9	Analytical with 30% market share weighting.	0	9	9	9
Soy beverage, unflavoured	61	Analytical	0	61	61	61
Yeast-based spreads	2100	Label and analytical.	0	2100	2100	2100

Food	Baseline folic acid concentration data		Bread making flour content – (%)	Scenario: folic acid concentrations in food product (µg/100g)#		
	Folic acid concentration (µg/100 g)	Origin of baseline concentration data		100ug of folic acid added per 100g of BMF*	200ug of folic acid added per 100g of BMF*	300ug of folic acid added per 100g of BMF*
Pizza	0		20 – 45 depending on the type of crust and topping	20 – 45	40 -90	60 - 135
Hamburger with meat, bread, other ingredients	0		20			
Bun, sweet, various types	20		38	38	76	114
Scone, various types	0		60	60	120	180
Hot dog in bun	0		30	30	60	90
Pancakes and pikelets	0		25	25	50	75
Doughnuts, yeast type	0		40	40	80	120
Crumbed meat, chicken and fish	0		15 - 20 depending on type	15 - 20	30 – 40	45 - 60
Soups with croutons	0		4	4	8	12
Stuffing, bread based	0		35	35	70	105
Sandwiches, various	18		25 – 40 depending on type	25 – 40	50 – 80	75 - 120
Meal replacement powders	310 – 660^	Label and analytical depending on brand.	0	310 - 666	310 - 666	310 - 666

Concentrations listed apply to both 'Scenario 1 – mandatory folic acid fortification of all bread-making flour' and 'Scenario 2 – mandatory folic acid fortification of white bread-making flour' unless specifically stated.
* BMF refers to bread-making flour which was assumed to be used as an ingredient in all plain, fancy, sweet, and flat breads and bread rolls, English muffins, crumpets, scones, pancakes, pikelets, crepes, yeast donuts, pizza bases and crumbed products.
^ 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 A3.2: Concentration data for main New Zealand products assumed to contain folic acid

Food	Baseline folic acid concentration data		Bread making flour content – (%)	Scenario: folic acid concentrations in food product (µg/100g)#		
	Folic acid concentration (µg/100 g)	Origin of baseline concentration data		100ug of folic acid added per 100g of BMF*	200ug of folic acid added per 100g of BMF*	300ug of folic acid added per 100g of BMF*
White bread	0 – 120^	Label and analytical, depending on type recorded in NNS.	60	60	120	180
Multigrain bread	0 – 120^	Analytical depending on type recorded in NNS	Scenario 1' - 50 'Scenario 2' - 40	Scenario 1' - 50 'Scenario 2' - 40	Scenario 1' - 100 'Scenario 2' - 80	Scenario 1' - 150 'Scenario 2' - 120
Wholemeal bread	0 – 120^	Analytical depending on type recorded in NNS	Scenario 1' - 60 'Scenario 2' - 20	Scenario 1' - 60 'Scenario 2' - 0	Scenario 1' - 120 'Scenario 2' - 0	Scenario 1' - 180 'Scenario 2' - 0
Fruit breads	0	Label, with 15% market share weighting.	‘Scenario 1’ - 55 ‘Scenario 2’ – 20	55	110	165
Maize flake style breakfast cereal	326 – 439^	Analytical depending on type recorded in NNS	0	326 - 439	326 - 439	326 - 439
Puffed rice style breakfast cereal	290	Analytical	0	290	290	290
Extruded & sweetened breakfast cereal	199	Analytical	0	199	199	199
Bran & fruit style breakfast cereal	222 – 470^	Label and analytical, depending on type recorded in NNS.	0	222 - 470	222 - 470	222 - 470
Wheat biscuit style breakfast cereal	313	Analytical	0	313	313	313
Nut-based breakfast cereal	167	Analytical	0	167	167	167
Orange juice	11	Analytical with 25% market share weighting	0	11	11	11
Soy beverage, unflavoured	61	Analytical	0	61	61	61

Food	Baseline folic acid concentration data		Bread making flour content – (%)	Scenario: folic acid concentrations in food product (µg/100g)[#]		
	Folic acid concentration (µg/100 g)	Origin of baseline concentration data		100ug of folic acid added per 100g of BMF[*]	200ug of folic acid added per 100g of BMF[*]	300ug of folic acid added per 100g of BMF[*]
Yeast-based spreads	2100 – 2200^	Label and analytical, depending on type recorded in NNS.	0	2100 – 2200	2100 – 2200	2100 – 2200
Pizza	0		20 – 35 depending on crust and topping type	20 - 35	40 - 70	60 - 105
Hamburger with meat, bread, other ingredients	0		15 - 25 depending on type	15	30	45
Bun, sweet, various types	0		40 - 65 depending on type	40 - 65	80 - 130	120 - 195
Scone, various types	0		50	50	100	150
Pancakes and pikelets	0		30	30	60	90
Doughnuts, yeast type	0		35	35	70	105
Crumbed meat, chicken and fish	0		6 - 15 depending on type	6-15	12-30	18-45
Croutons	0		55	55	110	165
Stuffing, bread based	0		40	40	80	120
Sandwiches, various	0		25 - 40 depending on type	25 – 40	50 – 80	75 - 120
Meal replacement powders	40 – 90^	Label and analytical depending on brand	0	40 - 90	40 - 90	40 - 90

[#] Concentrations listed apply to both ‘Scenario 1 – mandatory folic acid fortification of all bread-making flour’ and ‘Scenario 2 – mandatory folic acid fortification of white bread-making flour’ unless specifically stated.
[*] BMF refers to bread-making flour which was assumed to be used as an ingredient in all plain, fancy, sweet, and flat breads and bread rolls, English muffins, crumpets, scones, pancakes, pikelets, crepes, yeast donuts, pizza bases and crumbed products.
^ 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.

Complete information on dietary intake assessment results

Table A4.1: Estimated mean and 95th percentile dietary folic acid intakes for 'Baseline' and 'Scenario 1 – mandatory folic acid fortification of all bread-making flour' models for Australian and New Zealand women of child-bearing age

			Baseline Folic Acid Intake (µg/day)		Scenario 1: Mandatory folic acid fortification of all bread making flour					
					Mean Folic Acid Intake (µg/day)			95th Percentile Folic Acid Intake (µg/day)		
Country	Target Group	No. of respondents	Mean	95th percentile	100µg/100g	200µg/100g	300µg/100g	100µg/100g	200µg/100g	300µg/100g
Australia	16-18 years	218	103	261	145	210	274	310	376	474
	19-44 years	2,960	94	271	134	193	253	324	396	478
	16-44 years	3,178	95	271	135	195	254	322	394	477
New Zealand	16-18 years	95	51	152	121	191	260	252	354	396
	19-44 years	1,414	58	178	123	188	254	245	323	410
	16-44 years	1,509	58	177	123	189	254	245	323	408

Table A4.2: Estimated mean and 95th percentile dietary folic acid intakes for 'Baseline' and 'Scenario 1 – mandatory folic acid fortification of all bread-making flour' models for various Australian population sub-groups

			Baseline Folic Acid Intake (µg/day)		Scenario 1: Mandatory folic acid fortification of all bread making flour					
Population Group	Gender	No. of respondents	Mean	95th percentile	Mean Folic Acid Intake (µg/day)			95th Percentile Folic Acid Intake (µg/day)		
					100µg/100g	200µg/100g	300µg/100g	100µg/100g	200µg/100g	300µg/100g
2 years and above	All	13,858	115	314	161	231	301	374	474	582
2-3 years	All	383	112	207	148	202	256	250	309	381
	M	170	123	242	163	222	281	276	347	413
	F	213	103	198	135	186	237	231	293	340
4-8 years	All	977	123	243	163	224	286	293	361	450
	M	513	138	272	183	250	317	318	411	503
	F	464	106	210	142	196	251	244	290	366
9-13 years	All	913	144	337	190	258	325	385	461	555
	M	474	173	357	224	300	376	408	517	617
	F	439	112	278	152	212	271	306	370	436
14-18 years	All	734	147	357	201	280	360	430	546	669
	M	378	189	424	254	349	443	569	677	811
	F	356	102	257	144	207	270	300	369	471
19-29 years	All	2,203	131	337	185	264	343	423	555	688
	M	1,014	163	406	231	332	432	508	667	819
	F	1,189	104	266	145	205	266	322	418	490
30-49 years	All	4,397	104	314	151	223	295	372	485	594
	M	2,080	122	331	179	264	350	406	542	681
	F	2,317	87	281	127	186	245	330	392	471

			Baseline Folic Acid Intake (µg/day)		Scenario 1: Mandatory folic acid fortification of all bread making flour					
Population Group	Gender	No. of respondents	Mean	95th percentile	Mean Folic Acid Intake (µg/day)			95th Percentile Folic Acid Intake (µg/day)		
					100µg/100g	200µg/100g	300µg/100g	100µg/100g	200µg/100g	300µg/100g
50-69 years	All	3,019	104	309	146	212	279	357	446	535
	M	1,442	119	342	169	247	325	409	509	617
	F	1,577	89	283	125	180	236	316	376	442
70+ years	All	1,232	108	300	147	210	272	340	416	505
	M	545	116	281	162	234	306	325	418	538
	F	687	101	347	136	190	245	371	413	456

Table A4.3: Estimated mean and 95th percentile dietary folic acid intakes for 'Baseline' and 'Scenario 1 – mandatory folic acid fortification of all bread-making flour' models for various New Zealand population sub-groups

Population Group	Gender	No. of respondents	Baseline Folic Acid Intake (µg/day)		Scenario 1: Mandatory folic acid fortification of all bread making flour					
			Mean	95th percentile	Mean Folic Acid Intake (µg/day)			95th Percentile Folic Acid Intake (µg/day)		
					100µg/100g	200µg/100g	300µg/100g	100µg/100g	200µg/100g	300µg/100g
15 years and above	All	4,636	69	203	143	218	292	296	409	537
15-18 years	All	246	75	180	159	243	326	324	449	606
	M	109	104	240	204	305	406	390	551	744
	F	137	51	158	122	193	263	236	310	401
19-29 years	All	804	69	185	147	226	305	292	438	575
	M	286	101	212	200	300	400	345	539	725
	F	518	51	158	118	185	252	232	311	396
30-49 years	All	1,883	70	211	146	223	299	309	427	557
	M	787	80	230	175	269	363	343	484	624
	F	1,096	62	195	125	189	253	259	333	419
50-69 years	All	1,147	70	214	139	210	281	292	390	488
	M	538	79	248	161	245	330	344	429	561
	F	609	63	197	120	179	238	245	317	390
70+ years	All	556	66	184	129	195	261	255	336	417
	M	207	67	186	140	218	296	269	361	463
	F	349	65	173	122	181	240	225	302	376

Table A4.4: Estimated mean and 95th percentile dietary folic acid intakes for 'Baseline' and 'Scenario 2 – Mandatory folic acid fortification of white bread-making flour' models for Australian and New Zealand women of child-bearing age

			Baseline Folic Acid Intake (µg/day)		Scenario 2: Mandatory folic acid fortification of white bread making flour					
Country	Target Group	No. of respondents	Mean	95th percentile	Mean Folic Acid Intake (µg/day)			95th Percentile Folic Acid Intake (µg/day)		
					100µg/100g	200µg/100g	300µg/100g	100µg/100g	200µg/100g	300µg/100g
Australia	16-18 years	218	103	261	137	192	248	308	375	474
	19-44 years	2,960	94	271	124	174	223	319	382	453
	16-44 years	3,178	95	271	125	175	225	316	381	453
New Zealand	16-18 years	95	51	152	116	179	243	250	341	382
	19-44 years	1,414	58	178	115	173	230	236	305	384
	16-44 years	1,509	58	177	115	173	231	236	305	383

Table A4.5: Estimated mean and 95th percentile dietary folic acid intakes for 'Baseline' and 'Scenario 2 – Mandatory folic acid fortification of white bread-making flour' models for various Australian population sub-groups

			Baseline Folic Acid Intake (µg/day)		Scenario 2: Mandatory folic acid fortification of white bread making flour					
Population Group	Gender	No. of respondents	Mean	95th percentile	Mean Folic Acid Intake (µg/day)			95th Percentile Folic Acid Intake (µg/day)		
					100µg/100g	200µg/100g	300µg/100g	100µg/100g	200µg/100g	300µg/100g
2 years and above	All	13,858	115	314	149	207	265	359	449	545
2-3 years	All	383	112	207	141	187	234	244	290	357
	M	170	123	242	155	205	255	274	344	408
	F	213	103	198	129	173	218	227	275	324
4-8 years	All	977	123	243	156	210	265	287	357	440
	M	513	138	272	175	234	292	317	400	485
	F	464	106	210	136	185	234	239	283	356
9-13 years	All	913	144	337	183	244	306	384	454	550
	M	474	173	357	217	286	355	406	522	608
	F	439	112	278	146	200	253	302	364	429
14-18 years	All	734	147	357	192	263	334	420	527	635
	M	378	189	424	245	331	417	555	639	751
	F	356	102	257	136	191	246	298	368	461
19-29 years	All	2,203	131	337	175	245	314	407	531	652
	M	1,014	163	406	221	311	402	485	621	762
	F	1,189	104	266	136	188	240	316	396	476

Population Group	Gender	No. of respondents	Baseline Folic Acid Intake (µg/day) Mean	Baseline Folic Acid Intake (µg/day) 95th percentile	Scenario 2: Mandatory folic acid fortification of white bread making flour — Mean Folic Acid Intake (µg/day) 100µg/100g	200µg/100g	300µg/100g	95th Percentile Folic Acid Intake (µg/day) 100µg/100g	200µg/100g	300µg/100g
30-49 years	All	4,397	104	314	139	199	258	359	453	555
	M	2,080	122	331	166	239	311	387	494	629
	F	2,317	87	281	115	163	210	326	383	432
50-69 years	All	3,019	104	309	130	181	231	337	414	493
	M	1,442	119	342	152	213	274	385	465	537
	F	1,577	89	283	110	151	192	300	351	413
70+ years	All	1,232	108	300	128	172	217	323	371	437
	M	545	116	281	143	197	251	311	375	450
	F	687	101	347	117	153	190	337	367	404

Table A4.6: Estimated mean and 95th percentile dietary folic acid intakes for 'Baseline' and 'Scenario 2 – Mandatory folic acid fortification of white bread-making flour' models for various New Zealand population sub-groups

			Baseline Folic Acid Intake (µg/day)		Scenario 2: Mandatory folic acid fortification of white bread making flour					
Population Group	Gender	No. of respondents	Mean	95th percentile	Mean Folic Acid Intake (µg/day)			95th Percentile Folic Acid Intake (µg/day)		
					100µg/100g	200µg/100g	300µg/100g	100µg/100g	200µg/100g	300µg/100g
15 years and above	All	4,636	69	203	133	197	261	278	374	486
15-18 years	All	246	75	180	151	227	303	292	407	530
	M	109	104	240	195	286	378	345	516	653
	F	137	51	158	116	181	244	229	297	388
19-29 years	All	804	69	185	140	212	283	279	402	529
	M	286	101	212	191	282	373	318	503	641
	F	518	51	158	112	173	234	228	297	380
30-49 years	All	1,883	70	211	135	201	267	286	386	503
	M	787	80	230	162	244	325	324	447	561
	F	1,096	62	195	116	171	225	243	311	387
50-69 years	All	1,147	70	214	127	185	243	276	355	430
	M	538	79	248	147	218	288	322	387	506
	F	609	63	197	108	156	204	231	289	347
70+ years	All	556	66	184	116	168	222	239	304	379
	M	207	67	186	125	189	254	256	323	398
	F	349	65	173	110	156	203	213	269	339

Appendix 5

Complete information on risk characterisation

Table A5.1: Number and per cent of 'Baseline' and 'Scenario 1 – mandatory folic acid fortification of all bread-making flour' respondents with folic acid intakes above the Upper Level for Australian and New Zealand women of child-bearing age

Country	Target Group	No. of respondents	Baseline		Scenario 1: Mandatory folic acid fortification of all bread making flour					
					100 µg/100g		200 µg/100g		300 µg/100g	
			Number	%	Number	%	Number	%	Number	%
Australia	16-18 years	218	0	0	0	0	1	0.5	1	0.5
	19-44 years	2,960	5	0.2	5	0.2	4	0.1	5	0.2
	16-44 years	3,178	5	0.2	5	0.2	5	0.2	6	0.2
New Zealand	16-18 years	95	0	0	0	0	0	0	0	0
	19-44 years	1,414	1	0.1	1	0.1	1	0.1	3	0.2
	16-44 years	1,509	1	0.1	1	0.1	1	0.1	3	0.2

Table A5.2: Number and per cent of 'Baseline' and 'Scenario 1 – mandatory folic acid fortification of all bread-making flour' respondents with folic acid intakes above the Upper Level for various Australian population sub-groups

Population Group	Gender	No. of respondents	Baseline		Scenario 1: Mandatory folic acid fortification of all bread making flour					
					100 µg/100g		200 µg/100g		300 µg/100g	
			Number	%	Number	%	Number	%	Number	%
2-3 years	All	383	5	1	8	2	22	6	73	20
	M	170	4	2	7	4	15	9	46	25
	F	213	1	0.5	1	0.5	7	3	27	15
4-8 years	All	977	6	0.6	13	1	32	3	85	9
	M	513	4	0.8	10	2	29	6	76	15
	F	464	2	0.4	3	0.6	3	0.6	9	2
9-13 years	All	913	7	0.8	9	1	15	2	31	3
	M	474	5	1	6	1	12	3	26	6
	F	439	2	0.5	3	0.7	3	0.7	5	1
14-18 years	All	734	4	0.5	6	0.8	13	2	22	3
	M	378	4	1	6	2	12	3	21	6
	F	356	0	0	0	0	1	0.3	1	0.3
19-29 years	All	2,203	5	0.2	8	0.4	14	0.6	23	1
	M	1,014	4	0.4	7	0.7	13	1	22	2
	F	1,189	1	0.1	1	0.1	1	0.1	1	0.1
30-49 years	All	4,397	11	0.3	13	0.3	15	0.3	22	0.5
	M	2,080	6	0.3	8	0.4	11	0.5	18	0.9
	F	2,317	5	0.2	5	0.2	4	0.2	4	0.2
50-69 years	All	3,019	4	0.1	5	0.2	6	0.2	10	0.3
	M	1,442	2	0.1	3	0.2	4	0.3	8	0.6
	F	1,577	2	0.1	2	0.1	2	0.1	2	0.1
70+ years	All	1,232	0	0	0	0	0	0	1	0.1
	M	545	0	0	0	0	0	0	1	0.2
	F	687	0	0	0	0	0	0	0	0

Table A5.3: Number and per cent of 'Baseline' and 'Scenario 1 – mandatory folic acid fortification of all bread-making flour' respondents with folic acid intakes above the Upper Level for various New Zealand population sub-groups

Population Group	Gender	No. of respondents	'Baseline'		Scenario 1: Mandatory folic acid fortification of all bread making flour					
					100 µg/100g		200 µg/100g		300 µg/100g	
			Number	%	Number	%	Number	%	Number	%
15-18 years	All	246	0	0	0	0	1	0.4	2	0.8
	M	109	0	0	0	0	1	0.9	2	2
	F	137	0	0	0	0	0	0	0	0
19-29 years	All	804	0	0	0	0	0	0	1	0.1
	M	286	0	0	0	0	0	0	1	0.3
	F	518	0	0	0	0	0	0	0	0
30-49 years	All	1,883	1	0.1	1	0.1	1	0.1	6	0.3
	M	787	0	0	0	0	0	0	3	0.4
	F	1,096	1	0.1	1	0.1	1	0.1	3	0.3
50-69 years	All	1,147	0	0	0	0	1	0.1	3	0.3
	M	538	0	0	0	0	1	0.2	2	0.4
	F	609	0	0	0	0	0	0	1	0.2
70+ years	All	556	0	0	0	0	0	0	0	0
	M	207	0	0	0	0	0	0	0	0
	F	349	0	0	0	0	0	0	0	0

Table A5.4: Number and per cent of 'Baseline' and 'Scenario 2 – mandatory folic acid fortification of white bread-making flour' respondents with folic acid intakes above the Upper Level for Australian and New Zealand women of child-bearing age

Country	Target Group	No. of respondents	Baseline		Scenario 2: Mandatory folic acid fortification of white bread making flour					
					100 µg/100g		200 µg/100g		300 µg/100g	
			Number	%	Number	%	Number	%	Number	%
Australia	16-18 years	218	0	0	0	0	0	0	1	0.5
	19-44 years	2,960	5	0.2	5	0.2	4	0.1	5	0.2
	16-44 years	3,178	5	0.2	5	0.2	4	0.1	6	0.2
New Zealand	16-18 years	95	0	0	0	0	0	0	0	0
	19-44 years	1,414	1	0.1	1	0.1	1	0.1	3	0.2
	16-44 years	1,509	1	0.1	1	0.1	1	0.1	3	0.2

Table A5.5: Number and per cent of 'Baseline' and 'Scenario 2 – mandatory folic acid fortification of white bread-making flour' respondents with intakes above the Upper Level for various Australian population sub-groups

Population Group	Gender	No. of respondents	Baseline		Scenario 2: Mandatory folic acid fortification of white bread making flour					
					100 µg/100g		200 µg/100g		300 µg/100g	
			Number	%	Number	%	Number	%	Number	%
2-3 years	All	383	5	1	8	2	18	5	52	15
	M	170	4	2	7	4	13	8	33	20
	F	213	1	0.5	1	0.5	5	2	19	9
4-8 years	All	977	6	0.6	12	1	29	3	73	8
	M	513	4	0.8	9	2	26	5	67	15
	F	464	2	0.4	3	0.6	3	0.6	6	1
9-13 years	All	913	7	0.8	9	1	16	2	30	3
	M	474	5	1	6	1	13	3	26	6
	F	439	2	0.5	3	0.7	3	0.7	4	0.9
14-18 years	All	734	4	0.5	6	0.8	9	1	16	2
	M	378	4	1	6	2	9	2	15	4
	F	356	0	0	0	0	0	0	1	0.3
19-29 years	All	2,203	5	0.2	7	0.3	11	0.5	19	0.9
	M	1,014	4	0.4	6	0.6	10	1	18	2
	F	1,189	1	0.1	1	0.1	1	0.1	1	0.1
30-49 years	All	4,397	11	0.3	13	0.3	13	0.3	17	0.4
	M	2,080	6	0.3	8	0.4	9	0.4	13	0.6
	F	2,317	5	0.2	5	0.2	4	0.2	4	0.2
50-69 years	All	3,019	4	0.1	4	0.1	4	0.1	6	0.2
	M	1,442	2	0.1	2	0.1	2	0.1	4	0.3
	F	1,577	2	0.1	2	0.1	2	0.1	2	0.1
70+ years	All	1,232	0	0	0	0	0	0	0	0
	M	545	0	0	0	0	0	0	0	0
	F	687	0	0	0	0	0	0	0	0

Table A5.6: Number and per cent of 'Baseline' and 'Scenario 2 – mandatory folic acid fortification of white bread-making flour' respondents with intakes above the Upper Level for various New Zealand population sub-groups

Population Group	Gender	No. of respondents	Baseline		Scenario 2: Mandatory folic acid fortification of white bread making flour					
					100 µg/100g		200 µg/100g		300 µg/100g	
			Number	%	Number	%	Number	%	Number	%
15-18 years	All	246	0	0	0	0	0	0	2	0.8
	M	109	0	0	0	0	0	0	2	2
	F	137	0	0	0	0	0	0	0	0
19-29 years	All	804	0	0	0	0	0	0	0	0
	M	286	0	0	0	0	0	0	0	0
	F	518	0	0	0	0	0	0	0	0
30-49 years	All	1,883	1	0.1	1	0.1	1	0.1	4	0.2
	M	787	0	0	0	0	0	0	1	0.1
	F	1,096	1	0.1	1	0.1	1	0.1	3	0.3
50-69 years	All	1,147	0	0	0	0	1	0.1	1	0.1
	M	538	0	0	0	0	1	0.2	1	0.2
	F	609	0	0	0	0	0	0	0	0
70+ years	All	556	0	0	0	0	0	0	0	0
	M	207	0	0	0	0	0	0	0	0
	F	349	0	0	0	0	0	0	0	0

Appendix 6

Complete information of folic acid intakes from food and supplements

Table A6.1: Estimated folic acid intakes from folic acid added to food and supplements for Australian women of child-bearing age*

Model	Added Folic Acid (µg/100g)	Folic acid intake from folic acid in food and supplements (µg/day)			
		Mean Intake + 200µg	Mean Intake + 500µg	95th %tile + 200 µg	95th %tile + 500µg
'Baseline'		295	595	471	771
'Scenario 1'					
All bread-making flour	100	335	635	522	822
	200	395	695	594	894
	300	454	754	677	977
'Scenario 2'					
White bread-making flour	100	325	625	516	816
	200	375	675	581	881
	300	425	725	653	953

* All females aged 16-44 years.

Table A6.2: Estimated folic acid intakes from folic acid added to food and supplements for New Zealand women of child-bearing age*

Model	Added Folic Acid (µg/100g)	Folic acid intake from folic acid in food and supplements (µg/day)			
		Mean Intake + 200 µg	Mean Intake + 800 µg	95th %tile + 200 µg	95th %tile + 800 µg
'Baseline'		258	858	377	977
'Scenario 1'					
All bread-making flour	100	323	923	445	1045
	200	389	989	523	1123
	300	454	1054	608	1208
'Scenario 2'					
White bread-making flour	100	315	915	436	1036
	200	373	973	505	1105
	300	431	1031	583	1183

* All females aged 16-44 years.

Table A6.3: Per cent (number) of respondents with folic acid intakes from folic acid added to food and supplements above the Upper Level for Australian women of child-bearing age*

Model	Added Folic Acid (µg/100g)	Per cent (number) of respondents with folic acid intakes from diet and supplements above the UL (%)	
		Individual's mean intake + 200µg	Individual's mean intake + 500µg
'Baseline'		0.3 (9)	2 (54)
'Scenario 1'			
All bread-making flour	100	0.3 (8)	2 (65)
	200	0.4 (13)	4 (112)
	300	0.8 (24)	6 (196)
'Scenario 2'			
White bread-making flour	100	0.2 (6)	2 (66)
	200	0.3 (10)	3 (102)
	300	0.7 (23)	5 (170)

* All females aged 16-44 years.

Table A6.4: Per cent (number) of respondents with folic acid intakes from folic acid added to food and supplements above the Upper Level for New Zealand women of child-bearing age*

Model	Added Folic Acid (µg/100g)	Per cent (number) of respondents with folic acid intakes from diet and supplements above the UL (%)	
		Individual's mean intake + 200µg	Individual's mean intake + 800µg
'Baseline'		0.07 (1)	9 (135)
'Scenario 1'			
All bread-making flour	100	0.07 (1)	15 (244)
	200	0.2 (3)	40 (604)
	300	0.5 (7)	70 (1042)
'Scenario 2'			
White bread-making flour	100	0.07 (1)	15 (231)
	200	0.2 (3)	35 (492)
	300	0.4 (6)	60 (885)

* All females aged 16-44 years.

Attachment 8

Evaluation of the health risk from mandatory folic acid fortification

Introduction

This document integrates the dietary exposure assessment and the available information on the potential hazards associated with high intakes of folic acid, in order to give an understanding of the overall risks to public health and safety associated with folic acid fortification.

Mandatory folic acid fortification of all bread-making flour at levels up to 200 µg/100 g flour, could potentially lead to a small percentage of individuals exceeding the Upper Level of Intake (UL) for folic acid (Table 1). The percentages of Australian and New Zealand consumers exceeding the corresponding age-specific UL is shown in Table 2.

1. Implications of exceeding the upper level of intake (UL)

1.1 Young children

If mandatory fortification of folic acid at a level of 200 µg/100 g flour were introduced, it is estimated that a small proportion of young children may exceed the UL – up to 6% of 2-3 year olds and 3% of 4-8 year olds.

In considering if the estimated intakes for young children are likely to represent a health and safety risk, a number of factors need to be taken into account.

The toxicological endpoint on which the UL for folic acid is based is the potential masking of diagnosis of vitamin B_{12} deficiency (See Section 5.2.2). High intakes of folic acid (>5,000 ug/day) in adults have been shown to resolve the haematological effects of vitamin B_{12} deficiency, thus masking diagnosis and potentially precipitating or exacerbating the related neurological effects. Undiagnosed vitamin B_{12}-related neuropathy can be serious and potentially irreversible. However, diagnosis of vitamin B_{12} deficiency does not depend solely on identification of haematological effects: other biochemical tests and neurological tests, unaffected by folic acid intake, are used for confirmation of the diagnosis.

The age-specific ULs for folic acid are not absolute threshold of concern but rather represent intake limits, which provide a comfortable margin of safety. While it is not desirable to routinely exceed the UL, such intakes do not automatically mean an adverse effect will result, although it does reduce the margin of safety.

No evidence exists to indicate that young children are more susceptible than adults to the adverse effects of excess folic acid. However, because children have a higher intake of food per kilogram body weight compared to adults, they are at greater risk of exceeding the UL. This risk decreases substantially with age, meaning any exceedance of the UL by children is likely to moderate over time. The age-specific ULs for young children have been derived from the adult UL by adjusting for body weight. However, as the prevalence of vitamin B_{12} deficiency is low in this age group, the applicability to young children of the adult derived UL remains uncertain.

Of the small proportion of children that are estimated to exceed the UL following the introduction of fortification at a level of 200 µg/100 g flour, all are predicted to have intakes below a level at which adverse effects might be observed. Therefore, the maximum estimated intake of this small proportion of children still remains within the margin of safety.

In conclusion, the introduction of mandatory fortification at a level of 200 µg folic acid/100g bread-making flour is likely to result in some young children exceeding the UL. While it is generally not desirable to exceed the UL, in this case the estimated maximum folic acid intakes for both 2-3 and 4-8 year old children are calculated to be well below a level at which adverse effects may be observed. This, and the low prevalence of vitamin B12 deficiency among children, means such intakes are unlikely to represent a health and safety risk, although there is a reduced margin of safety. Given the reduced margin of safety, consideration should be given to including young children in any monitoring program that may be undertaken.

1.2 Women in the target group (16-44 years)

The proportion of Australian and New Zealand women of child-bearing age likely to exceed the UL is shown in Table 3. Only a very small percentage (0.1%-0.2%) of women aged 16-44 years exceeded the UL at fortification levels of 100 µg/100 g flour and 200 µg/100 g flour. This is not an increase from baseline, where a similarly small percentage of women of child-bearing age are estimated to already exceed the UL (0.1%-0.2%).

When supplements are included in dietary intake, particularly the 800 µg supplement recommended in New Zealand, the percentage of the target group exceeding the UL increases significantly (up to 40% of New Zealand women). However, even in this group at the 95th percentile, intakes are below 1200 µg/day and well within the margin of safety. Due to the low prevalence of vitamin B_{12} deficiency in women of child-bearing age, intakes of folic acid at or above the UL are unlikely to have adverse effects. Furthermore, although folic acid supplements are recommended for all women in this age group, it would be very unlikely that all women who take supplements would take them regularly throughout their child-bearing years.

As 400 µg supplements are considered to be effective in the prevention of neural tube defects, consideration should be given to reducing the amount of folic acid in New Zealand supplements to avoid women having unnecessarily high intakes, therefore reducing the risk of potential adverse effects in this group.

1.3 Older people

The sub-group most at risk of adverse effects if the UL is exceeded are older people as vitamin B_{12} deficiency is most prevalent in this group. Dietary intake assessment showed none of the individuals aged 70 years and over exceeded the UL at fortification levels up to 200 µg/100 g flour. Only a very small proportion (0-0.2%) of individuals aged 50-69 years exceed the UL at the same fortification levels. This is very similar to the percentage exceeding the UL at baseline (0-0.1%). Therefore, it is unlikely that fortification at 200 µg/100 g flour will increase the risk of adverse effects in this population due to the masking of vitamin B_{12} deficiency.

1.4 Conclusion

Based on the available data, the fortification of all bread-making flour at levels up to 200 µg/100 g flour is unlikely to lead to a masking or exacerbation of vitamin B_{12} deficiency in either the target or non-target populations, and therefore does not represent a public health and safety concern.

Table 1: Age specific Upper Levels of Intake (ULs) of folic acid

Age group (years)	Upper level of intake (µg of folic acid/day)
1-3	300
4-8	400
9-13	600
14-18	800
19+	1,000

Table 2: Per cent of Australian and New Zealand 'Baseline' and 'Scenario 1' respondents with folic acid intakes above the Upper Level

Population Group	No. of respondents	Baseline (% > UL)	Folic acid fortification of all bread-making flour (% > UL)	
			100µg/100g	200µg/100g
Australia				
2-3 years	383	1	2	6
4-8 years	977	0.6	1	3
9-13 years	913	0.8	1	2
14-18 years	734	0.5	0.8	2
19-29 years	2,203	0.2	0.4	0.6
30-49 years	4,397	0.3	0.3	0.3
50-69 years	3,019	0.1	0.2	0.2
70+ years	1,232	0	0	0
New Zealand				
15-18 years	246	0	0	0.4
19-29 years	804	0	0	0
30-49 years	1,883	0.1	0.1	0.1
50-69 years	1,147	0	0	0.1
70+ years	556	0	0	0

Table 3: Per cent of respondents with folic acid intakes above the Upper Level for Australian and New Zealand women of child-bearing age*

Model	Added Folic Acid (µg/100g)	Per cent of respondents with folic acid intakes above the UL (%)					
		Australia			*New Zealand*		
		Individual Mean Intake	Individual Mean Intake + 200µg	Individual Mean Intake + 500µg	Individual Mean Intake	Individual Mean Intake + 200µg	Individual Mean Intake + 800µg
'Baseline'		0.2	0.3	2	0.1	0.07	9
'Scenario 1'							
All bread-making flour	100	0.2	0.3	2	0.1	0.07	15
	200	0.2	0.4	4	0.1	0.2	40

* All women aged 16-44 years.

2. Multiple births

Some studies suggest a possible association between folic acid and multiple births. However, the largest study did not find an increased risk of multiple births in women taking 400 µg folic acid/day compared to a control group (Li *et al*., 2003), nor was increased twinning observed in the United States post fortification (Waller *et al*., 2003; Shaw *et al*., 2003). It is not clear whether fortification of bread-making flour with folic acid at levels of 100 or 200 µg/100 g flour would have an effect on the number of multiple births in Australia and New Zealand. It seems unlikely there would be a significant effect as the mean increase in intakes from baseline is only expected to be around 100 µg/day or 131 µg/day for Australian and New Zealand women, respectively, at a fortification level of 200 µg/100 g in all bread-making flour (see Section 6.7.1, Table 3).

3. Cancer Incidence

The evidence for a relationship (either negative or positive) between cancer risk and folic acid intake is equivocal. No conclusions can be drawn with regard to potential increased risk of cancer from the intakes of folic acid shown in the dietary intake assessment.

4. Other risks

There is some concern that there may be interactions between particular drugs and folic acid. In particular anti-epileptic drugs, anti-folate drugs (such as methotrexate) and some anti-inflammatory drugs have been identified as potentially being affected by folic acid. However, interactions appear to occur at higher intakes of folic acid than would be delivered by mandatory fortification (e.g. 5 mg/day). Available evidence suggests that folic acid is unlikely to interfere with these drugs at intakes of 1 mg/day (Colinas and Cook 2005[2]). Dietary intake assessment indicates that the large majority of consumers will have intakes below 1 mg/day (the adult UL) when fortification levels are 200 µg/100 g flour, therefore the risk of interference by folic acid from fortified foods is low.

It is not expected that mandatory fortification with folic acid would have an effect on zinc status.

5. Uncertainties around increased population intakes of folic acid

In the absence of vitamin B_{12} deficiency, it is not known what the potential effects (adverse or beneficial) of an increase in folic acid intakes in the general population might be over the long term. There are significant uncertainties and insufficient evidence to be able to predict all possible outcomes from increase folic acid intakes.

For any sector of the population, it is likely mandatory fortification at any level will increase the amount of unmetabolised folic acid circulating in the blood. Although evidence indicates that short-term exposure to circulating folic acid causes no adverse health effects, it is not known what, if any, effect this might have in the long term. There are, however, no data reporting adverse effects in other countries that have implemented mandatory fortification with folic acid.

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

There is significant uncertainty concerning changes to the use of voluntary fortification permissions following the implementation of mandatory fortification. If the uptake of voluntary fortification increases, intakes of folic acid could be higher than estimated in the dietary intake assessment.

In conclusion, given the significant uncertainties around each of the potential intakes of folic acid, the potential adverse effects due to increased intakes, and the potential risk of adverse effects occurring, it is appropriate to take a conservative approach. For this reason, it is recommended that fortification at levels of 200 µg folic acid /100 g flour be put forward for further consideration.

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Attachment 9

Wald Model: NTD risk reduction according to increments of folic acid intake

Models have been developed that relate correlated folic acid intake and serum folate levels with reduction of risk of an NTD-related pregnancy. Of the few models published, the Wald model was considered the most appropriate to apply to Australian and New Zealand populations because it had been validated by direct observations in the literature and included technical corrections for bias. The model requires data on the serum folate status of women of childbearing age, and national NTD incidence rates. The model estimates the number of cases of NTD prevented at varied increases in folic acid intake.

1. Input data applied to the Wald Model

1. Post fortification serum folate data from a subset of 116 Perth women aged 30-45 years collected during follow-up from a larger study (Hickling *et al.,* 2005), were grouped according to consumption of folic acid supplements: 93 unsupplemented, 23 supplemented. The data for unsupplemented were corroborated by similar post fortification results from studies in Dunedin, New Zealand (Venn *et al*., 2002a; Venn *et al*., 2002b; Norsworthy *et al*., 2004). No folate status data on representative samples of the Australian or New Zealand population have been published.

   Baseline geometric means for serum folates of unsupplemented and supplemented women were 7.9 ng/mL and 12.6 ng/mL, respectively.

2. The average NTD incidence[3] 1999-2003 from the only three Australian jurisdictions with close-to-complete case ascertainment data (Western Australia, South Australia and Victoria) was extrapolated to represent Australia nationally. Australian indigenous birth prevalence rates 1996-2000 from Western Australia were selected. The Australian birth prevalence estimate was applied to New Zealand also because no complete data for terminations were available. Authoritative advice from New Zealand (B Boorman, personal communication) confirmed this was a reasonable assumption. The 2002 national total birth (live and stillborn) statistics including for Australian indigenous women, were selected as the most recent and reliable.

   The national numbers of NTD conceptions a year were estimated as 338 (67 livebirths, 36 stillbirths and 235 terminations) in Australia of which 23 are indigenous conceptions; and 72 (14 livebirths, 8 stillbirths and 50 terminations of pregnancy) in New Zealand. The same outcome proportions were assumed for New Zealand as for Australia.

3. Recently reports of the proportion of Australian women of childbearing age regularly taking folic acid supplements in two Australian jurisdictions (Bower and Stanley, 1989; Chan *et al*., 2001) were used, consistent with other surveyed findings (Allen *et al*., 2000; Maats and Crowther, 2002).

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[3] The incidence of NTDs is the sum of cases of all NTD occurring in livebirths, stillbirths and terminations of pregnancies divided by total births (livebirths plus stillbirths) and expressed as a rate per 1,000 total births.

A lower proportion for New Zealand was used based on findings from a 1999 survey of women (Ferguson *et al*., 1999). 36% of Australian and 20% of New Zealand target population were assumed to be regular folic acid supplement consumers during the critical peri-conceptional period, but indigenous women were assumed to be unsupplemented. The baseline number of NTD conceptions prevented are estimated for Australia: 122 supplements and 216 not supplements; and for New Zealand: 12 supplements and 60 not supplements.

2. Results

Application of the input data described above to the Wald Model provides estimates of the number of prevented NTD conceptions with increasing incremental intakes of 0.1 mg/day between 0.1 to 1.0 mg/day, and based on presently available folate status data of women in Australia and New Zealand. The results from the Model are shown for: supplemented and unsupplemented women, the subset of Australian indigenous conceptions, and also according to health outcome for Australia in Tables 1, 2 and 3, and for New Zealand in Tables 4 and 5.

Table 1: Australia – Predicted numbers of NTD conceptions prevented in supplemented and unsupplemented women of childbearing age, and not prevented, total population

Mg/day increase in folic acid intake	Number of NTD Conceptions Prevented			
	Prevented			*Not* prevented
	Supplemented	Unsupplemented	TOTAL	TOTAL
0 (baseline)	0	0	0	338
0.1	5	21	26	312
0.2	10	39	49	289
0.3	14	53	67	271
0.4	18	66	84	254
0.5	21	77	98	240
0.6	24	86	110	228
0.7	27	95	122	216
0.8	29	102	131	207
0.9	32	109	141	197
1.0	34	115	149	189

Table 2: Australia - Estimated number of NTD conceptions prevented according to outcome, total population

Mg/day increase in folic acid intake	Number of NTD conceptions prevented			
	TOTAL	Livebirths	Stillbirths	Terminations
0.1	26	5	3	18
0.2	49	10	5	34
0.3	67	13	7	47
0.4	84	17	9	59
0.5	98	19	10	69
0.6	110	22	12	77
0.7	122	24	13	85
0.8	131	26	14	91
0.9	141	28	15	98
1.0	149	29	16	104

Table 3: Australia – Predicted numbers of NTD conceptions prevented, and not prevented, indigenous population

Mg/day increase in folic acid intake	**Total Number of NTD Conceptions**	
	Prevented	*Not* prevented
0 (baseline)	0	23
0.1	4	19
0.2	7	16
0.3	9	14
0.4	10	13
0.5	11	12
0.6	12	11
0.7	13	10
0.8	14	9
0.9	14	9
1.0	15	8

Table 4: New Zealand – predicted numbers of NTD conceptions prevented in supplemented and unsupplemented women of childbearing age, and not prevented

Mg/day increase in folic acid intake	**Number of NTD Conceptions**			
	Prevented			*Not* prevented
	Supplemented	Unsupplemented	TOTAL	TOTAL
0 (baseline)	0	0	0	72
0.1	1	5	6	66
0.2	2	8	10	62
0.3	3	11	14	58
0.4	4	14	18	54
0.5	4	16	20	52
0.6	5	18	23	49
0.7	5	21	26	46
0.8	6	22	28	44
0.9	6	24	30	42
1.0	6	25	31	41

Table 5: New Zealand - Estimated number of NTD conceptions prevented according to outcome

Mg/day increase in folic acid intake	**Number of NTD conceptions prevented**			
	TOTAL	Livebirths	Stillbirths	Terminations
0.1	6	1	1	4
0.2	10	2	1	7
0.3	14	3	1	10
0.4	18	4	2	12
0.5	20	4	2	14
0.6	23	5	2	16
0.7	26	5	3	18
0.8	28	6	3	19
0.9	30	6	3	21
1.0	31	6	3	22

An increase in folic acid intake of 0.1 mg/day in Australia would prevent 5 NTD conceptions in supplemented mothers and 21 in unsupplemented mothers, a total of 26 NTD conceptions each year. At this level of intake, 18 terminations would be avoided and 8 total births spared. Similarly in New Zealand, the same increase in folic acid intake would prevent 1 NTD conception in supplemented mothers and 5 in unsupplemented mothers, a total of 6 NTD conceptions each year and comprising 4 terminations and 2 total births.

Estimates in Tables 1-5 of the proportion of preventable NTD conceptions range overall from 8% to 44% for increases in folic acid intake between 0.1 to 1.0 mg/day in the total population and 17% - 65% for the Australian indigenous population. For those regularly taking folic acid supplements in Australia, the preventable proportion is lower because of higher mean folate status, and ranges from 4% to 25%; it is higher for those not taking supplements with lower mean folate status at 10% to 53%. The data show increasingly smaller improvements in the number of cases prevented for every incremental increase in folic acid intake. This reflects the law of diminishing returns. For most intake scenarios, the number of conceptions *not* prevented exceeds the numbers that are prevented.

FSANZ is liaising with consultants to determine if confidence intervals around the point estimates in Tables 1-5 can be determined. At this stage, 95% confidence intervals are available for the total number of NTD conceptions prevented only.

Table 6: Predicted number of total NTD conceptions prevented in Australia, the Australian indigenous population and New Zealand with 95% confidence intervals

mg/day increase in folic acid intake	Total number of NTD conceptions prevented		
	Australia (95% CI)	Australia - indigenous (95% CI)	New Zealand (95% CI)
0.1	26 (14,49)	4 (2,7)	6 (3,11)
0.2	49 (27,84)	7 (4,11)	10 (6,18)
0.3	67 (39,110)	9 (5,13)	14 (8,24)
0.4	84 (50,130)	10 (6,15)	18 (11,28)
0.5	98 (60,147)	11 (7,16)	20 (13,31)
0.6	110 (69,161)	12 (8,16)	23 (15,34)
0.7	122 (77,172)	13 (9,17)	26 (16,37)
0.8	131 (86,183)	14 (9,18)	28 (18,39)
0.9	141 (93,191)	14 (10,18)	30 (20,41)
1.0	149 (100,199)	15 (11,18)	31 (21,43)

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Attachment 10

Food Technology Report

Folic acid and folates

Folates are water-soluble vitamins. The term folate is used generically to refer to the various forms of the vitamins, both naturally occurring and synthetic, and their active derivatives (Committee on Medical Aspects of Food and Nutrition (COMA)).

Natural forms of folate are found in a wide variety of foods including green leafy vegetables, cereals, fruits, grains, legumes, yeast extract and liver. This type of folate is referred to as naturally occurring folate in this report, to differentiate it from folic acid added to food in fortification. Naturally occurring folates generally contain more than one, typically five to seven, glutamate moieties attached to pteroic acid (Ball, 1998). Naturally occurring folate comprises a group of mono- and polyglutamate derivatives of pteroic acid (4-[(pteridine-6-methyl)amino] benzoic acid) (folic acid). Tetrahydro-, dihydro-, formyl-, and methyltetrahydrofolates are the predominate naturally occurring folates in foods.

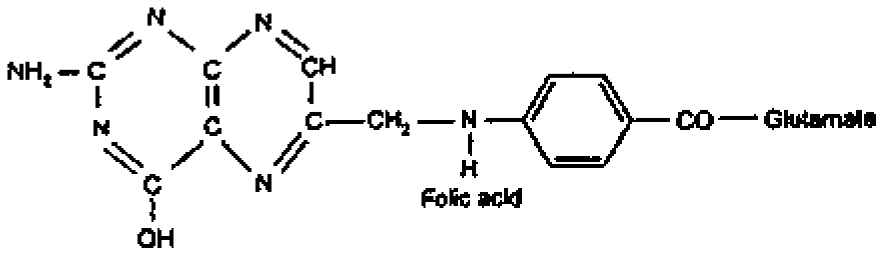
Folic acid, or pteroylmono-glutamic acid (PGA), is the most common synthetic form of folate and is the form used in food fortification and in the majority of supplements. Food Chemicals Codex 5th edition specifies folic acid with the structural formula $C_{19}H_{19}N_7O_6$ and molecular weight of 441.40. As its name indicates, it contains a single glutamate moiety attached to pteroic acid (Ball, 1998). Folic acid is sometimes supplied in the form of disodium folate. Folic acid is rarely found naturally occurring in foods (NHMRC, 1995).

Other forms of folate that could be used in food fortification in future include 5-methyltetrahydrofolate (5-Ch_3H_4PteGlu, or L-methylfolate) and mixtures of naturally occurring forms.
Folates function co-enzymatically as carriers of one carbon units in a variety of reactions involved primarily in the metabolism of certain nucleic acids and amino acids (Gregory, 1989). All folates are similar in structure to folic acid, which comprises a fully aromatic pteridine coupled via a carbon-nitrogen bond to para-aminobenzoic acid, which in turn is coupled via an amide bond through the carboxyl moiety to the amino group of L-glutamic acid. The pteridine moiety of folates can exist in three oxidation states; fully oxidised (aromatic) or as reduced dihydrofolate or tetrahydro folate forms. Tetrahydrofolates are the co-enzymatically active forms of the vitamin.

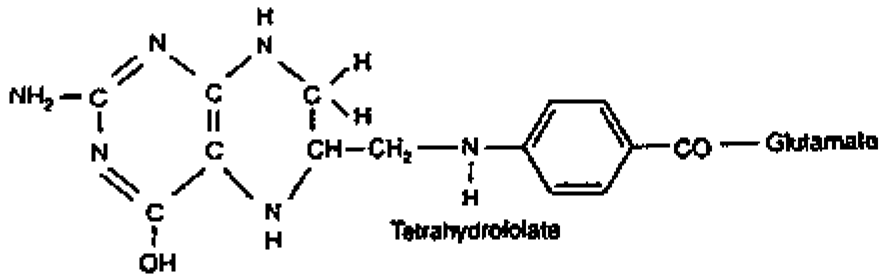
Nutritional deficiency of folate is common in people consuming a limited diet. Although folate is found in a wide variety of foods, it is present in a relatively low density except in liver. Folate losses during harvesting, storage, distribution, and cooking can be considerable. Likewise, folate derived from animal products is subject to losses during cooking. Some dietary staples, such as white rice and unfortified corn, are low in folate.

The literature on folate levels in processed foods is confusing with regard to reported losses as foods fortified with folic acid lose both naturally occurring folate and added folic acid.

The chemical formula of folic acid (synthetic form) and the most important natural folates.



Folic acid



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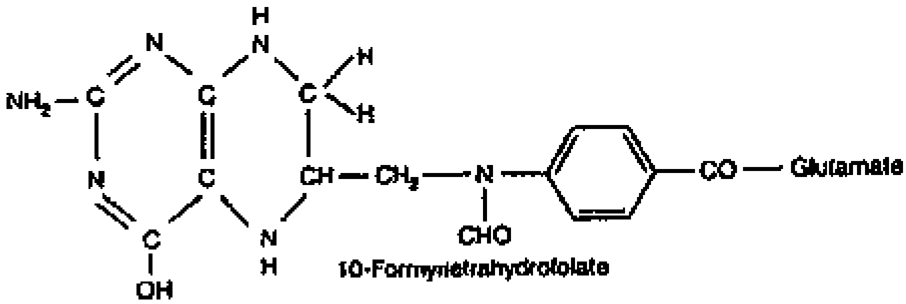
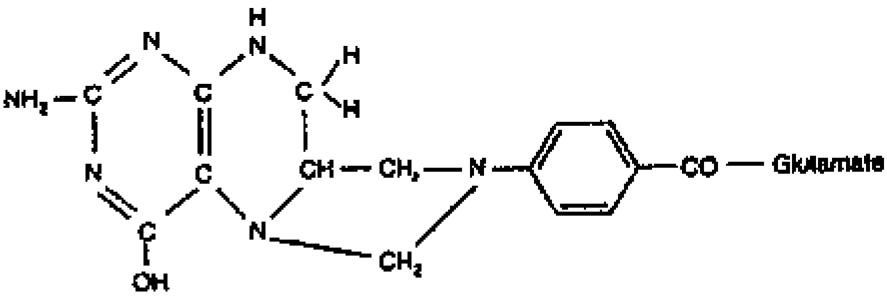
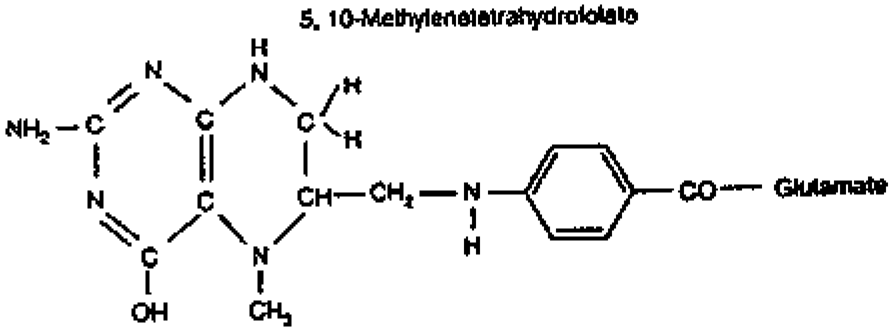


10-Formyltetrahydrofolate



5, 10-Methylenetetrahydrofolate



5-Methyltetrahydrofolate

Stability of folates and folic acid in foods

Stability of folates generally

Compared with other water-soluble vitamins, literature on the extent and mechanisms of folate loss during processing is limited. Studies examining the stability of naturally occurring folate in food indicate that folate retention is highly dependent both on the food in question and the method of preparation. For example, boiling of spinach and broccoli can result in less than 50% retention, while steaming may result in no significant decrease in folate content. In contrast, folate is well retained in potatoes during boiling. Folates of animal origin (i.e. beef) have been found to be relatively stable to cooking even for prolonged periods (McKillop *et al*., 2002). The different chemical forms of folate may also exhibit different responses to degradative factors such as exposure to light, oxygen and pH (Ball, 1998).

The United States Department of Agriculture (2003) publishes factors for the estimation of nutrient retention in cooked foods. These factors are in general agreement with the results of the studies described above. Folate was found to be relatively stable to cooking or processing methods such as freezing (e.g. 95% retention in frozen fruit), baking/roasting (70% retention in baked pasta, 95% retention in roast beef) and reheating (95% retention for a range of foods). Where the food was boiled, retention was notably lower (e.g. 25% retention in boiled legumes to 60% retention in boiled rice), which was likely to reflect leaching of this water-soluble nutrient into the cooking water. Retention factors for folic acid were equivalent to those for naturally occurring folates, which suggests no significant differences in stability of naturally occurring and added folate under normal domestic cooking conditions (USDA, 2003).

Processes such as fermentation may increase folate content through the growth of yeast, which is a rich source of folate. For example, Arcot *et al*. (2002) found increases in the folate content of bread doughs after fermentation, although levels in the finished breads declined by around one-third after baking. Baker's yeast *Saccharomyces cerevisiae* contributed markedly to the final folate content of wheat and rye breads due to its high folate content and also by synthesizing folates during processing (Kariluoto *et al*., 2004). Morgan (1995) cited a Canadian study that found increases in folate content after fermentation of milk to produce yoghurt.

Stability of added 5-methyltetrahydrofolate

Information on the stability of 5-methyltetrahydrofolate is quite limited. In a 1982 study, a lactose-casein liquid model food system fortified with 5-methyltetrahydrofolate was subjected to retort processing (121°C for 20 min). Approximately seventy-five per cent of the 5-methyltetrahydrofolate was degraded (Ball, 1998). A recent study on the stability of 5-methyltetrahydrofolate in frozen fruits and vegetables found no significant changes in levels for spinach, strawberries, oranges, broccoli, bananas, potatoes or apples stored for twelve months (Phillips *et al*., 2005).

Sulphurous acid and nitrites, two chemicals commonly used in food processing, have also been known to cause losses of 5-methyltetrahydrofolate in liquid model food systems (Tannenbaum *et al.,* 1985, Reed & Archer, 1979).

Stability of folic acid added to foods

Studies examining the stability of added folic acid appear to have focussed only on several specific classes of food including cereal products, dairy foods and fruit juices (NHMRC, 1995). There are two key issues to consider in reviewing the stability of added folic acid - stability during processing and stability during post-processing storage. In general, processing/production losses appear to be more significant than losses during storage. Foods with short shelf lives will also lose less folate due to storage.

Generally, studies have been able to demonstrate good stability of folic acid to heat. A 1975 study examined the retention of folic acid in aqueous solution and found that after boiling the aqueous solution, retention was 100%, after baking for 90 minutes 91%, and after baking for 120 minutes 81%, compared with an untreated aqueous solution (NHMRC, 1995).

A second study supporting the results obtained above, found that in aqueous solution, folic acid was stable at 100°C for 10 hours in a pH range of 5.0-12.0 when protected from light. However, it became increasingly unstable as the pH was decreased below 5.0 (Ball, 1998).

In another study, losses of folic acid during bread baking averaged about 11%. Common bread additives had no effect on the stability of added folic acid at any stage in this study. Other studies reported retention levels in baked breads made with fortified flours from 61% to 100% (Gregory, 2004). There is some confusion in comparison of studies of folic acid losses in breads as it is not always clear whether total folate is being measured or just folic acid as a fortificant and the folic acid content reported may be in the final bread or in the ingoing flour. Furthermore, different bread production methods using yeast or bacterial fermentations, the possible use of chemical raising agents as in soda breads, dough improving additives and the fermentation, baking or steaming processes used can all effect folic acid and total folate losses. The average loss of folic acid from fortified breads appears from the literature to be about 25% but may be as high as 40%. In terms used by millers to fortify flour to allow for these losses the respective overages would be 1.33 to 1.67.

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

These results are supported by a review of a number of studies on fortified cereal based products undertaken by Ranhotra and Keagy in 1995, as reported in Morgan (1996). The review indicated that the stability of added folic acid after various treatments including boiling (pasta), and baking (biscuits and bread) was high, with the retention ranging from 75-92%.

Ready-to-eat breakfast cereals were found to average a 25% production loss of folic acid. Cereals fortified prior to extrusion had losses varying between 8% and 65%, a huge range dependant on the amount of water present and the throughput of the process (Morgan, 1996).

Generally, the retention of folic acid is high during storage. Studies during the 1970s indicated that folic acid mixed with flour is stable (100% retention) after six months at room temperature or four weeks at 45^{0}C.

Even after one year of storage at around 45⁰C, flour showed only small losses. Similarly, retention was 90-100% in pre-mix fortified yellow corn (NHMRC, 1995). A 1995 study in which folic acid was added at either 100 μg/100 g or 500 μg/100 g of flour showed around 100% retention at a range of temperatures (-23 to 48.8°C) after one year's storage (Morgan, 1996).

With regard to juices, in a 1982 study, folic acid added to apple juice and tomato juice was found to very stable even after long periods of heating which would exceed those required for pasteurisation or sterilisation (NHMRC, 1995).

The stability of naturally occurring folate in dairy products has been studied extensively, but little attention has been paid to fortifying dairy products with folic acid. Pasteurisation of milk by conventional or ultra high temperature short time processes leads to less than 20% losses of folate. 24 hours at 4⁰C storage led to no change in folate content. In contrast, a progressive decline in folate occurred during storage at -20⁰C with about 55% loss over three months (Gregory, 1989).

Method of addition of folic acid to flour

The current method of adding thiamin to breadmaking flour as required in Australia is by using feeders at the end of the milling process. Adding further feeders for folic acid or preblending thiamin and folic acid would therefore be expected to be used for folic acid addition to breadmaking flour in Australia. As thiamine fortification of breadmaking flour is not mandatory in New Zealand, the process for addition of folic acid is not yet determined. To allow for the justification of new capital expenditure, ordering, delivery, installation and commissioning a period of 12 months would be expected to be required.

Milling process

Historically, the basic milling technique was to grind the grain between two stone surfaces. This enabled the tough fibrous bran skin to be separated from the endosperm, which then was ground into a fine powder and called "stone ground flour".

In modern flour mills, millstones have been replaced by steel rollers. The main aim of the milling process is to separate the maximum amount of endosperm (flour) from the non-endosperm material (bran and germ). The amount of non-endosperm material included in flour influences not only its colour, visual appearance and ash content but also its functional properties for end users due to a complex series of physical and chemical interactions. Flour produced from an entire wheat kernel is also known as 'Graham Flour'. The milling system of cereals differs according to the differences in anatomical structure of the cereal.

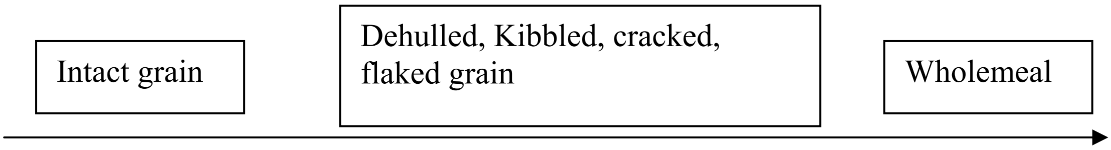
The steel roller milling system for the production of flour aims to open up the grain, remove the bran layers and the germ and to grind the pure endosperm into flour.

To achieve this, a series of grindings and separations are employed, the gradual nature of which is designed to produce white flour having a minimum of bran and germ content. The milling system can be divided into three distinct stages (1) a breaking operation; (2) a series of separations of the ground components by means of both particle size and density; and (3) a size reduction system.

The milling system contains two types of rolls, break rolls, which are fluted, and reduction rolls, which are smooth. The break rolls function to open up the structure, whereas the reduction rolls reduce the particle size.

Each grinding stage yields a ‘grind’ consisting of a mixture of course, medium, and fine particles, including a proportion of flour. The different size particles are sorted by sifting. Some of the course particles are potentially flour yielding: they are conveyed to a subsequent grinding stage; others can yield no useful flour; these are removed from the milling system and contribute to the milling by-products.

To describe how much of the wheat grain is found as flour after the milling the term ‘extraction rate’ is used. An extraction rate of 100% signifies that 100% of the wheat grain is delivered as flour; this flour could be described as a whole wheat meal. The bulk product from the mill, the straight-grade flour, generally represents an extraction of around 70%.



Cereal Products

Grains, flour and other milling products are used to produce a very wide range of food products, including bread, cakes, pastries, biscuits, pasta, noodles, breakfast cereals, cereal bars, snack foods etc. A few examples of these product processes are briefly described below.

Bread

White bread is made from white wheat flour which has been milled at a high extraction rate. Wholemeal bread (also labelled wheatmeal or wholewheat) is baked from wholemeal flour. Brown bread is usually made from a mixture of wholemeal flour and white flour. Mixed grain bread (multigrain) is made with a mixture of wholemeal and/or white flour, rye meal and/or flour with cracked or kibbled grains which stand out in the slice. Fibre increased breads have extra fibre (in the form of wheat, oat bran, or soy hulls) to increase the fibre content of the bread.

Conclusion

Nutritional deficiency of folate is common in people consuming a limited diet. Although folate is found in a wide variety of foods, it is present in a relatively low density except in liver. Folate losses during harvesting, storage, distribution, and cooking can be considerable.

Folic acid, or pteroylmono-glutamic acid (PGA), is the most common synthetic form of folate and is the form that is usually used in food fortification and for supplements. Folic acid appears to be the most stable in the majority of foods although there is a lot of conflict in the literature concerning stability and there is some confusion as to the forms measured.

Tetrahydrofolates are the co-enzymatically active forms of the vitamin, but the stability of these forms appears to be a limiting factor for many foods.

Studies examining the stability of naturally occurring folate in food indicate that folate retention is highly dependent both on the food in question and the method of preparation. Boiling foods can lead to significant losses by leaching. The different chemical forms of folate may also exhibit different responses to degradative factors such as exposure to light, oxygen and pH.

Retention factors for folic acid were equivalent to those for naturally occurring folates, which suggests no significant differences in stability of naturally occurring and added folate under normal domestic cooking conditions. Processes such as fermentation may increase folate content through the growth of yeast, which is a rich source of folate.

There are two key issues to consider in reviewing the stability of added folic acid - stability during processing and stability during post-processing storage. In general, processing/production losses appear to be more significant than losses during storage. Foods with short shelf lives will also lose less folic acid due to storage.

Losses of folic acid from bread average about 25% but may be as high as 40%.

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Attachment 12

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

Monitoring is a fundamental component of mandatory and voluntary fortification programs, to ensure that fortification is effective, both in meeting the objectives of improving the nutritional intake and status of the target population as well as ensuring the public health and safety of target and non-target groups (Stanley at al 2005, Nexus 2006). Information from an ongoing monitoring system will also provide evidence for future policy decision making on whether to continue a mandatory fortification program or not.

The Australia and New Zealand Food Regulations Ministerial Council *Policy Guideline on the Fortification of Food with Vitamins and Minerals* (Policy Guideline, ANZFRMC 2004) provided guidance on monitoring for both mandatory and voluntary fortification.

1. Policy Guideline

1.1 Mandatory Fortification Programs Monitoring Framework

The Policy Guideline states for mandatory fortification that:

> *Any agreement to require fortification should require that it be monitored and formally reviewed to assess the effectiveness of, and continuing need for, the mandating of fortification.*

In December 2004, FSANZ sought advice from the Food Regulation Standing Committee (FRSC) in relation to monitoring the impact of mandatory fortification, as required by the Policy Guideline. A FRSC sub-group working on this advice provided a draft framework in December 2005 for the development of monitoring systems to complement mandatory fortification programs. The FRSC sub-group met in June 2006 to further progress this draft framework for consideration by FRSC at its next meeting (FRSC sub group 2006). An agreement was also made at the FRSC sub group meeting to establish an expert group to develop the monitoring system specifically required for folate/folic acid.

The draft framework notes that for any given mandatory fortification program a monitoring program will need to be developed and will vary from nutrient to nutrient. The purpose of this monitoring will be to assess the effectiveness of and continuing need for the specific mandatory fortification program.

1.2 Monitoring the impact of food standards decisions on the voluntary addition of vitamins and minerals to specific foods

Similarly for voluntary fortification, the Policy Guideline states:

> *A permission to voluntarily 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.*

As part of its role in developing food standards that permit voluntary addition of vitamins and minerals to specific foods, FSANZ has agreed to develop a five year monitoring system to assess the impact of these decisions over time on the nutritional status of the Australian and New Zealand populations.

For nutrients such as folate, where there is likely to be a mandatory requirement to fortify some food products with folic acid as well as voluntary permissions to fortify other products, the monitoring system will need to include information on the impacts of both mandatory and voluntary fortification.

2. Proposed monitoring system

The responsibility of monitoring the impact of fortification of foods with folic acid extends beyond FSANZ's responsibilities under the *Food Standards Australia New Zealand ACT 1991*, and will require the concomitant involvement of health and regulatory agencies at a Commonwealth, State and Territory level in Australia and the New Zealand Government.

FSANZ has adapted the draft generic monitoring framework for mandatory fortification prepared by the FRSC working group and outlined the potential elements of a monitoring system that aims to assess the impact on consumers of mandatory fortification of the food supply with folic acid.

As for any monitoring system, the collection of baseline data prior to or just after the implementation of the fortification program and at some time in the future to assess changes in performance measures is essential.

2.1 Objective of monitoring system

The main objective of a comprehensive monitoring system for folate would be to investigate the impact of cumulative fortification permissions for folic acid (mandatory and voluntary) on the:

- food supply; and
- population as a whole and on population subgroups in relation to health (assessed in terms of incidence of NTDs for the target group of women of child bearing age, levels of folate, folic acid and homocysteine in the blood, adequacy of nutrient intakes, safety of nutrient intakes and incidence of adverse health affects linked to excessive folic acid intakes for general population).

2.2 Clarification of questions to be asked and answered by data collected via the monitoring system

In developing a monitoring system the FRSC sub group notes that the questions to be answered need clarification (FRSC sub group 2006). Figure 1 is an outcomes hierarchy outlining process, impact and outcome questions to be considered.

The draft FRSC sub group framework identifies three areas relating to the development of a monitoring system for the addition of vitamins and minerals to the food supply:

1. Monitoring components, for example nutritional status of the target and non-target population, nutrient composition and variability in fortified foods, industry and consumer awareness and support/acceptance of the fortification program.
2. Data collection and mechanisms, noting to use routine data collections if available and the need for specific market research regarding industry and consumer awareness.
3. Timeliness, noting that baseline data on health status, nutritional status and nutrient intake should ideally be collected prior to implementation of a fortification program.

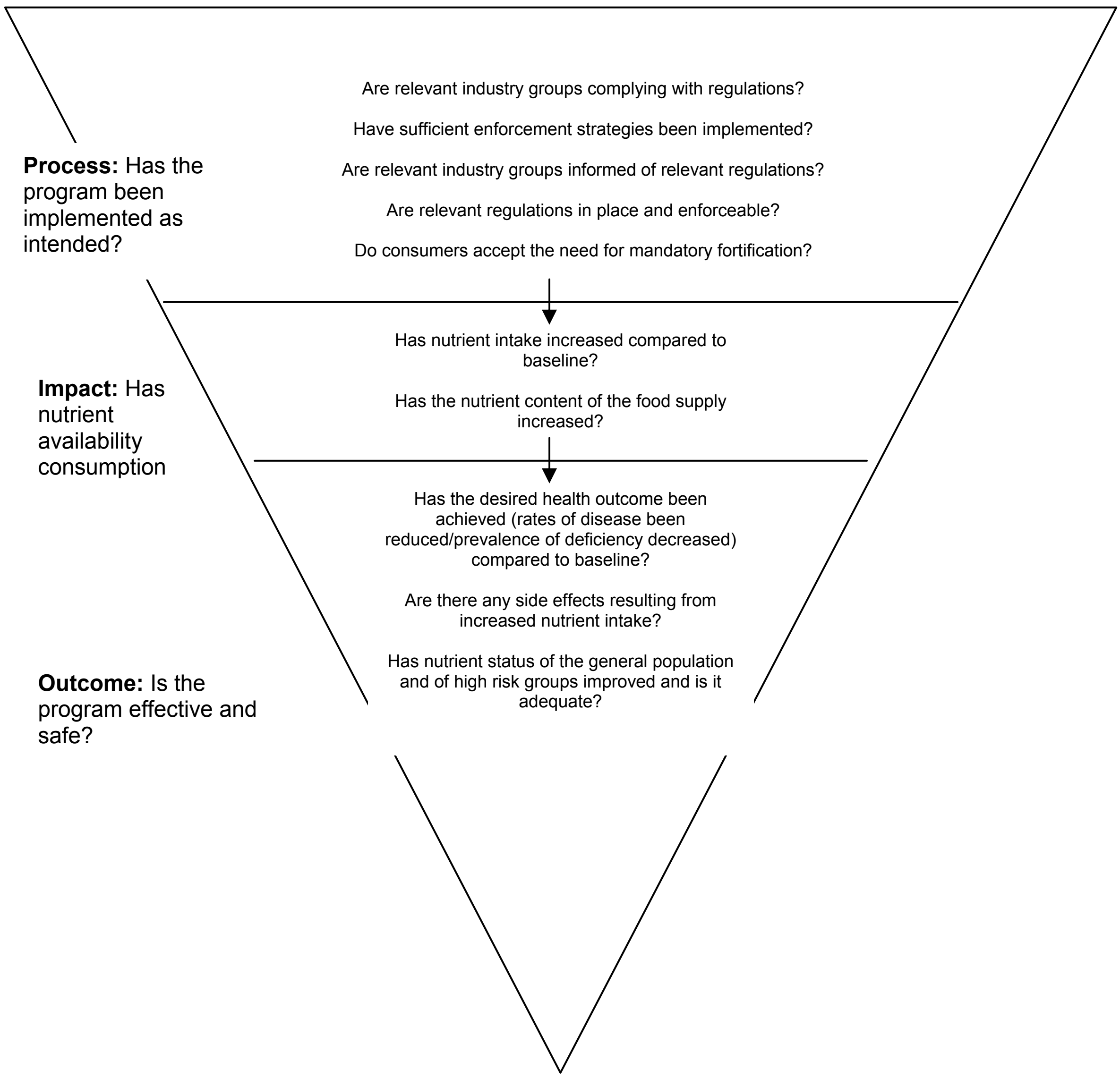


Figure 1: Outcomes hierarchy for monitoring mandatory fortification programs (adapted from Abraham B, Webb K 2001)

2.3 Developing a monitoring system for folic acid fortification

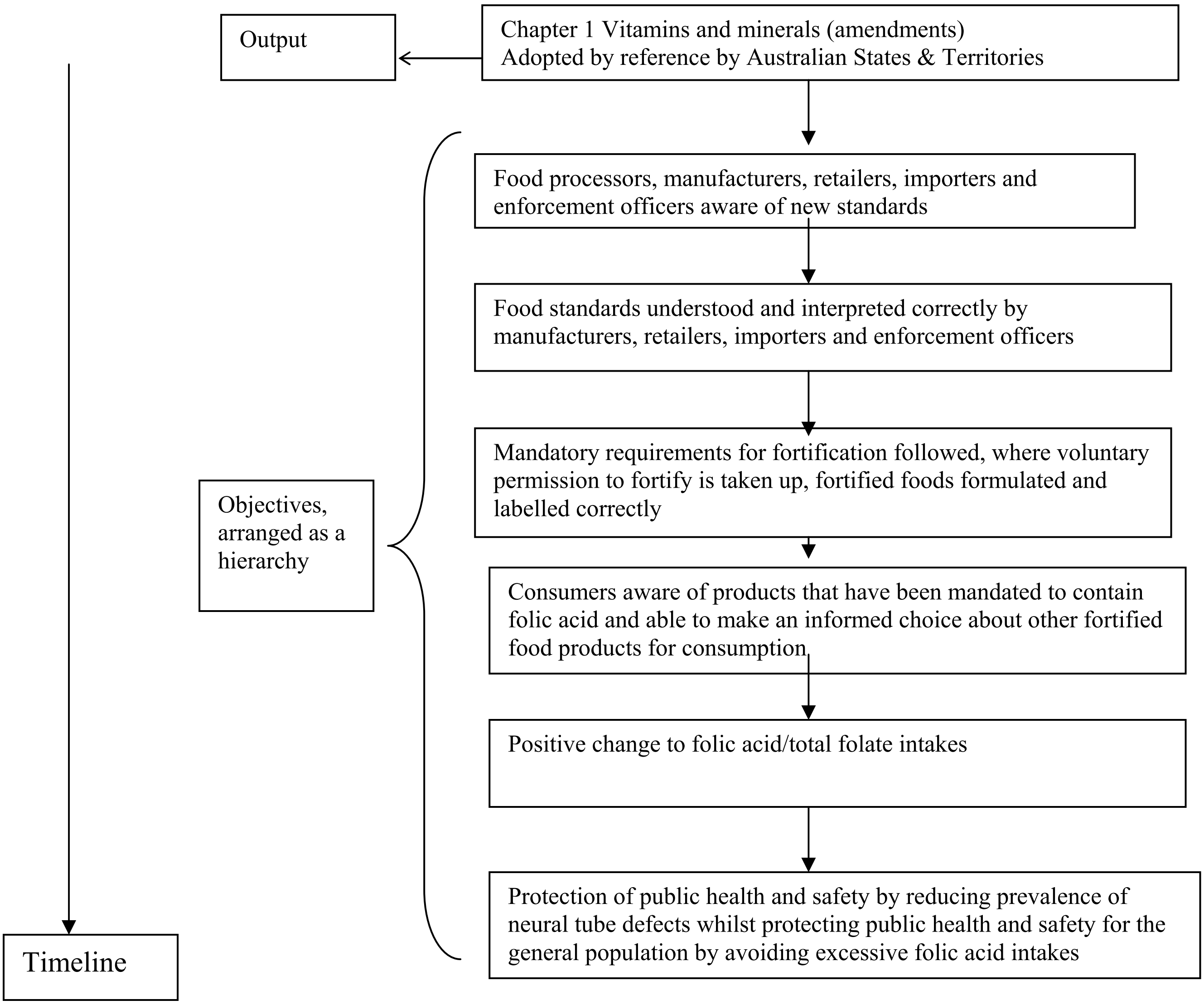
Ideally, most of the data required to monitor the impact of folic acid fortification would be collected as part of an existing ongoing national food and nutrition monitoring system (Nexus 2006, Marks et al 2001, Stanley 2005). In New Zealand national nutrition surveys are conducted on a regular basis. However, as such a system has not been established to date in Australia, the proposed monitoring system for folic acid fortification taps into existing data collections where possible and identifies where new work is required, similar to the approach taken in Canada to evaluate their fortification program (PHAC 2005). Parts of the monitoring system outlined here will be common to all monitoring systems for nutrients, for example, the collection of data on food consumption patterns.

Characteristics of good monitoring systems have been developed as part of the Tasmanian Iodine Monitoring Program and address issues such as acceptability, compatibility, cost, equity, performance and technical feasibility of the elements selected to form part of the comprehensive system (Appendix 1). Consideration of these and other characteristics provides a useful checklist for the development of monitoring systems in a health environment designed to support fortification programs.

2.3.1 Steps required to achieve an effective reduction in the prevalence of neural tube defects

In achieving the end objective of folate fortification of the food supply, protecting public health and safety by reducing the prevalence of NTDs in the Australian and New Zealand populations whilst maintaining the safety of the general population, it is useful to take a program logic approach to identify the interim steps and objectives that must be achieved before this end objective is reached, as shown in Figure 2 (UNDP 2002). This framework also indicates a timeline, in that each step has to be in place before the next step can be achieved or measured. For example, the food industry will be given a transition period to implement mandatory fortification and may take time develop new products once a voluntary permission to fortify is given. Measurement of impact on consumer awareness, behaviour , food consumption patterns and ultimately on the prevalence of neural tube defect must therefore be undertaken at a reasonable time interval after the products appear on the shelves for purchase.

Figure 2: Evaluation of permissions to fortify foods against FSANZ Act section 10, objectives



2.3.2 Assessing interim outcomes

As the main objective of a mandatory fortification program for folic acid is to reduce the incidence of NTDs, measurement of change in NTD incidence (including still births) would be an essential component of any monitoring system that aims to assess the effectiveness of the policy. It would also be necessary to collect information on potential unintended adverse health effects of increasing folic acid intakes for the target and non target groups in the population.

Although not absolutely essential it would also be very useful for future policy decision making on whether to continue a mandatory fortification program or not, to collect additional data on how the fortification policy has affected the whole food system.

This would be particularly important if implementation of the mandatory fortification program did **not** achieve the desired end outcome of reducing the incidence of NTDs by the expected amount, or if there was evidence that it was adversely affecting the population in general.

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

In many cases it is difficult to interpret data to assess the effect of implementing a food standard against the end objective of setting that standard. The external influences on public health and safety as a whole are so complex and influenced by many external factors that a measured change to the level of health and safety of a given population group cannot generally be attributed to a single influence, a single agency or action by an agency, such as a change in food regulatory measures. In this case, it is complicated by the fact that the expected decrease in NTDs would result in a relatively small number of NTDs avoided, hence it will be difficult to assess the statistical significance of any measured change. However, reasonable performance measures (indicators) can be developed for interim objectives to assess if they have been achieved.

In selecting performance measures for specific monitoring activities in a fortification monitoring system it is important to determine priority setting criteria and assign a relative importance to them (see Appendix 1, adapted from Reardon 2002). The determination of priorities for different elements of the monitoring system for assessing the impact of folic acid fortification will be the subject of discussion for the expert group to be established under the FRSC sub group. Selection of elements will be dependent on the usefulness of the data collected to measuring the success of the fortification program as well as the funds agreed and set aside for this purpose.

2.3.3. Proposed monitoring activities for folate fortification

The questions posed by the FRSC sub group that need to be asked and answered as part of any monitoring system for fortification (Figure 1) have been linked to the interim steps identified in Figure 2 that need to be in place to achieve a reduction in the prevalence of neural tube defects in Table 3. Performance measures are suggested for each step, with the method of measurement and the agency(ies) with potential responsibility for undertaking the proposed program activities outlined. Further details of each proposed program activity is given in Appendix 1.

It is apparent that an increasing number of external factors that may affect the outcome come into play as you go down the flow chart that shows the hierarchy of outcomes and that it will not be feasible for FSANZ on its own to develop a means of measuring all interim outcomes. The funding and staff resources required need to be considered for each option, as does the role and responsibilities of each agency and the potential usefulness of the information collected to FSANZ, other Commonwealth agencies and the jurisdictions.

Obviously, one of the most important data sources on the overall impact of fortification of the food supply on nutritional status will be that obtained from national nutrition surveys (NNS) as outlined in Table 2, Interim objective 6, providing a baseline and follow up survey are undertaken. Suggestions for other data collections to assess interim objectives 1-5 are intended to complement NNS data, not replace these data.

Table 3: Monitoring the impact of regulatory decisions to add folic acid to foods (mandatory and voluntary)

Interim objective	Questions to be answered	Performance measure	Method	Responsibility
1. New V&M standard in place (mandatory and/or voluntary requirements)	Are relevant regulations in place and enforceable?	Standards implemented in S&T, NZ.	Report back from jurisdictions when standards adopted into their food laws, with assessment of enforcement capability.	FSANZ, NZFSA, S&T agencies with food regulatory responsibilities
2 & 3. Food processors, manufacturers, retailers, importers and enforcement officers aware of new standards **Food standards understood and interpreted correctly by manufacturers, retailers, importers and enforcement officers**	Are relevant industry groups informed of relevant regulations? Have sufficient enforcement strategies been implemented?	Proportion of food processors, manufacturers, retailers, importers and enforcement officers who know about and interpret standard correctly.	Stakeholder surveys	FSANZ
4. **Mandatory requirements for fortification followed, where voluntary permission to fortify is taken up, fortified foods formulated and labelled correctly**	Are relevant industry groups complying with regulations? Has folate content of food supply increased?	**Foods available:** Proportion of different categories of foods that have added folic acid. **Labelling requirements**: Proportion of different categories of foods labelled correctly. Proportion of fortified foods where actual content reflects label claims. **Nutrient content:** Changes in folic acid concentrations in food.	Data from manufacturers on brands available in market with added folic acid, and content to be updated annually. Folic acid disappearance data. Collect data on labelling of foods with added folate via ongoing label monitoring survey. **Analytical survey of level of folic acid/folate compared with label information.** Update Australian and NZ national food composition databases on regular basis	FSANZ/AFGC/NZFGC to coordinate ISC Coordinated survey plan project - FSANZ lead agency S&T, NZ could assist with analysis of foods vs. labelling claim FSANZ NZFSA with NZ Crop and Food Institute

Interim objective	Questions to be answered	Performance measure	Method	Responsibility
5. Consumers aware of products that have been mandated to contain folic acid and able to make an informed choice about other fortified food products for consumption	Do consumers change their attitudes and behaviour in relation to food purchases and consumption? Why? Do consumers accept the need for mandatory fortification? How do consumers use folic acid supplements?	**Food consumption patterns**: Proportion of consumers consuming foods with added folic acid, amounts of food consumed. Changes in food purchase patterns for Aboriginal and Torres Strait Islander groups **Supplement consumption** Proportion of target and non target group consuming supplements with added folic acid, amounts consumed. **Research consumer attitudes and behaviours towards fortified foods:** Changes in consumer understanding and behaviour in relation to folic acid fortified foods and food labelling.	Survey of individuals (type of food consumed, frequency, amount): a) National dietary survey of individuals (FFQ survey and 24-hour recall) every 10 years. b) Roy Morgan Single Source survey (Australia and NZ) and Young Australian survey, frequency of food consumption for individuals every 3 months. c) Market basket surveys of remote area stores National dietary survey of individuals (as above). Other national, S&T surveys. Consumer attitudes to food standards issues tracking survey. Targeted consumer surveys on specific issues incl response to education campaigns, substitution patterns for new products, consequential behaviour change. Call back surveys to sub set of respondents in Roy Morgan Single Source survey and Young Australian survey on specific foods/issues.	DOHA with jurisdictions, FSANZ NZFSA/MOH NZ FSANZ as coordinating agency S&T As above Inclusion of relevant questions to be negotiated FSANZ, NZFSA

Interim objective	Questions to be answered	Performance measure	Method	Responsibility
6. Positive change to folic acid/folate intakes	Has folic acid/folate intake increased compared to baseline? Is folic acid/folate status of the general population and target groups improved and adequate compared with NRVs?	Changes in proportion of consumers meeting reference health standards for folic acid/folate	Nutrient intake assessments: a) NNS 24- hour recall survey with repeat 24 hour record for second day nutrient adjustments, preferably with information on folic acid supplements consumed.	Inter-agency (incl TGA), FSANZ NZFSA/MOH NZ
7. Protection of public health & safety by reducing prevalence of neural tube defects and no adverse effects for general population	Has the desired health outcome been achieved for target group (i.e. rates/incidence of NTDs decreased compared to baseline)? Are there any side effects resulting from increased intake for target or non target groups?	Changes in rates of NTDs, Changes in serum folate, RBC folate, vit B12 levels, homocysteine blood levels Changes in proportion of consumers exceeding upper levels of folic acid intake Changes in other health indicators to which links to excessive folic acid intake have been made	Perinatal statistics (national minimum data set) Blood tests NNS 24- hour recall survey with repeat 24 hour record for second day nutrient adjustments, preferably with information on folic acid supplements consumed. Health statistics for twin birth rates, cancer rates etc from existing data collections. Literature review of existing programs with published data	AHMAC, National Perinatal Statistics Unit Could be incorporated in existing studies by negotiating extra funding for add on component e.g. AUSDIAB, NZNHS? Inter-agency (incl TGA), FSANZ NZFSA/MOH NZ AIHW

3. Key consumer issues

There is a growing evidence base on Australian and New Zealand consumer attitudes and behaviour in relation to general food labelling issues (FSANZ 2001, 2003a, 2003b, 2003c, 2004a, 2004b, 2005c, 2005d). However, there is a paucity of data and research covering consumer response to fortification of the food supply and in particular to voluntary fortification, where there may be a choice of fortified and non-fortified products within a given food category (Frewer 2003, Health Canada 2005a, 2005b). The situation is further complicated when considering voluntary fortification, as additional opportunities for consumer choice may be provided in a fluid and evolving marketplace. The nature and scale of impacts on public health and safety as a consequence of mandatory and voluntary fortification will be determined in part by the actions and behaviour of consumers. However the behaviour of consumers is complex, difficult to predict, and is influenced by many factors.

With respect to fortification some of the key consumer issues that have been raised include (in no specific order):

- awareness and understanding of the fortification of foods;
- likely consumption patterns including degrees of substitution of existing foods by new fortified foods, and of the addition of fortified foods to diet;
- impacts of product consumption on other lifestyle/health behaviours (e.g. alcohol use and exercise levels)
- likely consumption patterns within demographic and cultural groups;
- degrees of consumer choice/autonomy;
- advertising claims and the construction of fortified foods as healthy;
- complexity of health and diet messages and potential for conflicting advice; and
- ensuring informed consumer choice.

A monitoring study provides an opportunity to collect relevant data and research on consumer attitudes and behaviour and to substantiate or qualify the assumptions made in risk assessments undertaken by FSANZ in preparing standards on fortification on how consumers may behave when faced with a choice of fortified and unfortified products, for example, what product may be substituted in the diet if a fortified version of the product is selected, and to assess the overall impact of these decisions on the resultant nutritional status of the population.

4. Costs and resources

Comprehensive monitoring systems are expensive and difficult to resource on an ongoing basis, however an ongoing system is much more effective, minimising the costs of lost expertise and resources overtime compared to one off systems (Nexus 2006). As mentioned above there will be a need for joint sharing of costs and resources for a monitoring system between Commonwealth, State, Territory and NZ agencies. Wherever possible data collections should be added onto existing surveys or data collection systems as this will minimise the overall costs.

Table 5 gives some indicative costs for assessing the outcome of each component in the proposed monitoring system, drawn from current costs for consumer research, predicted costs for the proposed Australian national children's nutrition and physical activity survey and proposed costs to AHMAC for the development of a national minimum data set for perinatal statistics (including still births). At its June 2005 meeting, AHMAC agreed to advise Health Ministers that establishing a national monitoring system for neural tube defects should accompany any decision on mandatory fortification.

Further details are given in Appendix 2, noting that for each interim objective there may be several program activities that will contribute to the collection of data for performance measures, each with a different allocation of funds. The priority accorded to each program activity will need to be agreed by all participating jurisdictions and agencies and used as a guide to allocate funding overall. As this monitoring system will generate a large amount of baseline and follow up data, funding for a program support officer has been included in the costs to provide a coordinating role for system establishment, data collation, reporting and communication of outcomes.

Table 5: Indicative costs for the proposed monitoring program activities for Australia

Interim objective	**Program activities**	**Costs over 5 years**
1. New V&M standard in place (mandatory and/or voluntary requirements)	Report from jurisdictions to FSANZ	NIL
2 & 3. Food processors, manufacturers, retailers, importers and enforcement officers aware of new standards Food standards understood and interpreted correctly by manufacturers, retailers, importers and enforcement officers	Baseline and follow up stakeholder attitude and behaviour surveys (email or CATI)	$ 180 000
4. Mandatory requirements for fortification followed, where voluntary permission to fortify is taken up, fortified foods formulated and labelled correctly	Update National food Composition Database regularly Reporting system for food industry on products available, Label monitoring survey Label compliance analytical surveys	$365 000 per country (Excl label compliance surveys)
5. **.** Consumers aware of products that have been mandated to contain folic acid and able to make an informed choice about other fortified food products for consumption	National nutrition survey (costed in (6), Food frequency surveys (Roy Morgan) Market basket store surveys in remote communities Consumer attitude and behaviour research State and Territory surveys (add on to existing surveys)	$ 590 000 (Excl S&T surveys)
6. Positive changes to folic acid/folate intakes	National Nutrition Survey	$ 100 000* per country (Excl S&T surveys)
7. Protection of public health & safety by reducing prevalence of neural tube defects	National nutrition survey (as above) Perinatal statistics collection (minimum data set) Add on to existing blood surveys, other health data collections	$ 390 000 (Excl blood surveys)
Overall system support	Project support officer	$ 500 000

* It should be noted that the cost of reporting one nutrient from a national nutrition survey has been included here, assuming a national nutrition survey program is in place, by diving the total cost of a survey by the number of nutrients to be reported . If a food consumption survey had to be established as a one-off cost for the folic acid monitoring system the costs would be much higher (see Appendix 2).

4.1 FSANZ's contribution to the monitoring system

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

- tracking changes in the food supply for fortified/unfortified foods in key food categories in consultation with the food industry (interim step 2/3);
- updating the food composition databases via the Key Foods Analytical Program and entry of results into the Australian National Nutrient Database that FSANZ manages and subsequent national nutrition survey databases (interim step 4);
- tracking labelling changes on fortified foods via the ongoing FSANZ label monitoring survey (interim step 4);
- tracking changes in food consumption patterns for different demographic groups (food consumption frequency only) in key food categories that are likely to be fortified via purchase of Roy Morgan Single Source Survey data (interim step 5); and
- researching changes in consumers' attitudes and behaviour towards fortified foods (interim step 5).

FSANZ may also be involved indirectly in other program activities.

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Appendix 1

Table 1: General characteristics of a good monitoring and surveillance system in a health environment (adapted from Reardon 2002)

Characteristics	***Explanation***
Management structure	• Access to an advisory committee or expert group • A focus on building partnerships and providing leadership – links with both the research and practice sector, links with interventions to improve nutrient status and health outcomes • Links with policies and other key client groups • Sound data management processes and data confidentiality procedures and expertise in interpreting and analysing the data • Commitment to data development and harmonisation, where required • Sound understanding of data ownership
Communication	• Regular reporting/publication of findings • Results accessible to stakeholders (in a user-friendly form) • Follow-up and feedback to participants and stakeholders • Capacity to produce high quality, timely and accessible statistical reports and information
Sustainability	• Adequate infrastructure to ensure ongoing monitoring and minimise loss of expertise) • Commitment to and access to ongoing funding • Retention of expertise and avoidance of start up costs resulting from intermittent funding • Alignment with the broader health monitoring systems
Flexibility	• Regular reviews to respond to scientific developments • Capacity to identify and address data gaps and deficiencies

Table 2: Priority setting criteria for selecting performance measures (adapted from Reardon 2002)

Priority setting criteria	**Explanation of meaning**	**Relative importance**
Acceptability	How acceptable is it to the target population? How acceptable is it to the field staff doing tests? Are there any ethical concerns?	High
Compatibility	Are selected measures compatible with other monitoring and surveillance programs on nutrient status?	Medium
Cost	What is overall cost (capital, recurring cost for consumables, maintenance costs, training, admin and salary costs)? Is cost of program proportionate to problem? Who gains benefits, who bears the cost? Will it save resources overall?	Medium-high
Equity	Will there be an unequal burden on sub groups of population? Are all sub groups considered? If not why not?	Medium
Interpretability	Will measures be reflective of whole population? Are there adequate reference data to interpret results? Is there capacity to provide data for evaluation of national and state programs?	High
Performance	How useful is measure in terms of sensitivity, specificity and reliability? What is validity of measure?	High
Technical feasibility	How practical is the performance measure? (sample collection, preparation and storage, access to subjects in sampling frame, skills and resources needed to interpret data)	High
Using a combination of indicators	What is the minimum number of performance measures needed to ensure an effective monitoring and surveillance program?	Medium

Appendix 2

Table 5: Indicative costs for the proposed program activities

Program activity	Establishment/baseline research cost first year	Costs over remaining 4 year period	Lead agency	Priority for funding*
2/3a Stakeholder surveys Attitudes, awareness and understanding of new requirements in Code CATI or email survey with two stakeholder groups (industry, enforcement officers)	Baseline survey $ 100 000	Follow up surveys $ 80 000	FSANZ	Low
4a Food supply survey Data from manufacturers on brands available in market place with added folic acid, and content to be updated annually.	$ 75 000 x 1 year APS6 project officer to set up system and collate data	$ 80 000 ongoing data purchase ($ 20 000 per year)	FSANZ with AFGC/NZFGC	High
4b Label monitoring survey Collect data on labelling of foods with added folate via ongoing label monitoring survey.	$ 20 000 purchase of sales data (EAN or bar code data)	$ 40 000 ($ 10 000 per year)	FSANZ	Low – medium
4c Update National Food Composition Database Analyse key foods for folate/folic acid on regular basis	FSANZ survey established, add on of $ 10 000 to collect extra baseline data	$ 80 000 each country	FSANZ/NZFSA with NZ Crop and Food Research Institute	High
4d Compliance survey Analyse levels of folic acid/folate compared with label information.	$ 60 000 each country Already completed in Australia ($ 150 per single folic acid or folate analysis)	TBC	S&T, NZFSA	Low - medium

Program activity	Establishment/baseline research cost first year	Costs over remaining 4 year period	Lead agency	Priority for funding*
5a) Food consumption patterns from National dietary survey of individuals (FFQ survey and 24-hour recall, repeat 24 hour survey, individual records of food and supplements consumption) **5b) Roy Morgan Single Source survey (Australia and NZ) and Young Australian survey** **5c) Other national, S&T surveys.** **5d) Store market basket surveys** **5e) Consumer attitudes to food standards issues tracking survey.**	Baseline data – no costs 1995 NNS 1997 adults NZNNS 2002 children's' NZNNS $ 230 000 for back data for Jan 2001-Mar 2006 Frequency of key food consumption for individuals every 3 months. Assess current data holdings Baseline audit of foods available in remote areas (minimal added costs) $ 60 000 baseline Targeted consumer surveys on specific issues incl substitution patterns for new products, consequential behaviour change.	See NNS costs for (6) Follow up : 2007 Australian children's' NNS 2007 NZ adults survey $ 200 000 ($50 000 subscription per year for next 4 years for new data on 3 month basis) TBC Follow up survey $ 100 000 follow up surveys (targeted foods)	DOHA, S&T NZFSA FSANZ S&T S&T FSANZ	High High Low-medium Medium Medium
6a) Folate/folic acid intakes from NNS 24-hour recall survey with repeat 24 hour record for second day nutrient adjustments, preferably with information on folic acid supplements consumed. **6b) Folate/folic acid intakes from existing S&T surveys**	Australian NNS data with updated folic acid food content (no supplements) 1997, 2002 NZNNS data with updated folic acid food content (some supplement data) (as modelled by FSANZ in P295) S&T surveys costs TBC	Data from follow up NNSs ~ $ 100 000 per nutrient per country (assuming 36 nutrients reported per survey, $3.6 mill cost for whole survey incl development of a food composition survey database)** S&T surveys costs TBC	DOHA, S&T S&T	High Low - medium

Program activity	Establishment/baseline research cost first year	Costs over remaining 4 year period	Lead agency	Priority for funding*
7a. Minimum data set for birth anomalies incl NTDs **7b Literature review of relevant health statistics** **7c Blood tests**	$150 000 Establishment costs Perinatal statistics (incl still births) $ 20 000 Add onto existing surveys (cost effective)	$ 20 000 Ongoing costs ($ 50 000 per year) $ 20 000 at end of 5 years TBC	AHMAC cost share DOHA/AIHW DOHA/S&T	High Medium Medium
Overall monitoring system support	$ 100 000 (APS6 with some admin support) Project officer to assist in establishing system, collate data/prepare reports	$ 100 000+ inflation per year for next four years	FSANZ/AIHW, other agencies	High

*To be confirmed after discussion with relevant health and regulatory agencies

**It should be noted that the cost of reporting one nutrient from a national nutrition survey has been included here, assuming a national nutrition survey program is in place, by diving the total cost of a survey by the number of nutrients to be reported . If a food consumption survey had to be established as a one-off cost for the folic acid monitoring system the costs would be much higher