Monitoring the Australian population's intake of dietary folic acid before and after mandatory fortification

Report by Food Standards Australia New Zealand (FSANZ)

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Table of Contents

Executive summary 3

1. Introduction 4

2. Background to development of the mandatory folic acid fortification standard 5

3. FSANZ bread surveys for amounts of folic acid in bread 6

3.1 Survey methodology 7

3.1.1 Sampling protocol for the surveys 7

3.1.2 Sampling for the surveys 7

4. Sample preparation and analysis 8

5. Survey results – Post-fortification amounts of folic acid in breads 8

5.1 Summary of the survey results 9

6. Assessing the Australian population's intake of dietary folic acid 10

6.1 Methodology 10

6.1.1 Calculations required to estimate folic acid intakes 10

6.1.2 Calculations required to estimate dietary folate equivalents intakes 12

6.1.3 Australian Health Survey data 13

6.2 Estimated mean folic acid intakes – target group, other adults and children 13

6.3 Estimated 10th and 90th percentile dietary folic acid intakes by age group 15

6.4 Proportion of Australians with estimated dietary folic acid intakes above the recommended upper level 16

6.5 Estimates of the Australian populations usual intake of dietary folate equivalents 18

6.6 Proportion of population with usual intakes of dietary folate equivalents below the estimated average requirement 20

7. Major food contributors to estimated dietary folic acid intake of Australians (target and non-target populations) 22

8. Major food contributors to estimated total intake of dietary folate equivalents of Australians (target and non-target populations) 25

9. Comparison of the current folic acid intake estimates of the Australian population to previously predicted estimates 28

10. Limitations of the dietary intake assessments 29

10.1 Age of the food consumption data and respondent age groups 29

10.2 Period of food manufacture and effect on nutrient levels 30

11. Conclusion 30

12. References 32

Appendix 1 34

List of Figures and Tables

List of Figures

Figure 1: Diagrammatic representation of FSANZ's folic acid bread survey sampling periods 6
Figure 2: Estimated mean folic acid intake - target group and non-target populations 14
Figure 3: Estimated mean folic acid intake of children (with and without use of dietary supplements) before and after fortification 15
Figure 4: Estimated mean usual intake of DFEs by target and non-target groups 18
Figure 5: Estimated mean usual intake of DFEs (with and without dietary supplement use) of children between the ages of 2 and 16 years before and after fortification 20

List of Tables

Table 1: Summary data - amount of folic acid in the bread samples: all jurisdictions 9
Table 2: Folic acid and moisture content of FSANZ-prepared unfortified* bread samples - Survey 2 9
Table 3: Estimated mean folic acid intake by age group before and after fortification 14
Table 4: Estimated mean, 10th and 90th percentile folic acid intakes for Australian population groups 16
Table 5: Proportion of population (target and non-target groups) with folic acid intakes above the upper level 17
Table 6: Proportion of children (all sexes) with folic acid intakes above the UL post-fortification - includes consumption of dietary supplements 18
Table 7: Estimated mean usual DFE intake by target and non-target groups before and after fortification 19
Table 8: Proportion of females aged 16-44 years with DFE intakes below the EAR 21
Table 9: Proportion of non-target population groups with estimated usual DFE intakes below the EAR 21
Table 10: Major food contributors (>5%) to estimated total folic acid intake (target group and other adults) 22
Table 11: Major food contributors (>5%) to estimated total folic acid intake of children (non-target population) before and after mandatory fortification of bread - by age group (both sexes), no supplements 23
Table 12: Major food contributors (>5%) to total folic acid intake of children (non-target population¥) before and after mandatory fortification of bread - by age groups (both sexes), including supplements 24
Table 13: Major food contributors (>5%) to estimated total intake of DFE (target group and other adults) before and after fortification 25
Table 14: Major food contributors (>5%) to children's estimated total intake of DFEs before and after mandatory fortification by age groups (both sexes), no supplements¥ 26
Table 15: Major food contributors (>5%) to children's estimated intake of DFEs before and after mandatory fortification of bread by age group (both sexes), including supplements¥ 27

Executive summary

This report provides results of surveys of the folic acid content of breads commonly eaten by Australians, and estimates of the population's intake of dietary folic acid following implementation of food standard for mandatory folic acid fortification of wheat flour for making bread. Food Standards Australia New Zealand (FSANZ) undertook this work as part of its contribution to the monitoring program of the impact of the mandatory fortification standard, Standard 2.1.1 *Cereals and cereal products*.

Mandatory folic acid fortification of wheat flour for making bread (excluding bread presented as organic) was implemented in Australia in September 2009. The objective was to increase the intake of dietary folic acid among women of child-bearing age (females 16-44 years) and thereby reduce the incidence of neural tube defects, which are serious birth defects. Bread was selected as the food vehicle for fortification because it is widely consumed within the Australian population and by the target group. It was also a practical fortification option for Australia because wheat flour for bread-making had been mandatorily fortified with thiamin since January 1991.

Monitoring the impact of the mandatory fortification standard is an integral part of the standard's implementation, as the Policy Guideline for the Fortification of Food with Vitamins and Minerals, specifies that: 'a*ny agreement to require fortification should require that it be monitored and formally reviewed to assess the effectiveness of, and continuing the need for, the mandating of fortification*'[1]. The monitoring framework developed for the impact of the mandatory fortification standard has several components as shown in the Australian Institute of Health and Welfare's (AIHW) publication *Mandatory folic acid and iodine fortification in Australia and New Zealand – Baseline report for monitoring* (AIHW, 2011).

FSANZ's folic acid fortification monitoring activities under the framework were not compliance related. They aimed to determine:

- the amounts of folic acid in bread and related products on the Australian market after fortification.
- whether estimated dietary intake levels within the target group and the other sub-groups of the Australian population increased following mandatory fortification when compared to intake levels before fortification.
- major contributors to total folic acid intakes before and after fortification.

To determine the amounts of folic acid in the breads commonly consumed by Australians following mandatory fortification of bread, FSANZ undertook two phases of bread analytical surveys in 2010 and 2012, as part of the ISFR National Coordinated Survey Plan. The bread samples were purchased from representative food retail outlets in the capital cities of all Australian States and Territories. The phasing of the surveys enabled assessment of the consistency of folic acid amounts present at different time periods. Although there were variations in the folic acid amounts in the breads sampled during the two surveys, they resulted in only minor differences in the mean folic acid levels for the bread types. The analytical results also demonstrated that bakeries were using folic acid fortified wheat flour to bake bread.

[1]Ministerial Council Policy Guidelines for the Fortification of Foods with Vitamins and Minerals.

The bread folic acid values, together with the food consumption data from the two available national nutrition surveys and folic acid values for other foods from an updated version of the Australian food composition database AUSNUT 2007[2], were used to estimate the population's intake of dietary folic acid before and after mandatory fortification of bread. The dietary intake estimates indicate a substantial increase in the mean daily folic acid intake of the target population and of other sub-groups of the Australian population, following mandatory folic acid fortification of bread.

1. Introduction

This report summarises activities undertaken by FSANZ to monitor the impact of mandatory fortification of bread. Standard 2.1.1 *Cereals and cereal products* of the Australian New Zealand Food Standards Code (the Code) requires the use of folic acid fortified wheat flour for making bread except where the bread is presented as organic. The objective of mandatory folic acid fortification of bread was to increase the intake of dietary folic acid among females of child-bearing age (females aged 16-44 years) and thereby reduce the incidence of neural tube defects (NTDs), which are serious birth defects, within the Australian population.

FSANZ's monitoring activities were part of the monitoring framework for mandatory food fortification to determine the effectiveness of the folic acid fortification standard. The monitoring framework was established by the Food Regulation Standing Committee (FRSC) and agreed by the Australian Population Health Development Principal Committee in August 2007, and accepted by Australian Health Ministers' Advisory Council (AHMAC) in October 2007.

Details of the framework are provided in the Australian Institute of Health and Welfare's first report on monitoring mandatory folic acid and iodine fortification in Australia and New Zealand *(*AIHW 2011a). Information on baseline estimates of dietary intakes of folic acid and iodine in Australia, based on work undertaken by FSANZ during the standard development phase, was published in a supplementary monitoring report (AIHW 20011b).

The impact of the implementation of the mandatory fortification standard is currently undergoing an independent review by FRSC and the AHMAC in a three phase process that includes an evaluation of: the effectiveness of the public health initiative; the level of compliance of the food industry with the standard and impact on enforcement agencies; and, the adequacy of the monitoring framework.

The mandatory folic acid fortification standard was not mandated in New Zealand. Monitoring and reporting on the dietary folic acid intake of New Zealanders is the responsibility of the New Zealand Ministry for Primary Industries.

FSANZ's fortification monitoring activities under the framework were not compliance related. They aimed to determine:

[2] AUSNUT 2007 was prepared for the 2007 Australian National Children Nutrition and Physical Activity Survey and folic acid values for some products using fortified flour were updated for the post-fortification dietary models.

- the amounts of folic acid and iodine in bread and related products on the Australian market after fortification
- whether estimated dietary intake levels within the target group and the other sub-groups of the Australian population increased following mandatory fortification when compared to intake levels before fortification
- major food or food group contributors to total folic acid and total iodine intakes before and after fortification.

In addition, consumers' attitudes to fortification of food were also researched by FSANZ. The reports on two surveys (qualitative and quantitative) on consumer awareness, attitudes and behaviour to fortified foods were published previously on the FSANZ website and are not part of this report (FSANZ 2010 and FSANZ 2013)[3].

2. Background to development of the mandatory folic acid fortification standard

In October 2005, the then Australian New Zealand Food Regulation Ministerial Council (Ministerial Council)[4] noted the advice of the Australian Health Ministers' Advisory Council (AHMAC) and the Australian Health Ministers' Conference (AHMC) that, mandatory fortification with folic acid was an effective public health strategy to address the incidence of neural tube defects (NTDs) in the Australian population, subject to clinical safety and cost-effectiveness.

NTDs are a group of serious birth defects of the spine (e.g. spina bifida) and the brain (e.g., anencephaly) that occur *in utero* during early pregnancy, often before a woman knows she is pregnant. Since the early 1990s, there has been convincing scientific evidence that increased intakes of folic acid by females prior to, and during the early parts of pregnancy, can reduce the risk of NTDs.

Subsequently, at its May 2006 meeting, the then Ministerial Council agreed to amend the fortification policy guideline to include the appropriate text to request FSANZ to undertake work on a proposal for mandatory folic acid fortification. Based on the Ministerial advice that mandatory fortification with folic acid was an effective strategy for reducing NTDs in Australia, FSANZ developed a proposal for mandatory folic acid fortification of wheat flour for making bread as the preferred regulatory approach.

In September 2009, following extensive consultation, mandatory folic acid fortification of wheat flour for making bread (excluding bread presented as organic) was implemented in Australia. The folic acid standard was not mandated in New Zealand. Permissions to voluntarily fortify some foods with folic acid were retained under the Code.

The level of folic acid in wheat flour for making bread mandated in the new fortification standard (2-3 mg/kg flour) was expected to increase the mean intake of folic acid among the

[3] FSANZ consumer attitudes to fortification reports are available at: http://www.foodstandards.gov.au/publications/Pages/Consumers-awareness-attitudes.aspx

[4] Now known as Legislative and Governance Forum on Food Regulation (FoFR)

target group by ~100 µg/day. This would be above the levels already achieved through use of foods voluntarily fortified with folic acid and use of dietary supplements. FSANZ estimated during the development of the standard that the target population's intake of folic acid from voluntarily fortified foods, which included intakes from breakfast cereals and yeast-based spreads, was 108 µg folic acid per day. The estimated additional 100 µg folic acid from mandatory fortification of bread was expected to increase total folic acid intake (from voluntary and mandatory fortified foods), and bring about the reduction in the number of pregnancies affected by NTDs in Australia by up to 14%. It was assumed that the uptake of voluntary folic acid fortification permissions by the food industry would remain the same (FSANZ 2006).

Consumers were to be informed of the presence of folic acid in breads through ingredient labelling, and where bread was unpackaged as in hot-bread shops, the information would be through direct communication with the baker at the point-of-sale.

3. FSANZ bread surveys for amounts of folic acid in bread

As part of the FSANZ monitoring activities several bread surveys were undertaken to determine the amount of folic acid and iodine in commonly consumed breads available on the Australian market with assistance from the states and territories as part of the National Coordinated Food Survey Plan of the Implementation Subcommittee on Food Regulation (ISFR). Two surveys were to determine the amounts of folic acid in the different bread types commonly consumed by Australians following implementation of the mandatory fortification standard.

The first survey (phase 1) was in June/July 2010, nine to ten months after implementation of the mandatory fortification standard, and the second in March to April 2012 about two and a half years post introduction of mandatory fortification. The bread samples for the two surveys were purchased from representative food retail outlets in the capital cities of all Australian States and Territories. Sampling the breads at different times and in different years was important in determining the consistency of the analysed amounts of folic acid at different points in time.

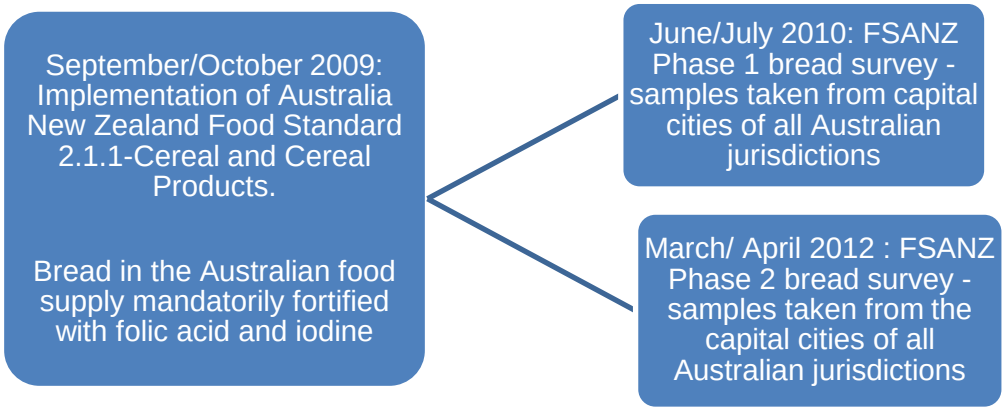

Figure 1: Diagrammatic representation of FSANZ's folic acid bread survey sampling periods

The samples were chemically analysed by the National Measurement Institute (NMI) of Australia's food analytical laboratories in Melbourne. The amount of folic acid in the samples was determined using a modified form of the triple enzyme microbiological method AOAC 2004.5 that is accredited by the National Accreditation Association of Testing Authorities, Australia (NATA).

3.1 Survey methodology

3.1.1 Sampling protocol for the surveys

Prior to undertaking the first bread survey in 2010, FSANZ researched market share data from the 2009 Retail World's Australasian Grocery Guide (19th edition, p59) to get information on the bread types commonly consumed by Australians. The data showed *Bread Loaf* was the bread category with the highest market share (58%) of the B*read, Rolls and Hotplate* food category in Australia and the three main sandwich bread (*bread loaf*) types commonly consumed by Australians were white, wholemeal, multigrain and seed.

FSANZ developed and provided specific sampling plans for the purchase of the bread types required. The sampling plan and protocol provided details of where the samples were to be purchased, how many of each bread type was to be bought and how they were to be packaged for transportation to the laboratory. A template was provided for recording the details required for each bread sample purchased.

Each jurisdiction was provided with their specific sampling plan and the full sampling plan was provided to NMI, the contracted food analytical laboratory. The sampling plan ensured consistency in the process across all jurisdictions, that the purchase of samples reflected the market share of the bread types consumed, and adequate samples were purchased from big commercial industry bakeries, supermarket chain bakeries and small-scale local bread shops.

The description of retail outlets in the different bakery categories used is as follows:

- Supermarket bakeries - include bakeries owned by supermarket shops such as Woolworths, Coles, Supabarn and Aldi.
- Local small-scale bakeries - include hot bread shops and pastry shops.
- Industry bakeries - include George Weston Foods and Goodman Fielder, the two major ones in the country that account for brands such as Tip Top, Helga's, Burgen, Wonder White and Buttercup and franchise bakeries.

Details of the samples purchased from the different retail outlets for the surveys and an example of the sampling plan is provided in Appendix 1.

3.1.2 Sampling for the surveys

Bread samples for the first survey were collected in June and July of 2010. One hundred samples of bread from seven bread types were purchased from major supermarkets and small bread shops in the capital cities of the states and territories. Although the focus was on the three main sandwich bread types commonly consumed by Australians (white, wholemeal, multigrain and seed), a small number of other sandwich bread types were sampled to assess the amounts of folic acid they may contain.

The bread types sampled in survey 1 were:

- White bread
- Wholemeal bread
- Multigrain and seeds bread
- Flat breads i.e. Wraps, Focaccia, Naan, and Lavash.
- English Muffins
- Organic bread
- Gluten free bread

The second survey samples were collected in March and April 2012, about two and a half years after the fortification standard was implemented. This survey only sampled the three commonly consumed sandwich bread types. Ninety-six samples were purchased from all the states and territories using representative food retail outlets similar to those for survey one. FSANZ prepared four loaves of 'unfortified bread samples' using unfortified wheat flour and non-iodised salt, which were included in the survey as blanks to assess the amount of naturally occurring folic acid they contained.

4. Sample preparation and analysis

The survey samples were prepared and analysed by NMI food analytical laboratory in Melbourne. The same preparation and analytical methods were used for bread samples from both surveys. Samples were transported under refrigeration to the NMI laboratories. At the laboratory, each individual loaf was weighed (all slices plus the two crusts) and divided into two halves. One half was left to dry at ambient temperature and the other labelled and frozen. Following the drying, all the samples were individually re-weighed, homogenised thoroughly to below 0.25mm particle size (preferably <0.125mm) and stored in labelled air-tight containers to be used for the required chemical analyses. A portion of the homogenised material for each bread sample was then taken and prepared for folic acid analysis. No composite samples were used.

The FSANZ-baked samples of the three bread types were similarly prepared for analysis to determine the amount of folic acid they contained, noting that these samples were made with unfortified wheat flour.

The amount of folic acid in the bread samples was determined using a modified form of the triple enzyme microbiological method AOAC 2004.5 (AOAC, 2005) accredited by the National Accreditation Association of Testing Authorities, Australia (NATA). The method eliminated the protease and conjugase digestion steps from the tri-enzyme digestion for measuring total folate using *Lactobacillus casei* (spp *rhamnosus*) ATCC 7469 (Chun et al. 2006). The Limit of Detection for folic acid was 3 µg/100 g.

5. Survey results – Post-fortification amounts of folic acid in breads

A summary of the mean amounts of folic acid present in the bread types sampled across the capital cities of all the jurisdictions for the two surveys is provided in Table 1. The values are rounded to the nearest whole number. The folic acid values provided by the laboratory for

the bread samples are on ‘as purchased’ weight basis, although the samples were dried for the analysis.

The mean amount of folic acid in the bread types range from 200 to 134 µg per 100g of bread and show that the breads contain levels of folic acid that indicate use of folic acid fortified wheat flour in their making. The presence of a minimum value below that shown by FSANZ unfortified samples is an indication of that some bakeries were still in the transition phase during the period of the first bread survey.

Table 2 shows the folic acid levels in the unfortified bread samples baked by FSANZ as blanks for the second survey samples and indicate the amounts that would have been present if fortified wheat flour had not been used, hence these results served as a baseline for folic acid in bread.

Table 1: Summary data - amount of folic acid in the bread samples: all jurisdictions

Bread type	Bread fortification monitoring program	No. of samples	Folic acid value (µg/100g)			Standard deviation	Mean moisture content (g/100g)
			Maximum	Minimum	Mean		
White	Survey 1	28	270	19	200	52	38
	Survey 2	32	370	73	169	49	38
Wholemeal	Survey 1	16	240	130	189	37	40
	Survey 2	32	240	110	155	35	36
Multigrain and seeds	Survey 1	17	230	100	164	32	37
	Survey 2	32	200	90	134	29	38

Table 2: Folic acid and moisture content of FSANZ-prepared unfortified* bread samples - Survey 2

Bread type	No. of samples	Mean folic acid value (µg/100g)	Mean moisture content (g/100g)
White	2	42	38
Wholemeal	1	44	39
Multigrain and seeds	1	40	38

*Samples made with unfortified wheat flour

Information on the amount of folic acid in the bread samples purchased for survey 1 for organic, gluten free and flat bread is provided in Appendix 1. These values were not used to derive mean folic acid levels in bread for use in estimating dietary intakes of folic acid.

5.1 Summary of the survey results

The survey results show an increase in the amount of folic acid present in the three main sandwich bread types after mandatory use of folic acid fortified wheat flour in baking bread. Although there were some variations in amounts from the two surveys and for the bread types, they were not considered to be major differences. In assessing the analysed values,

FSANZ considered factors that impact the detectable levels of folic acid in baked breads including:

- proportion of folic acid fortified flour used in the bread recipe
- constituents of the bread type (e.g. white bread versus wholemeal/wholegrain or wholegrain with other grains and seeds)
- possible folic acid degradation during the dough proving stage of bread production
- water loss from the dough during baking
- heat degradation of folic acid during the baking process.

Results for folic acid content in breads from the 2010 and 2012 surveys, together with food consumption data from national nutrition surveys were used to: estimate the Australian population's intake of dietary folic acid before and after the implementation of bread fortification in September 2009; compare estimated folic acid intakes for different population groups with relevant nutrient reference values; and identify food groups that were major contributors to folic acid intake before and after fortification. The focus of the estimates was primarily on the target population.

The results of the bread surveys were also used to update the Australian food composition database that is compiled by FSANZ (FSANZ 2014).

6. Assessing the Australian population's intake of dietary folic acid

The Australian target population group is women of child-bearing age, identified as females aged between 16 to 44 years. The aim of the mandatory fortification was to increase the intake of dietary folic acid among females in this age group thereby reducing the incidence of neural tube defects, which are serious birth defects.

6.1 Methodology

6.1.1 Calculations required to estimate folic acid intakes

Dietary intake assessment of a nutrient requires data on concentrations of the nutrient of interest (folic acid) in the foods consumed, and food consumption data that have been collected through a national nutrition survey. The 1995 Australian National Nutrition Survey data (1995 NNS) was used for estimating nutrient intakes for adults and the 2007 Australian National Children's Nutrition and Physical Activity Survey (2007 ANCNPAS) for children aged 2-16 years of age, together with the analytical results of the amounts of folic acid in the commonly consumed breads on the Australian market. The bread survey data were used to revise the nutrient content of foods coded as bread, contained bread (e.g iced bun), or were mixed dishes that contained components made of bread for the post-fortification calculations. The nutrient content of other foods that the bakery industry indicated were likely to contain fortified flour e.g pizza bases, crumpets, were also updated for the post-fortification folic acid intake calculations, using the Australian food composition database, prepared for the 2007 ANCNPAS as a starting point.

To estimate the Australian population's intake of folic acid after implementation of the mandatory folic acid fortification standard, FSANZ used the updated Australian food

composition data for both adults and children and dietary modelling methodologies that enabled the best estimates to be established for folic acid consumed by individual respondents using DIAMOND (FSANZ custom-developed computer program).

The 1995 NNS data were used for the target population (females aged 16-44 years) and the adult Australian population aged 19 years and older, because they were the most recent available national data for this age group at the time of this analysis. The dietary intake estimates for children aged 2-16 years used data from the 2007 ANCNPAS.

It is best practice to compare usual nutrient intakes to current Nutrient Reference Values (NRVs) for nutrients. Usual intakes are an estimate of what people 'usually' eat, as opposed to what they reported eating on the particular days they were surveyed. Normally, the 2-day statistical adjustment method that takes intra-individual variation into account is used to estimate usual intakes for nutrients. However, the average of two days' food consumption data (24 hour food intake recall) was used to estimate the Australian population's intake of folic acid before and after mandatory fortification. This approach was used because it was not considered appropriate to use the 2-day statistical adjustment method due to the non-normality of the distribution of folic acid intakes (large proportion of zero intakes). The 2-day average methodology was applied to both the 1995 NNS and the 2007 ANCNPAS data sets for folic acid only.

The 1995 NNS data used for the target population estimates had second day food consumption data for only 10% of the respondents from Day 1. Therefore, the data used to estimate the two day average intakes were for those respondents with food intake information from both day 1 and day 2. This approach restricted the number of respondents for the various adult age groups, and therefore the data used for the target population may not be fully representative of the total population of women of child-bearing age in Australia. For example, while there were 3178 female respondents aged 16-44 years in the 1995 NNS data, the number of consumers in the age group was reduced to 328 when food consumption data for only those with both day 1 and day 2 were compiled. Similarly, although there were 10,851 consumers in the 19+ age group for day 1 consumption data, the number was reduced to 1,163 when those with both a day 1 and day 2 data were compiled. FSANZ has separately verified that the 1995 NNS Day 1 results for these sub-sets of the population were not statistically different from the whole population sub-group therefore this was considered a reasonable approach in the absence of other information (see section 10.1). This was not an issue for the 2007 ANCNPAS as two days of data were collected from all respondents.

The folic acid intake estimates for children aged 2-16 years considered two separate scenarios based on whether the children consumed dietary supplements or not, as information on the amount of supplements consumed was available as part of the 24-hour recalls in the ANCNPAS data. However, for the target group and the general adult population, information on supplement use was not available in the 1995 NNS data set.

The analytical results of the amounts of folic acid in the commonly consumed breads on the Australian market were used for the folic acid intake estimates after fortification. The amount of folic acid in all foods consumed by individuals represented in the data sets before and after mandatory fortification were established and used. This included foods which may contain folic acid from voluntary addition by the food industry (as permitted in Standard

1.3.2), and from mixed foods containing bread, as well as foods likely to contain fortified flour (as notified by the industry e.g pizza bases, crumpets).

The pre-fortification estimates of folic acid intake were re-calculated to generate the appropriate data for comparison with the intake estimates after fortification. In establishing the post-fortification 2-day average intake of dietary folic acid for the population, the mean of the estimated intakes calculated using the folic acid amounts from each survey (1995 NNS, 2007 ANCNPAS) was used.

Despite the differences in the survey methodologies for the two food consumption data sets, the folic acid intake estimates presented in this report reflect as accurately as possible, the Australian population's intake of folic acid following implementation of the mandatory use of folic acid fortified wheat flour in making bread. The estimated dietary folic acid intakes in the report are based on the amounts of folic acid in all foods consumed by the individuals including bread.

6.1.2 Calculations required to estimate dietary folate equivalents intakes

To assess the proportion of the population with intakes of folate below the estimated average requirement (EAR) following mandatory fortification, the population's usual intake of folate as dietary folate equivalents (DFEs) was estimated using the 2nd day adjusted approach for nutrients for all survey respondents.

To determine the post-fortification amount of DFEs in bread and foods containing bread (mixed dishes) that were consumed by each respondent in the two surveys for dietary modelling purposes, the following approach was used.

First, the mean amount of natural folate in each of the bread types was calculated from the mean total folate concentration and the mean folic acid concentration (which were based on the individual sample values) using the following formula:

Mean natural folate (food folate) = mean total folate – mean folic acid (per 100g)

Second, the average of natural folate values determined for each bread type from the three scenarios (survey 1, survey 2 and the weighted mean of surveys 1 and 2) was used to calculate the mean amount of DFE for each bread type using the formula:

DFE = Natural folate (food folate) + (folic acid X 1.67) (per 100g)

- The folic acid value is the mean of the analysed values for each bread type (which was also used in the first calculation step above).
- The factor 1.67 is used to convert synthetic folic acid to folate.

Third, the mean total DFE calculated for each bread type was then matched to the individual foods consumed in the nutrition surveys for the three scenarios and baseline. DFE values were generated for each individual food consumed in the nutrition survey for the scenarios and baseline, including for mixed dishes where the specific breads were used as ingredients

and the new concentrations for the mixed foods derived, using FSANZ's specially developed *hybrid spread sheets*[5].

Fourth, the DFE concentrations from the *hybrid spread sheets* were used in DIAMOND to calculate the DFE intake for each respondent taking into account all situations where bread was consumed either as a single food or as part of a mixed dish. Estimates of mean intake of DFEs by the target and non-target groups were derived using non-log transformed 2nd day nutrient adjusted method. This method was used with both the food consumption dataset for the 1995 NNS and the 2007 ANCNPAS, before and after mandatory fortification.

6.1.3 Australian Health Survey data

New food consumption data for the Australian population were published from the 2011-12 National Nutrition and Physical Activity Survey (NNPAS) component of the Australian Health Survey (AHS) by the Australian Bureau of Statistics in 2014 (ABS, 2014a). The survey data have not yet been incorporated into FSANZ's dietary modelling system and therefore could not be used to assess the nutrient fortification scenarios required. Bread consumption data for regular breads and rolls from the 2011-12 NNPAS were summarised and a comparison made with previous surveys in general terms (see Appendix 1, Table A.7).

For children aged 2-16 years the proportion of consumers and mean consumption for consumers for bread and rolls only were similar to those from the 2007 ANCNPAS. For adults 19 years and above and females 16-44 years, the proportion of consumers and mean consumption of regular bread and rolls for consumers only for the 2011-12 NNPAS were lower than those for the 1995 NNS, with mean consumption of bread and rolls being around 20 grams per day less (one slice of bread is equivalent to around 30 grams). These differences could be real differences but could also partly be due to other factors: differences in the recording and coding of composite foods, such as bread in sandwiches and bread based dishes being assigned to different food groups; and/or due to the increase in under-reporting in the 2011-12 NNPAS compared to the 1995 NNS, which was reported to a greater extent in males and described as due to higher carbohydrate foods, of which bread is one (ABS, 2014b). Further in-depth research is required on these differences and potential impact on estimated folic acid and total DFE intakes.

6.2 Estimated mean folic acid intakes – target group, other adults and children

The estimated mean 2-day average intakes of dietary folic acid for the target population and other age groups of the Australian population, following mandatory folic acid fortification of bread, are shown in Table 3. The table also shows the increases in mean 2-day average folic acid intake by age group. There is a noticeable increase in the estimated 2-day average acid intake of all age groups of the Australian population following mandatory folic acid fortification of bread.

The estimated increase in the target population's estimated mean 2-day average intake of folic acid after fortification was 145 µg, an increase of 142%. The general adult population's

[5] "Hybrid spread sheets" is the commonly used term that refers to the complex spread sheets that are able to recalculate the nutrient concentrations for all relevant foods in a nutrition survey based on changes in nutrient concentrations in certain/selected/key foods, by taking into account where these certain/selected key foods are used in mixed foods using a custom developed set of recipes.

(19+ years) estimated mean 2-day average dietary folic acid intake also increased by about 134%, following mandatory fortification although they had a slightly higher pre-fortification folic acid intake level compared to the target group. Both population sub-groups experienced a substantial increase in estimated mean 2-day average intake of dietary folic acid (Figure 2).

Table 3: Estimated mean folic acid intake by age group before and after fortification

Age group (both sexes)	Estimated mean folic acid intakes (µg/day)♦		Increase in mean intake (µg/day)
	Pre-fortification	Post-fortification	
2-3 years ¥	104	215	111
4-8 years ¥	108	260	152
9-13 years ¥	107	290	183
14-16 years ¥	110	323	213
2-16 years ¥	108	277	169
19 years and above#	127	297	170
16-44 years (Females) #	102	247	145

♦ Estimates are usual average intakes and do not include use of dietary supplements.
¥ denotes use of data derived using the 2007 ANCNPAS.
# denotes use of data derived using the 1995 NNS

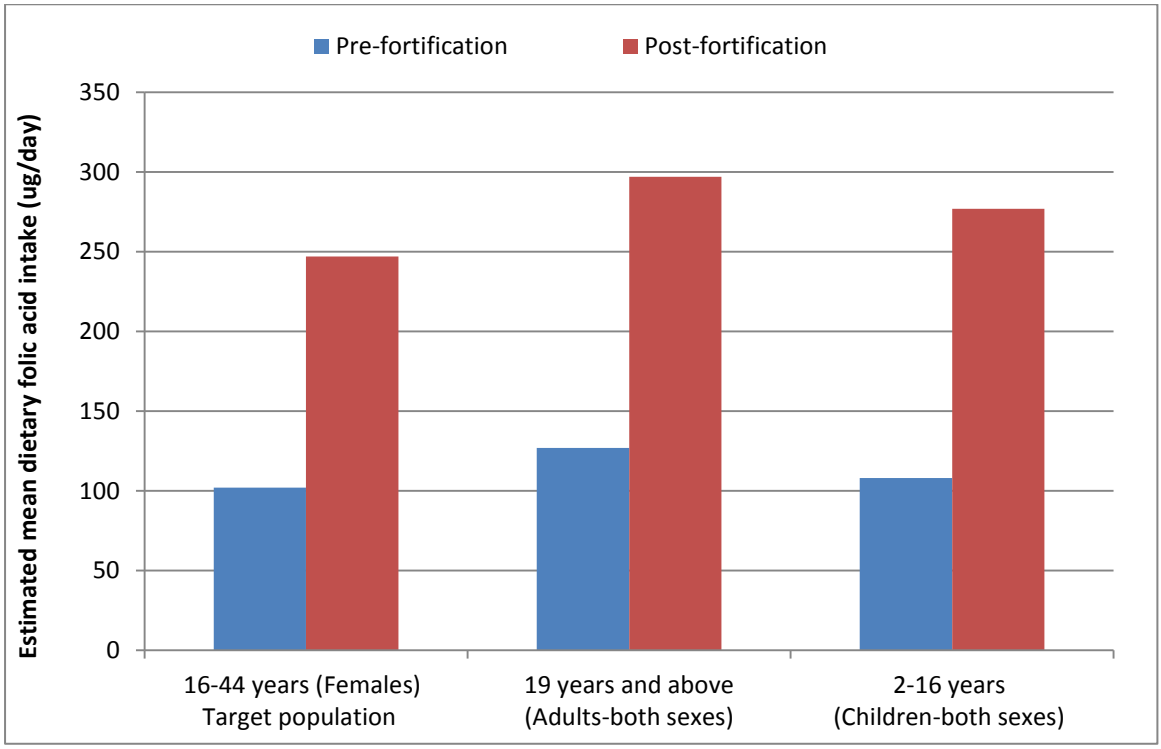

Figure 2: Estimated mean folic acid intake - target group and non-target populations

Figure 3 shows the changes in estimated mean 2-day average folic acid intake for children in the different age groups from 2-16 years before and after fortification, with and without supplements. It shows an increase in mean folic acid intake with increasing age, after

mandatory folic acid fortification of bread, and contrasts with the almost identical pre-fortification folic acid intake levels for all children aged between 2 to16 years.

Consumption of dietary supplements did not appear to have a major impact on the children's estimated dietary folic acid intake values either before or after mandatory folic acid fortification of bread, as just about 12% of children consumed some form of dietary supplement. Irrespective of whether the children consumed dietary supplements or not, their estimated folic acid intake levels increased substantially after fortification of bread. Information on the estimated mean folic acid intake of children aged from two to sixteen years (with and without the use of dietary supplements) is provided in Appendix 1.

Figure 3 further shows that the estimated amount of folic acid consumed by children after fortification increased steadily as the children got older. Using the estimated values for those who did not consume dietary supplements, the increase in mean 2-day average intake ranged from 111 µg/day to 212 µg/day.

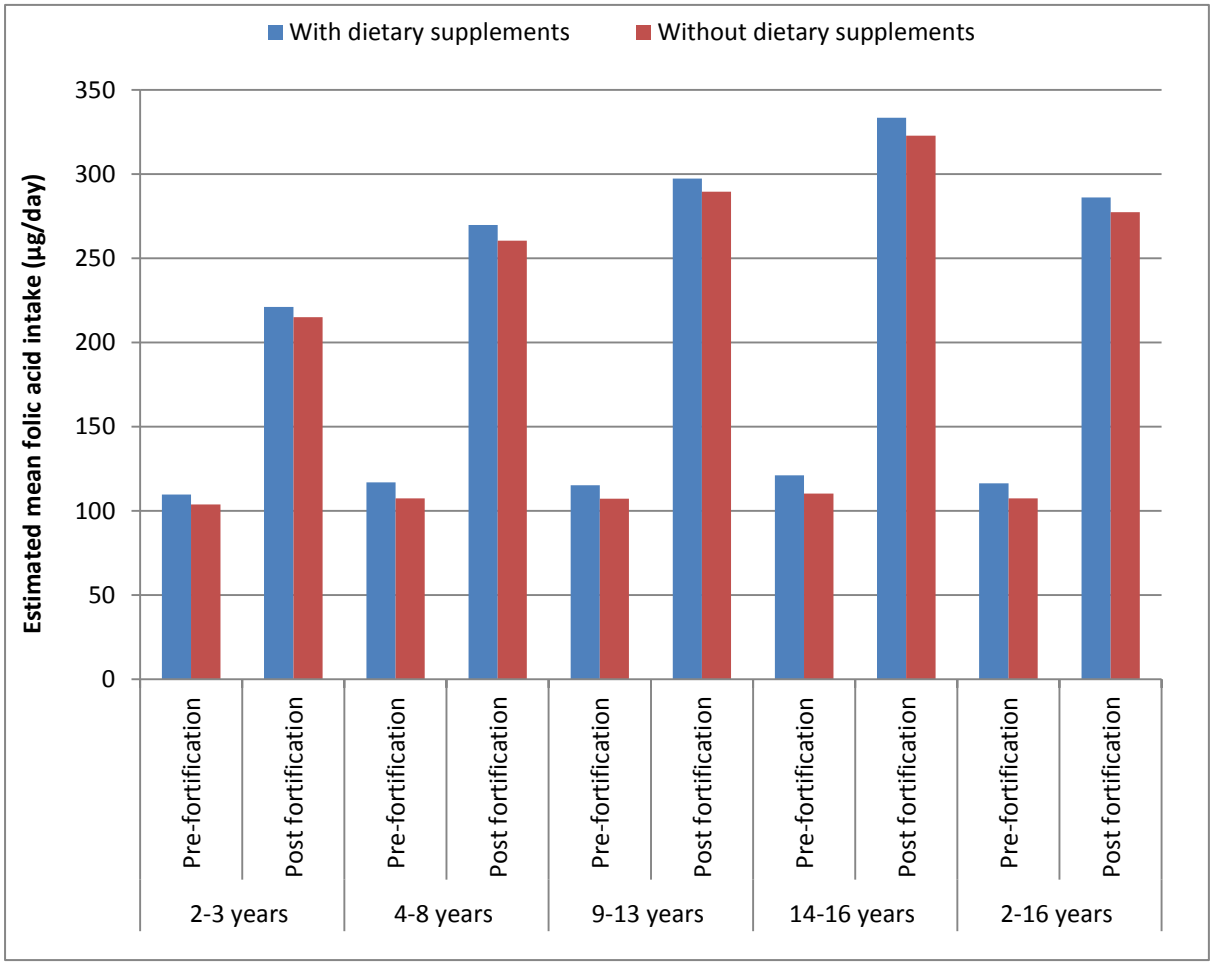

Figure 3: Estimated mean folic acid intake of children (with and without use of dietary supplements) before and after fortification

6.3 Estimated 10th and 90th percentile dietary folic acid intakes by age group

Generally, the 5th and 95th percentiles are used as the most appropriate representation of low and high consumers for other nutrients where it is possible to report 2nd day adjusted or usual intakes. However for folic acid this is not the case. FSANZ made the decision to use

the 10th and 90th percentiles as the most appropriate representation of low and high consumers of dietary folic acid, due to the use of an average of two days food consumption data, which restricted the sample numbers for the target group and the non-target adult population.

For consistency, the same percentiles were used for low and high consumers in the children's age groups, although that data set had the same respondent numbers for the two days of food consumption. The approach is in line with international best practice for presenting dietary exposures for food chemicals other than nutrients.

The estimated 10th and 90th percentile folic acid intakes for the Australian population, before and after mandatory folic acid fortification of bread, by age group, are given in Table 4. The mean intake values are also provided for comparison.

The lowest 10% of estimated intakes of dietary folic acid by the different age groups including the target population show a marked increase after fortification, compared to before fortification. The post-fortification intakes for the different age groups at the 90th percentile level also show substantial increases in dietary folic acid consumption.

Table 4: Estimated mean, 10th and 90th percentile folic acid intakes for Australian population groups

Age group (both genders)	Estimated folic acid intake (µg/day)♦					
	Mean		10th percentile		90th percentile	
	Pre-fortification	Post-fortification	Pre-fortification	Post-fortification	Pre-fortification	Post-fortification
2-3 years¥	104	215	1	69	231	389
4-8 years¥	108	260	2	108	261	458
9-13 years¥	107	290	1	106	246	514
14-16 years¥	110	323	0	102	294	588
2-16 years¥	108	277	0	100	257	499
19 years and above#	127	297	14	98	302	553
16-44 years (Females) #	102	247	11	73	251	445

♦ Estimates are usual average intakes and do not include use of dietary supplements.
¥Estimates for age groups derived using the 2007ANCNPAS data: number of respondents aged 2-3 years = 552; 4-8 years = 1,520; 9-13 years = 1,493; 14-16 years = 922. # Estimates for age group derived using the 1995 NNS: number of respondents aged 16-44 years (females only) = 328; respondents aged 19 years and above (both genders) = 1,163.

6.4 Proportion of Australians with estimated dietary folic acid intakes above the recommended upper level

To determine whether the increased intake of dietary folic acid by the target group and the rest of the population might pose public health and safety concerns, the estimated folic acid 2-day average dietary intakes were compared to the recommended upper level of intake (UL) for the different age-groups. The UL is *the highest average daily nutrient intake level likely to pose adverse health effects to almost all individuals in the general population*

(NHMRC 2006). The proportions of the different population groups with folic acid intakes above the UL indicate those with excessive daily folic acid intake.

The proportion of the target group and the non-target population groups estimated to have exceeded the UL for dietary folic acid intake is shown in Table 5. The target population's estimated dietary folic acid intake was below the UL both before and after mandatory fortification of bread. Of the non-target group, about 1% of adults exceeded the UL after fortification. For children aged 2 to 8 years a higher proportion exceeded the UL for folic acid intake after fortification (15-21%) than before fortification (3-5%); this decreased for children aged 9-16 years to 4-6 % exceeding the UL after fortification.

The estimates used for the development of the fortification standard showed that respondents aged 2-8 years were the most likely of the non-target population groups to have intakes exceeding the UL under all scenarios. The projection was that 9% of 2-3 year olds and 4% of 4-8 year olds would exceed the UL under mandatory fortification.

Table 5: Proportion of population (target and non-target groups) with folic acid intakes above the upper level

Age group (both sexes)	Proportion of respondents with folic acid intakes above the UL (%)		
	UL(µg/day)	Pre-fortification	Post-fortification
2-3 years¥	300	5	21
4-8 years¥	400	3	15
9-13 years¥	600	1	6
14-16 years¥	800	0	4
19 years & above#	1,000	<1	1
16-44 years (Females) #	No prescribed value for age group (FSANZ used relevant UL for each individual in estimates)	0	0

¥ Data derived using the 2007 ANCNPAS using usual average intakes, does not include the use of dietary supplements.

Data derived using the Australian 1995 NNS using usual average intakes for a 10% sub-set of the population, does not include the use of dietary supplements.

Table 6 shows estimates of the proportion of children exceeding the UL when the consumption of dietary supplements is considered. The estimates in Tables 5 and 6, show little difference between the proportion of children of the different age groups that may exceed the daily folic acid intake UL whether they were consumers or non-consumers of dietary supplements. In both tables, age group with the highest proportions exceeding the UL were for children aged 2-8 years.

Table 6: Proportion of children (all sexes) with folic acid intakes above the UL post-fortification - includes consumption of dietary supplements

Age group (both sexes)	Proportion of children with intakes above UL (%)		
	UL by age group (µg/day)	Pre-fortification	Post-fortification
2-3 years[¥]	300	5	23
4-8 years[¥]	400	3	16
9-13 years[¥]	600	1	6
14-16 years[¥]	800	1	4
2-16 years[¥]	No prescribed value for this age group. FSANZ used relevant UL for each individual in the estimates	2	11

[¥] Derived using the 2007 ANCNPAS, includes use of dietary supplements using usual intakes

6.5 Estimates of the Australian populations usual intake of dietary folate equivalents

To calculate the population's intake of dietary folate, dietary folate equivalents (DFEs) were used. Dietary folate is an umbrella term used to represent folate in food and folic acid from fortified foods and from dietary supplements if that information is available, and is expressed as DFEs. This approach accounts for the lower availability of folates that occur naturally in foods in a variety of forms (mixed folates) compared with synthetic folic acid. Folic acid is the most stable oxidised form of folate and is synthetic therefore this form of folate is used in dietary supplements and in the fortification of foods such as breakfast cereals, flour and fruit juices.

Use of total DFEs from all sources is recommended for planning and evaluating the adequacy of people's folate intake because the National Health and Medical Research Council (NHMRC) recommended levels of dietary folate for the Australian and New Zealand populations are expressed as DFEs (NHMRC 2006).

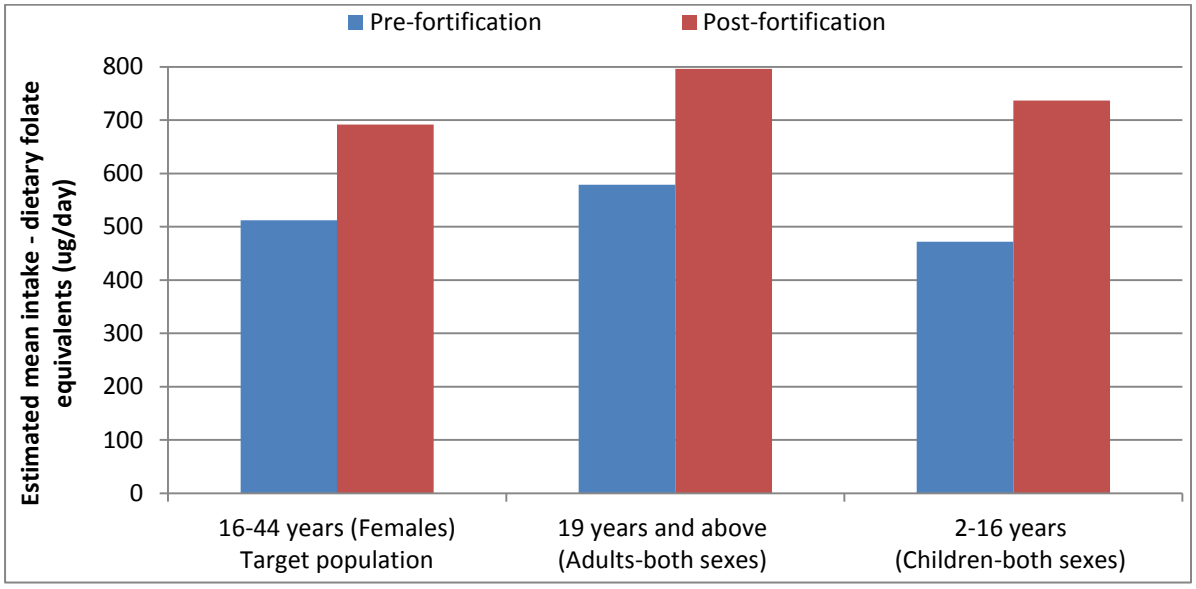

Figure 4: Estimated mean usual intake of DFEs by target and non-target groups

The estimated usual intake of dietary folate equivalents of the target population and the rest of the adult population before and after folic acid fortification of bread is shown in Figure 4. It is noticeable that estimated post-fortification intakes of DFEs were higher than intakes before fortification, although the percentage increase was not as high as that observed for post-fortification folic acid intakes.

Table 7 shows the estimated mean usual intake of DFEs for children and adults, including the target population, and the corresponding increases in intakes of DFEs for the different age groups following mandatory folic acid fortification of bread. As was noted with respect to changes in the estimates of folic acid intakes after fortification, the changes in DFEs intake of children increased with age.

Table 7: Estimated mean usual DFE intake by target and non-target groups before and after fortification

Age group (both sexes)	Estimated mean usual DFE intake♦ (µg/day)		
	Pre-fortification	Post-fortification	Increase in DFE intake
2-3 years¥	430	602	172
4-8 years ¥	454	698	244
9-13 years ¥	481	760	279
14-16 years ¥	510	846	336
2-16 years¥	472	737	266
19 years and above	579	796	218
16-44 years (Females)	512	692	180

♦ Denotes the estimates are usual average intakes and do not include use of dietary supplements
¥ Denotes data derived using the 2007 ANCNPAS

Figure 5 summarises usual intakes of DFEs for children who consumed dietary supplements and those who did not consume dietary supplements. As expected from the low proportion of children using folic acid supplements, there was little difference in the estimated intakes of DFE between consumers and non-consumers of dietary supplements.

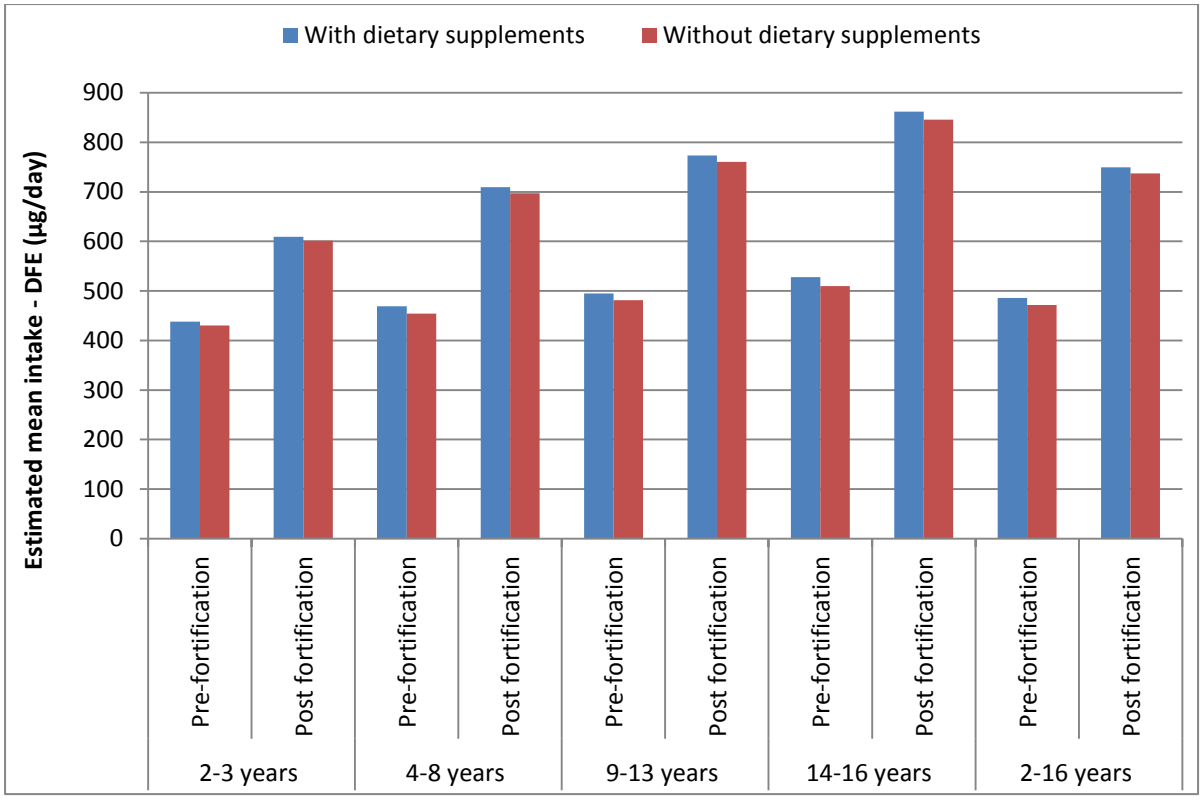

Figure 5: Estimated mean usual intake of DFEs (with and without dietary supplement use) of children between the ages of 2 and 16 years before and after fortification

6.6 Proportion of population with usual intakes of dietary folate equivalents below the estimated average requirement

To determine the proportion of the various population sub-groups with inadequate folate intake after mandatory folic acid fortification of bread, their usual DFE intakes were compared to the recommended estimated average requirement (EAR). The folate EAR is the daily intake estimated to meet the requirement of half the healthy individuals in a particular life stage and gender group.

The proportion of the target and non-target groups estimated to have DFE intakes below the EAR are considered to have inadequate folate intakes. For the target group, the proportion below the relevant EAR for non-pregnant women, pregnant women and lactating women before and after fortification were assessed because of the importance of folate/folic acid intake in the prevention of NTDs.

Table 8 shows the proportion of the target population (females 16-44 years – women of child-bearing age) with 2-day average DFE intakes below the relevant EARs before and after mandatory folic acid fortification of bread.

Table 8: Proportion of females aged 16-44 years with DFE intakes below the EAR

Sub group of females of child- bearing age	EAR (µg/day)	Proportion of females aged 16-44 years[#] with usual DFE intakes below the EAR (%)	
		Pre-fortification	Post-fortification
Non-pregnant EAR	320	11	1
Pregnancy EAR	520	64	22
Lactation EAR	450	46	10

Does not include use of dietary supplements.

The table shows that almost 65% of females aged 16-44 years had usual DFE intakes below the pregnancy EAR before fortification, and the proportion decreased substantially to 22% after mandatory folic acid fortification of bread, a 66% reduction for those with inadequate folate intakes.

Although 22% of females aged 16-44 years still have inadequate folate intakes after fortification, it should be noted that the level of folic acid fortification provided in the new standard aimed to increase the amount of folic acid consumed by the target population while minimising any potential health risk to the non-target groups of the population. It is for this reason that females planning pregnancies continue to be advised to consult with their medical practitioners for additional folic acid supplementation as required.

Table 9 shows the proportion of the non-target groups of the population with inadequate folate intakes (DFEs) before and after mandatory folic acid fortification of bread. The table shows that 17% of 14-16 years olds were estimated to have inadequate folate intakes before fortification but this decreased to less than 1% with folic acid fortification of bread. This reduction in the proportion of teenagers with inadequate folate intake with fortification is important, particularly when considering teenage pregnancies.

Table 9: Proportion of non-target population groups with estimated usual DFE intakes below the EAR

Age group (both sexes)	EAR (µg/day)	Proportion of age group with usual DFE intakes below the EAR♦ (%)	
		Pre-fortification	Post-fortification
2-3 years¥	120	0	0
4-8 years¥	160	0	0
9-13 years¥	250	0	0
14-16 years¥	330	17	<1
2-16 years¥	No prescribed level. FSANZ used relevant EAR for each individual in the estimates	4	<1
19 years and above	320	9	1

♦ Denotes data using usual average intake estimates, does not include use of dietary supplements.
¥ Denotes data derived using the 2007 ANCNPAS.

7. Major food contributors to estimated dietary folic acid intake of Australians (target and non-target populations)

This section provides information on the amount of folic acid each food group contributed to the total mean daily folic acid intake. Major food contributors are those food groups that contribute five percent or more to the estimated total dietary folic acid intake for the target and non-target groups of the Australian population and are shown in Table 10.

Before mandatory folic acid fortification of bread, breakfast cereals and yeast/yeast based foods were the main contributors to estimated total folic acid intakes for the two population sub-groups. However, with fortification, the contribution from bread exceeded that of the previous major food contributors. Table 10 clearly shows that following mandatory folic acid fortification, the proportion of folic acid contributed by regular breads and rolls to the dietary intake of folic acid of the target population increased from 19% to 53%. A similar trend is shown for the non-target adult population (19+ years).

Table 10: Major food contributors (>5%) to estimated total folic acid intake (target group and other adults)

	Contributors to total folic acid intakes (% folic acid intake)♦			
	Females 16-44 years		19 years and above	
Food Group	**Pre-fortification**	**Post-fortification**	**Pre-fortification**	**Post-fortification**
Regular breads, and rolls	19	50	19	53
Breakfast cereals, plain, single source	21	9	27	12
Breakfast cereals, mixed source	26	11	25	11
Yeast, yeast, vegetable and meat extracts	24	10	22	9
Fancy breads, flat breads, English-style muffins, crumpets	<5	8	<5	5

♦Based on Day 1 data, does not include use of dietary supplements.

Tables 11 and 12 provide information on the percent contribution of different food groups to the estimated total intake of folic acid by children of various age groups before and after bread fortification, with and without supplements. The two tables demonstrate that whether the children consumed dietary supplements or not, bread was not a major contributor to their estimated total folic acid intake before fortification. The principal contributors to their total folic acid intake before fortification were foods belonging to the *yeast/meat extract group* and *breakfast cereals and bars group*. Following mandatory folic acid fortification of bread, regular breads and bread rolls became the principal food group contributing over 40% to the folic acid intake of all children.

Table 12 further shows that the contribution of dietary supplements (as multivitamins and/or mineral supplements) to estimated total folic acid intake for children who consumed them was not substantial. They contributed between 5% and 9% before fortification, and dropped to less than 5% after fortification, for all the age groups.

Table 11: Major food contributors (>5%) to estimated total folic acid intake of children (non-target population) before and after mandatory fortification of bread - by age group (both sexes), no supplements

Food Group	Contribution of food group to total folic acid intake (%)									
	2-3 years		4-8 years		9-13 years		14-16 years		2-16 years	
	Pre-fortification	Post-fortification	Pre-fortification	Post-fortification	Pre-fortification	Post-fortification	Pre-fortification	Post-fortification	Pre-fortification	Post-fortification
Regular Breads, And Bread Rolls (Plain/ Unfilled/ Untopped Varieties)	6	43	8	47	6	43	5	43	6	44
English-Style Muffins, Flat Breads, And Savoury and Sweet Breads	<5	6	<5	7	<5	8	<5	7	<5	7
Yeast, Yeast, Vegetable And Meat Extracts	63	30	54	22	44	16	48	16	50	20
Mixed Dishes Where Cereal Is The Major Ingredient	<5	<5	<5	6	<5	12	<5	15	<5	10
Breakfast Cereals and Bars, Unfortified and Fortified Varieties	27	13	33	14	45	17	42	14	38	15

[¥] Derived using the 2007 ANCNPAS data, (does not include use of dietary supplements).

Mixed Dishes Where Cereal Is The Major Ingredient - includes sandwiches and filled rolls, pizzas, hamburgers, taco and tortilla dishes, pasta and noodle dishes, savoury rice dishes and savoury dumplings.

Table 12: Major food contributors (>5%) to total folic acid intake of children (non-target population[¥]) before and after mandatory fortification of bread - by age groups (both sexes), including supplements

Food Group	Contribution of food group to total folic acid intake (%)									
	2-3 years		4-8 years		9-13 years		14-16 years		2-16 years	
	Pre-fortification	Post-fortification	Pre-fortification	Post-fortification	Pre-fortification	Post-fortification	Pre-fortification	Post-fortification	Pre-fortification	Post-fortification
Regular Breads, And Bread Rolls (Plain/ Unfilled/ Untopped Varieties)	5	42	7	45	5	42	<5	42	6	43
English-Style Muffins, Flat Breads, And Savoury and Sweet Breads	<5	6	<5	6	<5	8	<5	7	<5	7
Yeast, Yeast, Vegetable And Meat Extracts	59	29	49	21	41	16	44	16	47	19
Mixed Dishes Where Cereal Is The Major Ingredient	<5	<5	<5	6	<5	11	<5	14	<5	10
Breakfast Cereals and Bars, Unfortified and Fortified Varieties	26	13	31	13	42	16	38	14	35	14
Multivitamin and/or Mineral supplement (Dietary supplement)	5	3	8	4	7	3	9	3	8	3

[¥] Derived using the 2007 ANCNPAS data, includes use of dietary supplements.

Mixed Dishes Where Cereal Is The Major Ingredient - includes sandwiches and filled rolls, pizzas, hamburgers, taco and tortilla dishes, pasta and noodle dishes, savoury rice dishes and savoury dumplings.

8. Major food contributors to estimated total intake of dietary folate equivalents of Australians (target and non-target populations)

Natural folate calculated as dietary folate equivalents (DFEs) is present in a variety of foods and hence there are many more food groups contributing to estimated total DFE intakes than for added folic acid. Table 13 lists the foods that were major contributors to the estimated total intake of DFEs by the target population and the rest of the adult population, before and after mandatory folic acid fortification of bread. The major food contributors to the total DFE intake of children aged between 2 and 16 years with no supplements and with supplements included are shown in Tables 14 and 15.

Table 13: Major food contributors (>5%) to estimated total intake of DFE (target group and other adults) before and after fortification

Food Group	Contributors to total DFE intakes (% folic acid intake)♦			
	Females 16-44 years		19 years and above	
	Pre-fortification	Post-fortification	Pre-fortification	Post-fortification
Regular breads, and rolls	15	34	16	36
Breakfast cereals, plain, single source	7	5	10	7
Breakfast cereals, mixed source	10	8	9	7
Yeast, yeast, vegetable and meat extracts	12	9	10	7
Fancy breads, flat breads, English-style muffins, crumpets	<5	<5	<5	<5
Fruit and vegetable juices and drinks	6	<5	<5	<5
Tea	7	<5	8	5
Dairy milk	6	<5	5	<5

♦ Based on Day 1 data, does not include use of dietary supplements.

Following mandatory folic acid fortification of bread, the proportional contribution of regular breads and bread rolls to DFE intake doubled for the target group and for all adults. For children, the per cent contribution by the same food group increased markedly (almost quadrupled) across all the age groups, after fortification. For both the target and the non-target groups, yeast and yeast extract foods remain relatively high contributors post-fortification in comparison to their pre-fortification proportions.

It is to be noted that the list of major contributors to the intake of DFEs does not include a dietary supplement food group even for the children population that consumed dietary supplements.

Table 14: Major food contributors (>5%) to children's estimated total intake of DFEs before and after mandatory fortification by age groups (both sexes), no supplements[¥]

Food Group	Contribution of food group to total DFE intake[♦] (%)									
	2-3 years		4-8 years		9-13 years		14-16 years		2-16 years	
	Pre-fortification	Post-fortification	Pre-fortification	Post-fortification	Pre-fortification	Post-fortification	Pre-fortification	Post-fortification	Pre-fortification	Post-fortification
Regular Breads, And Bread Rolls (Plain/ Unfilled/ Untopped Varieties)	7	28	9	31	8	28	8	29	8	29
Yeast, Yeast, Vegetable And Meat Extracts	31	22	26	17	19	12	18	11	23	14
Breakfast Cereals and Bars, Unfortified and Fortified Varieties	14	10	16	11	20	13	19	11	18	11
Dairy Milk (cow, sheep and goat)	11	8	8	5	9	6	8	<5	9	6
Fruit And Vegetable Juices, And Drinks	6	<5	8	5	8	5	9	6	8	5
Pome Fruit	6	<5	7	<5	6	<5	<5	<5	6	<5
Mixed Dishes Where Cereal Is The Major Ingredient	<5	<5	<5	5	<5	8	<5	10	<5	7
English-Style Muffins, Flat Breads, And Savoury and Sweet Breads	<5	<5	<5	<5	<5	<5	<5	6	<5	<5

[♦] Denotes the estimates do not include use of dietary supplements. [¥] Derived using the 2007 ANCNPAS.

Mixed Dishes Where Cereal Is The Major Ingredient - includes sandwiches and filled rolls, pizzas, hamburgers, taco and tortilla dishes, pasta and noodle dishes, savoury rice dishes and savoury dumplings.

Table 15: Major food contributors (>5%) to children's estimated intake of DFEs before and after mandatory fortification of bread by age group (both sexes), including supplements[¥]

Food Group	Contribution of food group to total DFE intake (%)									
	2-3 years		4-8 years		9-13 years		14-16 years		2-16 years	
	Pre-fortification	Post-fortification	Pre-fortification	Post-fortification	Pre-fortification	Post-fortification	Pre-fortification	Post-fortification	Pre-fortification	Post-fortification
Regular Breads, And Bread Rolls (Plain/ Unfilled/ Untopped Varieties)	7	28	9	30	8	28	8	29	8	29
Yeast, Yeast, Vegetable And Meat Extracts	31	22	25	17	19	12	18	11	22	14
Breakfast Cereals and Bars, Unfortified and Fortified Varieties	13	10	16	10	19	12	18	11	17	11
Dairy Milk (cow, sheep and goat)	11	8	8	5	9	6	8	<5	8	5
Fruit And Vegetable Juices, And Drinks	6	<5	8	5	8	5	9	5	8	5
Pome Fruit	6	<5	6	<5	6	<5	<5	<5	6	<5
Mixed Dishes Where Cereal Is The Major Ingredient	<5	<5	<5	5	<5	8	<5	10	<5	7
English-Style Muffins, Flat Breads, And Savoury and Sweet Breads	<5	<5	<5	<5	<5	5	<5	6	<5	<5

[¥] Derived using the 2007 ANCNPAS**,** estimates include use of dietary supplements.

Mixed Dishes Where Cereal Is The Major Ingredient - includes sandwiches and filled rolls, pizzas, hamburgers, taco and tortilla dishes, pasta and noodle dishes, savoury rice dishes and savoury dumplings.

9. Comparison of the current folic acid intake estimates of the Australian population to previously predicted estimates

The current estimates of increases in mean 2-day average dietary folic acid intake for the target population, females aged 16-44 years (*women of child bearing age*), compare favourably with the predicted estimates before implementation of the mandatory fortification standard.

The current estimates showed an increase of 145 µg in the post-fortification intake of folic acid by the target group, which is more than the predicted increase of approximately 100 µg/day. The pre-implementation estimates of the proportion of the target group that would have folic acid intakes exceeding the UL was less than 1%. The current estimates demonstrated that based on the weighted mean of data collected at two different time points in the standard implementation period (9/10 months and 2.5 years), the proportion of the target group that exceeded the UL was 0%.

The pre-fortification estimates of folic acid intake indicated that females aged 16-44 years would not achieve the recommended intake of 400µg folic acid per day from fortified foods (voluntary and mandatory) without the use of dietary supplements. This observation was supported by the current post-fortification estimates which indicated that despite the substantial increases in daily folic acid intake, the target population will still need to use dietary supplements to meet their recommended intake requirements.

Children aged 2-8 years were the most likely of the non-target population groups predicted to have folic acid intakes exceeding their recommended ULs. The current estimates confirm that a higher proportion of children in these age groups were likely to have intakes exceeding their ULs after fortification than before fortification. Whilst this is undesirable, it is unlikely to pose a health risk as there is a considerable margin of safety inherent in setting the UL (fivefold margin of safety incorporated). The UL for adults (1,000 µg per day of folic acid) was set based on the potential to mask the diagnosis of vitamin B_{12} deficiency in the elderly and the potential to exacerbate the related neurological symptoms, and then extrapolated downwards by bodyweight for children (FSANZ 2006, NHMRC 2006). Of the proportion of children that were estimated to exceed the UL following the introduction of fortification, these intakes still remain within the margin of safety. This combined with the low probability of vitamin B_{12} deficiency within this age group and the transient nature of the exceedance related to age, means the potential exceedances are not considered to pose increased health risks to this group of children.

The current estimates have used both the 1995 NNS (adults only) and the 2007 ANCNPAS (children only) data whereas earlier estimates used data from only the 1995 NNS for all population groups. Direct comparisons cannot be made between results for children from the two sets of estimates due to differences in data collection methodology and approach to predicting intake estimates.

The sampling methodologies used for these two nutrition surveys and the questions asked, were not identical. Similarly, the food composition tables for the two surveys also differ slightly, due to new foods types introduced into the market place after the 1995 survey up to the time of the period of the 2007 survey. Further, there were differences in the food analytical methods and source of data used to determine the amount of folic acid present in the foods consumed for the 1995 and 2007 food composition data.

On the whole, the post-fortification estimates of folic acid intake, target and non-target groups, provided in this report are in line with the estimates made before the standard implementation. It supports the predicted increases in mean folic acid intake, the proportion of people that could have inadequate or excessive intakes, and the food groups that would be major contributors to the improved folic acid intake of the target group and the rest of the Australian population.

10. Limitations of the dietary intake assessments

10.1 Age of the food consumption data and respondent age groups

The 1995 NNS data was used for the population 16 years and above (including the target population), and the 2007 NCNPAS data was used for the population aged 2-16 years. Although both data sets have their own inherent limitations, the approach used provided the best option for estimating the population's intake of dietary folic acid following implementation of the mandatory fortification standard at the time of writing the report.

The limitations of using the 1995 NNS data for Australian adults aged 16 years and above, which includes females aged 16-44 years, relate to changes that have occurred to the types of foods consumed, new forms of the foods, and in people's eating habits, since the data were collected. Generally, it has been established that people's consumption of staple foods such as cereal products (which include breads), fruit, vegetable, meat and dairy products, which make up the basics of their diet, do not change markedly over time at the broad food group level (Cox, 2004). However, it is recognised that there may be changes to the types of these products consumed over time due to new food products in the market. Information from the recent 2011-12 national nutrition survey confirms cereal products, meat, fruit, vegetables and dairy food groups remain staple foods, consumed daily by the majority of Australians. However, the food types in these categories have changed over the last 15 years with the diversity of food products increasing.

The use of food recall information in estimating nutrient intake in itself poses limitations of under-or-over reporting by respondents. No adjustment was made for over- or under-reporting.

Variation in nutrient intake within individuals was addressed through use of the 2nd day adjusted method for total DFEs and to a limited extent through use of 2-day average of the folic acid intakes. The impact of this latter approach was that it restricted the number of respondents for the different adult age groups as only data for the 10% of the respondents completing a second day record in the 1995 NNS were included.

The 1995 NNS data used for the target population estimates had second day food consumption data for only 10% of the respondents who provided food consumption information on Day 1. Therefore, to estimate the dietary intakes of folic acid using the average of two days of food consumption data, only respondents with food intake information from both Day 1 and Day 2 were used. This restricted the number of respondents for the various adult age groups, including the target group. For that reason the folic acid intake estimates for the target population may not be fully representative of the total population of females aged 16-44 years (women of child-bearing age).

However, FSANZ has separately verified that the 1995 NNS Day 1 results for folic acid intakes for these sub-sets of the population were not statistically different from the whole population sub-group therefore this was considered a reasonable approach in the absence of other information. In 2012, FSANZ undertook the verification project with the help of a final year student (M.Sc. Nutrition and Dietetics) from the University of Canberra who was on placement at FSANZ. The project was a secondary analysis of the 1995 NNS data that compared the dietary folic acid intake in three sub-groups of females aged 16-44 years taken from the 1995 NNS. The sub-groups were the 90% with Day 1 food consumption data and the 10% with Day 1 food consumption data who also had food consumption data for Day 2. The results indicated very small differences in the median dietary folic acid intakes for Day 1 between the 90% Day 1 respondents and the 10% of Day 1/Day 2 respondents. It was therefore concluded that dietary folic acid intake results based on the 10% of respondents aged 16-44 years (1995 NNS) with two days of food consumption data can be used to represent that population sub-group (FSANZ, unpublished).

10.2 Period of food manufacture and effect on nutrient levels

Limitations may also be associated with changes that manufacturers may have made to the foods presently in the market in line with the current Food Standards Code. Changes to the market share information used to weight the proportion of voluntarily fortified foods may therefore not also fully reflect the current market situation. There are also limitations related to the values for folic acid concentrations in bread not fully reflecting actual levels due to the limitations of the analytical techniques used, and possible differences between batches of foods. These drawbacks mean that even with the updates made by FSANZ to the Australian National Food Composition databases used in the dietary modelling process, the estimated nutrient levels may not exactly represent the levels in some foods.

In determining the concentration of folic acid in mixed foods, the assumptions made about the proportion of bread in different bread-based mixed foods and recipes can also be limitations in the dietary modelling process, as they may not exactly reflect the foods consumed for each individual respondent.

11. Conclusion

This report provides evidence of two main changes in Australian's food supply. The first being that the results of the 2010 and 2012 bread surveys undertaken by FSANZ indicate bakeries (large or small-scale) in Australia are using folic acid fortified wheat flour in baking bread. The second is that mandatory folic acid fortification of bread through the use of folic acid fortified wheat flour in bread-making has substantially increased the estimated daily mean folic acid intake of Australians irrespective of age, particularly for the target population for the fortification, women of child bearing age (females aged 16-44 years).

As the estimated mean 2-day average intake of folic acid among the target population increased following fortification, the estimated proportion with inadequate intakes decreased substantially. The proportion of women of child bearing with inadequate folic acid intakes (expressed as DFEs) decreased from 11% to 1% when compared to the non-pregnant EAR, while the proportion of the target group with inadequate intakes decreased from 64% to 22% when compared to the pregnancy EAR.

The three major food groups that contributed to the post-fortification increased intake of dietary folic acid by Australians, particularly the target population, were regular breads and rolls (50%), breakfast cereals mixed source (11%) and yeast and yeast/vegetable/meat extracts (10%). Before mandatory folic acid fortification of bread, bread contributed only 19% to the total dietary folic acid intake of the target group.

Despite the identified limitations of the dietary intake assessment approach used, the results presented in this report provide estimates that are as accurate as possible given the data available at the time of analysis. The health outcome expected from the noted increase in mean intake of dietary folic acid by women of child-bearing age is a reduction in the incidence of neural tube defects within the Australian population.

Potential adverse effects are indicated when a proportion of a given population group exceeds the UL. The current estimates confirm that a higher proportion of children in the 2-8 year old age group were likely to have intakes exceeding their ULs after fortification than before fortification. Whilst this is undesirable, it is unlikely to pose a health risk as there is a considerable margin of safety inherent in setting the UL (fivefold margin of safety incorporated). Of the proportion of children that were estimated to exceed the UL following the introduction of fortification, their intakes were within the margin of safety. This combined with the low probability of vitamin B_{12} deficiency within this age group and the transient nature of the exceedance related to age, means the potential exceedances are not considered to pose increased health risks to this group of children.

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Appendix 1

Table A.1: Main bread types and proportions sampled from different bakeries – bread survey 1

Bread type	Number of samples	Supermarket bakeries (%)	Local small-scale bakeries (%)	Industry bakeries (%)	Bakery Franchises (%)
White bread	28	39	36	18	7
Wholemeal bread	15	20	34	33	13
Multigrain and seeds bread	18	17	33	33	17

Table A.2: Main bread types and proportions sampled from different bakeries – bread survey 2

Bread type	Number of samples	Supermarket bakeries (%)	Local small-scale bakeries (%)	Industry bakeries (%)	Bakery Franchises (%)
White bread	32	25	47	19	9
Wholemeal bread	32	19	47	28	6
Multigrain and seeds bread	32	28	44	22	6

Table A.3: An example of the bread survey sampling plan – All jurisdictions

The sampling is to focus on major supermarkets and local bakeries in the capital cities of the States/Territories. Local bakery refers to small-scale independent bakeries or hot bread shops.									
	Jurisdictions								
Bread categories	**NSW - Purchase samples from Woolworths supermarket**	**VIC- Purchase samples from Coles Supermarket**	**Western Australia**	**Queensland**	**SA - Purchase samples from Foodland**	**Northern Territory**	**ACT**	**TASMANIA - Purchase samples from Coles**	**Total number-samples all jurisdictions**
Bread, white, sandwich (sliced or unsliced). Excludes rolls, buns and hamburger rolls	1 loaf each of : Abbotts village bakery rustic white bread; Woolworths Homebrand white sandwich bread; Aldi brand white sandwich bread; white sandwich bread from local bakery. Number of samples = 4.	1 loaf each of: Lawson's Original white bread; Coles brand white bread; white sandwich bread from Baker's Delight; white sandwich bread from a local bakery . Number of samples = 4	1 loaf each of: Tip Top Sunblest - White sandwich bread; Baker's Delight white sandwich bread; Aldi brand White Bread; White sandwich bread from a local bakery. Number of samples = 4	1 loaf each of: Baker's Delight white block loaf, White Farmer's loaf and regular white sandwich bread from a local bakery. In the absence of specified white bread types purchase different varieties of white bread. Number of samples = 4	1 loaf each of 2 varieties of Foodland brand white bread; 2 varieties of white bread from local small-scale bakery. Number of samples = 4	1 loaf each of white bread from an Indigenous store and from a major supermarket (different brands); 1 package white rolls from major supermarket (any brand). Number of samples = 3	1 loaf of Supabarn White bread and 1 loaf white sandwich bread from a local bakery. Number of samples = 2	1 loaf each of Coles brand white bread, White bread from a local bakery and Tip Top White thick bread. Number of samples = 3	28
Bread, wholemeal/wholegrain - sandwich (sliced or unsliced). Excludes rolls, buns and hamburger rolls	1 loaf each Abbotts village bakery, farmhouse wholemeal bread & wholemeal sandwich bread from local bakery. Number of samples = 2	1 loaf each of Gold Split wholemeal bread and Coles supermarket brand wholemeal bread. Number of samples = 2	1 loaf each of Woolworths wholemeal bread and Tip Top 9 grain wholemeal bread. Number of samples = 2	1 loaf each of Baker's Delight wholemeal bread and wholemeal bread from local bakery. Number of samples = 2	1 loaf each of Gold Max brown bread and brown/wholemeal bread from local bakery. Number of samples = 2	1 loaf each of wholemeal bread (any brand) from Indigenous store and wholemeal bread from local bakery. Number of samples = 2	1 loaf each of Buttercup wholemeal bread and wholemeal bread from a local bakery. Number of samples = 2	1 loaf of wholemeal bread from major supermarket (any brand) and 1 loaf from local bakery. Number of samples = 2	16
Bread, Multigrain with seeds including specialty grain +seeds, (sliced or unsliced). Excludes rolls, cob bread, buns and hamburger rolls	1 loaf each of Burgen wholemeal and seeds bread and Woolworths homebrand multigrain and seed bread. Number of samples = 2	1 loaf each of Molenberg 9 Grains and pumpkin seeds bread and grain and seed bread from a local bakery. Number of samples = 2	1 loaf each of grain and seed bread from Baker's Delight and Burgen Pumpkin seeds bread. Number of samples = 2	1 loaf each of Molenberg wholegrain sesame and popy seed bread and Tip Top 9 grain plus pumpkin seeds bread. Number of samples = 2	1 loaf each of Specialty multigrain and seed bread from a local bakery. Number of samples 2	1 loaf each of multigrain and seed bread from major supermarket and from a local bakery. Number of samples = 2	1 loaf each of multigrain and seed bread from Baker's Delight and from a local bakery. Number of samples = 2	1 loaf of Woolworths Four Seed Bread and grain and seed bread from a alocal bakery. Number of samples = 2	16
Bread, Gluten free - White, sandwich (sliced or unsliced). Excludes rolls, buns, and hamburger rolls	1 loaf (any brand) from Woolworths and 1 loaf from a local bakery. Number of samples = 2	1 loaf (any brand) from Coles and 1 loaf from a local bakery. Number of samples = 2	1 loaf each of any brand from a major supermarket and from a local bakery. Number of samples = 2	1 loaf (any brand) from supermarket and 1 loaf from a local bakery. Number of samples = 2	1 loaf (any brand) from supermarket and 1 loaf from a local bakery. Number of samples = 2	1 loaf (any brand) from supermarket and 1 loaf from a local bakery. Number of samples = 2	1 loaf (any brand) from supermarket and 1 loaf from a local bakery. Number of samples = 2	1 loaf (any brand) from supermarket and 1 loaf from a local bakery. Number of samples = 2	16
Bread, Organic - White, sandwich (sliced or unsliced). Excludes rolls, buns and hamburger rolls	I loaf (any brand) from Woolworths. Number of samples =1	I loaf (any brand) from Coles. Number of samples =1	I loaf (any brand) from Woolworths. Number of samples =1	I loaf from local bakery. Number of samples =1	I loaf (any brand) from Foodland/Coles. Number of samples = 1	I loaf (any brand) from major supermarket. Number of samples = 1	I loaf (any brand) from Supabarn. Number of samples = 1	I loaf (any brand) from Coles. Number of samples = 1	8
Flat bread - types labelled as Flat, Wrap, Tortilla, Lavash or Naan bread	1 loaf of flat bread (any brand) labelled as 'flat bread' from Woolworths. Number of samples = 1	1 loaf of flat bread (any brand) labelled as 'wraps' from Coles. Number of samples = 1	1 loaf of flat bread (any brand) labelled as 'lavash bread' from major supermarket. Number of samples = 1	1 loaf of flat bread (any brand) labelled as 'Tortilla' from a major supermarket. Number of samples = 1	1 loaf of flat bread (any brand) labelled as 'Naan' from major supermarket. Number of samples = 1	1 loaf of flat bread (any brand) labelled as 'wraps' from a major supermarket. Number of samples = 1	1 loaf of flat bread (any brand) labelled as 'flat bread' from Supabarn. Number of samples = 1	1 loaf of flat bread (any brand) labelled as 'lavash bread' from major supermarket. Number of samples = 1	8
Bread, English muffin - white or original, wheat flour based. Excludes, wholemeal, multigrain and spicy fruit varieties	Tip Top English muffin - original. Number of samples = 1	Coles brand of plain English muffin. Number of samples = 1	Any brand of English muffin, white. Excludes Tip Top. Number of samples = 1	Any brand of English muffin, white. Excludes Tip Top. Number of samples = 1	Tip Top English muffin - original. Number of samples = 1	Any brand of English muffin, white. Excludes Tip Top. Number of samples = 1	Any brand of English muffin, white. Excludes Tip Top. Number of samples = 1	Tip Top English muffin - original. Number of samples = 1	8
Total number of samples per jurisdiction	13	13	13	13	13	12	11	12	100

Table A.4: Amount of folic acid in the bread types sampled in survey 1

Bread type	Highest amount of folic acid (µg/100g)	Lowest amount of folic acid (µg/100g)	Mean amount of folic acid (µg/100g)	Median amount of folic acid (µg/100g)	Standard deviation	Mean moisture content (g/100g)	Number of samples
White sandwich	270	19	**200**	205	52	38	28
Flat breads /Wraps	310	98	**197**	190	74	30	8
Wholemeal sandwich	240	130	**189**	190	37	40	16
English muffin	230	150	**180**	165	33	44	8
Multigrain & Seeds	230	100	**164**	160	32	37	17
Organic	120	<1.6	**39**	36	40	38	7 (No TAS sample)
Gluten free	76	<1.6	**21**	7	27	46	16

Note: The folic acid values have been arranged to show the mean amount of folic acid in decreasing order by the bread type and rounded to the nearest whole number.
The organic bread samples did not include a sample from Tasmania. Samples were not available for purchase

Table A.5: Estimated mean 2-day average folic acid intake of children (with and without the use of dietary supplements) before and after fortification

Age Group (both genders)	Estimated mean folic acid intake-with supps (µg/day)				Estimated mean folic acid intake-without supps (µg/day)			
	Pre-fortification	Post-fortification	Increase	% Increase	Pre-fortification	Post-fortification	Increase	% Increa
2-3 years	110	221	111	101	104	215	111	1
4-8 years	117	270	153	131	108	260	153	1
9-13 years	115	297	182	158	107	290	182	1
14-16 years	121	334	212	175	110	323	212	1
2-16 years	116	286	170	146	108	277	170	1

Table A.6: Estimated mean 2-day average dietary folate equivalents intake of children (with and without the use of dietary supplements) before and after fortification

Age Group (both genders)	Estimated mean DFE intake-with supps (µg/day)				Estimated mean DFE intake-without supps (µg/day)			
	Pre-fortification	Post-fortification	Increase	% Increase	Pre-fortification	Post-fortification	Increase	% Increase
2-3 years	438	609	172	39	430	602	172	40
4-8 years	469	709	240	51	454	698	244	54
9-13 years	495	773	279	56	481	760	279	58
14-16 years	528	862	335	63	510	846	336	66
2-16 years	486	750	264	54	472	737	266	56

Table A.7: Mean consumption for consumers only of regular breads and rolls (food code 122) from various nutrition surveys*

Gender	Age Group	Measure	Nutrition Survey** 2007 ANCNPAS	1995 NNS	2011-12 NNPAS
All	2-16 years	% consumers	76.5	NA	72.5
		Mean consumption (g/day)	89	NA	86
All	19 years and above	% consumers	NA	76.4	65.2
		Mean consumption (g/day)	NA	111	93
Females	16-44 years	% consumers	NA	76.4	58.2
		Mean consumption (g/day)	NA	97	75

* All results weighted.
** Day 1 only.