FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

7-06
4 October 2006

FINAL ASSESSMENT REPORT

PROPOSAL P295

CONSIDERATION OF MANDATORY FORTIFICATION WITH FOLIC ACID

Attachments 8, 9, 10 and 12

Contents

Attachment 8

Evaluation of the health risk from mandatory folic acid fortification

Introduction

This document integrates the dietary intake 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.

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

Mandatory folic acid fortification of all bread at levels of 135 µg/100 g, could potentially lead to a small percentage of individuals exceeding the Upper Level of Intake (UL) for folic acid (Table 1). The proportion of Australian and New Zealand consumers exceeding the corresponding age-specific UL is shown in Table 2.

As the dietary intake assessment was redone between Draft Assessment and Final Assessment to account for the change of food vehicle (from bread-making flour to bread), any changes in exceedances above the UL have been noted.

1.1 Young children

If mandatory fortification of bread with folic acid at a level of 135 µg/100 g were introduced, it is estimated that a small proportion of young children may exceed the UL – up to 7% of 2-3 year olds and 3% of 4-8 year olds. This is a slight increase in the proportion of 2-3 year olds exceeding the UL (up 1%) from the previous estimates based on the mandatory fortification of bread-making flour at a residual level of 200 µg/100 g. The proportion of 4-8 year olds exceeding the UL remains unchanged.

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 µg/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 135 µg/100 g of bread, 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 135 µg folic acid/100 g of 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 B_{12} 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)

Only a very small percentage (<1%) of Australian and New Zealand women aged 16-44 years exceeded the UL at Baseline and at a fortification level of 135 µg/100 g of bread (Table 3). These estimates are unchanged from Draft Assessment.

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 44% of New Zealand women). At Draft Assessment 40% of women were expected to exceed the UL. However, even in this group at the 95th percentile, intakes of folic acid are below 1,200 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.

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 a fortification level of 135 µg/100 g of bread. Only a very small proportion (<1%) of individuals aged 50-69 years exceed the UL at the same fortification levels which is similar to the percentage exceeding the UL at baseline (<1%). These percentages are the same as previously estimated at Draft Assessment. Therefore, it is unlikely that fortification of bread at 135 µg/100 g 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 bread at 135 µg/100 g is unlikely to lead to a masking of the diagnosis of vitamin B_{12} deficiency 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: Comparison of the proportion of Australian and New Zealand population likely to exceed the UL at 'Baseline' and with mandatory folic acid fortification of all bread

Population Group	No. of respondents	Baseline (% > UL)	All bread 135 µg/100 g (% > UL)
Australia			
2-3 years	383	1	7
4-8 years	977	<1	3
9-13 years	913	<1	2
14-18 years	734	<1	1
19-29 years	2,203	<1	<1
30-49 years	4,397	<1	<1
50-69 years	3,019	<1	<1
70+ years	1,232	0	0
New Zealand			
15-18 years	246	0	<1
19-29 years	804	0	0
30-49 years	1,883	<1	<1
50-69 years	1,147	0	<1
70+ years	556	0	0

Table 3: Comparison of the proportion of Australian and New Zealand women of child-bearing age* likely to exceed the UL with mandatory fortification and at different levels of supplement intake

Model	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'	<1	<1	1	<1	<1	9
All bread 135 µg/100 g	<1	<1	3	<1	<1	44

* All women aged 16-44 years.
** Assumes all women aged 16-44 years consume the supplement level.

2. Multiple births

The evidence for a relationship between increased risk of multiple births from increased folic acid intake is equivocal. No conclusions can be drawn with regard to potential increased risk of multiple births from the intakes of folic acid shown in the dietary intake assessment.

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[1]). Dietary intake assessment indicates that the large majority of consumers will have intakes below 1 mg/day (the adult UL) at a fortification level of 135 µg/100 g of bread, 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.

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

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.

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.

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 of bread at 135 µg of folic acid /100 g of bread be put forward for further consideration.

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[2] 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).

[2] 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 - Fortification of Bread with Folic Acid

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 for 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). Tetrahydro-, dihydro-, formyl-, and methyltetrahydrofolates are the predominant naturally occurring folates in foods. Folate can also be supplied in the form of disodium folate.

Folic Acid

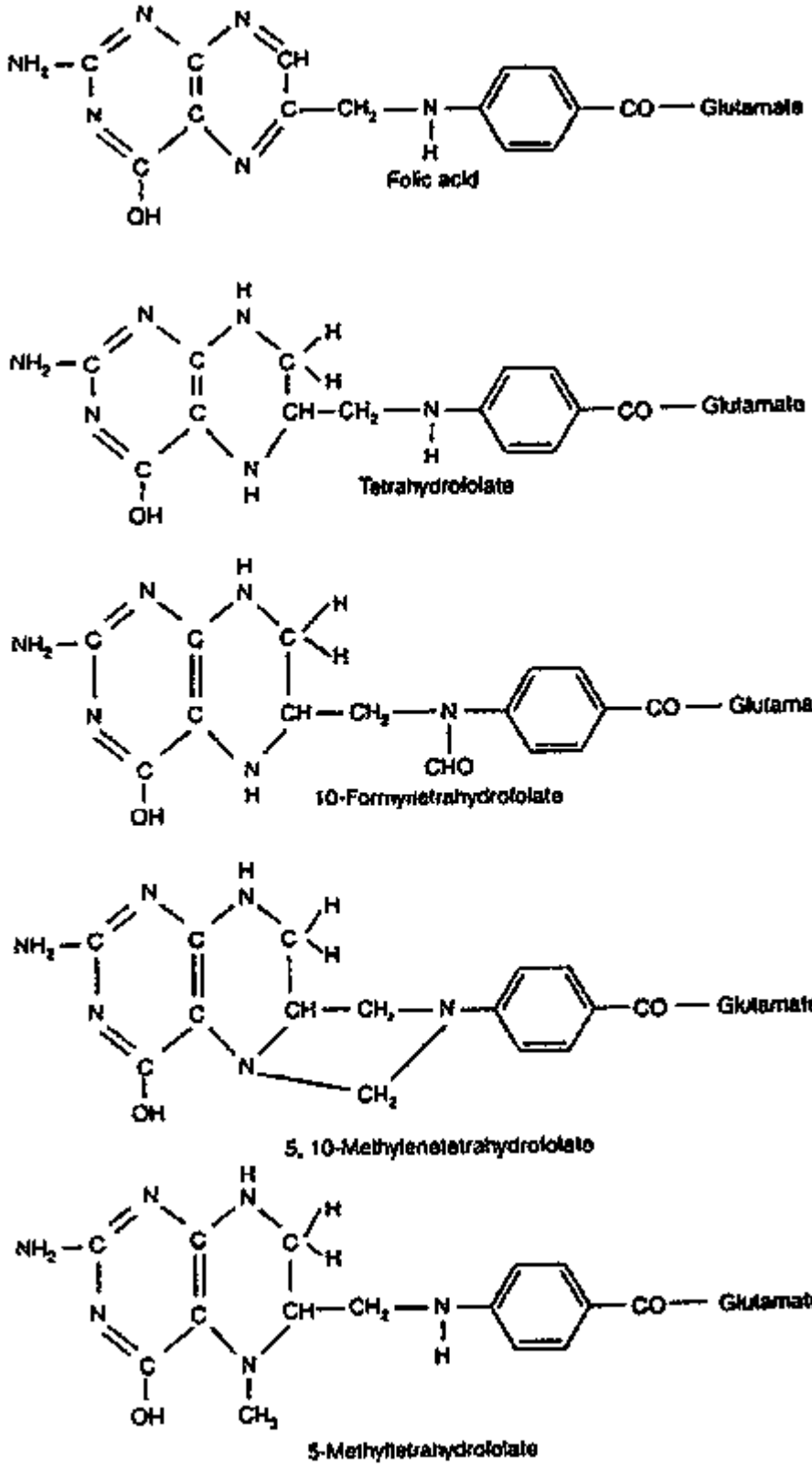
Folic acid, or pteroylmono-glutamic acid (PGA), is the most common synthetic form of folate and is the form used in food fortification and in the majority of supplements. Food Chemicals Codex 5th edition (FCC) specifies folic acid with the structural formula $C_{19}H_{19}N_7O_6$ and molecular weight of 441.40. Standard 1.3.4 – Identity and Purity, of the *Australia New Zealand Food Standards Code* specifies FCC as a primary source of specifications, which means that where folic acid is added to food it should comply with the FCC specification. As its alternate chemical name indicates, it contains a single glutamate moiety attached to pteroic acid (Ball, 1998). 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 or L-methylfolate (5-CH_3H_4PteGlu) and mixtures of naturally occurring forms. This report however refers to folic acid as the form that is specified for food use in FCC and by reference in Standard 1.3.4. Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions, lists only folic acid under the permitted forms of folate as an added vitamin.

Vitamin Activity

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.

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



Stability of Folates and Folic Acid in Foods

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.

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

Current information on the stability of 5-methyltetrahydrofolate (L-methylfolate) is 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). 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).

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).

FSANZ received an Application A566 to consider L-methylfolate, calcium as a permitted form of folate on 6 July 2005, but has not yet commenced work on this unpaid Application.

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 folic acid 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 45^{0}C, flour showed only small losses. Similarly, retention was 90-100% in pre-mix fortified yellow corn (NHMRC, 1995). A 1995 study in which folic acid was added at either 100 μg/100 g or 500 μg/100 g of flour showed around 100% retention at a range of temperatures (-23 to 48.8°C) after one year's storage (Morgan, 1996).

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 4^{0}C storage led to no change in folate content. In contrast, a progressive decline in folate occurred during storage at -20^{0}C with about 55% loss over three months (Gregory, 1989).

Addition of Folic Acid to Bread

There are a number of ways to add folic acid into the bread-making process. In Australia, thiamin is added currently by feeders at the end of the milling process to achieve the current mandatory minimum level. This process is not used in New Zealand as thiamin fortification of breadmaking flour is not required. Folic acid could be added at the end of the milling process, but industry questioned the accuracy of current thiamin dosing systems and the variability of flour flow rates, particularly as a range of folic acid levels is proposed to be specified. Folic acid can also be added with other bread ingredients including water, yeast, salt and where used, bread improvers and premixes containing miscellaneous ingredients. The method of delivery need not be specified if the requirement is to add folic acid to bread.

Standard 2.1.1. – Cereals and Cereal Products, defines bread in Clause 1 as the product made by baking a yeast-leavened dough prepared from one or more cereal flours or meals and water. A report on supply chain aspects of fortifying flour for bread with folic acid is at Appendix 1.

Adding further feeders for folic acid or preblending thiamin and folic acid would be possible methods used for folic acid addition to breadmaking flour in Australia.
As thiamin 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 could be expected to be required for a new system to fortify flour with folic acid.

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, although the wholemeal flour can be reconstituted by adding back bran to white 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 fibre, oat bran, or soy hulls) to increase the fibre content of the bread.

Flour Milling Processes

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". Flour produced from an entire wheat kernel is also known as 'Graham 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. 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%.

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.

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.

There are a number of possible ways to add folic acid into the bread-making process. Folic acid can be added to flour or with other bread ingredients including water, yeast, salt and where used, bread improvers and premixes containing miscellaneous ingredients. Losses of folic acid from bread average about 25% but may be as high as 40%.

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APPENDIX 1

Supply Chain Aspects of Fortifying Flour or Bread with Folic Acid in Australia and New Zealand

Report prepared for
Food Standards Australia New Zealand
by
Brooke-Taylor & Co Pty Ltd

18 August 2006

Acknowledgements & Disclaimers

Much of the data contained in this report were provided directly by industry personnel during meetings and telephone interviews with the consultant. The author would like to thank the Australian and New Zealand Milling and Baking industries for their assistance in preparing this report. In particular, the time given and information provided by the following industry personnel is gratefully acknowledged:

- Fiona Fleming & Dr Dai Suter – George Weston Technologies, Enfield, NSW, Australia;
- Craig Gough – Weston Cereal Industries, Enfield, NSW, Australia;
- Paul Esplin – Tip Top Bakeries, Australia;
- Graham Laucke, Laucke Flour Mills, Australia;
- Tony Fitzpatrick, Manildra Group, Australia;
- Colin Rushton, Goodman Fielder, Australia;
- Annette Campbell, Consultant, New Zealand Association of Bakers;
- Gary Urwin, Champion Mills, New Zealand;
- Mike Normington, NZ Bakels Ltd;
- Laurie Powell, George Weston Foods (NZ) Ltd;
- Garth Bradford, George Weston Milling, Auckland, New Zealand.

Glossary and Acronyms

bread improver	A combination of processing aids, additives and ingredients added to bread doughs to enhance dough handling, baking performance and loaf characteristics, including substances such as enzymes, emulsifiers, oxidants and antioxidants.
FSANZ	Food Standards Australia New Zealand.
grist	A batch of wheat, or other cereals, prepared for milling
NTD	Neural tube defects.
plc	Programmable Logic Controller
ppm	Parts per million.
premix	A combination of dry ingredients, such as raising agents, processing aids, additives and ingredients, possibly including bread improvers used for bread, cakes and biscuits prior to developing the dough.
µg	microgram = one millionth of a gram.
wholemeal	the product containing all the milled constituents of the grain in such proportions that it represents the typical ratio of those fractions occurring in the whole cereal.

Executive Summary

The flour milling businesses in Australia and New Zealand are essentially commodity focussed operations established to efficiently produce basic flour products with limited differentiation. Differentiation into baked or other products normally occurs in the bakery itself. Mills in both countries increasingly operate on a just in time model of production and have limited capacity to store or segregate bulk flour.

Australian mills are equipped to fortify flour with thiamin. However, the precision of the systems currently in place is poor with the principal objective being to ensure fortification is always in excess of the prescribed minimum level. In practice, there is little if any segregation of domestic hard wheat flours in the Australian market. In addition to bread, a majority of flour products are produced with a basic flour that may be fortified with thiamin for bread making. Current thiamin fortification standards of precision in Australia are incompatible with the standards proposed for folic acid fortification.

In response to concerns about the safety implications of excess folic acid consumption by non-target groups, Australian millers are concerned about the legal implications from fortification at levels above the target level proposed.

There is no current capacity in New Zealand mills to fortify flour with folic acid or to segregate fortified and non-fortified flour at a commercial level. In practice a degree of cross contamination would appear inevitable if fortification of flour for bread making with folic acid were mandatory. New Zealand millers have significant concerns about the impact of folic acid cross contamination for export markets, especially Japan.

Based on industry understanding of its obligations to meet the proposed standard of fortification, there are significant capital cost implications for Australian and New Zealand millers in relation to:

- installation of new more precise dosing equipment (as current equipment will not meet the proposed specifications);
- purchase of laboratory equipment to enable folic acid analysis in real time;
- training and staffing of laboratories;
- additional flour storage capacity for mills (minimum 2 silos per mill);
- duplication of flour conveyor systems at mills to reduce cross contamination risk;
- additional flour storage capacity at plant bakeries would be necessary if unfortified breads were also to be produced, to enable consumer choice; and
- additional labelling costs for millers and premix makers to write off packaging and redesign/ reprint labels/packaging for all flour and flour containing premix products.

Significant lowering of expectations of precision with respect to folic acid fortification would be necessary to enable Australian millers to utilise existing thiamin fortification systems.

Addition of an improver or a premix containing folic acid during dough mixing provides a precise and flexible means of fortifying bread with folic acid. This method could be applicable to most bakeries, where minor and micro ingredients are added manually or semi-automatically.

A regulation for mandatory fortification drafted on the basis of final bread weight will allow bakers to choose the vehicle most appropriate to their plant and operating practices.

In view of the significant number of (small) bakeries compared to the number of mills, the addition of folic acid during bread making may appear to present a more complex enforcement challenge than addition at mills, since enforcement will be required on an individual bakery by bakery basis.

However, in the case of fortification via flour, there remains an enforcement obligation to ensure that bakeries are actually using fortified flour in their bread making. Accordingly, in practice, the enforcement burden is unlikely to differ significantly between fortification of bread with folic acid via flour or directly into the dough. Both the compliance and enforcement burdens for mandatory folic acid fortification could be further reduced by the use of production records, rather than product analysis, to demonstrate that the prescribed amount of folic acid was being added to bread. Introduction

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

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

Mandatory fortification has been under active consideration since May 2004 when the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) adopted a Policy Guideline on the Fortification of Food with Vitamins and Minerals. Ministers have also requested that Food Standards Australia New Zealand (FSANZ) give priority consideration to mandatory fortification with folic acid.

FSANZ has addressed this proposal through the development of Proposal P295. The preferred approach identified by FSANZ in the Draft Assessment Report to Proposal P295 is:

1. Mandatory fortification of all bread-making flour with folic acid at a level of 230-280 micrograms (μg) of folic acid per 100 g of bread-making flour, to achieve an average residual level of approximately 200 μg folic acid in the flour component of the final food.

2. Maintenance of current voluntary folic acid permissions in foods other than bread.

The current report examines the technical and practical aspects of folic acid fortification in flour and bread with particular reference to:

1. Consideration of the technical aspect of mandatory fortification of bread with folic acid;

2. Review and examine consumer choice for bread and bread making flour in Australia and New Zealand;

3. Identify other options rather than bread making flour for mandatory fortification with folic acid; in particular consider bread improvers, yeast and premixes;

4. Review the milling process, particularly flour segregation practice, in New Zealand and the internal operations which may impact on the mandatory fortification;

5. Review the Australian and New Zealand millers' ability to implement a fortification range in bread-making flour including the technical aspects of the fortification; and

6. Such other related assessments as may be requested by FSANZ.

Milling

Flour Milling in Australia and New Zealand

The principal flour millers in Australia and New Zealand are:

Australia
- Weston Milling (a division of George Weston Foods, NSW, Victoria, Queensland, SA, WA)
- Allied Mills (NSW, Victoria, Queensland, SA, WA),
- Manildra (NSW),
- Laucke (Victoria and SA),
- Tasmanian Flour Mills,
- Ben Furney Flour Mills (NSW).

New Zealand
- Champion Flour Mills (Division of Goodman Fielder NZ Ltd, mills in Mt Manganui and Canterbury),
- Weston Milling (Division of George Weston Foods NZ Ltd, mills in Auckland, Wellington and Canterbury),
- Canterbury Flourmills (Canterbury),
- Milligans Food Group (Auckland).

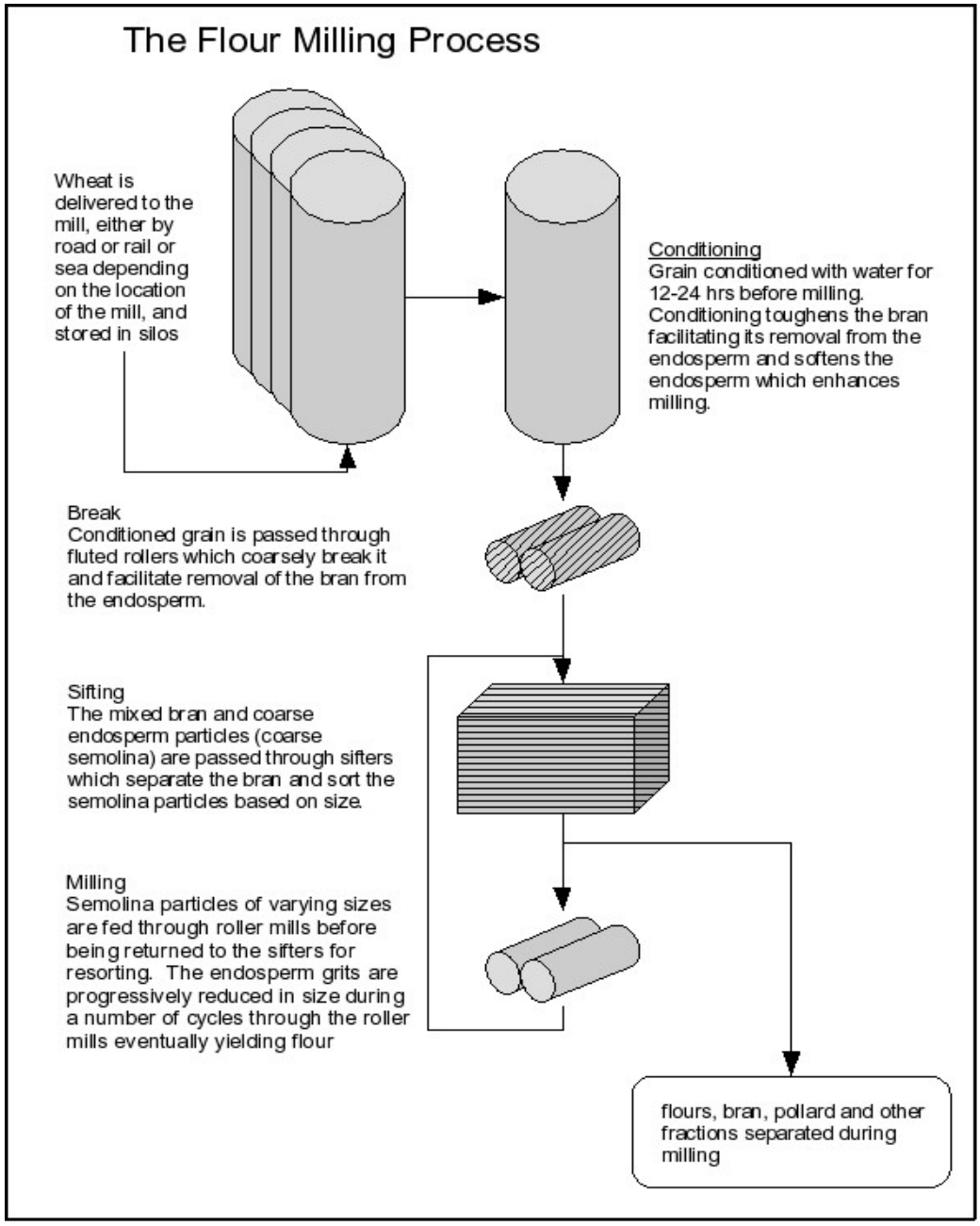
Flour Milling is undertaken in Australia and New Zealand by one of two methodologies:

1. Various wheats are blended into a "bakers grist", on the basis of their physical and compositional properties, such that when milled the flour will have met the required functional characteristics. This grist is milled as a blend. Minor correctional blending may be applied after milling to ensure compliance with specifications.

2. Single wheat varieties are milled individually and stored by variety as milled flour. Flours are batch mixed to achieve desired product specifications.

Australian and New Zealand millers predominantly mill mixed grists. If further blending of flours is required this is generally undertaken volumetrically, which is relatively imprecise.

The George Weston Foods mill in Auckland uses both methods in its operations, milling mixed grists and milling by individual variety and batch mixing to produce flour products. Mills are generally operated continuously. The rate at which flour is collected from the mill is primarily controlled by the rate at which wheat is introduced to it. Milling rate is dependent upon a number of variable factors including the wheat varieties in the grist, the corn hardness, the degree of conditioning and level of hydration of the grain. When one grist ends a new grist is introduced to the mill. Typically, four batches of flour would be produced per day. Between grists, there is a changeover period during which the flour may comprise a mixture of both grists. It is a standard industry practice for this mixed flour to be blended away through subsequent production thereby diluting any variation. Scheduling of milling operations will generally seek to assure that this carry-over flour can be accommodated in subsequent batches. For a large mill running at 20 tonnes per hour up to 7 tonnes of mixed flour may be collected at grist changeover.



Commodity flour milling in Australia & New Zealand

Both the Australian and New Zealand milling and baking industries operate on a paradigm that white flour is essentially a commodity product. Determination of a flour's basic characteristics, reflecting baking performance, takes place at milling by selection of wheat components in the grist. Thereafter, further differentiation necessary for the preparation of different flour or bread types takes place either at the bakery in the case of bulk flour or during packaging of bagged flours and premixes. Thus, the majority of plant bakeries[3], when producing wholemeal bread will use a standard white flour as the base and add the other components of wholemeal, such as bran and additional protein during dough mixing.

3 Only one plant baker in New Zealand was identified during consultations with millers as receiving bulk wholemeal flour, in addition to white flour.

In the case of an in-store bakery, bread dough may be prepared either using plain flour mixed with a wholemeal premix (containing the necessary wholemeal components) or wholemeal flour that has been reconstituted at the bagging plant may be used. Commodity base flour is also used in a wide range of other food and non-food applications, including the manufacture of pies & other baked goods, pasta and noodles, tinned spaghetti, soups and soup mixes, glue and building materials such as plywood.

As a consequence, a majority of mills in Australia and New Zealand have been designed for efficient production of a single commodity; base white flour. This streamlining of production in favour of flour production efficiency was exacerbated in New Zealand, where from 1950s until the 1980s the Wheat Board, operated a quota system in which it purchased sufficient wheat for the New Zealand bakery industry and also sold flour to bakers. Millers were allocated production quotas and supplied with wheat. All flour was purchased back by the Wheat Board at fixed prices. The imperative for millers was to maximise commodity base flour production efficiency irrespective of the quality of wheat supplied by the board. Furthermore, as a net wheat importer, New Zealand millers are under greater cost pressures than their Australian counterparts to compete with potentially cheaper imports.

Flour storage in Australian & New Zealand mills & bakeries

Business rationalisations have led to significant increases in Australian mill capacities during the past 20 years. However, this has not been matched by a commensurate increase in grain and flour storage capacity. Mills increasingly operate on a "just in time" basis with minimal capacity to store flour. Typical ratios reported for the Australian industry are: 5-6 days wheat storage and 2-4 days total flour storage. By contrast the typical ratio is reported to be lower in New Zealand at around 2 days total flour storage. In practice, much of this storage is dedicated to specialist and high value products and not available for long term storage of base flours. A typical mill producing 25 or more individual products requires very tight scheduling to ensure adequate storage is available to meet current production demands. The George Weston Foods mill at Enfield, NSW produces up to 40 distinct flour products, around 30 of which are intended for bread-making and may include export products. There is essentially no capacity to hold additional supplies of bulk products for significant lengths of time. As a consequence, there would unlikely be additional capacity to handle a range of unfortified bread flours or to store specification fortified flour for blending. The majority of plant bakeries in both countries are established to only handle one type of flour. In an integrated supply chain, such as that operated by the Goodman Fielder Mill in Mount Manganui, the mill has on line access to real time readouts of its customer bakery flour silos. The bakeries typically hold a 1 day stock and flour produced in the preceding 24hr may be dispatched from the mill each day (once cleared by quality control) to maintain bakery supply for the following days production.

Because of the commodity nature of milling the ratio of flour production to storage capacity is likely to continue decreasing in relative terms.

On-line sampling and testing of flour is standard industry practice in Australia and New Zealand. Flour is tested for its functional characteristics at the time of production. Results may be obtained within 1 hour. Product may be dispatched as soon as it is cleared, within 4 hour of production from a mill with 24hr on site quality control facilities and within 8 hour of production for a mill where the laboratory only operates during daytime shifts.

In the view of Australian and New Zealand millers, the paradigm in operation within Australian and New Zealand mills is, in production terms, the opposite of that adopted in North American (USA and Canada) flour mills, in which the priority is to produce a wide range of differentiated products from the mill. A North American mill may be required to fortify flours with as many as 9 different ingredients (e.g. salt, thiamin, ascorbic acid, L-cysteine, and bleaching agents) to meet bakery and retail demands. As a result mills in these countries may be equipped with multiple supply chain systems necessary for production, fortification and segregation of the different products produced. In contrast, Australian and New Zealand mills have relatively few (1-2) low technology discrete flour conveyors and storage networks compared to their North American counterparts.

Fortification and dosing systems for flour

A number of potential systems for dosing additional ingredients into flour have been identified in consultations as, in order of increasing accuracy:

1. A screw feed into the flour conveyor.

2. A screw feed into the flour conveyor with a feedback loop linked to the feed rate of the mill.

3. Batch mixing of the additive into flour on a weight for weight basis, post production.

System one is typical of the systems used in Australia for addition of thiamin to flour. These systems are relatively cheap to install, however, in operation they have poor accuracy and precision since the dosing feed rate and the flour conveyor capacity are not continuously linked. Any change in mill rate, and conveyor capacity will vary the fortification dose rate. Furthermore, without an additional mixing system they do not ensure homogeneous mixing of the flour and the dosed premix. Monitoring of the speed of the screw feed or the disappearance of additive premix, relative to the rate of operation of the mill provides a crude estimate of the effectiveness of dosing.

System two is essentially mechanically similar to system one except that the speed of addition of fortifying premix can be continuously adjusted in response to the rate at which grain is fed to the mill. These systems are, therefore, more accurate and precise than a simple "set up and leave" system but less accurate and precise than a batch mixing system. Systems of this type are reportedly used in mills in the UK for dosing of calcium carbonate and have been estimated to cost between $300-400 thousand dollars each. The accuracy obtained by mills in the UK using these type of systems is reported as not meeting the precision envisaged by FSANZ in the dose range proposed for folic acid in Australia and New Zealand. This system is essentially only suitable for a modern mill with existing plc control and therefore only applicable to very large mills.

Batch mixing (System three) involves adding standard weighed amounts of premix containing the fortifying agent to batches of flour. Since both components are being weighed, the rate of dosing can be both highly accurate and precise. In order to ensure that the fortifying agent is homogeneously mixed with the flour, a subsequent mixing step is necessary. The installation of a batch mixing system, or its use solely for the purpose of fortification, would not be a financially viable activity for the milling or baking industries.

However, the inclusion of a fortifying agent where an existing batch weighing and mixing process is being undertaken, for example in the preparation of a premix or during dough preparation, could be more cost effective.

Thiamin addition in Australian mills

Standard 2.1.1 Cereals and Cereal Products requires that, in Australia only, flour for making bread must contain no less than 6.4 mg/kg of thiamin.

In Australian mills, thiamin additions to bread-making flour are generally made directly into the base flour conveyor(s) leaving the mill and following the final pass through the sifters. Thiamin is formulated into a premix with flour at a rate of 60 ppm or higher. Preparation of the thiamin premix is normally undertaken by a specialist manufacturer, rather than by the miller. Rotary screw feed systems are used to add the thiamin premix. Whilst the rate at which dosing occurs is adjustable, Australian mills do not have automatic feedback controls to enable continuous adjustment of the feed rate. The feeder is set up to match the reported mill output conveyor capacity and monitored periodically. Once set up, the feeder runs at a constant rate that is not linked to the load in the flour conveyor. No dosing occurs into other fractions or specialist products collected from the mill.

Australian millers seek to ensure that the rate of addition of thiamin is maintained above the prescribed minimum level throughout the milling operation. As a consequence of variations in the load in the flour conveyor during the milling operation, significant over dosing with thiamin may occur during the milling operation. Confidential data volunteered by Australian millers during consultations indicated that levels of over fortification of 100% and greater may occur. Furthermore, flour produced during a changeover between a fortified and non-fortified flour is likely to have a thiamin content below that prescribed for bread-making flour. The addition of the changeover flour during blending away or of specific unfortified flour to adjust functional characteristics of bread-making flour will have a non-standard dilution effect on the net thiamin content of the flour. To compensate for this possible dilution, flour millers may also intentionally overdose thiamin into the base flour. Thiamin content is not normally analysed prior to clearance and release of the flour in Australia.

For products that are not subject to thiamin fortification, including sponge flours and export products, the thiamin dosing feeder is not operated. Larger mills may also have an alternative conveyor on which to collect the unfortified flour, however, there is unlikely to be duplication of the safety sifter or of storage conveyors or bins. As a result some degree of cross contamination of these flours with thiamin is inevitable.

Despite an apparent perception that segregation of thiamin fortified and unfortified flour occurs, as a result of the commodity nature of Australian milling, there is little, if any, segregation of thiamin fortified products exclusively for bread making in the domestic market. Thiamin fortified flour may be used for the full range of domestic products in which flour is used (see section - Commodity flour milling in Australia & New Zealand). Whilst the Food Standards Code permits voluntary fortification of flour products with thiamin, the presence of incidental thiamin in these products is not generally identified on food labels, possibly due to uncertainty about its presence, by manufacturers. The absence of thiamin labelling in non-bread flour products appears to have been assessed as being of low public health risk by regulatory authorities and acceptable in terms of achieving the objective of thiamin fortification for the target group.

A commitment made by governments to the milling industry, at the time mandatory thiamin fortification was introduced, that monitoring would be undertaken has, to date, not been implemented.

Direct folic acid addition to flour

It has been proposed by FSANZ that mandatory fortification of bread making flour with folic acid could be undertaken at the same time as thiamin fortification, possibly using the same dosing equipment. Whilst this is technically feasible to achieve in Australia, by adding folic acid at the required level to the premix currently used for the addition of thiamin, it should be noted that the performance inherent in current thiamin fortification systems is not capable of delivering the accuracy and precision envisaged in the FSANZ proposal for folic acid. Furthermore, implementation of this solution for New Zealand, where thiamin fortification of flour is not currently undertaken at the mill would require millers in that country to install dosing systems in their mills.

The majority of Australian millers have expressed concern about the narrow range proposed for folic acid fortification (230-280 micrograms (μg) of folic acid per 100 g of bread-making flour), especially the upper limit, and identified logistical difficulties in including folic acid in the analytical tests required before flour is cleared for dispatch.

In particular, because the proposed upper limit is safety based, Australian millers have indicated that they would be obliged to ensure that folic acid fortified flour met the standard before release from the mill. The introduction of folic acid testing prior to clearance could significantly delay release of flour. The folic acid test if undertaken in an on-site laboratory has a 5 hour turn around time. This may increase to up to 1 week if samples need to be sent away for analysis. Capital costs to equip a laboratory to undertake folic acid testing have been estimated by Australian millers at $120K per annum ($50-60K if the laboratory is only staffed during daytime shifts). Furthermore, the majority of mills do not have the storage capacity to hold or process failing product requiring further blending.

One major Australian miller has also indicated that in order to ensure the consistency of dosing proposed for folic acid, and having regard to the required folic acid concentration in flour (approximately 1/3 that of thiamin on a weight basis) they would consider it necessary to prepare the folic acid premix using a double process i.e. folic acid + carrier to make a primary premix followed by re-dilution of this with a second carrier. It was stated that this would significantly add to the cost of folic acid to millers, may require installation of new dosing equipment to handle the potentially larger volumes of premix (compared to thiamin) and could substantially increase the demand from the Australian premix manufacturers.

Another major Australian miller indicated that they currently produce flour containing a wide range of fortifying agents by addition of a premix including iron and B vitamins, for export markets such as Indonesia (where these components are mandated). A folic acid fortified flour is also being produced for a domestic client, with the folic acid incorporated in the thiamin premix. This miller did not appear to share the concerns about the consequences of failing to meet the proposed folic acid dose range, as expressed by other millers, and did not anticipate a need to undertake analyses of folic acid concentrations in real time, prior to product clearance. It was anticipated that accuracy of folic acid dosing would be monitored and controlled by periodic test weighing of the dosing equipment, as is currently the case for thiamin. This miller also reported that they had significant grain and flour holding capacity and, therefore, were able to adequately segregate fortified and non-fortified flours.

Data provided by Australian and New Zealand flour mills indicates that for any typical milling operation the rate of flour production may vary in excess of ±10%. Even with the most accurate dosing systems, without sophisticated feedback control to link dosing rate to flour production rate, mills would not have the capacity to fortify flour within the specifications proposed by FSANZ.

Segregation of folic acid treated flour

Australian millers generally indicate that they are able to differentiate thiamin fortified flours from unfortified flours at the point of production. In practice, in the domestic flour market there is currently little, if any, segregation of thiamin fortified products exclusively for bread making. Furthermore, mill conveyor and supply chain systems do not generally allow total segregation of products. There is a high probability that some inadvertent mixing of product will occur. Under normal milling conditions, millers will schedule milling runs to take account of and minimise the effects on the physical and baking properties of flours. It is anticipated that, without significant capital expenditure, this would also be the case for flours fortified with folic acid at the mill.

Based on current Australian experience with thiamin fortification, it is expected that the introduction of mandatory folic acid fortification of flour, without the introduction of additional facilities to segregate fortified and unfortified flours, would result in a very high proportion of all flour, excluding export products and soft flours for sponge making, being fortified with folic acid. This in turn could result in an overwhelming majority of other, non bread products being made with fortified flour.

Australian millers indicated that in order to ensure that folic acid treated flour could be segregated from untreated flour each mill would require at least two new flour storage bins. If segregation were to be carried through to the bakery, in order to enable consumer choice in the preparation of a range of unfortified breads, it would also be necessary for plant bakeries and flour premix makers to install additional flour silos to enable the receipt and holding of both fortified and unfortified flours.

The presence of small amounts of folic acid in "un-fortified" flour products arising from blending, flour produced during a changeover or simply from cross-contamination on shared supply chains, has also been identified as an issue of concern by some Australian millers. There is concern amongst millers that potentially all manufacturers of flour based foods could be subject to prosecution by enforcement agencies, if the unintentional presence of folic acid in the flour product is not adequately labelled. In this regard, there is an expectation amongst millers that, because of safety concerns arising from over consumption of folic acid by non-target groups, folic acid fortification will be subject to significantly greater regulatory scrutiny than has been the case for thiamin fortification.

New Zealand millers also expressed concern about the incidental presence of folic acid in "untreated" flour, especially in export products. New Zealand has significant export of flour products to Japan, including the supply of bread rolls for Subway restaurants[4]. The New Zealand Government has recently committed NZ$20M to research into the export flour products market.

4 The value of flour sales to meet Japanese Subway exports has been estimated at NZ$12M per annum.

New Zealand flour millers indicated that, in order to ensure product segregation and prevent incidental presence of folic acid in untreated flour, they would need to duplicate their entire port mill conveyor and storage capacity.

A number of smaller milling operations in both Australia and New Zealand (both independent operators and small mills operated by the larger groups) may find the necessary capital costs to enable folic acid fortification to be prohibitive and may cease to be viable.

Folic acid fortification of flour – Consequences for industry

The scenarios for folic acid fortification of flour raise the potential for significant capital and operation costs for Australian and New Zealand millers and related industries, arising from a requirement for mandatory fortification of flour with folic acid, including:

- installation of new more precise dosing equipment as current equipment will not meet the proposed specification
- laboratory equipment to enable folic acid analysis in real time
- training and staffing of laboratories
- additional storage capacity for mills (minimum 2 silos per mill)
- duplication of flour conveyor systems at mills
- additional flour storage capacity at plant bakeries
- additional labelling costs for millers and premix makers to write off packaging and redesign/ reprint labels/packaging for all flour and flour containing premix products
- if segregation was not required (i.e. applying the standards of precision currently applying to thiamin fortification), the cost of folic acid would exceed that merely needed to fortify flour used in bread making.

Due to the commodity nature of milling, the industry is highly competitive, manufacturers indicate that it would be difficult to pass on these costs to the consumer. In the case of small mills these costs may make continued operation unviable. Many of these potential costs are not identified in the Cost Benefit Analysis prepared for FSANZ. The reasons for this appear to lie in the assumptions made during the Cost-Benefit Analysis that thiamin fortification was a representative indicator of the standards required.

The principal concerns of Australian millers regarding the proposed folic acid fortification requirements arise from their interpretations and expectations regarding compliance and enforcement of the proposed standard. These concerns could potentially be addressed by enabling use of current thiamin dosing fortification systems through:

- removing the proposed upper limit,
- including a provision to the effect that the target range is intended as a guideline to aim at over a period of production but is not enforceable on an individual batch basis (for which wider tolerances may apply),
- permitting flour containing folic acid to be used for the manufacture of other flour products.

The concerns of New Zealand millers are potentially more difficult to address as there is no current history of fortification in that country.

Bread making

The Australian bread making industry accounts for approximately 45% of the total Australian baking sector[5]. In 2000 production in the Australian bread industry was reported as follows:

- Plant baker 61%
- Supermarket in-store bakeries 20%
- Franchised hot bread shops 14%
- Traditional hot bread shops 5%.

There are two national bakery companies, Goodman Fielder and George Weston Foods. Together these two companies account for 90% of plant bakery production. There are a number of franchise operators with Bakers Delight the leading brand with 40% of the franchise share.

Product breakdown in Australia in 2001 was reported as:

- White 62%
- Wholemeal 15%
- Grain 5%
- Speciality 12%
- Savoury 3%
- Par baked 3%

Functional white breads were reported to comprise 25% of the white bread market.

In New Zealand, the market share has been estimated by the New Zealand Association of Bakers as:

- Plant bakers 60%
- In-store bakeries (including franchised bakers) 30%
- Independent bakeries 5%
- Artisan bakers 5%

The following companies comprise 100% of the plant bakers in Australia: George Weston Foods Ltd, Goodman Fielder Ltd, Breadcraft (Wai) Ltd, Couplands Ltd, Northern Bakeries Ltd, Walter Findlay Ltd, Yarrows Ltd, Quality Foods Southland and Rivermill Bakeries Ltd. The leading franchise bakeries in New Zealand are Bakers Delight and Brumbies.
There are no figures available for product breakdown in New Zealand but, in consultations, industry representatives indicted a product spectrum similar to Australia.

The principal plant bakers in both countries are George Weston Foods (Tip Top) and Goodman Fielder. The leading supermarket own brand bread are also manufactured by these bakers.

5 The Australian Baking Industry – A Profile. Australian Government, Canberra 2003.

Alternative mechanisms for folic acid addition to bread

Standard commercial breads contain a number of common ingredients: flour, water, yeast, improver, sugar and oil. In addition, premixes are routinely used to enable streamlined addition of a range of dry micro-ingredients to dough. It has been proposed that at least two of the principal ingredients, yeast and improver could be used as alternatives to flour as vehicles for addition of folic acid. It has also been proposed that a premix containing folic acid could be added directly to the dough mix for folic acid fortified breads.

The addition of folic acid directly to bread dough, as opposed to fortification of flour, has the potential to enable the greatest level of consumer choice since it is readily controlled on a product by product basis with minimal capital and labour investment.

Yeasts

Bakeries may use liquid yeasts, pressed yeasts or dried yeast for bread-making. Because the amount of yeast added to the dough mix will vary between different bakeries and between types of bread, fortification of yeast with folic acid will not result in a uniform level of fortification. Furthermore, it is unclear whether the addition of a relatively high level of folic acid to the yeast will adversely affect its viability or whether, in the case of liquid or pressed yeast, the yeast will actually metabolise the folic acid itself whilst in storage. Yeast does not therefore present as a viable vehicle for the addition to bread.

Improver

Bread improvers are combinations of ingredients, such as enzymes, emulsifiers, and antioxidants that are added to dough to modify its characteristics and those of the bread, for example to enhance dough handling, baking performance and loaf characteristics.

Large commercial bakeries are likely to use sufficient volumes of improvers to justify having them made to their own specifications, whereas independent and small bakers are likely to purchase standard improvers from premix manufacturers. Furthermore, the amounts of improver added may vary between different bakeries, even within the same company, and different breads. As a result, there are opportunities for a plant bakery, in-store chains (e.g. supermarket bakeries) or franchise operations, to obtain custom made improvers containing folic acid and provided that this was added at a consistent level in all breads, to use this as a vehicle for folic acid fortification. Similarly, there would be opportunities for premix makers to produce a range of standardised improvers containing folic acid for use by independent bakeries. However, in other bakeries that might use varying levels of improver in different products or not use an improver, fortification of improver with folic acid will not achieve the goal of consistent fortification of all breads.

Premixes

A majority of bakeries undertake the addition of dry minor and micro ingredients to the dough mix in a manual or semi-automatic operation[6], in order to differentiate products.

6 A number of large plant bakeries in Australia and New Zealand (e.g. Tip Top Bakery, Chullora, NSW) have fully automated dough preparation systems for white bread, with no manual addition of micro-ingredients. Whilst the addition of a folic acid premix to each dough would be possible, it would require plant modification or direct operator intervention. The addition of a new bulk bin for a folic acid premix would have significant capital costs. Likewise, a change in production practices to introduce a manual addition of a premix to standard breads would have an associated ongoing labour cost.

These ingredients are likely to be specific to each bread type and may be weighed up/measured out individually on a batch by batch basis or supplied as a premix to be added to a specified weight of flour.

There are 3 principal manufacturers of premixes for bakers in both Australia and New Zealand:

- Bakels
- Cereform (a division of George Weston Foods)
- Cerol (recently purchased by Cereform)

Premixes are generally produced using a batch mixing process. It would be feasible for a premix manufacturer to either include folic acid in existing premixes or prepare a specific folic acid premix, for addition to bread dough. Because the dough recipe is standardised for each bread type, the amount of premix and, therefore, the amount of folic acid added could be matched either to the ingoing weight of flour or to the intended final weight of bread produced. Furthermore, this method of addition of folic acid, because it is undertaken on a by weight basis is a substantially more precise way of delivering folic acid than fortification of flour.

Not withstanding the difficulties inherent in folic acid fortification via bread dough for a plant baker with an automated dough preparation operation, the option of addition of a folic acid premix directly to the dough would be a highly effective and precise way of implementing folic acid fortification. From the perspective of regulatory development, due to the high level of accuracy of this method of fortification, it would be sufficient to specify a target level of fortification to be achieved, rather than a range, as has been proposed for flour.

The use of a premix added individually to each dough would also enable greater flexibility in the choice of which breads are to be fortified, thereby allowing fortification to be directed at those products consumed by the target group of consumers and enabling a potentially greater degree of consumer choice between fortified and non-fortified products.

The issue of effective enforcement to ensure that small bakery operations add the required folic acid premix has been raised as an issue of equity by some plant bakers. However, this situation is essentially no different to the enforcement of any other compositional provision in a food standard that may be monitored by analysis of the finished product. Responsibility for fortification would rest with appropriate State/Territory and New Zealand food enforcement officers.

Conclusions – Bakery addition of folic acid to bread

Both improver and premixes present suitable vehicles to achieve fortification of bread with folic acid. As both are added on a weight basis in a batch system, they present a significantly more precise means of achieving fortification of bread with folic acid than does fortification of flour. Due to the design and operation of different bakeries, both vehicles may have applications within the industry. A regulation for mandatory fortification drafted on the basis of final bread weight will allow bakers to choose the vehicle most appropriate to their plant and operating practices. The essential criteria would be that bakers add the appropriate premix to all relevant batches of bread dough.

In addition to the inherent precision, fortification of dough via an improver or a premix is likely to be a significantly more cost effective mechanism for the addition of folic acid for industry as it is unlikely to require substantial capital investment or ongoing labour costs for bakers when compared to the potential costs of fortification via flour.

Because the fortification takes place at a later stage in the bread making process and there are significantly more bakeries than mills, a requirement for mandatory fortification of bread with folic acid will, at face value, potentially increase the enforcement workload compared to fortification of bread-making flour. However, in the case of fortification of bread-making flour, in addition to ensuring that flour is fortified, there is also a responsibility for enforcement to ensure that bakeries are using fortified flour in their bread. Consequently, in practice, the enforcement burden is unlikely to differ significantly between fortification via flour or directly into bread.

Both the compliance and enforcement burdens could be further reduced by the use of audit trails rather than a reliance on product analysis to demonstrate the addition of the prescribed amount of folic acid to bread. Appropriate production records, maintained in a form consistent with normal food industry quality assurance procedures, could be employed to demonstrate to food enforcement authorities that a correct amount of folic acid had been, and was being, added to each batch of bread. Provided that, upon inspection, enforcement officers were confident of the veracity of such records, a risk based enforcement strategy would suggest that there would be little justification in subsequent analysis of individual products. Product analysis would only be applicable in cases where appropriate quality assurance could not be demonstrated through documentation.

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.

1. Policy Guideline

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.

1.1 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 and it was accepted by FRSC at its next meeting in July 2006 (FRSC 2006). The FRSC 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.

An agreement was also made at the FRSC sub group meeting in June 2006 to establish an expert group to develop the monitoring system specifically required for folate/folic acid. The first meeting of the expert group was convened in July 2006 to discuss the draft monitoring framework presented by FSANZ in the Draft Assessment Report. The expert group will meet again in September 2006 to progress the development of the monitoring system, with the expectation that a paper on the proposed monitoring system will be presented to the October meeting of the Australia New Zealand Food Regulation Ministerial Council (ANZFRMC).

The FRSC 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. It is intended that a review of the effectiveness and safety of the proposed mandatory fortification program will be undertaken when data are available or within five years from the date of implementation of a new standard.

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 generic monitoring framework for mandatory fortification now endorsed by FRSC 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 framework document notes that there are questions that need to be answered (FRSC 2006); Figure 1 is an outcomes hierarchy outlining process, impact and outcome questions to be considered.

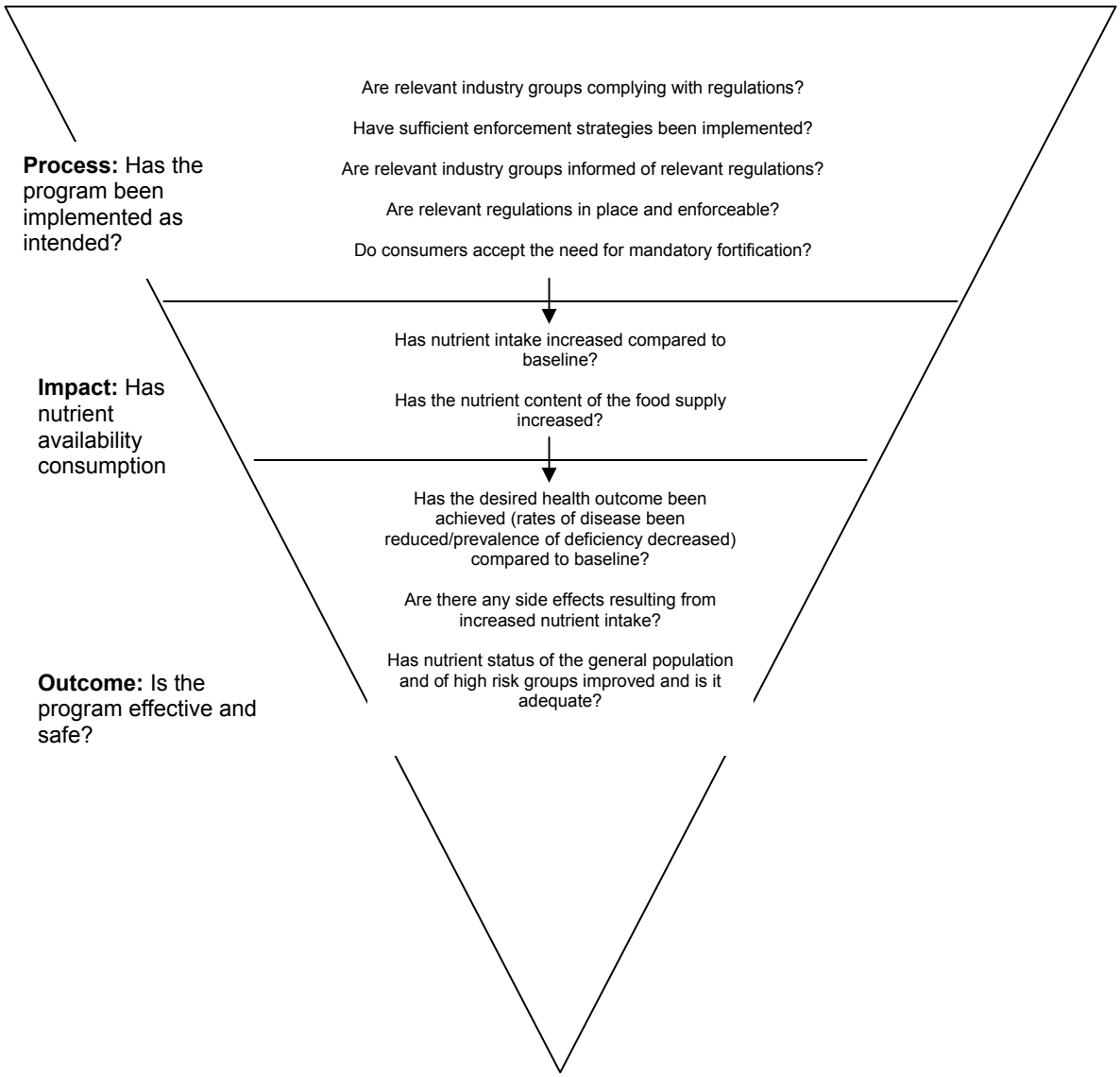


Figure 1: Outcomes hierarchy for monitoring mandatory fortification programs (adapted from Abraham B, Webb K 2001)

The FRSC 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.

2.3 Developing a monitoring system for folic acid fortification

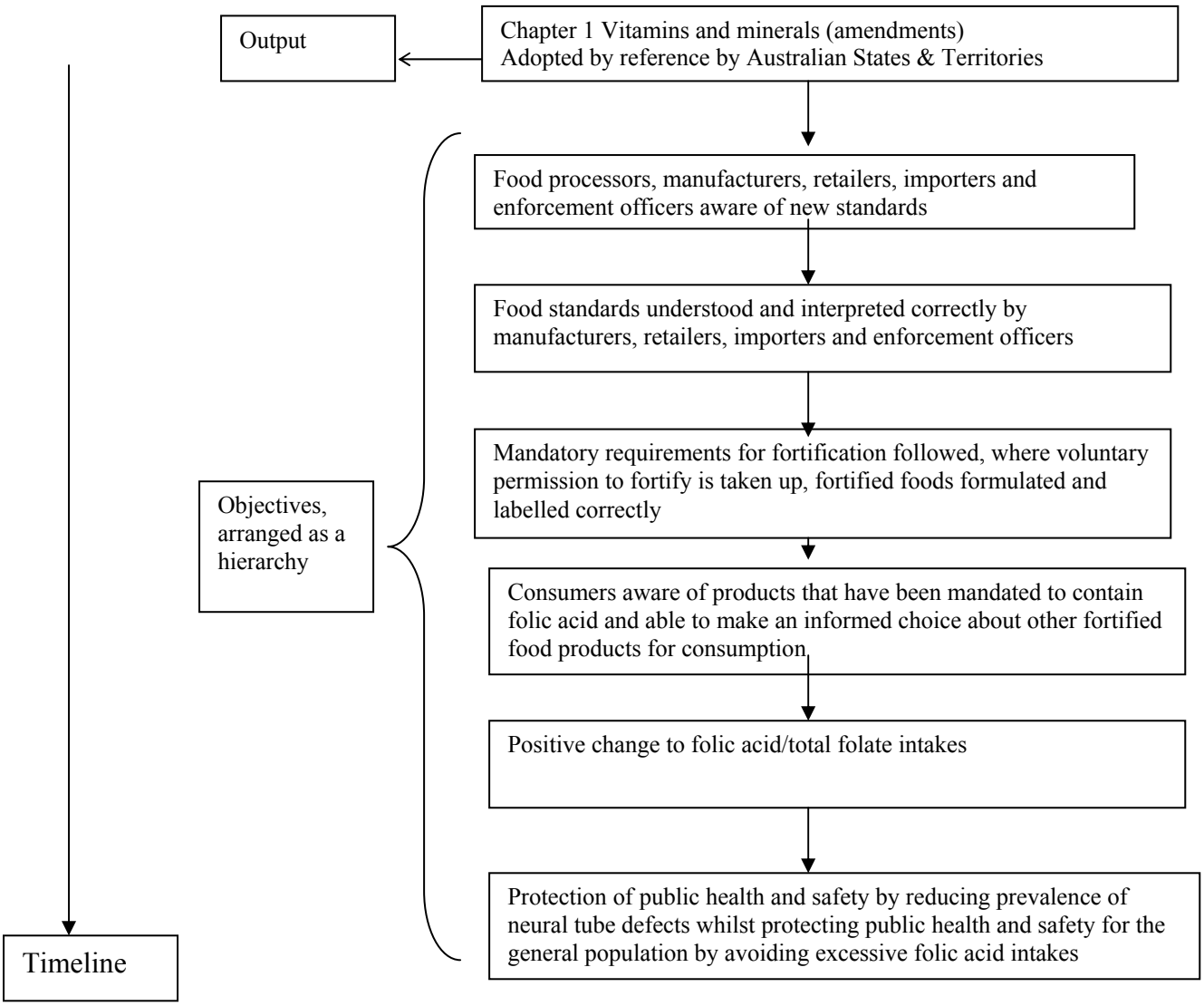
Ideally, most of the data required to monitor the impact of folic acid fortification would be collected as part of an existing ongoing national food and nutrition monitoring system (Nexus 2006, Marks et al 2001, Stanley 2005). In New Zealand national nutrition surveys are conducted on a regular basis. 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 monitoring framework document 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. 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 1, 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 1: 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?	**Research consumer attitudes and behaviours towards fortified foods:** Changes in consumer understanding and behaviour in relation to folic acid fortified foods and food labelling.	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.	FSANZ, NZFSA
	Do consumers change food consumption patterns?	**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.	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.	DOHA with jurisdictions, FSANZ NZFSA/MOH NZ FSANZ as coordinating agency S&T As above Inclusion of relevant questions to be negotiated

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)?	Changes in rates of NTDs, Changes in serum folate, RBC folate, vit B12 levels, homocysteine blood levels	Perinatal statistics (national minimum data set) Blood tests	AHMAC, National Perinatal Statistics Unit Could be incorporated in existing studies by negotiating extra funding for add on component e.g. AUSDIAB, NZNHS?
	Are there any side effects resulting from increased intake for target or non target groups?	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	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	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 2 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 2: 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	Consumer attitude and behaviour research State and Territory surveys (add on to existing surveys) National nutrition survey (costed in (6), Food frequency surveys (Roy Morgan) Market basket store surveys in remote communities	$ 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 A1.1: 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 A1.2: 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 A2.1: 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) Consumer attitudes to food standards issues tracking survey.	$ 60 000 baseline Targeted consumer surveys on specific issues incl substitution patterns for new products, consequential behaviour change	$ 100 000 follow up surveys (targeted foods)	FSANZ	Medium
5b) 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)	Baseline data – no costs 1995 NNS 1997 adults NZNNS 2002 children's' NZNNS	See NNS costs for (6) Follow up : 2007 Australian children's' NNS 2007 NZ adults survey	DOHA, S&T NZFSA	High
5c) Roy Morgan Single Source survey (Australia and NZ) and Young Australian survey	$ 230 000 for back data for Jan 2001-Mar 2006 Frequency of key food consumption for individuals every 3 months.	$ 200 000 ($50 000 subscription per year for next 4 years for new data on 3 month basis)	FSANZ	High
5d) Other national, S&T surveys.	Assess current data holdings	TBC	S&T	Low-medium
5e) Store market basket surveys	Baseline audit of foods available in remote areas (minimal added costs)	Follow up survey	S&T	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.	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)	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)**	DOHA, S&T	High
6b) Folate/folic acid intakes from existing S&T surveys	S&T surveys costs TBC	S&T surveys costs TBC	S&T	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	$150 000 Establishment costs Perinatal statistics (incl still births)	$ 20 000 Ongoing costs ($ 50 000 per year)	AHMAC cost share	High
7b) Literature review of relevant health statistics	$ 20 000	$ 20 000 at end of 5 years	DOHA/AIHW	Medium
7c) Blood tests	Add onto existing surveys (cost effective)	TBC	DOHA/S&T	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