Ministry for Primary Industries
Manatū Ahu Matua

Voluntary Folic Acid Fortification

Monitoring and Evaluation Report

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Scientific Interpretative Summary

This Scientific Interpretative Summary has been prepared to provide context to the following report for external readers.

Voluntary Folic Acid Fortification: Monitoring and Evaluation Report 2017

Folic acid is the synthetic form of the B vitamin folate and may be added to manufactured foods and drinks, or taken as a vitamin supplement.

Women who don't get enough folic acid before and during pregnancy have a higher risk of their baby developing abnormalities known as neural tube defects (NTDs). The most common NTDs are spina bifida and anencephaly. There is considerable scientific evidence showing that consuming folic acid prior to and early in pregnancy can reduce the risk of NTDs.

To support women to eat more folic acid, since 1996 certain food products have been permitted to be fortified with folic acid. Further, in 2012 the New Zealand Government issued a New Zealand Food Standard permitting the voluntary fortification of bread with folic acid. Combined with existing health promotion and education strategies, including the promotion of folic acid supplements, the aim is to improve the blood folate levels of women of childbearing age in order to reduce the prevalence of NTDs.

In 2014, members of the New Zealand Association of Bakers and their Private Label Partners' created a voluntary code of practice, committing them to fortifying with folic acid a minimum of 25% and up to 50% of breads by volume that they produce.
The key areas monitored to-date include folic acid in the food supply, blood folate levels, health benefits (reduction in NTDs) and consumer knowledge and attitudes towards folic acid fortification.

Some of the key findings in this report include:

- Most women of childbearing age do not have optimal blood folate levels for the prevention of NTD-affected pregnancies (based on 2014/15 New Zealand Health Survey data).
- From 2000 to 2013, there has been a reduction in the birth prevalence[1] of NTDs (8.60 per 10,000 total births in 2000, compared to 4.06 per 10,000 births in 2016), but it is not clear to what extent voluntary fortification has contributed to this trend.
- The number of products fortified with folic acid increased from 321 products in 2013 to 432 products in 2017.
- 2017 consumer research found just over half of New Zealand adults consider folic acid fortification of bread should be 'optional', and less than a quarter of adults considered it should be 'compulsory'.

Ongoing monitoring of the food supply, blood folate levels and the prevalence of NTDs will be essential in determining the long term impact of voluntary fortification of bread with folic acid.

[1] Birth prevalence is the proportion of neural tube defect-affected pregnancies that resulted in a birth (live or still) per 10,000 total births.

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Abbreviations

AIHW	Australian Institute of Health and Welfare
ANS	New Zealand Adult Nutrition Survey
AOAC	Association of Official Analytical Chemists
BIRT	The Baking Industry Research Trust
CDC	Centers for Disease Control and Prevention
CI	Confidence Interval
FSANZ	Food Standards Australia New Zealand
MFD	Manufactured Food Database
MPI	Ministry for Primary Industries
MTHF	Methyltetrahydrofolate
NHANES	National Health and Nutrition Examination Survey
NIP	Nutrition Information Panel
NTD	Neural Tube Defect
NZAB	New Zealand Association of Bakers
NZBDR	New Zealand Birth Defects Registry
NZDep	New Zealand Index of Deprivation
NZEO	New Zealand European or Other
NZFSA	New Zealand Food Safety Authority
NZHS	New Zealand Health Survey
RBC	Red Blood Cell
SD	Standard Deviation
WHO	World Health Organization

Symbols

%	percent
<	less than
>	greater than
≤	less than or equal to
≥	greater than or equal to
µg	microgram
g	gram
kg	kilogram
L	litre
mg	milligram
mL	millilitre
nmol	nanomole
ºC	degrees celsius

Executive Summary

Voluntary fortification of certain food products with folic acid has been permitted in New Zealand since 1996. In 2012, the New Zealand Government issued a New Zealand Food Standard permitting the voluntary fortification of bread with folic acid at a level of no more than 2.5 milligram (mg) per kilogram (kg) in total (MPI, 2012a). This report is the second monitoring and evaluation report following the introduction of the New Zealand Food Standard in 2012 (MPI, 2012a). Similar to the first 2012 report (MPI, 2012b), this report aims to address five key areas: folic acid fortified food composition and food industry compliance; consumer knowledge of folate and folic acid; folic acid intake; folate status and health benefits (reduction in neural tube defect (NTD) prevalence).

Higher intakes of folic acid in women are associated with a decreased risk of having a NTD-affected pregnancy (De-Rigil et al, 2010). Since 1993, the New Zealand Ministry of Health has promoted a health policy recommending women who are pregnant or planning a pregnancy take a folic acid supplement. Currently, women at a low risk of an NTD-affected pregnancy, who plan to become pregnant, are recommended to take an 800 microgram (µg) folic acid tablet daily for at least four weeks prior to and for 12 weeks following conception (MoH, 2016). Despite this, previous research has indicated that this advice to consume a folic acid tablet consistently during the peri-conceptional period has not been followed by a majority of women in the target group (FSANZ, 2006).

In response to the introduction of the 2012 New Zealand Food Standard (MPI, 2012a), in 2014 the New Zealand Association of Bakers (NZAB) and its members developed the NZAB and Private Label Partners' Code of Practice for Voluntary Folic Acid Fortification of Bread (NZAB, 2014). The Code of Practice specifies that a minimum of 25 percent (%), by volume, of packaged sliced loaf breads marketed and distributed by NZAB members are fortified with folic acid by the end of 2014. The target level of folic acid in bread was set at 200 µg per 100 grams (g) (or 2 mg per kg) of finished product.

Results of a labelling survey found that the number of products available for sale fortified with folic acid has increased over time (432 products in 2017 vs. 321 products in 2013). In 2017, breakfast cereals had the highest number of fortified products (34%) followed by bread (10%) and breakfast beverages (8%). The number of breads containing folic acid increased from 31 in 2013 to 45 in 2017. The median folic acid[2] concentration declared on the Nutrition Information Panel (NIP) of breads and breakfast cereals has remained stable at 200 µg per 100 g from 2014 to 2017.

The Baking Industry Research Trust (BIRT) annually audit NZAB member's compliance with the Code of Practice. In 2016, the BIRT analytical audit reported that 38% of NZAB packaged sliced breads were fortified with folic acid at a median level of 191 µg per 100 g, compared to 32% in 2015 and 14% in 2012 (Watson, 2017). Analytical testing, commissioned by MPI in 2016, found the median folic acid concentration of all nationally available folic acid fortified breads to be 130 µg per 100 g. The MPI analytical survey captured different brands and utilised a different sampling plan to that of the 2016 BIRT audit (Watson, 2017) and as such the results from the audit and survey are not directly comparable.

Consumer research indicates New Zealand adult consumers mostly continue to support voluntary folic acid fortification of bread and women of childbearing age (aged 16-44 years)[3]

[2] For simplicity, the term folic acid has been used to collectively describe the level of total folate or folic acid declared in the NIP of a product. This may mean that the true level of folic acid could be overestimated in some products.

[3] For the consumer survey women of childbearing age were defined as those aged 16-44 years, whereas in the 2014/2015 New Zealand Health Survey (data on folate status) women of childbearing age were defined as those aged 15-49 years.

are particularly supportive (61% in 2017; 60% in 2011) (MPI, 2017; FSANZ, 2013). Support for mandatory folic acid fortification has decreased amongst women of childbearing age (19% in 2017; 24% in 2011) (MPI, 2017; FSANZ, 2013). Consumers believe that they should have a choice and that the benefits of folic acid fortification are only for a small population (MPI, 2017). However, few people (2-3% in 2017) are actively avoiding products containing folic acid (MPI, 2017).

From the 2017 consumer research the proportion of women of childbearing age reporting consuming sliced, packaged bread potentially fortified with folic acid was 78%, with an average of 1.9 slices of bread reportedly eaten per day (MPI, 2017). Forty percent of women of childbearing age reported consuming other potentially fortified bread types (for example flat/pita breads, sourdoughs and baguettes) in 2017 at an average of 0.6 pieces per day (MPI, 2017).

From the 2014/2015 New Zealand Health Survey (NZHS) most women of childbearing age (15-49 years)[3] did not have optimal blood folate levels (≥748 nanomoles per litre (nmol/L)) for the prevention of NTD-affected pregnancies (MoH, November 2017). Women aged 15-24 years had a lower mean and median red blood cell (RBC) folate and a lower prevalence of optimal RBC folate for the prevention of NTDs than women aged 25-44 years. Asian women of childbearing age were less likely to have optimal RBC folate levels than non-Asian women (MoH, November 2017). Mean serum folate concentrations had improved slightly since the 2008/09 New Zealand Adult Nutrition Survey (ANS), although the increase was not statistically significant for women of childbearing age. It is important to note that since the NZAB and Private Label Partners' Code of Practice was introduced in the same year as the 2014/15 NZHS was implemented, the folate status results may not accurately reflect the impact of this fortification initiative.

There has been a statistically significant decline in live birth prevalence of spina bifida and all NTDs combined from 2000 to 2015. Further, there has been a statistically significant decline in birth prevalence (including live and still births) of spina bifida and NTDs combined from 2000 to 2013. In 2015 there were 21 live NTD-affected births at a live birth prevalence of 3.44, compared to in 2000 where there were 41 live NTD-affected births at a live birth prevalence of 7.24. The majority of all NTD-affected live and stillbirths across 2000 to 2016 were spina bifida cases. Maori women have a statistically significantly higher live birth prevalence of NTDs compared to New Zealand European and Other (NZEO) (excludes Pacific Island ethnicity) using pooled data from 2000 to 2015.

Although there has been an overall decline in live birth prevalence and birth prevalence of spina bifida and all NTDs since 2000, it is unknown whether the recent voluntary fortification initiatives, and subsequent increase in the number of breads containing folic acid, has contributed to the recent trend. This is because of the limited timeframe since the introduction of the 2012 New Zealand Food Standard (MPI, 2012a), the gradual uptake of the 2014 NZAB and Private Label Partners' Code of Practice (NZAB, 2014) and the lack in availability of up-to-date NTD data[4] as provided by the New Zealand Birth Defects Registry (NZBDR).

Ongoing monitoring of the levels of folic acid in bread and the wider food supply, the folate status of women of childbearing age and the number of NTD cases and prevalence in New Zealand will be essential in determining the impact on New Zealand bread consumers, especially women of childbearing age, following voluntary fortification of bread with folic acid. Up to date data on New Zealander's dietary intake of folic acid and folic acid

[4] The full set of live birth NTD data, still birth NTD data and terminations of NTD- affected pregnancies, as provided by the NZBDR, were only available for 2015, 2013 and 2015 respectively

supplement use should also be included in any future monitoring reports to provide a more comprehensive picture of the dietary sources of folic acid.

Overview of the data to inform key questions for the monitoring of baseline and post-voluntary fortification of bread in New Zealand

Key question and measurement	Baseline[1]	Update	Comments
Has the level of folic acid in our food supply increased? *Median folic acid level of bread*	A 2010/2011 analytical survey of 17 unique folic acid fortified breads found a median folic acid concentration of 144 µg per 100 g of bread (Bradbury et al., 2011).	The 2016 MPI analytical survey of 38 folic acid fortified breads found a median folic acid concentration of 130 µg per 100 g bread.	When comparing previous label data from the Manufactured Food Database (University of Auckland, 2008) (2008 and 2011) with recent label data from the Nutritrack database (2014-2017), the median level of folic acid[2] declared on the nutrition information panel of breads has remained the same at 200 µg per 100 g.
Is the food industry adequately complying with the voluntary New Zealand (Permitted Fortification of Bread with Folic Acid) Food Standard 2012 (MPI, 2012a)?	Not applicable	Baking businesses have systems in place to ensure compliance	The Baking Industry Research Trust (BIRT) complete regular audits of the bread industry's compliance with the NZAB and Private Label Partners' Code of Practice for Voluntary Folic Acid Fortification of Bread. The 2016 BIRT audit (Watson, 2017) found that 38% of NZAB packaged sliced breads were fortified with folic acid, up from 32% in 2015 and 14% in 2012. The audit included analysis of 91 breads in 2016 and found the median folic acid concentration to be 191 µg per 100 g of bread.
Have folic acid intakes of women of childbearing age increased?	Using data from the 1997 National Nutrition Survey the estimated average intake of folic acid in women of childbearing age was 62 µg per day (FSANZ, 2013) Adherence to Ministry of Health policy guidelines around consuming folic acid supplements (tablets) is variable. At best, approximately 60% of some sub-groups report taking a folic acid supplement during the periconceptional period (Kalafatelis and Fryer, 2011; Parnell et al, 2011 Morton et al., 2010).	No new data	The 2008/09 New Zealand Adult Nutrition Survey (ANS) was not able to reliably determine folate intake from dietary records, therefore we currently rely on biochemical measures as an indicator of folate status (see below). The 2008/09 ANS revealed there was large variability in the folic acid content of supplements reported to be consumed by adults, ranging from 5-1000 µg per daily dose (Parnell et al., 2011)
What are consumer's attitudes to folic acid fortification[3]?	In 2011, 54% and 29% of adults supported the 'optional' and 'compulsory' addition of folic acid to bread by manufacturers, respectively (FSANZ, 2013).	In 2017, 56% and 23% of adults supported the 'optional' and 'compulsory' addition of folic acid to bread by manufacturers, respectively (MPI, 2017).	Women of childbearing age were particularly supportive of the optional addition of folic acid to bread (61% in 2017; 60% in 2011) (MPI, 2017; FSANZ, 2013).

Key question and measurement	Baseline[1]	Update	Comments
What are consumer's behaviours towards foods with folic acid[3]?	In 2010, women of childbearing age (n=1000) reported consuming two to three slices of packaged sliced bread per day (NZFSA, 2011). In a 2011 survey, 93% of women of childbearing age (n=288) reported consuming bread, at an average of 1.7 slices per day (Bradbury et al., 2011).	In 2017, 2-3% of adults said they actively avoid buying foods with folic acid (MPI, 2017). The majority of adults (76-80%) stated that folic acid had no influence on their purchase behaviour (MPI, 2017). Seventy-eight percent of women of childbearing age (n=1000) said they eat packaged, sliced bread (MPI, 2017). On average they reported consuming 1.9 slices per day.	Note that the 2017 survey excluded the consumption of organic, gluten-free sliced packaged breads, which are not currently fortified, whereas the 2010 and 2011 surveys did not. Although not recent data, national nutrition surveys also suggest bread consumption is declining. Compared with the 1997 national nutrition survey, females in the 2008/09 ANS were less likely to report consuming bread (Smith, 2015).
What are consumer's understanding of folic acid and its benefits for women of childbearing age[3]?	From 2009 to 2011 (NZFSA, 2011; FSANZ, 2013), women of childbearing age were generally aware of folate and folic acid and its association with pregnancy. Half or less of surveyed women of childbearing age understood the specific intended benefits from consuming folic acid before and during pregnancy.	No new data.	Half of those surveyed in 2010 (NZFSA, 2011) knew of the recommendation that folate/folic acid intake should be increased before becoming pregnant. There was, however, little understanding of folate and folic acid and their food sources.
Has the folate status of women of childbearing age improved[3]?	From reanalysis of the 2008/09 ANS the mean serum folate level of women of childbearing age was 16.5 nmol/L.	From the 2014/15 NZHS (MoH, November 2017), women of childbearing had a mean serum folate level of 18.5 nmol/L and a mean RBC folate level of 544 nmol/L.	Due to differences in methodologies between the 2008/09 ANS and the 2014/15 NZHS (outlined in section 4 of this report), the folate status obtained from the two surveys could not be directly compared. A subset of the serum samples from the 2008/09 ANS were reanalysed for folate using the same methodology as the 2014/15 NZHS. For women of childbearing age, there was a 2.0 nmol/L (12% increase in serum folate), although this increase was not statistically significant. Blood samples from the 2008/09 ANS were not able to be reanalysed for RBC folate, therefore these results were not reported in this table.
Has the prevalence of NTDs decreased?	For the period 2001-2008 the total number of NTD-affected births (live and still births) was 254, giving a birth prevalence for NTDs of 5.4 (MPI, 2012b).	For the period 2000-2013 the total number of NTD-affected births (live and still births) was 532, giving a birth prevalence for NTDs of 6.34 (NZBDR, August 2017).	For the period 2000-2016 the total number of live NTD-affected births was 417, giving a live birth prevalence for NTDs of 4.12 (NZBDR, August 2017).

Key question and measurement	Baseline[1]	Update	Comments
Does voluntary folic acid fortification result in adverse health effects for the population?	The 2012 Voluntary Folic Acid Fortification Monitoring and Evaluation report (MPI, 2012b) concluded that from the weight of evidence available it does not indicate that folic acid supplements would increase the risk of total cancer incidence, colorectal cancer, or breast cancer. As yet, there is insufficient evidence to evaluate the effect of folic acid supplements and either the risk of prostate cancer, or the risk of colorectal cancer among people with established adenomas. Estimated folic acid intakes at the level proposed for voluntary fortification would be lower than those consumed by participants in folic acid supplement trials, for the majority of the population.	Not assessed in this report.	

Notes:

1. Baseline data for monitoring mandatory folic acid and iodine fortification in Australia and New Zealand was published by the Australia Institute of Health and Welfare report (AIHW, 2011a). However, due to differences in methodologies across some of the key monitoring areas, not all New Zealand data included in the baseline report was comparable to the updated data included in this report. In these instances comparable data prior to the introduction of the 2012 New Zealand (Permitted Fortification of Bread with Folic Acid) Food Standard 2012 (MPI, 2012a) was included in order to answer the key questions.
2. For simplicity, the term folic acid has been used to collectively describe the level of total folate or folic acid declared in the NIP of a product. This may mean that the true level of folic acid could be overestimated in some products.
3. For the consumer surveys women of childbearing age were defined as those aged 16-44 years, whereas for data on folate status women of childbearing age were defined as those aged 15-49 years.

1 Introduction

1.1 FOLIC ACID AND THE CURRENT POLICY

Folic acid is the synthetic form of the B vitamin folate. Natural sources of folate include leafy greens (spinach, broccoli), liver and beans (NHRMC, 2006). Folate naturally found in foods is inherently unstable and can have poor bioavailability (~50%), whereas, folic acid is highly stable and bioavailable (85% in folic acid fortified foods, 100% in supplemental form) (NHRMC, 2006). Folic acid converts to natural forms once ingested.

Higher intakes of folic acid in women are associated with a decreased risk of having an NTD-affected pregnancy (De-Rigil et al, 2010). Since 1993, the New Zealand Ministry of Health has promoted a health policy recommending that women who are pregnant or planning pregnancy take a folic acid supplement. Currently, women at a low risk of an NTD-affected pregnancy who plan to become pregnant, are recommended to take 800 µg of folic acid daily for at least four weeks prior to and 12 weeks following conception (MoH, 2016). Despite this, previous research has indicated that this advice to consume a folic acid tablet consistently during the peri-conceptional period has not been followed by a majority of women in the target group (FSANZ, 2006).

To help address this nutrient gap, voluntary fortification of certain food products with folic acid has been permitted since 1996 and in 2012 the New Zealand Government issued a New Zealand Food Standard permitting the voluntary fortification of bread with folic acid at a level of no more than 2.5 mg per kg (in total) (MPI, 2012a). Alongside existing health promotion and education strategies, including the ongoing promotion to consume folic acid tablets, the Standard was aimed at improving the folate status of women of childbearing age.

1.2 MONITORING AND EVALUATION APPROACH

In 2012, MPI released its first report on monitoring and evaluation of voluntary folic acid fortification (MPI, 2012b). This report provides the most up to date data on the implementation of the voluntary fortification initiative in New Zealand.

The arrangement of this report is broadly based on a previously agreed Food Regulation Standing Committee monitoring framework for mandatory food fortification (AIHW, 2011a). The structure also acknowledges the evaluation framework for voluntary folate fortification published by Abraham (2001) by adding an additional element on consumer knowledge.

This monitoring and evaluation report summarises information on four of the six main monitoring components and key questions, as outlined in Table 1-1.

Table 1-1: Folic acid fortification monitoring framework

Framework Component	Key Question
1. Folic acid fortified food composition and Food industry compliance	• Has the level of folic acid in our food supply increased? • Is the food industry adequately complying with the voluntary New Zealand (Permitted Fortification of Bread with Folic Acid) Food Standard 2012 (MPI, 2012a)?
2. Consumer knowledge of folate and folic acid	• What are consumer's attitudes to folic acid fortification? • What are consumer's behaviours towards foods with folic acid? • What are consumer's understanding of folic acid and its benefits for women of childbearing age?
3. Folic acid intake and folic acid supplement use	• Have folic acid intakes in women of childbearing age increased? • Are women of childbearing age consuming folic acid supplements according to policy guidelines?
4. Folate status	• Has the folate status of women of childbearing age improved?
5. Health benefits	• Has the prevalence of NTDs decreased?
6. Adverse health effects	• Does voluntary folic acid fortification result in adverse health effects for the population?

Source:
Adapted from Australian Institute of Health Welfare, 2011 (AIHW, 2011a)

Abbreviations:
NTD Neural Tube Defect

Although included in the 2012 monitoring and evaluation report (MPI, 2012b), this report does not include data and discussion on adverse health effects, folic acid intake and folic acid supplement use.

Due to the nature of certain data collection procedures and biological endpoints, some data and information for the most recent years were not available at the time of publication.

1.3 BASELINE DATA FOR MONITORING

In 2009, the Australian Health Minister's Advisory Council commissioned the Australian Institute of Health and Welfare (AIHW) to prepare relevant baseline data for monitoring mandatory folic acid and iodine fortification (AIHW, 2016). In June 2011, AIHW completed the necessary work to establish a monitoring program through the delivery of the following reports:

- *Mandatory folic acid and iodine fortification in Australia and New Zealand: baseline report for monitoring* (the Baseline Report) (AIHW, 2011a);
- *Mandatory folic acid and iodine fortification in Australia and New Zealand: supplement to the baseline report for monitoring* (the Baseline Supplement Report) (AIHW, 2011b).

MPI (formally the New Zealand Food Safety Authority (NZFSA)) provided AIHW with New Zealand data to inform these baseline reports[5]. The data provided included:

- Food composition (University of Auckland, 2008)

[5] The results from the 2008/09 Adult Nutrition Survey were not available until mid-2011 so were not able to be included in this report.

- Dietary folate intakes (1997 New Zealand National Nutrition Survey (Food Standards Australia New Zealand analysis for proposal P295 (FSANZ, 2006; 2007)), 2002 National Children's Nutrition Survey)
- Supplement use (Ferguson et al, 2000)
- Serum folate and RBC folate status (Ferguson et al, 2000)
- NTDs (1998-2003) (Ministry of Health: National Minimum Dataset) (live births); Adult and Perinatal Mortality Database (still births))
- Cancer incidence (1994-2005) and mortality (1994-2006) for bowel and prostate cancer (New Zealand Cancer Registry)

A summary of the baseline[6] and updated data on the key folic acid questions in the monitoring framework is provided following the Executive Summary (page 10). The updated data are also summarised at the beginning of each of the following sections in this report: 2. Availability and composition of folic acid fortified food; 3. Consumer surveys; 4. Folate status; and 5. Health benefits.

[6] Data collected prior to the introduction of the 2012 New Zealand (Permitted Fortification of Bread with Folic Acid) Food Standard (MPI, 2012a)

2 Availability and composition of folic acid fortified food

Key questions:

- Has the level of folic acid in our food supply increased?
- Is the food industry adequately complying with the voluntary New Zealand (Permitted Fortification of Bread with Folic Acid) Food Standard 2012 (MPI, 2012a)?

Data sources:

- 2013 - 2017 Nutritrack database, National Institute of Health Innovation
- 2016 MPI analytical survey of bread
- 2015 and 2016 BIRT bread analytical audit (Watson, 2016;2017)

Key findings:

Labelling survey (Nutritrack Database)

- In 2017, 432 products contained folic acid, an increase of 35% from 321 in 2013.
- In 2017, breakfast cereals (34%), breads (10%) breakfast beverages (8%) and bread products (7%) made up the top four categories of foods containing folic acid.
- The number of breads containing folic acid increased from 31 in 2013 to 45 in 2017. Similarly, bread products increased from 29 to 31 in 2013 and 2017, respectively.
- The median folic acid concentration declared on the NIP of breads and breakfast cereals has remained stable at 200 µg per 100 g from 2014 to 2017.
- Sauces and spreads contained the highest median folic acid concentration as declared on the NIP across 2014 to 2017 (2000 µg per 100 g).

2016 MPI analytical survey

- The median folic acid concentration of packaged, sliced breads, tested by MPI in 2016 was 130 µg per 100 g (range 8 – 254 µg per 100 g).
- The median folic acid concentration of flat breads, bagels, pizza bases and garlic breads were 147.5 µg, 23.4 µg, 93.1 µg and 92.6 µg per 100 g, respectively.

2016 BIRT industry analytical audit

- NZAB members produce in excess of 90% of the packaged sliced breads in New Zealand. This includes production of NZAB branded products, and also production of private label products.
- The 2016 BIRT audit tested 94 breads and found the median folic acid concentration to be 191 µg per 100 g of bread.
- 37.7% of packaged sliced bread (by production volume) marketed or distributed by the NZAB members was fortified with folic acid in 2016, up from 32% in 2015 and 14% in 2012.

2.1 PERMISSIONS TO ADD FOLIC ACID TO FOOD

Current permissions to add folic acid to food

Folic acid is permitted to be added to a range of foods[7] for sale in New Zealand regulated under New Zealand and trans-Tasman Food Standards. Two particular New Zealand Food Standards include permissions for folic acid:

1) the New Zealand (Permitted Fortification of Bread with Folic Acid) Food Standard 2012 (MPI, 2012a), which permits the use of folic acid and L-methyltetrahydrofolate (MTHF), calcium in bread at a level of not more than 2.5 mg per kg (in total); and

[7] Although dietary supplements are covered under the Food Act, the Dietary Supplements Regulations 1985 are administered by the Ministry of Health and are not covered in this report.

2) the New Zealand Food (Supplemented Food) Standard 2016 which permits the addition of folic acid to supplemented foods at a maximum 500 µg per daily serving recommendation (MPI, 2016).

The Australia New Zealand Food Standards Code (the Food Standards Code) (FSANZ, 2002) permits the addition of folic acid and L-MTHF, calcium to: Cereals and cereal products (including bread, biscuits, cereal flours and pasta); Extracts (including yeast, meat and vegetable extracts); Fruit and vegetable juices, fruit drink and cordials; Analogues derived from legumes; Analogues derived from cereals, nuts and seeds; Formulated beverages; Formulated supplementary foods; Formulated supplementary food for young children; and Formulated meal replacements. Infant and follow on formulas are required to contain a minimum level of folate. The maximum claimable level of folic acid in bread (that contains no wheat flour) in the Food Standards Code is 100 µg per 50 g of bread.

New Zealand Association of Bakers and Private Label Partners' Code of Practice and Audit

Following the introduction of the New Zealand (Permitted Fortification of Bread with Folic Acid) Food Standard 2012 (MPI, 2012a), in 2014 the NZAB and its members, in association with MPI, developed the NZAB and Private Label Partners' Code of Practice for Voluntary Folic Acid Fortification of Bread[8] (NZAB, 2014). The Code of Practice specifies that a minimum of 25%, by volume, of packaged sliced loaf breads marketed and distributed by NZAB members were to be fortified with folic acid by the end of 2014. An aspirational goal was set to fortify up to 50% of breads over time. The target level of folic acid in bread was set at 200 µg per 100 g (or 2 mg per kg) of finished product.

The NZAB is an association whose members include the large plant bakery companies in New Zealand. NZAB members produce in excess of 90% of the packaged sliced breads in New Zealand. This includes production of NZAB branded products, and also production of private label products (Watson, 2017). BIRT was established in 1989 and is a sub-committee of the NZAB (BIRT, n.d.). BIRT's objective is to identify and make recommendations to the NZAB executive of research projects which will benefit flour users, and then to supervise the implementation of the research approved. BIRT annually audit NZAB member's compliance with the Code of Practice. In 2015 and 2016, audits of the folic acid concentrations of bread marketed or distributed by NZAB members were completed (Watson, 2016; 2017). Details, including methodology and results of these audits are reported in Section 2.4 of this report.

[8] This Code of Practice does not cover the entire New Zealand bread supply, including a major retailer. NZAB members produce in excess of 90% of the packaged sliced breads in New Zealand. This includes production of NZAB branded products, and also production of private label products (Watson, 2017).

2.2 LABELLING SURVEY

This section outlines the results of a labelling survey of folic acid fortified packaged foods available for sale in New Zealand from 2013 to 2017. Data on packaged foods containing folic acid as an added ingredient available for sale were obtained from the Nutritrack database.

Methods

2.2.1.1 Overview of the Nutritrack database

The National Institute for Health Innovation, a research institute housed under Auckland UniServices at the University of Auckland, collect ingredient and nutrient data from the labels of packaged foods available for retail sale (NIHI, 2016). The database is called Nutritrack, and data are stored in a secure, private, online database (NutriWeb).

Images of all sides of packaged food products are collected annually between February and April from four major Auckland supermarket stores (Countdown, Pak ‘n’ Save, New World, and Four Square) using a bespoke smartphone application. These supermarkets represent the largest retail brands of the two main national supermarket retailers available elsewhere in New Zealand: Foodstuffs (Pak ‘n’ Save, New World and Four Square) and Progressive Enterprises (Countdown). In 2016, Foodstuffs and Progressive Enterprises stores make up 43% and 29% of grocery retailers’ market share, respectively (Euromonitor, 2016).

It is estimated that the Nutritrack database represents approximately 75% of available packaged products from the four major retailers. Information is not collected for products that are not packaged or that do not display a NIP i.e. most fresh fruit and vegetables, fresh meat, bulk buy items, and alcohol. Seasonal products such as Easter eggs and dietary supplements[9] are also excluded. The total number of manufactured food and beverage products collected in the database from 2014 to 2017 are summarised in the Table 2-1 below.

Table 2-1: Number of food and beverage products[1] collected in New Zealand supermarkets and added to the Nutritrack database from 2013 to 2017

Year	No. of products
2013	13 406
2014	14 191
2015	14 436
2016	15 370
2017	14 943

Source:

Eyles, H (19 October 2017) Personal communication. National Institute for Health Innovation.

Note:

1. Different package sizes of the same product are collected and considered unique

[9] Dietary supplements are defined as those that are covered under the Dietary Supplements Regulations 1985 and are labelled as dietary supplements. Cited at: http://www.medsafe.govt.nz/regulatory/DietarySupplements/Regulation.asp.

2.2.1.2 Data extraction from the Nutritrack database

Data on packaged foods containing folic acid as an added ingredient available for sale from 2013 to 2016 and 2017 were extracted from the Nutritrack database in August 2016 and 2017 respectively. The terms 'folate' and 'folic acid' were used to search across the ingredients database for each year. As a result, products were identified that had 'folate' or 'folic acid' appearing in the ingredients list. Unique products were identified by barcode in the database, as for some products there are multiple product lines for a particular product description, with variations by pack size.

Products were sorted into 12 broad food categories, three of which were broken down in to subcategories for further detailed analysis (Table 2-2). Similar food categories to those reported in 2012 (MPI, 2012b) were used to ensure comparisons could be made.

Where information on the folic acid[10] concentration of a food was reported on the NIP of the product, this data was analysed. In general, the concentrations declared on the label of foods and beverages were per 100 millilitre (mL) and per 100 g, respectively. In some cases a median folic acid[10] concentration per 100 g or per 100 ml could not be derived for a given food category as there was inconsistency in the units declared on the label between products. Data on folic acid concentrations was collected from 2014 onwards (refer to Table 2-3).

Results

2.2.1.3 Range of fortified foods

Table 2-2 provides a summary of categories of foods fortified with folic acid from 2013 to 2017 as reported in the Nutritrack database. It provides a breakdown of the number of foods fortified with folic acid and the percentage contribution the category makes across available folic acid fortified foods.

[10] For simplicity, the term folic acid has been used to collectively describe the level of total folate or folic acid declared in the NIP of a product. This may mean that the true level of folic acid could be overestimated in some products

Table 2-2: Categories of foods containing products fortified with folic acid from 2013 to 2017[1]

Food Category	No. of products and % of available folic acid- fortified products 2013		2014		2015		2016		2017	
	No.	%	No.	%	No.	%	No.	%	No.	%
Beverages, non-alcoholic	4	1%	7	1%	8	2%	5	1%	5	1%
Breads and bakery products	69	21%	92	20%	115	25%	114	24%	104	24%
• *Bread (rolls, sliced bread)*	*31*	*10%*	*21*	*4%*	*31*	*7%*	*44*	*9%*	*45*	*10%*
• *Bread products[2]*	*29*	*9%*	*40*	*9%*	*50*	*11%*	*38*	*8%*	*31*	*7%*
• *Cakes, muffins and pastries*	*1*	*<1%*	*21*	*4%*	*20*	*4%*	*20*	*4%*	*21*	*5%*
• *Other[3]*	*8*	*2%*	*10*	*2%*	*14*	*3%*	*12*	*3%*	*7*	*2%*
Other cereals and cereal products	150	47%	221	47%	202	44%	206	43%	196	45%
• *Biscuits and crackers[4]*	*16*	*5%*	*26*	*6%*	*21*	*5%*	*24*	*5%*	*27*	*6%*
• *Breakfast cereals*	*102*	*32%*	*168*	*36%*	*153*	*33%*	*155*	*33%*	*147*	*34%*
• *Cereal bars*	*32*	*10%*	*27*	*6%*	*28*	*6%*	*27*	*6%*	*22*	*5%*
Confectionery	2	1%	4	1%	6	1%	4	1%	2	<1%
Convenience foods[5]	10	3%	19	4%	9	2%	7	1%	9	2%
Fruits and vegetables	1	<1%	1	<1%	0	0%	1	<1%	1	<1%
Meat and meat products	0	0%	4	1%	5	1%	8	2%	9	2%
Milk and milk products[6]	1	<1%	12	3%	14	3%	16	3%	18	4%
Sauces and spreads	5	2%	9	2%	7	2%	9	2%	9	2%
Snack foods[7]	13	4%	11	2%	12	3%	14	3%	10	2%
Supplementary foods	60	19%	79	17%	75	16%	83	18%	63	15%
• *Breakfast beverages*	*30*	*9%*	*36*	*8%*	*33*	*7%*	*46*	*10%*	*33*	*8%*
• *Formulated meal replacements*	*19*	*6%*	*23*	*5%*	*19*	*4%*	*20*	*4%*	*8*	*2%*
• *Sports & weight loss products*	*11*	*3%*	*18*	*4%*	*17*	*4%*	*14*	*3%*	*22*	*5%*
• *Other[8]*	*0*	*0%*	*2*	*<1%*	*6*	*1%*	*3*	*1%*	*0*	*0%*
Miscellaneous[9]	6	2%	8	2%	7	2%	8	1%	6	1%
Total	321	100%	467	100%	460	100%	475	100%	432	100%

Source:
National Institute of Health Innovation: Nutritrack database 2013-2017

Notes:
1. Products identified as containing folate or folic acid in the ingredients list
2. Bread products include: naan, roti, wraps, flat breads, tortillas, pizza bases, English-styled muffins, crumpets, bagels and garlic bread
3. Bread mixes, breadcrumbs
4. Includes biscuit mixes
5. Convenience foods include burrito and taco kits, soups and ready-made pizzas
6. Includes milk-based desserts such as cheesecake
7. Includes crisps, snacks and cheese and crackers
8. Includes other nutritional products for children and powdered vitamin boosts
9. Includes milk substitutes, meat alternatives and vegetable powders

The total number of individual products fortified with folic acid has increased over time by 35%, from 321 products in 2013 to 432 products in 2017 (Table 2-2). However, in 2017 there were less fortified foods available for sale compared to 2014 (467 products), 2015 (460 products) and 2016 (474 products). In general, whilst absolute numbers have increased this has largely been a result of increased uptake of voluntary permissions across categories, rather than a result of increases in single food categories. For example, the number of fortified milk and milk products has increased from one product in 2013 to 18 in 2017. Similarly the number of meat and meat products has increased from zero products in 2013 to nine in 2017 and for cakes and muffins from one fortified product in 2013 to 21 in 2017.

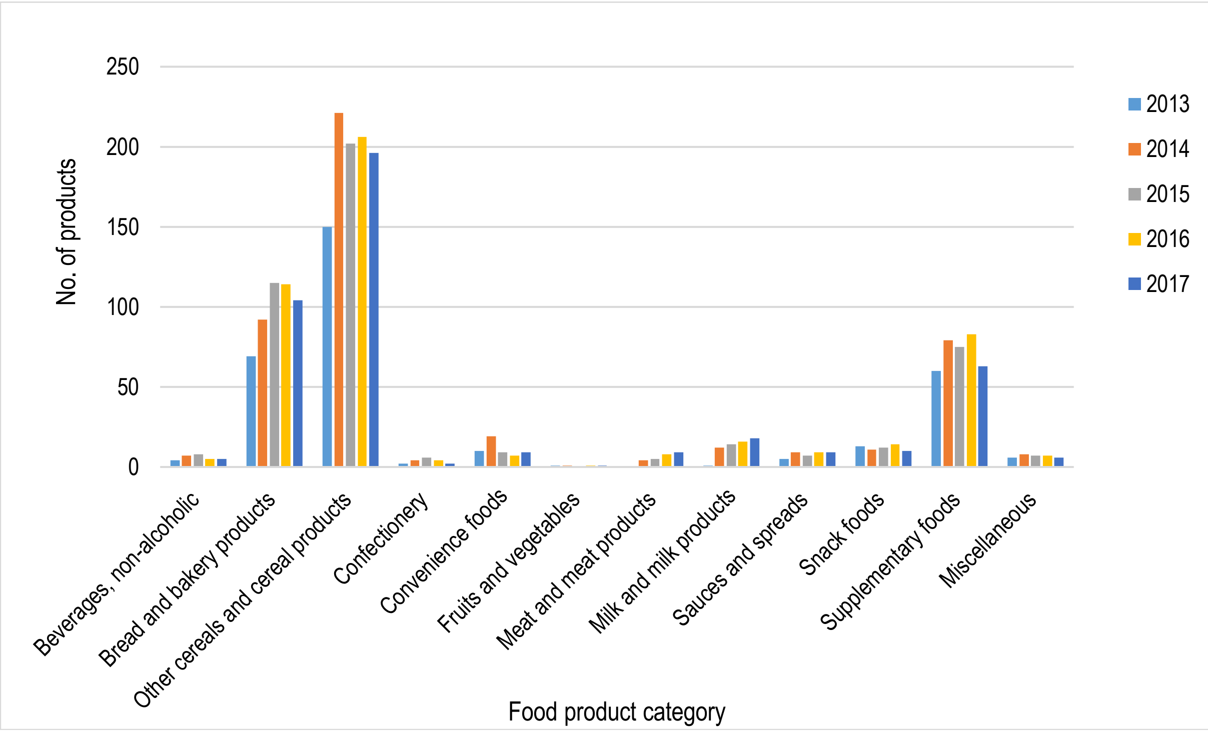
The food category ‘other cereals and cereal products’ contained the highest volume of folic acid fortified products, representing approximately 40% of all folic acid fortified products available (150 (47%) in 2013; 196 (45%) in 2017). The majority of these were breakfast cereals which, since 2013, have constituted approximately a third of all folic acid fortified products available. The categories ‘biscuits and crackers’ and ‘cereal bars’ also contain a range of fortified products, representing 6% and 5% respectively of available folic acid fortified products in 2017.

‘Bread and bakery products’ were the second largest category that contained folic acid fortified products with 69 (21%) in 2013 and 104 (24%) in 2017. Across all years, most of these were ‘bread’ and ‘bread products’. In 2017, ‘bread’ and ‘bread products’ made up 10% and 7% of all folic acid fortified products, respectively. In addition to this, some cakes, muffins, pastries, bread mixes and breadcrumbs also contained folic acid.

‘Supplementary foods’ contained the third largest proportion of folic acid fortified products (60 (19%) in 2013 and 63 (15%) in 2017). Of these, breakfast beverages made up the greatest proportion of the supplementary foods (8% of all folic acid fortified products).

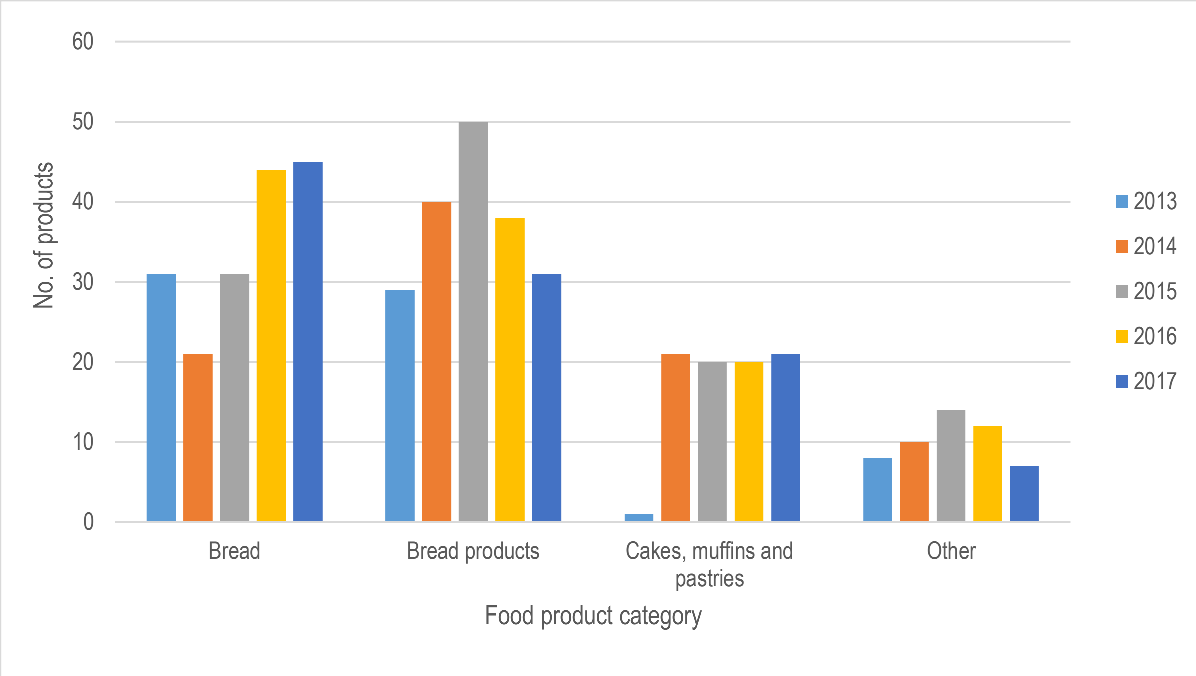
Figure 2-1 provides an overall summary of the number of products, by food product category, fortified with folic acid from 2013 to 2017, as declared on the food label. Figure 2-2, Figure 2-3 and Figure 2-4 show a breakdown of the products within the bread and bakery products, other cereals and cereal products and supplementary foods categories.

Figure 2-1: Number of products fortified with folic acid from 2013 to 2017



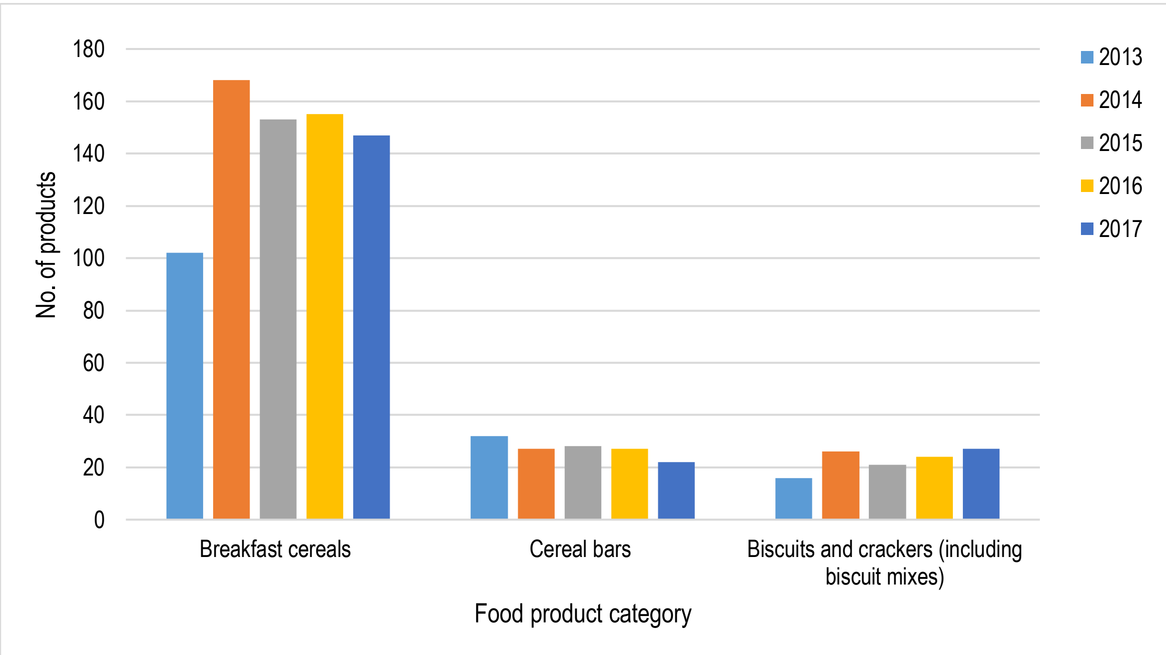
Source:
National Institute of Health Innovation: Nutritrack database 2013-2017 (products with folic acid as declared on label)

Figure 2-2. Number of bread and bakery products (by subcategory) fortified with folic acid from 2013 to 2017



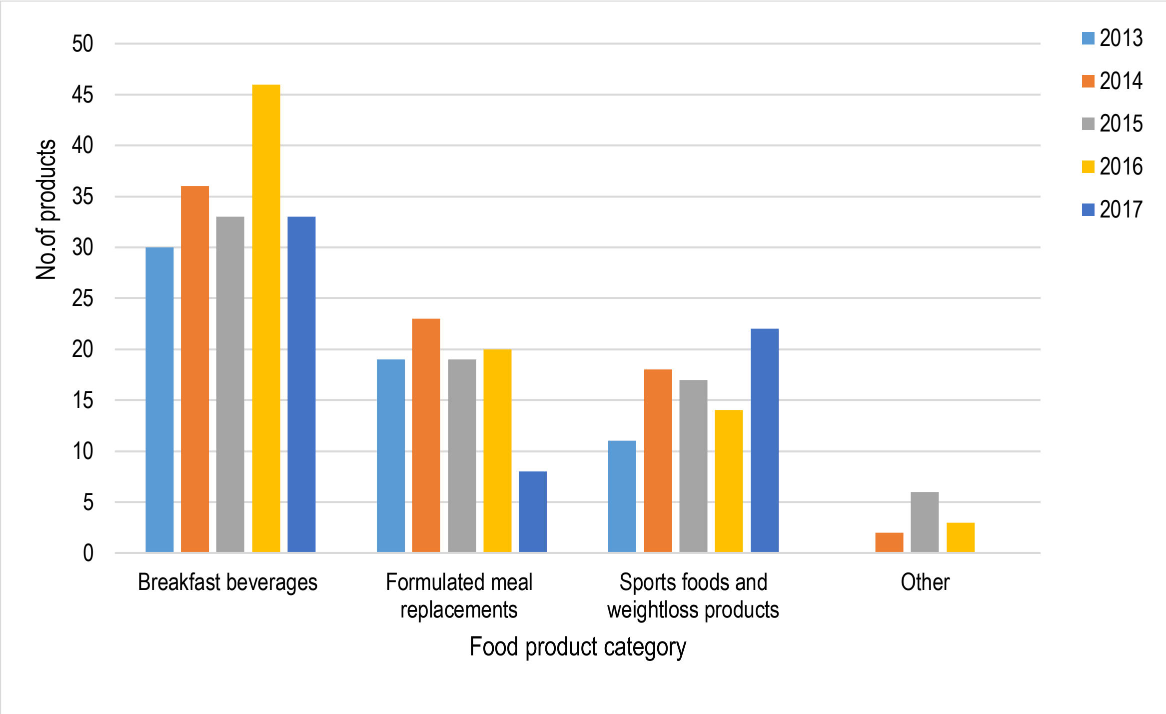
Source:
National Institute of Health Innovation: Nutritrack database 2013-2017 (products with folic acid as declared on label)

Figure 2-3. Number of other cereals and cereal products (by subcategory) fortified with folic acid from 2013 to 2017



Source:
National Institute of Health Innovation: Nutritrack database 2013-2017 (products with folic acid as declared on label)

Figure 2-4. Number of supplementary food products (by subcategory) fortified with folic acid from 2013 to 2017



Source:
National Institute of Health Innovation: Nutritrack database 2013-2017 (products with folic acid as declared on label)

2.2.1.4 Comparison with the 2012 Voluntary Folic Acid Fortification report on numbers of folic acid fortified foods

Based on a comparison with the 2012 Voluntary Folic Acid Fortification Monitoring and Evaluation report (MPI, 2012b), the number of folic acid fortified products available on the market has increased since 2008. The 2012 report identified that there were 102 folic acid fortified products on the market in 2008 and 161 in 2011. The overall trend observed between the 2012 report and 2017 is that there has been an increase in fortified foods available for sale, with the total number of folic acid fortified products peaking at 474 in 2016 but declining to 432 in 2017.

Although an increase has been observed between 2008 and 2017, there are some limitations associated with a direct comparison between the two reports due to the difference of data sources used. In the 2012 report (MPI, 2012b), data from the Manufactured Food Database (MFD) (University of Auckland, 2008) was used however this database is no longer operational. The MFD relied on the acquisition of label information from manufacturers on a voluntary basis and consequently contained fewer products.

Breakfast cereals remain the food category with the largest number of individual products fortified with folic acid across the two reports. In 2008, there were 49 folic acid fortified breakfast cereals, which increased to 86 in 2011, 102 in 2013, and 147 in 2017. Although breakfast cereals remain the category with the most fortified products in 2017, they contribute a lower proportion of the overall number of fortified products compared to 2011 (34% in 2017 vs. 57% in 2011). This is likely due to the higher uptake of voluntary permissions to fortify bread and bread products.

In the 2012 report (MPI, 2012b), the number of breads fortified with folic acid was seven in 2008 and 26 in 2011. The increase to 31 breads in 2013 and 45 breads in 2017 is likely due to the introduction of the New Zealand (Permitted Fortification of Bread with Folic Acid) Food Standard 2012 (MPI, 2012a) and the NZAB and the Private Label Partners' Code of Practice for Voluntary Folic Acid Fortification of Bread (NZAB, 2014). Bread products were not included in the 2012 report, and therefore a comparison could not be made.

The second largest category reported in 2012 was non-alcoholic beverages (22 in 2008 and 2011). It is likely that these included breakfast beverages, which have been separated out in this report. Although the number of non-alcoholic beverage products remained the same in 2008 and 2011, the number of breakfast beverages alone increased to 30 in 2013 and 33 in 2017.

2.2.1.5 Median folic acid concentrations as reported in the nutrition information panel

Under the Food Standards Code (FSANZ, 2002) manufacturers are permitted to declare either total folate or folic acid content in the NIP. Total folate includes naturally occurring folate as well as added folic acid. As some product categories such as bread and bread products contain naturally occurring folate, the level of total folate and folic acid declared on these products may not be equivalent. For example, according to the Australian nutrient tables referred to as NUTTAB, white bread has a total folate content of 172 µg per 100 g, which is made up of 123 µg per 100 g of folic acid and 49 µg per 100g of natural occurring folate (FSANZ, 2011).

The level of folate (listed as either total folate or folic acid) in a product is not required to be listed in the NIP under the Food Standards Code (FSANZ, 2002). However, when folic acid is added to a product, it must be declared in the ingredient list. As such not all products declare the level of folate or folic acid in the NIP. Table 2-3 provides a summary of the median folic acid concentration[11] of products as reported in the NIP for the years 2014 to 2017. Folic acid concentration data was not available for 2013.

Of those products in the Nutritrack database that contain folate or folic acid, approximately half declared the amount contained in the NIP (Table 2-3). The median folic acid content of fortified products, where it could be determined each year, has remained relatively constant from 2014 to 2017.

The median folic acid concentration of those breads fortified with folic acid has remained stable at 200 µg per 100 g from 2014 to 2017. It is interesting to note that although the number of breads containing folic acid has increased since 2014, the proportion of breads declaring its concentration in the NIP decreased from 62% in 2014 to 38% in 2017. None of the bread products or cakes, muffins and pastries available for sale across all four years declared folic acid in the NIP.

There has been no change in the median folic acid concentration of breakfast cereals over the past four years: 200 µg per 100 g in 2014, 2016 and 2017 and 199 µg per 100 g in 2015. The majority of products declare the folic acid concentration; a trend seen across all four years (76% in 2014, 69% in 2015, 79% in 2016 and 82% in 2017).

The median folic acid concentration of cereal bars was the same over the past four years at 39 µg per 100 g. However, along with the increase in the number of cereal bars available for

[11]For simplicity, the term folic acid has been used to collectively describe the level of total folate or folic acid declared in the NIP of a product. This may mean that the true level of folic acid could be overestimated in some products.

sale, the proportion of those that declare folic acid in the NIP has increased from 22% in 2014 to 55% in 2017.

There was little change in the median folic acid concentration of breakfast beverages across the four years: 35 µg per 100 mL in 2014 and 2016 and 40 µg per 100 mL in 2015 and 2017. All products declared the folic acid concentration in the NIP.

Sauces and spreads had the highest median folic acid concentration across all products and all four years at 2000 µg per 100 g. Two keys brands of yeast extract spreads (folic acid content of 2000 µg per 100 g), attributed to the very high median folic acid concentration.

Table 2-3: Median folic acid[1] concentration of products as declared in the nutrition information panel for 2014 – 2017

	2014			2015			2016			2017		
Food category	**No.**	**% products declaring nutrient content (no.)**	**Median (range) folic acid concentration (µg/100 g)**	**No.**	**% products declaring nutrient content (no.)**	**Median (range) folic acid concentration (µg/100 g)**	**No.**	**% products declaring nutrient content (no.)**	**Median (range) folic acid concentration (µg/100 g)**	**No.**	**% products declaring nutrient content (no.)**	**Median (range) folic acid concentration (µg/100 g)**
Beverages, non-alcoholic	7	86% (6)	ND	8	88% (7)	16 (5.5-99.9)[2]	114	15% (17)	ND	5	100% (5)	8 (5.5-16)
Breads and bakery products	92	14% (13)	200 (130-200)	115	14% (16)	200 (130-200)	114	15% (17)	200 (190-296)	104	17% (18)	200 (190-296)
• *Bread (rolls, sliced bread)*	21	62% (13)	200 (130-200)	31	48% (15)	200 (130-200)	44	39% (17)	200 (190-296)	45	38% (17)	200(190-296)
• *Bread products*	40	0	-	50	0	-	38	0	-	31	0	-
• *Cakes, muffins and pastries*	21	0	-	20	0	-	20	0	-	21	0	-
• *Other*	10	0	-	14	7% (1)	200	12	0	-	7	14% (1)	200
Other cereals and cereal products	221	61% (135)	200 (27-334)	202	57% (115)	166 (17-866)	206	65% (134)	182 (17-333)	196	68% (133)	200 (27-333)
• *Biscuits and crackers*	26	4% (1)	200	21	0	-	24	0	-	27	0	-
• *Breakfast cereals*	168	76% (128)	200 (6.7-344)	153	69 (106)	199 (27-866)	155	79% (123)	200 (60-333)	147	82% (121)	200 (27-333)
• *Cereal bars*	27	22% (6)	39 (38-39)	28	32% (9)	39 (17-39)	27	41% (11)	39 (17-40)	22	55% (12)	39 (39-40)
Sauces and spreads	9	100% (9)	2000 (125- 2000)	7	100% (7)	2000 (125- 2000)	9	89% (8)	2000 (2000)	9	89% (8)	2000 (800-2000)
Confectionery	4	0	-	6	0	-	4	0	-	2	0	-
Convenience foods	19	0	-	9	0	-	7	0	-	9	0	-
Fruits and vegetables	1	0	-	0	0	-	1	0	-	1	0	-
Meat and meat products	4	0	-	5	0	-	8	0	-	10	0	-
Milk and milk products	12	0	-	14	36% (5)	14 (14-20)	16	38% (6)	20 (20)	18	72% (13)	ND
Snack foods	11	0	-	12	0	-	14	0	-	10	0	-
Supplementary foods	79	87% (69)	ND	75	88% (66)	ND	83	78% (65)	ND	63	95% (60)	ND
• *Breakfast beverages*	36	100% (36)	35 (20-40)[2]	33	100% (33)	40 (20-82)[2]	46	100% (46)	35 (20-71)[2]	33	100% (33)	40 (10-40)[2]
• *Formulated meal replacements*	23	96% (22)	167 (64-370)	19	100% (19)	ND	20	55% (11)	48 (48-277)	8	100 (8)	ND
• *Sports foods & weight loss products*	18	61% (11)	195 (89-305)	17	71% (12)	319 (67-675)	14	50% (7)	235 (204-346)	22	86% (19)	313 (64-675)
• *Other*	2	0	-	6	33% (2)	15	3	33% (1)	15	0	0	-
Miscellaneous	8	25% (2)	ND	7	29% (2)	ND	8	2	ND	6	33% (2)	ND
Total	467	63% (295)	ND	460	53% (245)	ND	475	55% (262)	ND	432	55% (239)	ND

Source:
National Institute of Health Innovation: Nutritrack database 2014-2017

Notes:

1. For simplicity, the term folic acid has been used to collectively describe the level of total folate or folic acid declared in the NIP of a product. This may mean that the true level of folic acid could be overestimated in some products
2. Median folic acid concentration (µg per 100 mL)

Abbreviations:
ND Not determined. Median folic acid concentrations unable to be calculated due to inconsistent units used within the category

2.2.1.5.1 *Comparison with the 2012 Voluntary Folic Acid Fortification Monitoring and Evaluation report on median folic acid concentrations*

Data from the 2012 Voluntary Folic Acid Fortification Monitoring and Evaluation report (MPI, 2012b) showed that although the number of breads fortified with folic acid increased from 2008 to 2011 (from seven to 26), the median folic acid concentration declared on the label had remained the same at 200 µg per 100 g.

For breakfast cereals, a median folic acid concentration of 222 µg per 100 g was reported from 1997 to 2011. From 2014 to 2017, the median folic acid concentrations were less at 200 µg per 100 g.

Miscellaneous products had the highest median folic acid concentration of 2000 µg per 100 g in 2008 and 2011. The yeast extract products containing the high median folic acid concentration are the same captured in the 'sauces and spreads' category in this report.

Limitations and assumptions

The Nutritrack database is an inventory of ingredient and nutrition information collected from the labels of manufactured and packaged food. Folic acid concentrations reported have been recorded from photos of product labels; no independent testing of these has been undertaken as part of this work.

Since the Nutritrack database aims to capture approximately 75% of the packaged food supply, it is likely that some products containing folic acid have not been captured. It is also assumed that the database is accurate in terms of the label data recorded. The National Institute of Health Innovation group conduct their own quality control processes in terms of checking for data entry errors. For this piece of work, a full cross check was not completed, but checks were made where it was obvious a data entry error had occurred. In reporting the folic acid concentrations, only those products where a 'nutrition claim' on the folic acid/ folate concentration was made on the label (i.e. declared in the NIP) were included.

For simplicity, the term folic acid has been used to collectively describe the level of total folate or folic acid declared in the NIP of a product. This may mean that the true level of folic acid could be overestimated in some products.

Products were categorised in to one of the 12 categories based on the information available. Best efforts have been made to provide information on the products included in these categories

2.3 MINISTRY FOR PRIMARY INDUSTRIES ANALYTICAL SURVEY

This section outlines the results of an analytical survey of folic acid fortified breads and bread products commissioned by MPI in 2016. The aim of this survey was not to measure compliance with the standard, but to provide a snapshot of the current levels of folic acid in bread and to inform this monitoring work.

Methodology

The sampling plan was based on information on fortified breads available in the market place taken from three sources: the Nutritrack database, Nielsen Homescan® and the 2015 BIRT bread analytical audit (Watson, 2016).

2.3.1.1 Nutritrack and Baking Industry Research Association data

In August 2016, data on bread and bread products containing folate or folic acid as an added ingredient available for sale in 2016 were extracted from the Nutritrack database ((NIHI, 2016) see Section 2.2.1.1 for detailed overview). From this, 39 breads and 42 bread products (such as pizza bases, tortillas and bagels) were identified as containing folate or folic acid as an ingredient. Three of the 42 bread products were produced in one instore bakery. As the data was collected from Auckland-based supermarkets, it is not known whether the remaining 39 bread products were available nationally. In the Nutritrack database, breads of varied thickness (for example sandwich, toast and super thick) are collected as separate product lines, however are likely to be the same compositionally, so for the purpose of this survey were treated as identical samples.

As described on page 17 of this report, the BIRT annually audit the folic acid concentration of breads covered under the NZAB and Private Label Partners' Code of Practice (NZAB, 2014). The 2015 BIRT audit (Watson, 2016) identified 62 breads that contain folic acid; 50 of which were available for sale nationally[6]. Similar to the Nutritrack database, breads of varying thickness were collected as separate product lines.

When Nutritrack and BIRT audit data was consolidated, a total of 52 breads were identified to contain folic acid as an ingredient, across 10 brands that were available for sale nationally[12].

2.3.1.2 Nielsen Homescan Panel

Nielsen Homescan® is a geographically and demographically representative panel of approximately 2500 New Zealand households who scan all foods and beverages purchased for consumption in the home. The Nielsen Homescan® panel has been in existence for 20 years, and the weighted panel data represent products from approximately 80% of total food and grocery retail businesses in New Zealand.

Households are provided with handheld barcode scanners and are instructed to scan the barcodes of all purchased food items taken home after a grocery shop. Scanning occurs continuously throughout the year and includes products purchased from supermarkets, convenience stores, specialist stores and department stores.

To ensure the analytical survey captured the top selling bread varieties in New Zealand, data from Nielsen Homescan® was used to identify the seven top selling white, mixed grain and wholemeal breads (21 breads in total) in New Zealand in 2016. Using data collected from the Nutritrack database and the BIRT audit, ten of these breads were identified as containing folic acid.

[12] Includes breads that are sold nationally, excluding the lower North Island.

2.3.1.3 Sampling Overview

It was planned that the folic acid concentration of all unique breads[13] (within the 10 brands identified as being fortified with folic acid) available for sale nationally in New Zealand during 2016 be measured. The sample would encompass all of the top selling white, wholemeal and mixed grain breads identified as containing folic acid (as per the Nielsen homescan® data); and take account of potential batch and regional differences in the manufacture of bread.

In addition to this, a selection of the 39 bread products identified as being fortified with folic acid available for sale in 2016 were planned to be analysed to determine their concentration of folic acid. Information on whether these bread products were available nationally was not available, however it was aimed that two batches of the identified bread products from one region be sampled. Details on the sampling plan are provided in more detail below.

2.3.1.4 Sampling Plan

All of the breads were to be sampled in two New Zealand regions: Auckland and Christchurch. The bread products would only be sampled in the Auckland region. Table 2-4 outlines the sampling plan for bread and bread products.

Table 2-4: Sampling plan for bread and bread products

Category	No. of samples				Total no. of samples
	Auckland		Christchurch		
	Batch 1	Batch 2	Batch 1	Batch 2	
			Breads		
White[1]	8	8	8	8	32
Mixed Grain	25	25	25	25	100
Wholemeal	6	6	6	6	24
Rye	1	1	1	1	4
Total	40	40	40	40	160
			Bread products		
Flat breads[2]	9	9	…	…	18
Bagels	5	5	…	…	10
Pizza bases	2	2	…	…	4
Garlic breads	1	1	…	…	2
Total	17	17	…	…	34

Notes:
1. Includes fibre white bread
2. Includes tortillas, Turkish bread and wraps

Two individuals, one in each location, were contracted to complete sample collection and were provided with a detailed sampling protocol of the breads and bread products to be collected. They were required to collect two samples from different batches from the exact brand and bread type indicated on the sampling list. Samples could be collected from any retailer and in the case of bread either the toast, sandwich or superthick version of a given brand could be purchased[13]. Where a bread on the list could not be located at any of the retail outlets, after several attempts this was recorded and MPI notified.

Sampling was carried out on multiple occasions during 2016 in Auckland (2nd September, 5th September, 7th September and 8th September) and several occasions in Christchurch (14th September and 21st September). In total, 160 breads were expected to be collected; 80 from

[13] It is assumed that the toast, sandwich and superthick versions of a product are the same compositionally.

Auckland and 80 from Christchurch. This is equivalent to two samples of 40 unique breads in each location. In addition, 34 bread products were expected to be collected from Auckland, equivalent to two samples of the 17 unique bread products.

Upon purchasing, each product was given a unique identifier (sticker on product) and the relevant information detailed in the sampling protocol recorded. Each packet of bread was checked to confirm that folic acid or folate was listed as an ingredient. The fresh breads were packaged and sent to the contracted laboratory for analysis within 24 hours of purchase.

2.3.1.5 Laboratory Methodology

AsureQuality were contracted to analyse the bread and bread products for folic acid. All analyses were performed at AsureQuality, 131 Boundary Road, Blockhouse Bay, Auckland. AsureQuality are an accredited laboratory under International Accreditation New Zealand (IANZ) for the Biacore folic acid test. AsureQuality has participated in a few rounds of proficiency studies conducted by the National Measurement Institute Australia for folic acid in flour. They also undertake ongoing competency assessment on dairy and food matrices using various proficiency programmes. Global proficiency samples were used as an in-house control (Asure Quality, 24 November 2016).

Qflex kits are used to run specific assays with a Biacore Q system delivering rapid, reliable and automated quantification of vitamin content. All kits have been certified as Performance Tested Methods by the Association of Official Analytical Chemists (AOAC) Research Institute (certificate number for folic acid: 080201) (AOAC, 2014). In the testing process, free, non-bound folic acid and endogenous protein bound 5-MTHF in the sample was dissolved in water and the starch hydrolysed using α-amylase. The solution was then filtered and analysed using the Biacore Q instrument. The Biacore Q utilises bio-molecular interaction with anti-folic acid monoclonal antibody and detection by Surface Plasmon Resonance. As an inhibition assay, the excess antibody binds to the folic acid-immobilised sensor chip generating the Surface Plasmon Resonance response, which is inversely related to folic acid content in standard or unknown sample extract (Asure Quality, 24 November 2016).

Samples were stored at room temperature prior to analysis. Composite samples for breads were obtained by homogenising two slices from the top, middle and bottom of the bread loaf; for bread products, composites were obtained by homogenising equal amounts from each item within the pack. A 1 g test portion of this mixture was used to test folic acid. If the level of folic acid in the sample was too low (below 50 µg per 100g), the sample was re-analysed using 2 g of the mixture. The limit of detection for the method is 4 µg per 100 g.

Results

2.3.1.6 Median folic acid concentration of bread and bread products

A total of 152 breads and 34 bread products were collected and analysed for folic acid content. Of all the breads, 10 unique brands and 39 unique types were sampled and of all the bread products, 12 unique brands and 17 unique types were sampled. These products were grouped into four bread categories: white, mixed grain, wholemeal, rye; and four bread product categories: flat breads, bagels, pizza bases and garlic breads. Due to a number of breads not being available at the time of purchase, the sample size of the bread categories differs from what was originally proposed. Overall eight less breads, or three unique types, were sampled. The median folic acid concentrations of the bread and bread products are provided in Table 2-5.

Table 2-5: Median folic acid concentration (µg per 100 g and per serving) by bread and bread product category

Bread and bread product category	No.	Median folic acid (µg/100g bread (SD))	Median folic acid (µg/serving)	Estimated serving size (g)
		Breads		
White[1]	32	110.0 (71.0)	42.9	39[2]
Mixed Grain	94	141.5 (51.6)	48.3-83.5	33-57[2]
Wholemeal	22	120.5 (61.0)	45.8	38[2]
Rye	4	183.0 (52.0)	86.0	47[2]
Total	152	130.0 (59.0)	55.9	42
		Bread products		
Flat breads[3]	18	147.5 (50.0)	36.9-107.7	25-73[2]
Bagels	10	23.4 (33.3)	20.8	89
Pizza bases	4	93.1 (111.3)	187.1	201
Garlic breads	2	92.6 (119.4)	201.9-206.5	218-223
Total	34	114.0 (72.8)	130.5	145

Sources:
Serving sizes taken from the Concise New Zealand Food Composition Tables 12th ed. 2017 (Sivakumaran and Huffman, 2017)
National Institute of Health Innovation: Nutritrack database, 2016

Notes:
1. Includes fibre white bread (n=2)
2. Based on the weight of one toast slice
3. Includes tortillas, Turkish bread and wraps

Abbreviations:
SD Standard deviation

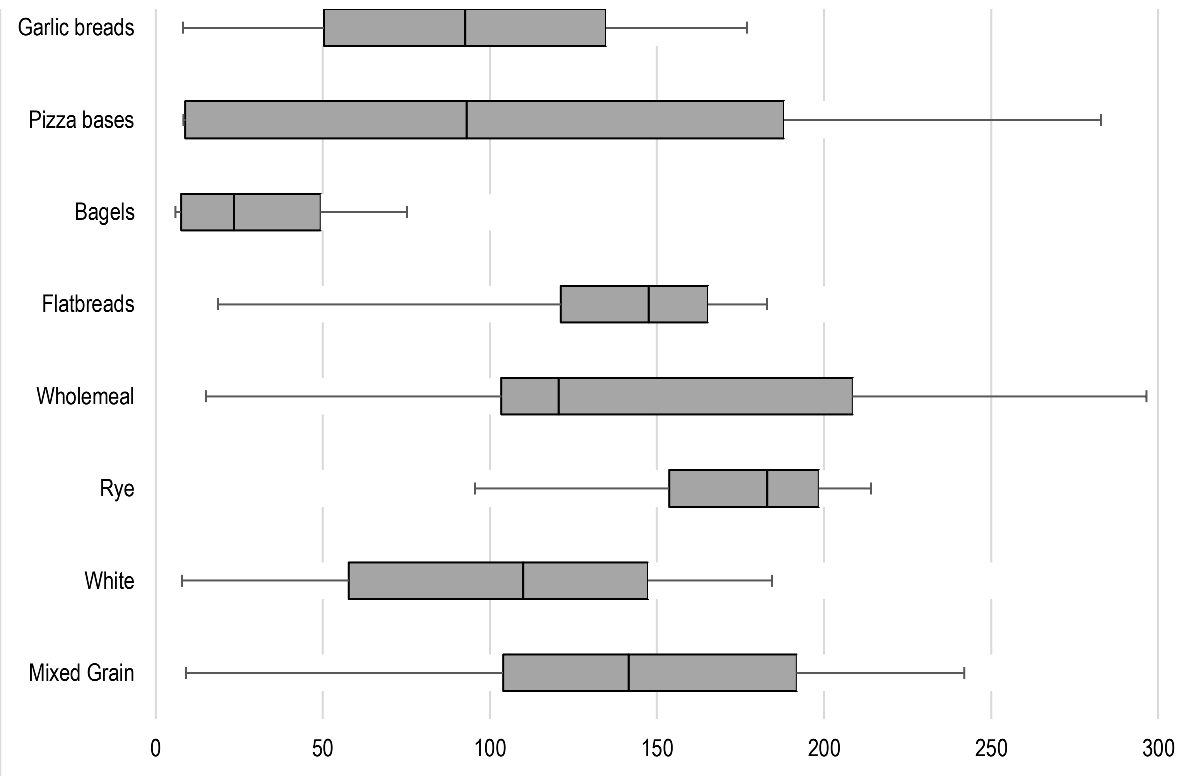
The median folic acid concentration of packaged, sliced breads (white, mixed grain, rye and wholemeal) ranged from 110-183 µg per 100 g. In contrast the median folic acid concentration of flat breads, bagels, pizza bases and garlic breads were 147.5 µg, 23.4 µg, 93.1 µg and 92.6 µg per 100 g, respectively. Of the breads, rye and mixed grain breads were found to have the highest median folic acid concentrations of 183 µg per 100 g and 141.5 µg per 100 g respectively. Overall, the median folic acid concentration of fortified packaged sliced breads was 130 µg per 100 g (range 8 – 254 µg per 100 g).

Per serving of bread (33-57 g) the median folic acid concentration ranged from 42.9 µg (white) and 86 µg (rye). Of all the bread products, the garlic breads category provided the highest median folic acid concentration per weight-based serving (201.9-206.5 µg per 218-223 g serving).

2.3.1.7 Range of folic acid concentrations of bread and bread products

The box plot provided in Figure 2-5 illustrates the range of folic acid concentrations present by bread and bread product categories. Of the breads, rye had the lowest and most narrow range in folic acid concentration (96 - 215 µg per 100 g) and white bread had the widest range (7.9 - 254 µg per 100 g). Even between different batches, the folic acid concentration of some breads varied greatly, with one bread having a difference of 226 µg/100 g. However, the median difference of folic acid concentration between bread batches was 21 µg per 100 g.

Figure 2-5: Box plot of folic acid concentrations (µg per 100 g) by bread and bread product category[1]



Notes:

1. The boundary of the box closest to zero indicates the 25th percentile, the line within the box marks the median, and the boundary of the box farthest from zero indicates the 75th percentile. Extremes of the whiskers at the top and bottom of the box indicate the 10th and 90th percentiles.

2.3.1.8 Comparison with Nutrition Information Panel

All of the bread and bread products had folic acid listed in the ingredients list. Nineteen unique breads declared folic acid in the NIP[14] with the amount per 100 g. Of these, 16 breads listed the folic acid content as 200 µg per 100 g; the remaining three breads listed the folic acid content as 296 µg, 148 µg and 190 µg per 100 g. Amongst the breads that declared the amount of folic acid in the NIP, the median difference between the amount declared and the results of the analytical survey was 91 µg/ 100 g. This ranged from 5 µg per 100 g up to 192 µg per 100 g, with the majority of these breads (84%) containing less folic acid than declared in the NIP. No bread products declared the folic acid or folate concentration in the NIP.

2.3.1.9 Comparison with the 2010/2011 folic acid analytical survey as reported in the 2012 Voluntary Folic Acid Fortification Monitoring and Evaluation report

The 2012 Voluntary Folic Acid Fortification Monitoring report (MPI, 2012b) included results of a 2010/2011 analytical survey (Bradbury et al, 2011), carried out by the University of Otago, on the folic acid content of bread.

The survey was undertaken between October 2010 and February 2011 and included 17 breads (seven in the North Island and 10 in the South Island). Sample selection was based on information provided by BIRT on the main bread companies and the top-ten ranking folic

[14] For simplicity, the term folic acid has been used to collectively describe the level of total folate or folic acid declared in the NIP of a product. This may mean that the true level of folic acid could be overestimated in some products

acid fortified breads by sales volume in both the North and South Island. The median folic acid concentration (interquartile range) for all 17 breads was 144 µg per 100 g (41, 189). (Bradbury et al, 2011).

In comparison, the 2016 analytical survey found that the median folic acid content of bread (38 unique types) was 130 µg per 100 g. However, because of differences in survey methodology (including laboratory methods), caution should be applied when making a direct comparison between the analytical survey results.

Limitations and assumptions

The 2016 MPI analytical survey included nationally available folic acid fortified breads and as such may not capture all of the folic acid fortified breads available for sale in New Zealand. Furthermore, the folic acid fortified bread products were identified through label data from Auckland-based supermarkets (using the Nutritrack database) and therefore it is not known whether these products are available nationally.

Bread samples were only collected in two locations (Auckland and Christchurch) and bread product samples only from Auckland, so the results may not be generalisable to the wider New Zealand bread supply. Further, not all of the identified folic acid fortified breads were able to be sampled in each location. In particular one identified bread was not able to be sampled in either Christchurch or Auckland so could not be included in the analysis.

As outlined previously, the term folic acid has been used to collectively describe the level of total folate or folic acid declared in the NIP of a product. This may mean that the true level of folic acid could be overestimated in some products. This could explain why some products contained less folic acid than the concentration declared on the NIP.

2.4 INDUSTRY ANALYTICAL AUDIT OF BREADS

The NZAB and Private Label Partners' Code of Practice (described previously in Section 2.1 of this report), requires that an annual analytical audit of all bread formulations declaring folic acid fortification covered under this Code of Practice, by manufacturer, be undertaken (Watson, 2017). This section outlines the results of the analytical audit of folic acid fortified breads marketed or distributed by NZAB members and their private label partners' conducted by the BIRT in 2015 and 2016 (Watson, 2016; 2017). NZAB members produce in excess of 90% of the packaged sliced breads in New Zealand. This includes production of NZAB branded products, and also production of private label products (Watson, 2017).

Details on the methodology and results of the audits were taken from the 2015 and 2016 *Voluntary Fortification of Bread with Folic Acid Annual Report* prepared by the BIRT (Watson, 2016; 2017).

Methodology

NZAB member companies each provided the BIRT with a list of the folic acid fortified products they manufacture and in which regions the products are available. For each NZAB member company, every folic acid fortified bread formulation they manufacture was audited by BIRT. If a company produces that formulation in both the North and South Island, samples were collected in both Islands. Audit samples were collected in August and/or December for 2015 and August/September and/or November/December for 2016. All formulations were audited at least once (Watson, 2016; 2017).

In 2015, this sampling regime resulted in 77 bread samples being taken (Watson, 2016). Five products which had unexpectedly high results[15] in the August sampling round were re-audited in December 2015. This meant that 82 breads in total were tested in 2015. In 2016, this sampling regime resulted in 91 bread samples being taken (Watson, 2016). Three products which had low results, indicating that no folic acid was added, in the August/September sampling round were re-audited in December 2016. This meant that 94 breads in total were tested in 2016.

Samples (one loaf of each product) for each company were collected from stores in areas where their products were known to be sold. The lead auditor assigned a shopping list to an independent 'shopper' in each of the applicable regions. Samples were purchased and details such as date code, colour of closure tag, date of purchase and store location were noted. Products were then couriered overnight to Auckland or Christchurch, where NIP and ingredient list pack information was scanned. Following this, samples were coded and then delivered to AsureQuality for testing (Watson, 2016; 2017). Samples were tested for folic acid by AsureQuality using the Biacore Method (based on AOAC method 992.05) (described in Section 2.3.1.5 of this report).

Results

2.4.1.1 Proportion of New Zealand Association of Bakers members and Private Label Partners' breads fortified with folic acid

The proportion of breads fortified with folic acid were calculated as a percentage of production volume of packaged sliced breads marketed and/or distributed in New Zealand by NZAB members (Watson, 2016; 2017). NZAB members produce in excess of 90% of the

[15] The five breads that were deemed to have unexpectedly high folic acid concentrations and were consequently retested had mean folic acid concentrations of 257, 262, 342, 384 and 436 µg per 100 g.

packaged sliced breads in New Zealand (Watson, 2017). This includes production of NZAB branded products, and also production of private label products (Watson, 2017). Individual companies provided production volumes to the BIRT who then collated the information to determine the percentages as shown in Table 2-6 below.

Table 2-6: Percentage of New Zealand Association of Bakers members and Private Label Partners' packaged slice breads fortified with folic acid

	2012 Production	2013 Production	2014 Production	2015 Production	2016 Production
NZAB Branded	18.0%	16.6%	15.6%	28.0%	32.3%
Private Label	9.0%	9.1%	27.0%	44.3%	56.9%
Total	14.1%	14.4%	19.0%	32.2%	37.7%

Source:
Voluntary fortification of bread with folic acid annual report 2016, BIRT (Watson, 2017).

In 2012, 14.1% of packaged sliced bread (by production volume) marketed or distributed by NZAB members was fortified with folic acid. By the end of 2015, the level of fortification had increased to 32.2% and further to 37.7% in 2016 (Watson, 2017).

2.4.1.2 Analytical audit results

The 2015 audit (Watson, 2016) found that the median folic acid concentration of the 82 breads tested was 178 µg folic acid per 100 g of bread (range 92 - 436 µg per 100 g). Eighty-three percent of breads had a folic acid concentration between 100 and 250 µg per 100 g of bread[16]. The 2016 audit (Watson, 2017) tested 94 breads and found the median folic acid concentration to be 191 µg per 100 g of bread (range 6.5 - 359 µg per 100 g). Seventy-one percent of the breads had a folic acid concentration between 100 and 250 µg per 100 g.

Limitations and assumptions

Since the BIRT audit only sampled folic acid fortified breads marketed and distributed by NZAB members and their private label partners', it is unlikely to have captured all of the folic acid fortified breads available for sale in New Zealand.

The BIRT audits utilised a different sampling plan to that of the 2016 MPI analytical audit (Watson, 2017). The BIRT audits sampled all packaged sliced breads marketed and distributed by NZAB members, whereas the MPI analytical survey sampled all identified nationally available folic acid fortified breads available for sale in New Zealand. The BIRT audits also reanalysed a sub set of samples that were found to have unexpectedly high or low levels of folic acid, whereas the MPI audit did not. Given these methodological differences between the BIRT audit and MPI survey, results are not directly comparable.

[16] The BIRT Audit report noted that there was an international shortage of folic acid from mid 2015 to mid 2016, which meant that the level of fortification for some products was reduced to 120 µg per 100 g of bread.

2.5 SUMMARY

The two key questions being addressed in this section were whether the level of folic acid in the food supply has increased and if the food industry are adequately complying with the voluntary New Zealand (Permitted Fortification of Bread with Folic Acid) Food Standard 2012 (MPI, 2012a).

Folic acid is currently permitted to be added to a range of foods for sale in New Zealand regulated under New Zealand and trans-Tasman Food Standards. Results of a labelling survey found, the total number of individual products available for sale fortified with folic acid has generally increased over time, with 432 folic acid fortified products available for sale in 2017, compared with 321 in 2013. In 2017, breakfast cereals remained the food category with the largest proportion of individual fortified products (34%), followed by bread (10%) and breakfast beverages (8%).

The median folic acid[17] concentration declared on the NIP for food categories has remained remarkably stable from 2014 to 2017. The median folic acid concentration declared on the NIP for breads was 200 µg per 100 g each year (2014-2017). Breakfast cereals also declared a median folic acid centration of 200 µg per 100 g most years, with the exception of 2015 where the median folic acid concentration declared was 199 µg per 100 g. Sauces and spreads declared the highest median folic acid concentration on the NIP each year at 2000 µg per 100 g.

The New Zealand (Permitted Fortification of Bread with Folic Acid) Food Standard 2012 permits the voluntary fortification of bread with folic acid (MPI, 2012a). The NZAB and Private Label Partners' Code of Practice for Voluntary Folic Acid Fortification of Bread (NZAB, 2014) encourages NZAB members to work towards fortifying 50%, by volume, of their packaged sliced breads marketed and distributed in New Zealand at a level of 200 µg per 100 g finished product. The 2016 BIRT audit (Watson, 2017) found that 38% of NZAB packaged sliced bread were fortified with folic acid, up from 32% in 2015 and 14% in 2012. The 91 breads tested in 2016 had a median folic acid concentration of 191 µg per 100g of bread (range 6.5 - 359 µg per 100 g).

Analytical testing commissioned by MPI in 2016, found the median folic acid concentration of 39 unique nationally available folic acid-fortified breads was 130 µg per 100 g (range 8 – 254 µg per 100 g). Seventeen unique bread products were also tested and the median folic acid concentration of flat breads, bagels, pizza bases and garlic breads, was 148 µg, 23 µg, 93 µg and 93 µg per 100 g, respectively. The MPI analytical survey captured different brands and utilised a different sampling plan to that of the 2016 BIRT audit (Watson, 2017); as such the results from the audit and survey are not directly comparable.

[17] For simplicity, the term folic acid has been used to collectively describe the level of total folate or folic acid declared in the NIP of a product. This may mean that the true level of folic acid could be overestimated in some products.

3 Consumer surveys

Key questions:

- What are consumer's attitudes towards folic acid fortification?
- What are consumer's behaviours towards foods with folic acid?
- What are consumer's understanding of folic acid and its benefits for women of childbearing age?

Data source:

- 2017 Consumer survey on folic acid fortification (MPI, 2017)
- 2011 Consumer survey on food fortification (FSANZ, 2013)
- 2010 Consumer survey on folate and folic acid (NZFSA, 2011)
- 2009 Qualitative consumer research on fortified foods (FSANZ, 2010)

Key findings:

Attitudes to fortification of bread with folic acid[18]

- Most adults support the 'optional' addition of folic acid to bread by manufacturers (56% in 2017; 54% in 2011) so that consumers can have choice and because they perceive the benefits are only for a small population. Women of childbearing age are particularly supportive (61% in 2017; 60% in 2011).
- Less than a quarter of adults (23%) support 'compulsory' addition of folic acid to bread in 2017, down from 29% in 2011 (19% for women of childbearing age in 2017 and 24% in 2011). Reasons given for such support were the benefit to babies and general health benefits for all.
- There was no significant difference in attitudes towards folic acid fortification in bread when different descriptors were used for folic acid in the 2017 survey (i.e. '*Folic acid, sometimes known as folate*' vs '*An essential B vitamin, folic acid (sometimes known as folate)*').

Behaviours towards foods with folic acid

- In 2017, 2-3% of adults said they actively avoid buying foods with folic acid (depending on how folic acid was described). The majority of adults (76-80%) stated that folic acid had no influence on their purchase behaviour.
- In 2017, 78% of women of childbearing age said they eat packaged, sliced bread. On average they reported consuming 1.9 slices per day.

Understanding of folic acid and its benefits for women of childbearing age

- From 2009 to 2011, women of childbearing age were generally aware of folate and folic acid and its association with pregnancy. Half of those surveyed in 2010 knew of the recommendation that folate/folic acid intake should be increased before becoming pregnant (NZFSA, 2011). There was, however, little understanding of folate and folic acid and their food sources.
- Half or less of surveyed women of childbearing age from 2009 to 2011 understood the specific intended benefits from consuming folic acid before and during pregnancy (FSANZ, 2010; 2013; NZFSA, 2011).

This section explores consumer's attitudes towards folic acid fortification, their behaviours towards foods fortified with folic acid and their understanding of folic acid and its benefits for women of childbearing age.

[18] Attitudes to 'optional' and 'compulsory' addition of folic acid to bread are reported as these terms were used in the wording of the consumer survey questions rather than voluntary and mandatory folic acid fortification.

This section draws from four consumer studies conducted from 2009 to 2017. These studies include all consumers but have a focus on women of childbearing age (aged 16-44 years)[19].

3.1 METHODS

In 2017, MPI commissioned an online quota survey of 2000 broadly representative New Zealand adults aged 16 years and over to test their attitudes and behaviours towards folic acid fortification (MPI, 2017). The cohort included oversampling of women of childbearing age to 1000 (50% of the sample) to ensure there was enough power to determine statistical significance. Corrective weighting to adjust for this boost was applied to the final sample.

To determine the impact of question-wording on answers, half of respondents in the survey were shown selected questions with the words *'folic acid, sometimes known as folate'* while the other half were shown the same questions but with the words *'an essential B vitamin, folic acid (sometimes known as folate)'*.

Food Standards Australia New Zealand's (FSANZ) 2011 telephone survey (FSANZ, 2013), which was based on the findings of its 2009 qualitative study (FSANZ, 2010) involved 800 Australian and 802 New Zealand randomly selected respondents aged 16 years and over, living in households with landline telephones. The purpose of the survey was to examine consumers' awareness, attitudes and behaviours towards food fortification, including folic acid fortification. For the New Zealand component, 36% of the respondents were men and 22% were women of childbearing age.

The above two surveys had the same target population and used the same attitudinal questions regarding voluntary and mandatory fortification. This facilitated comparisons, although unquantifiable differences may have resulted due to the latter survey using an online methodology (MPI, 2017) while the earlier study used a telephone methodology (FSANZ, 2013).

In 2010, the then NZFSA commissioned a survey to specifically consider the issue of folic acid (NZFSA, 2011). One thousand New Zealand women of childbearing age were interviewed by telephone using a pre-tested questionnaire. Certain ethnic groups were oversampled to ensure representative proportions were collected and the data was weighted by age and ethnicity so the results could be generalised to the New Zealand population.

The fourth relevant study involved qualitative research in Australia and New Zealand in 2009 (FSANZ, 2010). The purpose was to investigate consumer awareness, attitudes and behaviours towards fortified foods, including folic acid fortification. Four of the 10 focus group discussions, and half of the eight shopping trips were conducted with New Zealand adults. Both urban and rural locations and a range of age groups, family backgrounds and levels of interest in health issues were represented.

For both the 2011 and 2013 consumer awareness surveys (FSANZ, 2013; 2010), only New Zealand results have been included in this monitoring report.

Response rates for the three reported surveys varied from 11% to 49%, however differing methodologies in how response rates were calculated for each survey limits direct comparison.

[19] For the consumer survey's women of childbearing age were defined as those aged 16-44 years, whereas in the 2014/2015 New Zealand Health Survey (data on folate status) women of childbearing age were defined as those aged 15-49 years.

In this section, all reported differences are statistically significant at the 95% confidence level.

3.2 KEY RESULTS

Attitudes to fortification of bread with folic acid[20]

3.2.1.1 'Optional' folic acid fortification

In 2017 and 2011, after being informed of the intended health benefits of adding folic acid to bread, most respondents stated they supported manufacturers 'optionally' adding folic acid to bread (56% in 2017 (MPI, 2017); 54% in 2011 (FSANZ, 2013)). Women of childbearing age were particularly supportive of 'optionally' adding folic acid to bread (61% in 2017; 60% in 2011). Other groups more likely to support such an approach in the 2017 survey were women (of all ages), those with a polytechnic or wānanga[21] qualification, New Zealand Europeans, those who eat at least one slice of sliced multigrain bread (non-organic and contained gluten) a day and those who do not trust government decisions which make manufactures add certain vitamins or minerals to food (MPI, 2017).

There has been an increase in the proportion of adults who 'feel very strongly' that folic acid fortification should be 'optional', from 9% in 2011 to 14% in 2017 (MPI, 2017; FSANZ, 2013).

Reasons for supporting 'optional' fortification of bread with folic acid relate to providing consumers with choice (MPI, 2017; NZFSA, 2011; FSANZ, 2009) and the benefits only being for a small proportion of the population (MPI, 2017; FSANZ, 2009). Other reasons include increased food prices (MPI, 2017; FSANZ, 2009), concerns about consuming too much folic acid (even though the vitamin was viewed as being generally benign) (NZFSA, 2011; FSANZ, 2009) and the belief that folic acid is available as a supplement or from other sources (MPI, 2017).

3.2.1.2 'Compulsory' folic acid fortification

In 2017, after being informed of the intended health benefits of adding folic acid to bread, less than a quarter of adults (23%) considered that fortification of bread with folic acid should be 'compulsory'(MPI, 2017), down from 29% in 2011 (FSANZ, 2013). For women of childbearing age 24% considered that fortification should be compulsory in 2011 compared to 19% in 2017. In the 2010 NZFSA survey where the question was worded differently[22], there were mixed views amongst women of childbearing age, with 30% agreeing with 'compulsory' folic acid fortification in bread, 25% disagreeing and 37% rating their view as 'neutral' (NZFSA, 2011).

Groups more likely to support 'compulsory' folic acid fortification in bread in the 2017 survey were fathers, parents, men, those aged 60 years and over, those with a university

[20] Attitudes to 'optional' and 'compulsory' addition of folic acid to bread are reported as these terms were used in the wording of the consumer survey questions rather than 'voluntary' and 'mandatory' folic acid fortification.

[21] Wānanga are recognised tertiary institutions, regarded as the peers of universities, polytechnics and colleges of education. Under the Education Act 1989, Wānanga are characterised by teaching and research that maintains, advances, and disseminates knowledge and develops intellectual independence, and assists the application of knowledge regarding ahuatanga Maori (Maori tradition) according to tikanga Maori (Maori custom).

[22] In the NZFSA study, respondents were provided with the statement 'All bread products should have folic acid added' and asked to agree or disagree on a scale of – to 10 where 0=strongly disagree and 10=strongly agree. Results are presented here where 6-10 is 'agree' and 1-4 is 'disagree'. For both the 2017 MPI survey and the 2011 FSANZ survey, respondents were told 'Folic acid, sometimes known as folate can be added to bread. The reasons bread would have folic acid added to it is to reduce the risk of babies being born with neural tube defects like spina bifida. Knowing this, would you say…'. The options to choose from were 'It should be compulsory for manufacturers to add folic acid to **all** bread', 'It should be optional for manufacturers to add folic acid to bread', 'It's difficult to decide either way' and 'Or, you don't care either way'.

qualification and those who trust government decisions which make manufacturers add certain vitamins or minerals to food (MPI, 2017). FSANZ's survey in 2011, which had different segmentation analysis to the 2017 survey, found that for all Australian and New Zealand respondents, the following groups were more likely to support 'compulsory' folic acid fortification: men, adults over 45 years, non-main grocery buyers, those who considered there was too little regulation of immediate food risk, those who indicated that there was too little regulation of long term food risks and those who were aware of the intended benefit of folic acid fortification (FSANZ, 2013).

There has been a decrease in the proportion of adults who 'feel very strongly' about 'compulsory' folic acid fortification in bread, from 15% in 2011 to 9% in 2017 (MPI, 2017).

The key perceived benefits of adding folic acid to bread as described by those who supported 'compulsory' folic acid fortification in bread are that it is good for health in general (MPI, 2017; NZFSA, 2011) and reduces birth defects (MPI, 2017; NZFSA, 2011). Similar responses were found amongst all adults in a qualitative study in 2009 (FSANZ, 2010).

Descriptors for folic acid affected the perceived benefits of adding folic acid to bread. Those who were asked about 'folic acid' in the 2017 survey tended to emphasise the benefit to babies whereas those asked about 'an essential B vitamin, folic acid' tended to emphasise general health benefits for all, despite both sets of respondents being told that the intended benefit is to reduce NTDs in babies (MPI, 2017).

There was no significant difference in attitudes to folic acid fortification of bread when different descriptors for folic acid were used in the 2017 survey (i.e. *'Folic acid, sometimes known as folate'* vs *'An essential B vitamin, folic acid (sometimes known as folate)'*) (MPI, 2017).

3.2.1.3 Consumption of bread and folic acid tablets

In 2017, 78% of women of childbearing age stated that they ate non-organic packaged sliced bread containing wheat/gluten (MPI, 2017). These breads are permitted to contain folic acid and in 2014 the NZAB Private Label Partners' Code of Practice for Voluntary Folic Acid Fortification was introduced to encourage the fortification of these products (NZAB, 2014). Additionally 38% reported consuming non-organic, gluten/wheat pita/flat breads, sourdough/baguettes or similar bread types. These bread types are also permitted to contain folic acid, but there is no industry code of practice in place that specifically encourages voluntary fortification.

On average, women of childbearing age reported consuming 1.9 slices of non-organic packaged sliced bread containing wheat/gluten per day (MPI, 2017). This is lower than the reported average of 2.5 slices per day consumed by all adults (MPI, 2017). As a comparison, in 2010, consumption of two to three slices per day were reported by women of childbearing age (noting that the question wording in 2010 did not exclude organic, gluten-free sliced packaged breads, which are not currently fortified) (NZFSA, 2011). In a 2011 survey of 288 women of childbearing age (18-44 years) from Wellington and Dunedin, 93% reported consuming bread, at an average of 1.7 slices per day (Bradbury et al, 2011). Although not recent data, national nutrition surveys also suggest bread consumption is declining. According to Smith et al, females were less likely to report consuming bread ($P<0.001$) in the 2008/09 NZANS compared with the 1997 National Nutrition Survey (Smith, 2015). Pita/flat breads and sourdough/baguettes around 0.6 pieces were reported as eaten per day (MPI, 2017).

Qualitative and quantitative studies have found that the vast majority of women who have been pregnant said they took a supplement containing folic acid during their pregnancy (FSANZ, 2010; NZFSA, 2011). In NZFSA's survey, almost equal numbers indicated taking folic acid supplements before becoming pregnant (41%), compared to when they found out they were pregnant (38%) (NZFSA, 2011). Outside of pregnancy, it appears little thought is given to folate or folic acid intake, with women of childbearing age neither choosing nor avoiding products based on the folate/folic acid content (NZFSA, 2011).

In 2017, 2-3% of adults (depending on how folic acid was described) said they actively avoid buying food containing folic acid. In NZFSA's 2010 study, only 1% of all women of childbearing age said they specifically avoided certain products because of the folic acid content (NZFSA, 2011). For the 2017 study, the majority (76-80%) stated that folic acid had no influence on their purchase behaviour as other factors were more important. Another 3%, who were asked about '*folic acid*' and 7%, who were asked about '*an essential B vitamin, folic acid*, said they currently buy products containing the nutrient. The remainder (14-15%) said that they were uncertain.

3.2.1.4 Awareness and understanding of 'folate' and 'folic acid' and the links to neural tube defects

Women who were or had been pregnant in FSANZ's qualitative study were generally aware of folate, although awareness was low amongst the general adult population (FSANZ, 2010). In NZFSA's survey the following year, just over two thirds of women of childbearing age, (68%) reported having heard of folate and nearly all of them (95%) said they had heard of folic acid (NZFSA, 2011). Over half of all surveyed women (54%) also mentioned, without being prompted, that folate and/or folic acid was needed before or during pregnancy. This increased to 72% when prompted.

Despite good awareness of folate/folic acid, two of three consumer studies demonstrated little understanding of folate/folic acid as a B vitamin or its specific link to NTDs (FSANZ, 2010; NZFSA, 2011). While some participants in FSANZ's qualitative study associated folic acid with spina bifida, others linked it to improving the production of breast-milk or to fertility (FSANZ, 2010). In NZFSA's survey, only 38% of all women of childbearing age linked folate/folic acid to babies' nerve development or to reducing the risk of NTDs (NZFSA, 2011). Most of them said they just assumed its benefit because it was recommended by doctors and other health providers.

FSANZ's 2011 study, however, found higher levels of understanding amongst women of childbearing age (FSANZ, 2013). When asked in an open-ended question what the intended benefits would be if all wheat bread (except for organic bread) had to have folic acid added to it, more than a half of them (54%) could give a specific and correct answer. This was higher than the 42% who responded specifically and correctly amongst all surveyed New Zealand adults.

Half the women of childbearing age in NZFSA's survey understood that it was recommended that pregnant women should increase the folate/folic acid intake before they become pregnant (NZFSA, 2011).

Finally, over a third of New Zealand adults (37%) in 2011, including women of childbearing age (38%) mistakenly thought that New Zealand bread had to be fortified with folic acid (FSANZ, 2013).

Knowledge of sources of folate and folic acid

NZFSA's 2010 survey of women of childbearing age found that three quarters of respondents believed pregnant women and/or women planning to conceive needed to make sure they were getting the right amount of folate or folic acid (NZFSA, 2011). While most of these respondents (88%) were aware that folic acid was available through supplements, nearly a third of them (30%) considered that pregnant women and/or those planning to conceive could get enough folate and folic acid through their diet alone (22% of the total respondents).

Understanding of foods that are naturally rich in folate was low amongst New Zealand adults in 2010 and 2011, including women of childbearing age (FSANZ, 2010; NZFSA, 2011). For example, a quarter of women of childbearing age could not identify a specific food source. Only a quarter of them (24%) specifically mentioned green vegetables as good natural sources of folate (NZFSA, 2011).

Similarly most women (39%) did not know, when unprompted, which types of food have folic acid added to them. Less than a third (30%) mentioned bread. Even fewer identified other products. Orange/fruit juice (19%), breakfast cereals (13%) and milk/dairy products (14%) were most commonly mentioned after bread (NZFSA, 2011).

3.3 SUMMARY

The key questions being addressed in this section are consumer's attitudes to folic acid fortification, consumer's behaviours towards foods with folic acid and consumer's understanding of folic acid and its benefits for women of childbearing age.

Two surveys with the same question, in 2011 and 2017, showed that New Zealand adult consumers mostly continue to support voluntary folic acid fortification of bread, with just over half of survey respondents expressing this view. The reasons continue to be the same, based around the belief that consumers should have a choice and the benefits are only for a small population.

Support for mandatory folic acid fortification of bread decreased by 6% between the two surveys, from 29% in 2011 to 23% in 2017. The key perceived benefits of adding folic acid to bread as described by those who supported 'compulsory' folic acid fortification in bread are that it is good for health in general and reduces birth defects. Few people (around 2-3% adults in 2017) actually avoid products containing folic acid.

The proportion of women of childbearing age who reported consuming packaged, sliced bread potentially fortified with folic acid in 2017 was 78%, with an average of 1.9 slices of bread eaten per day (MPI, 2017). Forty percent of women of childbearing age reported consuming other potentially fortified bread types (for example flat/pita breads, sourdoughs and baguettes) in 2017 at an average of 0.6 pieces per day (MPI, 2017).

4 Folate status

Key question:

- Has the folate status of women of childbearing age improved?

Data source: 2014/15 New Zealand Health Survey (NZHS), Ministry of Health (MoH, November 2017).

Key findings:

- In 2014/15 mean RBC folate concentrations for all women of childbearing age were 544 nmol/L. Sixteen percent of all women of childbearing age had an optimal RBC folate status for the prevention of NTDs of ≥748 nmol/L.
- Women aged 15-24 years had lower mean and median RBC folate levels, and a lower prevalence of optimal RBC folate for the prevention of NTDs than women aged 25-44 years. Asian women of childbearing age were less likely to have optimal RBC folate levels than non-Asian women.
- Mean serum and RBC folate concentrations were significantly lower in women living in more deprived areas, although this did not translate into higher rates of folate deficiency.
- Mean serum folate concentrations have improved slightly since the 2008/09 ANS, although the increase was not statistically significant for women of childbearing age.

This section draws on data from the 2014/15 NZHS to examine the folate status (serum and RBC folate) of women of childbearing age[23]. Comparisons in mean serum folate concentrations between the 2008/09 ANS and 2014/15 NZHS for the total population and women of childbearing age were also made.

4.1 BIOMEDICAL REFERENCE VALUES FOR ASSESSING FOLATE STATUS

Serum folate levels are an indicator of more recent dietary intake of folate, whereas RBC folate is a measure of longer term folate status due to the slower turn over in erythrocytes (which have a 120-day life span). Therefore, RBC folate can be considered the most useful indicator of long term folate status (WHO, 2015a; Chanarin, 1986).

The reference values used to assess folate status in the 2014/15 NZHS are summarised in Table 4-1 below.

[23] For the consumer survey's women of childbearing age were defined as those aged 16-44 years, whereas in the 2014/2015 New Zealand Health Survey (data on folate status) women of childbearing age were defined as those aged 15-49 years.

Table 4-1: Reference values for assessing folate status in the 2014/15 New Zealand Health Survey

Population	Folate status indicator	Sample	Cutoff
Total	Deficiency*	Serum folate	< 6.8 nmol/L[1]
Total	Deficiency*	RBC folate	< 227 nmol/L[1]
Women of childbearing age	Optimal for the prevention of NTDs	RBC folate	≥ 748 nmol/L[2,3]

Sources:

1. WHO 2015a
2. WHO 2015b
3. Crider et al, 2014

Notes:

*Deficiency based on macrocytic anaemia as a haematological indicator

Abbreviations:

RBC Red Blood Cell
NTD Neural Tube Defect

The reference values in the World Health Organization (WHO) guidelines for assessing folate status in populations (WHO, 2015a) and for assessing risk of NTDs in women of childbearing age (WHO, 2015b) are based on various analytical methods. The WHO cut-off for assessing optimal RBC folate for the prevention of NTD-affected pregnancies is ≥ 906 nmol/L (WHO, 2015b). This cut-off is based on the microbiological assay calibrated to folic acid, which is known to give substantially higher results than when the assay is calibrated to 5-MTHF.

The WHO guidelines state that reference values may need to be adjusted depending on the analytical method used, but they do not provide guidance on how to adjust these. Therefore advice on appropriate thresholds for assessing folate status in the 2014/15 NZHS was obtained from Christine Pfeiffer, from the Centers for Disease Control and Prevention (CDC) (Pfeiffer, 22 December 2016), as the international expert on folate measurement in population surveys.

The assay-adjusted cut-off for assessing optimal RBC folate in women of childbearing age in the 2014/15 NZHS was defined as ≥ 748 nmol/L. This cut-off was derived using the following equation (Crider et al 2014):

$$\textit{RBC, nmol/L (5-MTHF calibrator)} = \textit{RBC folate (folic acid calibrator)} \times 0.7876 + 34.2802.$$

For the total population, low serum folate was defined as <6.8 nmol/L and low RBC folate defined as < 227 nmol/L (WHO 2015a).

4.2 METHODS

The 2014/15 NZHS had a multi-stage, stratified, probability-proportional-to-size sampling design. The study was designed to yield an annual sample size of approximately 13 000 adults, and aimed to include a proportionately higher number of Māori, Pacific and Asian people to ensure sub-group analyses could be made. More detailed information on the methodology is provided in Appendix 1.

Just over half of the adult respondents were selected for the biomedical module. The probability of selection varied by ethnicity, age and sex; with all Māori and Pacific respondents selected, and between one third and one half of other respondents selected. A total of 1588 women (including 110 pregnant women) of childbearing age (aged 15-49 years)[24] provided blood and/or urine samples. Serum and RBC folate results are available for 1584 and 1567 women aged 15-49 years, respectively. Table 4-2 provides a breakdown of the sample sizes for women of childbearing age.

Table 4-2: Sample sizes for serum and red blood cell folate results by age group for women of childbearing age[1]

Age Group (years)	Sample Size	Serum Samples	RBC Samples
15-24	322	320	314
25-34	550	549	547
35-44	487	486	480
45-49	229	229	226
15-49	1588	1584	1567

Source:
2014/15 New Zealand Health Survey

Notes:
1. Includes pregnant women

Abbreviation:
RBC Red Blood Cell

Folate was measured in whole blood and serum using the microbiological assay calibrated to 5-MTHF, as per the CDC laboratory procedure manual for the US National Health and Nutrition Examination Survey (NHANES) 2009-2010 (CDC, 2009-2010). 5-MTHF is considered a more appropriate calibrator for the assay because it is the most common form of folate circulating in the blood.

RBC folate was calculated using the following equation (Senti and Pilch, 1985):

$$\textit{RBC folate} = \frac{\textit{whole blood folate - serum folate x (1-haematocrit)}}{\textit{haematocrit}}$$

Both means and medians are presented in the results. Generally, the means are higher than the median values because they can be skewed by those who have high folate intakes.

Significant differences in folate status by age group are based on non-overlapping 95% confidence intervals (CIs). Significant differences in folate status by ethnicity and deprivation are based on the 95% CI for adjusted mean ratios excluding 1.00 (noting that the adjusted mean ratios have not been shown in the results). Adjusted mean ratios were used as they control for other demographic factors that may influence (confound) the comparison, such as age and ethnicity. For comparisons in mean serum folate between the 2014/15 NZHS and 2008/09 ANS, significant differences are based on the 95% CI for the difference excluding 0 (MoH, 2015).

More detailed information on the methodology is provided in Appendix 1.

4.3 RESULTS

The folate status of women of childbearing age (15-49 years) is reported using both RBC folate (a measure of long term folate status) and serum folate (a measure of short term folate status).

[24] For the consumer survey women of childbearing age were defined as those aged 16-44 years, whereas in the 2014/2015 New Zealand Health Survey (data on folate status) women of childbearing age were defined as those aged 15-49 years.

Table 4-3 shows mean and median RBC folate concentrations, and the prevalence of optimal RBC folate among women of childbearing age.

Table 4-3: Red blood cell folate status in women of childbearing age[1], by age, ethnicity and index of deprivation, 2014/15[2]

	Mean (95% CI) (nmol/L)	Median (95% CI) (nmol/L)	% Optimal[3] (95% CI)
Women 15-49 years	544 (528-560)	496 (478-521)	16.2 (13.5-19.2)
Age group			
15-24	471 (448-495)	439 (418-478)	7.6 (4.8-11.9)
25-34	574 (543-604)	531 (490-562)	22.7 (17.6-28.7)
35-44	577 (534-620)	527 (492-569)	18.7 (12.7-26.8)
45-49	566 (525-608)	532 (472-582)	15.7 (10.1-23.7)
Ethnicity			
Māori	534 (510-558)	476 (455-506)	15.9 (12.2-20.5)
Pacific	513 (471-555)	471 (436-512)	11.1 (6.3-18.9)
Asian	512 (471-553)	477 (443-519)	9.6 (5.7-15.8)
NZEO	551 (530-572)	507 (474-536)	17.5 (13.9-21.7)
NZDep2013 quintile			
1 (least deprived)	599 (528-670)	531 (468-613)	23.4 (13.5-37.6)
2	546 (509-584)	507 (480-582)	14.8 (9.2-22.8)
3	558 (523-593)	516 (464-560)	17.4 (12.5-23.8)
4	512 (481-542)	474 (444-516)	12.7 (8.9-17.9)
5 (most deprived)	522 (494-550)	463 (439-499)	14.5 (11.1-18.6)

Source:
2014/15 New Zealand Health Survey (MoH, November 2017)

Notes:
1. Includes pregnant women
2. Provisional, unpublished results (MoH, November 2017)
3. Optimal defined as RBC folate ≥ 748 nmol/L

Abbreviations:

NZEO	New Zealand European and Other
NZDep2013	New Zealand Index of Deprivation

In 2014/15, mean RBC folate concentrations for all women of childbearing age were 544 nmol/L. Sixteen percent had an optimal RBC folate status for the prevention of an NTD-affected pregnancy of ≥748 nmol/L.

Women aged 15-24 years have lower mean and median RBC folate levels, and a lower prevalence of optimal RBC folate than women aged 25-44 years. After adjusting for age, Asian women were less likely to have an optimal RBC folate than non-Asian women. After adjusting for age and ethnicity, women living in the most deprived neighbourhoods had significantly lower mean RBC folate concentrations compared with women living in the least deprived neighbourhoods[25].

Table 4-4 shows the mean and median serum folate concentrations, and the prevalence of folate deficiency among women of childbearing age.

[25] Neighbourhood deprivation refers to the New Zealand Index of Deprivation (NZDep). NZDep 1 represents the 20% of areas with the lowest levels of deprivation and NZDep 5 represents the 20% of areas with the highest level of deprivation.

Table 4-4: Serum folate status in women among childbearing age[1], by ethnicity and index of deprivation, 2014/15[2]

	Mean (95% CI) (nmol/L)	Median (95% CI) (nmol/L)	% Deficient[3] (95% CI)
Women 15-49 years	19.6 (18.5-20.7)	15.8 (15.1-16.4)	6.7 (5.0-8.9)
Age group			
15-24	16.6 (15.4-17.9)	15.0 (13.0-15.9)	7.1 (4.4-11.3)
25-34	21.0 (19.3-22.8)	16.9 (15.6-19.2)	6.7 (3.9-11.3)
35-44	19.9 (17.5-22.3)	14.6 (14.0-16.9)	7.7 (4.3-13.3)
45-49	22.1 (19.1-25.2)	18.9 (16.0-21.9)	3.9 (1.3-8.7)
Ethnicity			
Māori	18.6 (16.9-20.2)	15.3 (14.2-16.4)	5.4 (3.6-8.1)
Pacific	18.1 (13.3-22.9)	14.0 (12.5-16.3)	4.9 (1.8-10.3)
Asian	21.6 (18.7-24.5)	16.0 (14.3-20.3)	3.8 (1.0-9.7)
NZEO	19.3 (18.0-20.6)	15.8 (15.2-17.2)	8.0 (5.6-11.3)
NZDep2013 quintile			
1 (least deprived)	21.5 (17.6-25.5)	18.4 (15.1-22.3)	5.1 (1.2-18.9)
2	19.3 (16.8-21.8)	15.5 (13.0-17.5)	6.1 (3.1-11.6)
3	20.7 (18.2-23.2)	17.6 (14.2-19.8)	6.0 (2.8-12.5)
4	18.2 (16.5-19.8)	15.6 (14.2-16.3)	8.8 (5.0-15.0)
5 (most deprived)	19.0 (16.8-21.3)	15.0 (13.4-15.9)	6.9 (4.4-10.6)

Source:
2014/15 New Zealand Health Survey (MoH, November 2017)

Notes:
1. Includes pregnant women
2. Provisional, unpublished results (MoH, November 2017)
3. Deficient defined as serum folate < 6.8 nmol/L (WHO 2015a)

Abbreviations:
NZEO New Zealand European and Other
NZDep2013 New Zealand Index of Deprivation

In 2014/15 mean serum folate concentrations were 19.6 nmol/L in all women of childbearing age. Approximately 7% of all women of childbearing age had low serum folate concentrations indicating deficiency (<6.8nmol/L).

Serum folate concentrations did not differ significantly by ethnicity, but they did vary by neighbourhood deprivation. After adjusting for age and ethnicity, women living in the most deprived neighbourhoods had significantly lower mean serum folate concentrations compared with women living in the least deprived neighbourhoods[26].

The prevalence of serum folate deficiency among women of childbearing age did not vary significantly by ethnicity or neighbourhood deprivation.

4.4 COMPARISONS WITH THE 2008/09 ADULT NUTRITION SURVEY

Monitoring biomarkers of nutritional status over time require stable analytical methods. While the microbiological assay was used to measure folate in both the 2008/09 ANS and 2014/15 NZHS, the calibrator used in the assay changed between surveys. The calibrator used in the 2008/09 survey was folic acid. The 5-MTHF is considered a more appropriate calibrator for the assay because it is the most common form of folate circulating in the blood. The change in calibrator means that results from the 2014/15 NZHS presented in this report cannot be

[26] Neighbourhood deprivation refers to the New Zealand Index of Deprivation (NZDep), NZDep 1 represents the 20% of areas with the lowest levels of deprivation and NZDep 5 represents the 20% of areas with the highest level of deprivation.

compared with published results from the 2008/09 ANS (University of Otago and MoH, 2011; Bradbury et al, 2013; 2016).

In 2016, a bridging study was carried out to see if the impact of the change in calibrator could be quantified and adjusted for. Based on expert advice (Pfeiffer, 24 February 2016), folate was measured in 105 randomly selected serum samples from the 2008/09 ANS using the analytical method used in the 2014/15 NZHS.

There was a strong (linear) correlation between the new and old serum folate results, however a high correlation does not indicate there is good agreement between the two methods. Further analysis showed that there was some concentration dependent bias, with the differences between the new and old methods positive at lower values and negative at higher values. This concentration dependent bias meant that it was not possible to derive an equation to adjust results at an individual level. However, it was possible to compare mean serum folate results for the total population and women of childbearing age. Results from this comparison are shown in Table 4-5.

Table 4-5: Comparison of mean serum folate concentrations (nmol/L) in 2008/09 New Zealand Adult Nutrition Survey and 2014/15 New Zealand Health Survey

	2008/09 ANS (95% CI) (nmol/L)	2014/15 NZHS[1] (95% CI) (nmol/L)	Difference (95% CI) (nmol/L)
Total population (15+ years)	18.3 (27.9-30.1)	20.0 (19.3-20.7)	1.7 (0.0-3.4)
Women 15-49 years	17.1 (13.8-20.4)	19.1 (18.0-20.1)	2.0 (-1.4-3.4)

Source:
MoH, November 2017

Note:
1. Excludes pregnant women, since they were not included in 2008/09

Abbreviations:
ANS New Zealand Adult Nutrition Survey
NZHS New Zealand Health Survey

For the total adult population there was 1.7 nmol/L (9%) increase in serum folate concentrations between surveys, with this increase on the threshold of statistical significance. For women of childbearing age, there was a 2.0 nmol/L (12%) increase in serum folate, although this increase was not statistically significant.

4.5 SUMMARY

The key question being addressed in this section is whether the folate status of women of childbearing age has improved.

Red blood cell folate is the most useful indicator of long term folate status, whereas serum folate can indicate more recent dietary intake of folate (WHO, 2015a; Chanarin, 1986).

Most women of childbearing age do not have optimal blood folate concentrations for the prevention of NTD-affected pregnancies. Results from the 2014/15 NZHS show that mean RBC folate concentrations for all women of childbearing age were 544 nmol/L, with approximately 16% having an optimal RBC folate status of ≥748 nmol/L.

Women aged 15-24 years were found to have lower mean and median RBC folate concentrations, and a lower prevalence of optimal RBC folate than women aged 25-44 years. Asian women of childbearing age were also less likely to have an optimal RBC folate concentration than non-Asian women. After adjusting for age and sex, women living in the most deprived neighbourhoods had significantly lower mean RBC folate concentrations compared with women living in the least deprived neighbourhoods [27]

The 2014/15 NZHS results show that mean serum folate concentrations were 19.6 nmol/L in all women of childbearing age, with approximately 7% of all women of childbearing age identified as having folate deficiency (<6.8 nmol/L).

After adjusting for age and sex, women living in the most deprived neighbourhoods had significantly lower mean serum folate concentrations compared with women living in the least deprived neighbourhoods.

In comparing the results between the 2008/09 ANS and the 2014/15 NZHS, there was a small, but not statistically significant, increase (2.0 nmol/L) in mean serum folate for women aged 15-49 years.

It is important to note that the RBC and serum folate status results presented from the 2014/15 NZHS may not reflect the recent introduction of fortification initiatives, including the voluntary fortification of bread with folic acid introduced in 2012 and the NZAB and Private Label Partners' Code of Practice introduced in 2014. This is because both initiatives are voluntary and the Code of Practice, in particular, was introduced in the same year as the 2014/15 NZHS was implemented. It is likely that future monitoring of folate status across the New Zealand population will provide a clearer picture of the impact of these voluntary fortification initiatives.

[27] Neighbourhood deprivation refers to the New Zealand Index of Deprivation (NZDep), NZDep 1 represents the 20% of areas with the lowest levels of deprivation and NZDep 5 represents the 20% of areas with the highest level of deprivation.

5 Health benefits

Key question:

- Has the prevalence of NTDs decreased?

Data source: New Zealand Birth Defects Registry (NZBDR)

Key findings:

- There has been a statistically significant decline in the live birth prevalence of NTDs from 2000 to 2015, and birth prevalence of NTDs (including live and still births) from 2000 to 2013.
- In 2015 there were 21 live NTD-affected births at a live birth prevalence of 3.44, compared to 2000 where there were 41 live NTD-affected births at a live birth prevalence of 7.24.
- The majority of all NTD-affected live and still births across 2000 to 2016 were spina bifida cases.
- In 2013 there were 24 live and still NTD-affected births at a birth prevalence of 4.06, compared to 2000 where there were 49 live and still NTD-affected births at a birth prevalence of 8.60.
- Maori women have a statistically significant higher live birth prevalence of NTDs compared to NZEO (excludes Pacific Island ethnicity) using data pooled from 2000 to 2015.

5.1 NEURAL TUBE DEFECTS

The principal health benefit considered in this report is a reduction in the prevalence of NTDs. NTDs are a major group of birth defects where the brain, spinal cord, or the covering of these organs has not developed properly. Spina bifida and anencephaly are the most common types of NTDs[28].

5.2 METHODS

New Zealand Birth Defects Registry

The NZBDR is funded by the Ministry of Health and has been monitoring the occurrence of all birth defects (including NTDs) in New Zealand since 1977. Since the 1990s birth defect data have been collected from multiple sources and include live births, patients requiring treatment in a public hospital, fetal deaths[29] and all death records. Data on NTD-affected pregnancies which have resulted in a termination have been included in the database since 2008.

The NZBDR receives quarterly updates from the Ministry of Health records of livebirths with a diagnosed birth defect and admissions to a public hospital for birth defects. The NZBDR has been collecting data on terminations of pregnancy since 2008. Since 2011, the NZBDR has collaborated with the Ministry of Justice and the Abortion Supervisory Committee to implement a voluntary system for the notification of birth defects in terminations of pregnancy. The NZBDR is a passive surveillance system although the level of ascertainment, especially of the major birth defects, is as high as any other programme in the world (including those with any active ascertainment).

[28] This section reports on spina bifida, anencephaly and encephalocele
[29] Fetal deaths are the same as still births

Data on live births are currently available for the 1990s up to 2016, and for still births only up to 2013. Data on terminations are currently available from 2008 to 2015.

The NZBDR has a ‘rolling’ period of ascertainment. Therefore, if a person born in 2000 with no defect diagnosed but is admitted to hospital in 2007 and a defect reported, the case would retrospectively be included in the 2000 birth cohort.

Classification of neural tube defects

The classification of birth defects among live births and fetal deaths in the NZBDR is in accordance with definitions used by the International Clearinghouse for Birth Defects Surveillance and Research (WHO, 2014) and follows that of the International Classification of Diseases (ICD-9). The classification of birth defects among terminations of pregnancy uses the Perinatal Society of Australia and New Zealand’s perinatal death classification and neonatal classification.

The classification of NTDs includes the following types of birth defects:

- Anencephaly - total or partial absence of the upper part of the brain, the bones of the top of the skull, and the covering skin. There may be disorganisation or damage to the remaining brain tissue.
- Spina bifida - exposure of the spinal cord, nerves of the tissues that covers them through an opening in the skin and one or more of the backbones (the spinal column). The exposed nerves and spinal cord may be disorganised or damaged.
- Encephalocele - exposure of part of the brain or the tissues through an opening in the skin and skull bones.

Neural tube defects population measures

Three NTD population measures were used in this report. These include:

1. NTD rate - the number of NTD-affected pregnancies that resulted in a birth (live or still) or termination, divided by the population of total births (live birth and still births) in a specified time.
2. Birth prevalence of NTDs - the proportion of NTD-affected pregnancies that resulted in a birth (live or still)
3. Live birth prevalence of NTDs - the proportion of NTD-affected pregnancies that resulted in a live birth.

The three NTD population measures are calculated per 10 000 births using standard formulae presented in Figure 5-1 below. Cases refers to those diagnosed with a NTD. Denominator data on the number of total live births and still births were sourced from Statistics New Zealand (Statistics New Zealand, March 2017.).

Figure 5-1: Formulae for neural tube defect population measures[1]

$$\text{NTD rate} = \frac{\text{Live birth cases + still born cases + termination cases}}{\text{Total live births + still births}} \times 10\,000$$

$$\text{Birth prevalence of NTDs} = \frac{\text{Live birth cases + still born cases}}{\text{Total live births + still births}} \times 10\,000$$

$$\text{Live birth prevalence of NTDs} = \frac{\text{Live birth cases}}{\text{Total live births}} \times 10\,000$$

Source:

1. Total live and still birth data from (Statistics New Zealand, March 2017).

Abbreviation:

NTD Neural Tube Defect

Statistical analysis

Ninety-five percent confidence intervals using the Poisson method were calculated for all NTD population measures. Significant differences for live birth prevalence of pooled ethnicity data are based on non-overlapping 95% CIs. Significant differences for linear trends across birth prevalence of NTDs and live birth prevalence of NTDs for all women of childbearing age was determined using the Cochran-Armitage test (NZBDR, 2 November 2017).

5.3 RESULTS

Table 5-1 shows the live birth prevalence of NTDs, by NTD subtype, from 2000 to 2016. Spina bifida accounts for the majority of all NTD-affected live births across all years.

From 2000 to 2015[30] there has been a statistically significant decline in the live birth prevalence of NTDs for spina bifida and all NTDs. There was no statistically significant trend for anencephaly or encephalocele over this time. In 2015 there were 21 live NTD-affected births at a live birth prevalence of 3.44, compared to 2000 where there were 41 live NTD-affected births at a live birth prevalence of 7.24.

[30] Due to timing of data collection, the 2016 dataset for live births is not complete. Therefore statistical significance was assessed for the years 2000 to 2015.

Table 5-1: Total number of live birth cases and live birth prevalence of neural tube defects by subtype for 2000-2016

	Anencephaly		Spina bifida		Encephalocele		NTDs	
Year	No.	Prevalence (95%CI)[1]	No.	Prevalence (95%CI)[1]	No.	Prevalence (95%CI)[1]	No.	Prevalence (95%CI)[1]
2000	4	0.71 (0.19-1.81)	35	6.18 (4.31-8.6)	2	0.35 (0.04-1.28)	41	7.24 (5.00-9.83)
2001	0	0 (0-0.66)	23	4.12 (2.61-6.18)	3	0.54 (0.11-1.57)	26	4.66 (3.04-6.83)
2002	2	0.37 (0.04-1.34)	17	3.15 (1.83-5.04)	2	0.37 (0.04-1.34)	21	3.89 (2.41-5.94)
2003	1	0.18 (0-0.99)	22	3.92 (2.46-5.93)	2	0.36 (0.04-1.29)	25	4.45 (2.88-6.57)
2004	2	0.34 (0.04-1.24)	19	3.27 (1.97-5.11)	5	0.86 (0.28-2.01)	26	4.48 (2.92-6.56)
2005	0	0 (0-0.64)	23	3.98 (2.52-5.98)	5	0.87 (0.28-2.02)	28	4.85 (3.22-7.01)
2006	5	0.84 (0.27-1.97)	20	3.38 (2.06-5.22)	0	0 (0-0.62)	25	4.22 (2.73-6.23)
2007	1	0.16 (0-0.87)	22	3.44 (2.15-5.20)	5	0.78 (0.25-1.82)	28	4.37 (2.91-6.32)
2008	1	0.16 (0-0.87)	27	4.20 (2.77-6.11)	5	0.78 (0.25-1.81)	33	5.13 (3.53-7.20)
2009	3	0.48 (0.10-1.40)	11	1.76 (0.88-3.15)	2	0.32 (0.04-1.16)	16	2.56 (1.46-4.15)
2010	2	0.31 (0.04-1.13)	13	2.03 (1.08-3.48)	5	0.78 (0.25-1.83)	20	3.13 (1.91-4.83)
2011	4	0.65 (0.18-1.67)	22	3.58 (2.25-5.42)	4	0.65 (0.18-1.67)	30	4.89 (3.30-6.97)
2012	3	0.49 (0.10-1.43)	15	2.45 (1.37-4.04)	3	0.49 (0.10-1.43)	21	3.43 (2.12-5.25)
2013	1	0.17 (0-0.95)	14	2.38 (1.30-4.00)	3	0.51 (0.11-1.49)	18	3.07 (1.82-4.84)
2014	3	0.52 (0.11-1.53)	20	3.49 (2.13-5.40)	4	0.70 (0.19-1.79)	27	4.72 (3.11-6.86)
2015	2	0.33 (0.04-1.18)	14	2.29 (1.25-3.85)	5	0.82 (0.27-1.91)	21	3.44 (2.13-5.26)
2016[2]	0	0 (0-0.62)	9	1.51 (0.69-2.87)	2	0.34 (0.04-1.22)	11	1.85 (0.92-3.31)
2000-2016	34	0.34 (0.23-0.47)	326	3.22 (2.88-3.59)	57	0.56 (0.43-0.73)	417	4.12 (3.74-4.54)

Source:
NZBDR, August 2017

Notes:
1. Prevalence per 10 000 live births; 95% confidence interval
2. Due to timing of data collection, the 2016 dataset for live births is not complete

Abbreviation:
NTD Neutral Tube Defect

Table 5-2 shows the birth prevalence of NTDs (live and still births), by NTD subtype, from 2000 to 2013. At the time of writing this report, data on fetal and infant mortality was not available for 2014-2016, and therefore birth prevalence of NTDs could not be determined for this period. Spina bifida accounts for the majority of all NTD-affected live and stillbirths across all years. From 2000 to 2013 there has been a statistically significant decline in the birth prevalence of NTDs (live and still births) for spina bifida and all NTDs. There was no statistically significant trend for anencephaly or encephalocele over this time. In 2013 there were 24 live and still NTD-affected births at a birth prevalence of 4.06, compared to 2000 where there were 49 live and still NTD-affected births at a birth prevalence of 8.60.

Table 5-2: Total number of birth cases and birth prevalence of neural tube defects by subtype for 2000-2013[1]

	Anencephaly		Spina bifida		Encephalocele		NTDs	
Year	No.	Prevalence (95%CI)[2]	No.	Prevalence (95%CI)[2]	No.	Prevalence (95%CI)[2]	No.	Prevalence (95%CI)[2]
2000	10	1.76 (0.84-3.23)	37	6.50 (4.57-8.95)	2	0.35 (0.04-1.27)	49	8.60 (6.37-11.37)
2001	6	1.07 (0.39-2.33)	24	4.28 (2.74-6.36)	3	0.53 (0.11-1.56)	33	5.88 (4.05-8.26)
2002	7	1.29 (0.52-2.65)	21	3.86 (2.39-5.90)	2	0.37 (0.04-1.33)	30	5.52 (3.72-7.88)
2003	9	1.59 (0.73-3.02)	27	4.78 (3.15-6.96)	2	0.35 (0.04-1.28)	38	6.73 (4.76-9.23)
2004	12	2.05 (1.06-3.58)	29	4.95 (3.32-7.11)	6	1.02 (0.38-2.23)	47	8.03 (5.90-10.67)
2005	7	1.20 (0.48-2.48)	34	5.85 (4.05-8.18)	5	0.86 (0.28-2.01)	46	7.92 (5.80-10.56)
2006	12	2.01 (1.04-3.52)	29	4.87 (3.26-6.99)	1	0.17 (0-0.94)	42	7.05 (5.08-9.53)
2007	8	1.24 (0.54-2.44)	30	4.65 (3.14-6.64)	7	1.09 (0.44-2.24)	45	6.98 (5.09-9.33)
2008	9	1.39 (0.63-2.63)	31	4.78 (3.25-6.79)	6	0.93 (0.34-2.01)	46	7.09 (5.19-9.46)
2009	10	1.59 (0.76-2.92)	12	1.91 (0.99-3.33)	4	0.64 (0.17-1.63)	26	4.13 (2.70-6.05)
2010	7	1.09 (0.44-2.24)	17	2.64 (1.54-4.23)	6	0.93 (0.34-2.03)	30	4.66 (3.15-6.66)
2011	11	1.78 (0.89-3.18)	31	5.01 (3.41-7.12)	5	0.81 (0.26-1.89)	47	7.60 (5.59-10.11)
2012	7	1.14 (0.46-2.34)	19	3.09 (1.86-4.82)	3	0.49 (0.0-1.42)	29	4.71 (3.15-6.76)
2013	4	0.68 (0.18-1.73)	16	2.71 (1.55-4.40)	4	0.68 (0.18-1.73)	24	4.06 (2.60-6.05)
2000-2013	119	1.42 (1.17-1.70)	357	4.25 (3.82-4.72)	56	0.67 (0.50-0.87)	532	6.34 (5.81-6.90)

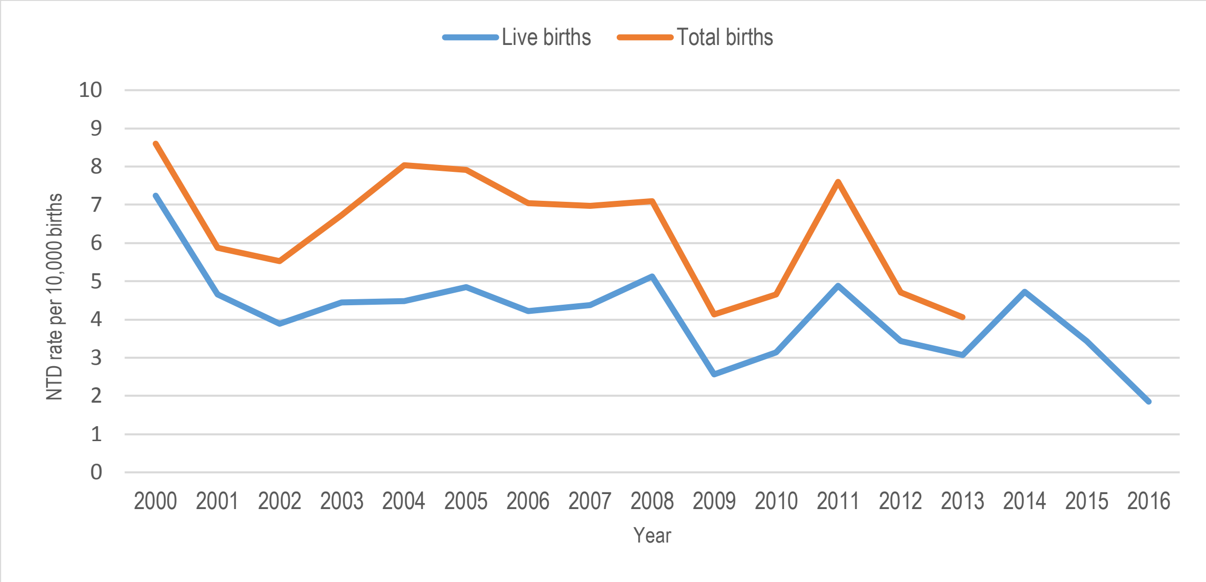
Source:
NZBDR, August 2017

Notes:
1. 2014, 2015 and 2016 fetal and infant mortality data was not available at the time of reporting
2. Prevalence per 10 000 total births (live births and still births); 95% confidence interval

Abbreviation:
NTD Neutral Tube Defect

Figure 5-2 shows trends in live birth prevalence of NTD's from 2000 to 2016 and birth prevalence of NTD's (live and still births) from 2000 to 2013. Prevalence fluctuate from year to year, but as described previously there has been an overall statistically significant decline in NTD prevalence over this period.

Figure 5-2: Live birth and birth prevalence[1] of neural tube defects for 2000 - 2016[2,3]



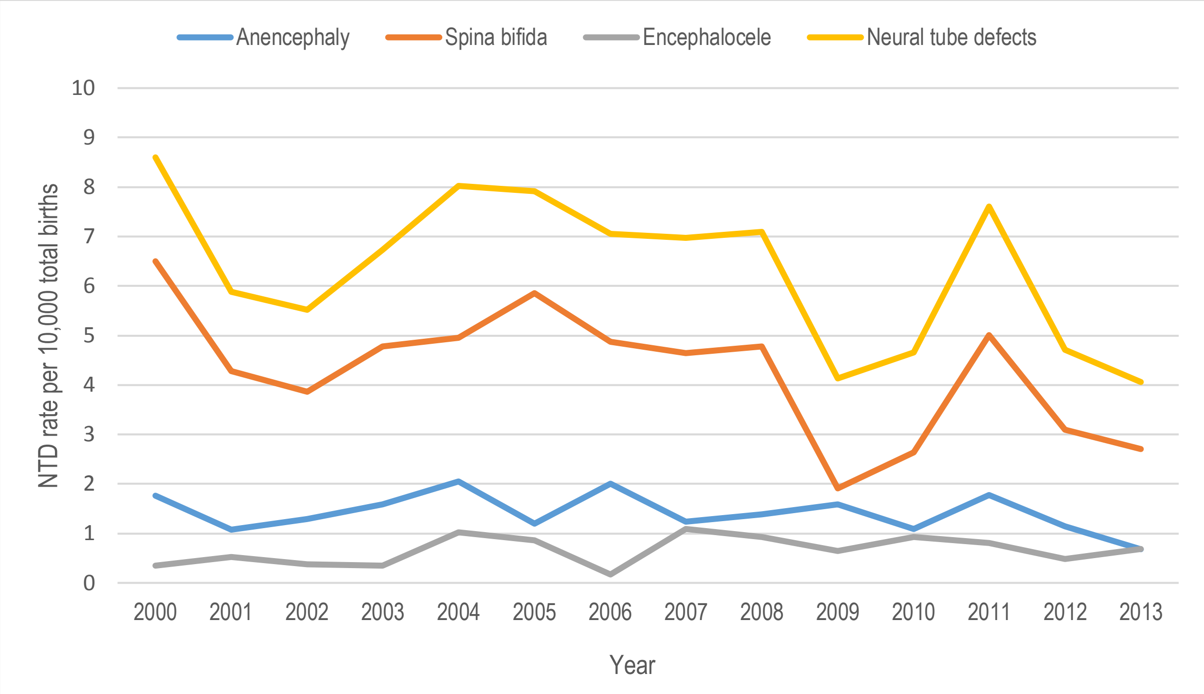
Source:
NZBDR, August 2017.

Notes:
1. Birth prevalence includes live and still births
2. 2014, 2015 and 2016 fetal and infant mortality data was not available at the time of reporting
3. Due to timing of data collection, the 2016 dataset for live births is not complete

Abbreviation:
NTD Neural Tube Defect

Figure 5-3 shows that there was a decline in spina bifida birth prevalence (and overall NTD rates) from 2000 to 2013. There was little change in the prevalence of anecephaly and encephalocele prevalence during the same period.

Figure 5-3: Birth prevalence[1] of neural tube defects by subtype for 2000 – 2013[2]



Source:
NZBDR, August 2017

Notes:
1. Birth prevalence includes live and still births
2. 2014,2015 and 2016 fetal and infant mortality data was not available at the time of reporting

Abbreviation:
NTD Neural Tube Defect

Table 5-3 shows the total number of NTD-affected live births, still births and terminations of pregnancy and the NTD rate from 2008 to 2013. Terminations of pregnancy accounted for almost half of all NTDs during this period. Data on stillbirths were not available at the time of reporting for 2014 and 2015, therefore the NTD rate could not be calculated for these years.

Table 5-3: Total number of live birth, still birth and termination cases, and neural tube defect rate in New Zealand from 2008 to 2013[1]

Year	No.	Rate (95%CI)
2008	84	12.95 (10.33-16.04)[2]
2009	54	8.58 (6.45-11.20)[2]
2010	57	8.86 (6.71-11.48)[2]
2011	78	12.62 (9.97-15.75)[2]
2012	57	9.26 (7.01-11.99)[2]
2013	51	8.64 (6.43-11.63)[2]
2008-2013	381	10.17 (9.18-11.25)

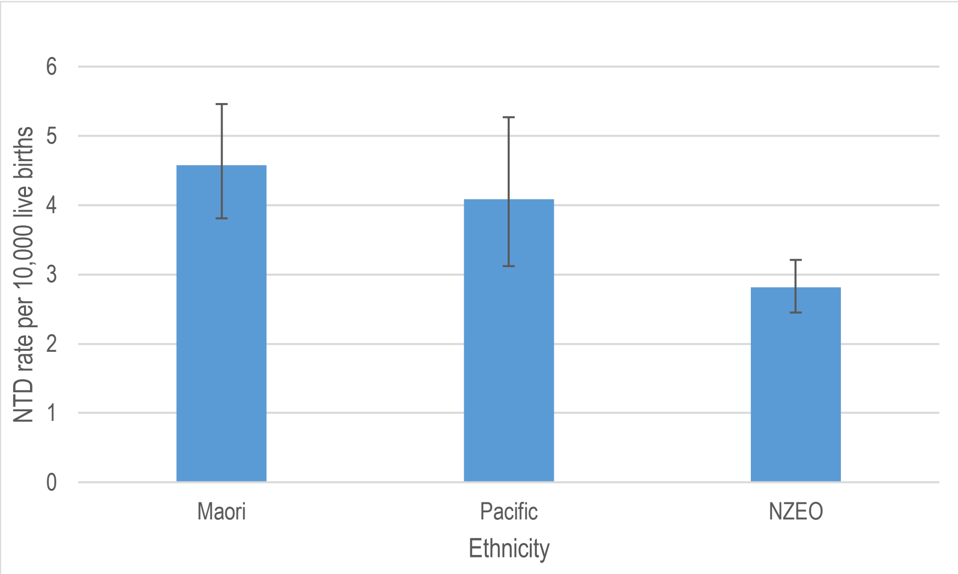
Sources:
NZBDR, August 2017
Terminations of pregnancy data from the Perinatal and Maternal Mortality Review Committee, 2017

Notes:
1. 2014 and 2015 stillbirth data were not available at the time of reporting, therefore the NTD prevalence rate could not be calculated for 2014 and 2015.

2. Rate per 10 000 total births (live births and still births); 95% confidence interval

To examine live birth prevalence of NTDs by ethnic group, data were pooled across all years. Figure 5-4 shows that overall from 2000 to 2015 the live birth prevalence of NTDs were significantly higher in Maori women (4.58) than in women of NZEO ethnicity (excludes Pacific Island ethnicity) (2.81). Pacific women also appear to have higher live birth prevalence of NTDs over this time (4.09) compared to NZEO (excludes Maori ethnicity) women (2.81), however this difference was not statistically significant.

Figure 5-4: Live birth prevalence of neural tube defects by ethnic group for 2000 – 2015[1] combined



Source:
NZBDR, August 2017

Note:
1. Due to timing of data collection, the 2016 dataset for live births is not complete

Abbreviations:
NZEO New Zealand European and Other (excludes Maori and Pacific Island ethnicities)
NTD Neural Tube Defect

5.4 SUMMARY

The key question being addressed in this section is whether the prevalence of NTDs has decreased.

There has been a statistically significant decline in live birth prevalence of spina bifida and all NTDs combined from 2000 to 2015. Further, there has been statistically significant decline in the birth prevalence (which includes live and still births) of spina bifida and all NTDs combined from 2000 to 2013.

In 2015 there were 21 live NTD-affected births at a live birth prevalence of 3.44, compared to 2000 where there were 41 live NTD-affected births at a live birth prevalence of 7.24. Spina bifida accounted for the majority of all NTD-affected live birth cases across all years. Maori women have a significantly higher live birth prevalence of NTDs compared to NZEO (excludes Pacific Island ethnicity) using data pooled from 2000 to 2015.

In 2013 there were 24 live and still NTD-affected births at a birth prevalence of 4.06, compared to 2000 where there were 49 live and still NTD-affected births at a birth prevalence of 8.60. The majority of all NTD-affected live and stillbirths across 2000 to 2013 were spina bifida cases.

Although there has been an overall decline in live birth prevalence and birth prevalence of spina bifida and all NTDs since 2000, due to the lag in reporting of birth defect data to the NZBDR, and consequent reporting here, the results presented are unlikely to reflect the recent introduction of fortification initiatives (including the voluntary fortification of bread with folic acid introduced in 2012 and the NZAB and Private Label Partners' Code of Practice introduced in 2014). This is because the NZAB and Private Label Partners' Code of Practice, in particular, was introduced in 2014, and the full set of live birth data, still birth data and terminations of pregnancy, as provided by the NZBDR, were only available for 2015, 2013 and 2015 respectively. Future monitoring of NTD-affected pregnancies in New Zealand women will provide a clearer picture of the impact of these voluntary fortification initiatives.

6 Overall summary and conclusion

Folic acid is currently permitted to be added voluntarily to a range of foods for sale in New Zealand regulated under New Zealand and trans-Tasman Food Standards. The most recent changes include the introduction of a New Zealand Food Standard in 2012 (MPI, 2012a) permitting the voluntary fortification of bread, and the introduction the NZAB and Private Label Partners' Code of Practice for Voluntary Fortification of Bread in 2014 (NZAB, 2014).The number of products available for sale fortified with folic acid has increased since data collection commenced in 2013. In 2017, the breakfast cereals category had the highest number of fortified products (34%), followed by bread (10%) and breakfast beverages (8%).

Overall, it is apparent that the introduction of the 2012 New Zealand Food Standard permitting the voluntary fortification of bread (MPI, 2012a) and the introduction of the NZAB and Private Label Partners' Code of Practice (NZAB, 2014) has had a positive impact on the number of breads that are fortified with folic acid. In 2016, 38% of NZAB packaged sliced breads were fortified with folic acid, up from 32% in 2015 and 14% in 2012 (Watson, 2017). A label survey also confirms that the number of breads fortified with folic acid has increased over time from 69 in 2013 to 104 in 2017. Analytical testing, commissioned by MPI in 2016, found the median folic acid concentration of all nationally available folic acid fortified breads to be 130 µg per 100 g. The 2016 BIRT audit found the median concentration of folic acid fortified bread marketed and distributed by NZAB members was 191 µg per 100 g (Watson, 2017). The MPI analytical survey utilised a different methodology and included different samples to that of the BIRT audit (Watson, 2017) and as such the results from the audit and survey are not directly comparable.

New Zealand adult consumers mostly continue to support voluntary fortification of bread and support for mandatory folic acid fortification has decreased (MPI, 2017; NZFSA, 2011). Support for voluntary fortification is greater amongst women of childbearing age[31] than the general population.

It is evident that most women of childbearing age[31] do not have optimal blood folate status for the prevention of NTD-affected pregnancies (MoH, November 2017). Data from the 2014/15 NZHS shows that only 16% of all women of childbearing age have an optimal RBC folate level for the prevention of NTDs at ≥748 nmol/L (MoH, November 2017).

Data from the NZBDR show that there has been a statistically significant decline in live birth prevalence of spina bifida and all NTDs combined from 2000 to 2015. Further, there has been a statistically significant decline in birth prevalence (including live and still births) of spina bifida and all NTDs combined from 2000 to 2013.

Although there has been an overall decline in live birth prevalence and birth prevalence of spina bifida and all NTDs since 2000, it is unknown whether the recent voluntary fortification initiatives, and subsequent increase in the number of breads containing folic acid, has contributed to the recent trend. This is because of the limited timeframe since the introduction of the 2012 New Zealand Food Standard, the gradual uptake of the 2014 NZAB Code of Practice and the lack in availability of up-to-date NTD data[32] as provided by the NZBDR.

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[31] For the consumer survey women of childbearing age were defined as those aged 16-44 years, whereas in the 2014/2015 New Zealand Health Survey (data on folate status) women of childbearing age were defined as those aged 15-49 years.
[32] The full set of live birth NTD data, still birth NTD data and terminations of NTD- affected pregnancies, as provided by the NZBDR, were only available for 2015, 2013 and 2015 respectively

Similarly, because the NZAB Code of Practice was introduced in the same year as the 2014/15 NZHS was implemented, the impact of this fortification initiative may not be reflected in the most up to date folate status results presented in this report.

Ongoing monitoring of the levels of folic acid in bread and the wider food supply, the folate status of women of childbearing age and the number of NTD cases and prevalence in New Zealand will be essential in determining the impact on New Zealand bread consumers, especially women of childbearing age, following voluntary fortification of bread with folic acid. In addition to this, up to date data on New Zealander's dietary intake of folic acid and folic acid supplement use should be included in any future monitoring reports in order to provide a more comprehensive picture of the sources of folic acid.

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8 Appendix 1- New Zealand Health Survey methodology

The New Zealand Health Survey is a population-based health survey commissioned by the New Zealand Ministry of Health. Since July 2011 the survey has operated continuously and includes a core set of questions and measurements that are repeated every year and a series of modules that change each year.

The core component of the survey covers health status, long-term conditions, health behaviours and risk factors, health service utilisation and socio-demographics. The rotating modules collect more detailed information on these and other topics. In the 2014/15 survey, a biomedical module (blood and urine tests) was included for adults.

A brief overview of the survey methodology is provided below. A detailed description of the 2014/15 NZHS methodology is published elsewhere (MoH, 2015).

8.1 SAMPLING

The target population for the survey is the New Zealand usually resident population of all ages including those living in non-private accommodation. Approximately 98% of the New Zealand resident population of all ages are eligible to participate in the survey. The survey includes people living in aged-care facilities (rest homes) and those temporarily living away from their household in student accommodation (university hostels and boarding schools), but for practical reasons excludes people living in other types of non-private dwellings (prisons, hospitals, hospices, dementia care units and hospital-level care in aged-care facilities) and households in remote areas.

The survey has a multi-stage sampling design that involves randomly selecting a sample of small geographic areas, households within the selected areas, and individuals within the selected households. The design yields an annual sample size of approximately 13 000 adults (aged 15+ years) and 4500 children (aged 0-14 years). The survey aims to include a proportionately higher number of Māori, Pacific and Asian people to provide sufficient sample sizes for sub-group analyses. One adult and one child (if any in the household) were chosen at random from each selected household to take part in the survey.

Of those invited to participate in the 2014/15 survey, 79% of selected adults (n=13,497) agreed to be interviewed. The 2014/15 results refer to the sample selected from 1 July 2014 to 30 June 2015, with data collection completed by the end of July 2015.

8.2 DATA COLLECTION

The survey is voluntary and households selected were invited to participate through an invitation letter from the Ministry of Health mailed to their address with an information pamphlet. Interviewers took copies of the information pamphlet in 11 languages when they subsequently visited households to seek agreement to participate in the survey (MoH, 2015). Respondents were able to elect a friend or family member to act as an interpreter during the survey, or for a professional interpreter to be present. Where possible, attempts were made to match respondents and interviewers by ethnicity and sex when requested.

Professional social research surveyors conducted interviews and measurements for the survey in participants' homes, with the surveyor entering responses directly into a laptop computer.

8.3 BIOMEDICAL MODULE

The biomedical module was conducted in a sub-sample of survey respondents, with a target sample size of 5000 adults. A little over half (55%) of the 13 497 adult respondents in the 2014/15 survey were selected for the biomedical module. The probability of selection varied by ethnicity, age and sex; with all Māori and Pacific respondents as well as all pregnant women selected[33], and between one third and one half of other respondents selected.

Respondents selected for the biomedical module were provided with an information sheet and had the opportunity to ask the interviewer questions before signing the biomedical consent form. The majority (92%) of respondents selected for the biomedical module consented to take part. Consenting respondents were given a sample collection kit (containing tubes and instructions) and asked to attend their local medical laboratory to provide blood and urine samples.

A total of 5027 adults provided blood and/or urine samples. This represents 73% of those who consented to take part in the biomedical module, or 67% of those who were invited to take part. Respondents who provided samples were sent their test results and a 50 dollar gift (koha).

Blood and urine samples were collected by local medical laboratories and sent to Canterbury Health Laboratories in Christchurch for processing and storage at -70^{o}C. Frozen serum and whole blood samples were packaged in dry ice and sent in batches to the University of Otago in Dunedin where they were stored at -70^{o}C until they were analysed for folate and a range of other analytes.

8.4 ANALYTICAL METHOD FOR MEASURING FOLATE IN 2014/15

Folate status can be assessed using a variety of methods, including microbiological assays, protein-binding assays, and chromatography-based assays. The microbiological assay has long been considered the best method for assessing folate status (WHO, 2015a). The main advantages of the microbiological assay include its high sensitivity, need for only small volumes of sample, and relatively low cost to set up.

Serum and whole blood samples were analysed for folate at the University of Otago, Dunedin, in batches from December 2014 to November 2015. The analytical method used was the microbiological assay, based on the CDC laboratory procedure manual 2011-12 (CDC, 2009), adapted for use for the New Zealand population. The CDC protocol is calibrated to 5-MTHF, which is the main folate form found in human blood. In order to obtain accurate results using the microbiologic assay it is recommended to use the 5-MTHF calibrator. The microbiologic assay employed by the University of Otago for the 2014/15 survey was compared against target values from the CDC in a round robin comparison. Values produced by Otago were 13.8 ± 9% (mean ± SD) lower for serum folate compared with target values, and 4.2 ± 9.6% higher for whole blood folate. Preliminary findings of the round robin study showed that calibration did not account for microorganism differences in some laboratories, despite use of the same strain of microorganism. Results produced at Otago were similar to target values for whole blood folate regardless of calibrator or microorganism. For serum, the discrepancy in results with CDC target values was likely due to the microorganism.

[33] Asian respondents did not have a higher probability of being selected for the biomedical module, however, Asian people were proportionately higher in the original sample to allow for sub-group analysis.

RBC folate was calculated using the following equation (Senti and Pilch, 1985):

$$\textit{Red blood cell folate} = \frac{\underline{\textit{whole blood folate - serum folate x (1-haematocrit)}}}{\textit{haematocrit}}$$

8.5 SURVEY WEIGHTS

The 2014/15 survey uses the calibrated weighting method to construct survey weights that rate up the responding sample to represent the target population. This method takes into account the probability of selection of each respondent, and uses external population benchmarks (typically based on the most recent population census) to correct for any discrepancies between the sample and population benchmarks (by age, sex, ethnicity and the 2013 New Zealand Index of Deprivation (NZDep)).

Because the biomedical module was conducted in a sub-sample of adult respondents from the main survey, a separate weight for biomedical analysis was constructed for each respondent who participated in the biomedical module. The first step was to divide each respondent's main survey weight by their probability of being selected for the biomedical module. The second step calibrated the biomedical weights to minimise the impact of any differences in the characteristics of people who did or did not choose to participate in the biomedical module.

The calibration ensured that:

- the sum of the biomedical weights agreed with the same population figures used in the calibration of the final survey weights, by age, sex, ethnicity and the NZDep.
- key statistics generated from only the biomedical sample agreed with the same statistics generated from the full survey sample. These key statistics focused on health conditions, behaviours and measurements collected from all survey respondents that are likely to be related to biomedical test results.

8.6 DATA ANALYSIS

Survey weights were used in all analyses so that estimates of means, medians and prevalence's presented in this report can be said to be representative of the usually resident population (aged 15 + years) of New Zealand. Results are reported with 95% CI's.

Ethnicity was output to the following four ethnic groups: Māori, Pacific, Asian and NZEO. The 'total response standard output' was used to classify ethnicity, with participants counted in each of the ethnic groups they identified with.

Neighbourhood deprivation refers to the NZDep, which measures the level of socioeconomic deprivation for each neighbourhood according to a combination of New Zealand Census variables such as income, benefit receipt, household crowding, home ownership, employment status, and qualifications. NZDep 2013 was used for the 2014/15 New Zealand Health Survey. Results are presented for quintiles: quintile 1 represents the 20% of areas with the lowest levels of deprivation and quintile 5 represents the 20% of areas with the highest level of deprivation.

To compare results for different population groups, adjusted mean or prevalence ratios were calculated. The ratios are adjusted for other demographic factors that may influence (confound) the comparison, such as age, sex and ethnicity. Adjusted ratios were calculated for the following groups:

- men and women (adjusted for age)
- Māori and non-Māori (adjusted for age and sex)

- Pacific and non-Pacific (adjusted for age and sex)
- Asian and non-Asian (adjusted for age and sex)
- people living in the most and least deprived areas (adjusted for age, sex and ethnicity)

Adjusted ratios are not shown in the results, but comments about significant differences by sex, ethnicity and neighbourhood deprivation are based on the adjusted ratios.

Both mean and median folic acid concentrations are presented as measures of central tendency in the data sets. Means are higher than medians because serum and red blood cell folate distributions are skewed to the right. This skewness may be due to some respondents having very high folate intakes.

8.7 COMPARISONS WITH THE 2008/09 ADULT NUTRITION SURVEY

Monitoring biomarkers of disease over time requires stable analytical methods. The microbiological assay was used in both the 2008/09 Adult Nutrition Survey and the 2014/15 New Zealand Health Survey, but the calibrator used in the assay changed between surveys. In 2008/09 the calibrator was folic acid, whereas in 2014/15 it was 5-MTHF. 5-MTHF is the main folate form circulating in the blood and is therefore considered to be the more appropriate calibrator. However, calibration with 5-MTHF is known to give lower results than calibration with folic acid (Pfeiffer et al 2011). Therefore, results from the 2014/15 survey cannot be compared directly with previously published results from the 2008/09 survey (Ministry of Health 2011, Bradbury et al 2013; 2016).

In 2016, a small bridging study was undertaken to see if the change in calibrator could be quantified and adjusted for. Given that the old method was no longer available, the new method was used to analyse folate in stored serum samples from the 2008/09 survey. The 2008/09 samples had been stored at -70°C freezer with no freeze/thaw cycles and serum folate is known to be stable under these conditions (Pfeiffer, 4 August 2016).

Based on expert advice (Pfeiffer, 24 February 2016), folate was measured in 105 randomly selected serum samples from the 2008/09 survey using the analytical method used in the 2014/15 survey.

There was a strong (linear) correlation between the new and old serum folate results (r^2 =0.90). However, a strong correlation does not automatically imply there is good agreement between the two methods. Further analysis showed that there was some concentration dependent bias, with Bland-Altman plots showing that the differences between methods were positive at lower values and negative at higher values.

The concentration dependent bias meant that the overall agreement between assays was not considered good enough to derive a regression equation and adjust individual-level results from the 2008/09 survey. The agreement between assays was considered good enough to calculate assay-adjusted mean serum folate concentrations for the total population and women of childbearing age, provided that the uncertainty of these estimates was acknowledged.

Assayed-adjusted mean serum folate concentrations were calculated by recalibrating survey weights in the 2008/09 survey. This approach implicitly makes use of the strong relationship between new and old folate values and produces similar means to regression equations, but produces standard errors that better reflect the uncertainty of the new means due to reanalysing only 105 samples (3% of the original sample).

8.8 REFERENCES

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