Barriers and enablers to uptake of folic acid fortification of bread in New Zealand

An investigation into the alignment of manufacturer and consumer positions on the necessity, safety, and ethics of fortification

A research report conducted by Group C2 for the Public Health component of the fourth year MBChB program, Advanced Learning in Medicine

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Abstract

Objective: In this study we investigate barriers to and enablers of uptake of voluntary folic acid fortification of bread in New Zealand, by assessing the degree of alignment between manufacturer and consumer viewpoints, as well as how effectively current marketing informs consumers of which bread products are fortified.

Methods: The clarity of packaging of fortified breads with regard to folic acid content was systematically evaluated. Manufacturers' opinions on fortification, and understanding of public opinion, were assessed through study of position statements and publications, alongside an invitation for structured interview. A survey of bread consumers was conducted in supermarkets across the greater Wellington region, focussing on knowledge and opinions around folic acid fortification and the likely effect of increased fortification on purchasing habits.

Results: The clarity of bread packaging was found to be poor, likely representing a barrier to informed consumer choice. The main barrier for manufacturers was the various costs associated with fortification, especially due to predicted loss of sales. 54% of survey respondents were aware of some level of folic acid fortification of bread. Māori and Pacific Islanders, and younger women, were less aware than others. 80% of respondents either supported or had a neutral view of fortification. 10% of respondents were opposed to fortification and indicated that they would avoid fortified bread; this figure was independent of awareness of fortification, ethnicity, age and gender. Awareness of fortification was however associated with lower levels of uncertainty, higher levels of support for fortification, and increased likelihood of intent to purchase fortified bread, and is therefore an enabler of improved uptake. For those opposed, the predominant concern was around folic acid being an 'artificial' or 'processed' additive.

Conclusion: We suggest that mandatory fortification in New Zealand would avoid many of the barriers identified in this report. If folic acid fortification is to remain voluntary, initiatives to improve awareness and understanding of fortification may lead to better delivery to women of reproductive age, as well as increased public support for fortification and uptake of fortified bread. The latter may encourage manufacturers to strive to meet predefined targets of 25-50% fortification of bread by volume, as current industry research already overestimates the prevalence of opposition. Such initiatives should be coupled with improved bread labelling, which currently makes it difficult for consumers to make informed choices. To avoid inequalities, interventions should focus particularly on Māori/Pacific people, and young women.

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Finally we wish to acknowledge the individuals living with spina bifida and other neural tube defects throughout New Zealand, as well as their families. We hope that this report might form part of the ongoing effort to encourage the leaders of our nation to look beyond politics and profits, and take positive steps toward reducing the considerable burden of these diseases.

List of acronyms

ANS 08/09 - 2008/09 New Zealand Adult Nutrition Survey
BIANZ - Baking Industry Association of New Zealand
BIRT - Baking Industry Research Trust
CDC - Centers for Disease Control and Prevention (US)
FDA - Food and Drug Administration (US)
FGC - Food and Grocery Council (NZ)
FSANZ - Food Standards Australia and New Zealand
IUPAC - International Union of Pure and Applied Chemistry
MOH - Ministry of Health (NZ)
MPI - Ministry for Primary Industries (NZ)
NTD - Neural Tube Defect
NZ - New Zealand
NZAB - New Zealand Association of Bakers
NZFSA - New Zealand Food Safety Authority
TVNZ - Television New Zealand
UN - United Nations
US(A) - United States (of America)
WHO - World Health Organization

1. Introduction

Despite an international trend towards mandatory fortification of bread products with folic acid in an effort to reduce the prevalence of Neural Tube Defects (NTDs), fortification remains voluntary for bread manufacturers in New Zealand (NZ). As of 2015, only 14% of bread (by production volume) is fortified, indicating poor uptake of voluntary fortification by bread manufacturers (Ministry for Primary Industries, 2012a).

Public opposition to the idea of large-scale mandatory fortification exists in NZ, representing a barrier to achieving the goals of folic acid fortification. However, little is known about the nature of such opposition. Political discourse (Wilkinson & MPI, 2012; New Zealand Press Association, 2009) and media coverage (TVNZ, 2009; Fisher, 2009) have framed the debate around *ethics* (freedom of consumer choice, or opposition to "mass medication"), *necessity* (is the government and the baking industry responsible for ensuring pregnant women get sufficient folic acid?) and *safety* (concerns about adverse effects of dietary folic acid). However, it is not clear how well these line up with the actual viewpoints of bread consumers.

The prevalence of public opposition is also unclear. Existing research commissioned by bread manufacturers suggests that 32% of consumers would move away from fortified products, which would represent a significant loss of revenue to the industry (Wilkinson & MPI, 2012), however there have been no independent assessments of consumer opinion. Industry concerns over loss of revenue, however warranted, are likely to represent a significant barrier to increasing levels of fortification when participation in the scheme is voluntary.

This research aims to better understand the barriers to and enablers of uptake of voluntary fortification in NZ. Identifying and understanding *barriers* is clearly a prerequisite for developing solutions that avoid such barriers. In addition, identifying *enablers* to improved uptake of fortification should allow positive steps to be taken, by taking advantage of such enablers. The problem is likely to be multidimensional - there may be barriers and enablers on both the consumer and manufacturer sides. Future development of effective strategies for improving uptake of folic acid fortification will depend critically on understanding the balance of these factors. For this reason, we set out to answer the following research question:

> *What is the degree of alignment between manufacturer and public positions on the necessity, safety and ethics of folic acid fortification of bread in New Zealand?*

On the consumer side, we aimed to assess public awareness of fortification, identify the prevailing arguments for and against, and understand their effects on purchasing behaviour. Because our aim was to compare these views with the interests of bread manufacturers, we chose New Zealand bread consumers as our study population. Previous studies have focused on women planning a pregnancy, or more generally, women of reproductive age (Mallard & Houghton, 2012).

On the manufacturer side, we aimed to identify perceived barriers to increased fortification (particularly those around consumer behaviour), and compare these with actual data on consumer beliefs and behaviour. We also assessed how easy it is for consumers to make use of the current voluntary situation: specifically, if only 14% of bread produced is fortified, how clear is it to consumers which breads are fortified and which are not? Clear labelling is essential to allow consumers to make informed choices.

International evidence suggests that for NZ to reduce the considerable burden of NTDs, fortification must occur at much higher levels, or be made mandatory. Ultimately, the power to enforce such requirements lies only with central Government. However, before such a decision can be made, it is essential that manufacturer and consumer positions are properly understood, and any tensions or misunderstandings identified and resolved. We hope that this research might contribute to this important cause.

2. Background

Neural tube defects (NTDs) are a group of severe congenital abnormalities resulting from failure of the neural tube to close completely during the third or fourth week of pregnancy. The most common NTDs are spina bifida and anencephaly (Frey & Hauser, 2003). Spina bifida is a disabling, permanent condition requiring ongoing supportive care. Symptoms are both physical (lower limb deformity, weakness and paralysis, mobility problems, incontinence) and cognitive (reduced attention span and executive function, increased risk of learning disabilities).

Each year, NTDs affect around 300,000 births globally (CDC, 2013). In 2008, New Zealand had 64 NTD affected pregnancies, comprising 23 live births, 11 stillbirths and 30 terminations, at a rate of almost 1 per 1,000 total births (Ministry for Primary Industries, 2012a). NTD prevalence varies internationally, from as low as 0.5 to as high as 10 per 1000 total births (Greene & Copp, 2014). NTDs are a public health concern in NZ given their extremely high (and ongoing) emotional, physical, and financial burden on the individual and their family. The economic cost has been valued at around $5.5 million per case, with the majority of this burden attributed to the loss of life and disability associated with the disease (Access Economics Pty Limited, 2006).

The aetiology of NTDs is known to be multifactorial, with various genetic, metabolic and environmental risk factors identified over the past 40 years (Greene & Copp, 2014). The identification of low serum folate (vitamin B9) levels in mothers of NTD foetuses (Hibbard & Smithells, 1965; Smithells, Sheppard, & Schorah, 1976) led to interest in the role of folate in the aetiology, pathogenesis, and prevention of NTDs. Many studies have since shown that maternal folic acid[1] supplementation significantly reduces the risk of occurrence and recurrence of NTDs. While early studies investigated supplementation at 4mg/day (Laurence, James, Miller, Tennant, & Campbell, 1981; Wald, Sneddon, Densem, Frost, & Stone, 1991), further research indicated that a lower dose was effective (Czeizel & Dudás, 1992). Current evidence from interventional studies indicates that intake of 400µg/day can reduce NTD prevalence by 20-80% (Czeizel, Bánhidy, Dudás, & Paput, 2011).

In 1992, the Centres for Disease Control and Prevention (CDC) in the US recommended that all women of childbearing age should consume 400µg of folic acid per day to reduce the risk of NTDs (CDC, 1992). Many other nations followed, including New Zealand in 1993. The current recommendation in NZ is that women planning a pregnancy take 800 µg folic acid for four weeks prior to conception and for 12 weeks after conceiving, with a higher dose in women with a higher risk (for example, those with a history of an NTD-affected pregnancy) (Ministry of Health, 2003). Approximately 2% of NZ women are biochemically folate deficient (serum folate below 315nmol/L) (University of Otago & Ministry of Health, 2011). Despite this low prevalence, the threshold for reducing NTD risk is much higher, at 906nmol/L (Daly, Kirke, Molloy, Weir, & Scott, 1995). Therefore it is likely that many women who are not folate deficient are still at increased risk of an NTD-affected pregnancy.

Despite evidence for the efficacy of supplementation in interventional studies (Wald, et al., 1991; Czeizel & Dudás, 1992), observational studies conducted both internationally and in NZ show that government recommendations around peri-conceptual supplementation alone fail to improve consumption of folic

[1] By standard IUPAC convention, *folic acid* and *folate* strictly refer to the same molecule, the latter being the deprotonated conjugate base of the former. However, the food industry tends to reserve the term *folic acid* for the synthetic, high purity product used in supplements or for fortification. For this reason, legislation, media and public discussion tends to use the term *folic acid fortification*.

acid, or reduce the prevalence of NTDs (Botto, et al., 2005). Because NTDs occur early in gestation, supplementation must be started before becoming pregnant, however in a study of over 6000 postpartum women in NZ, only 39% took folic acid prior to conception (Morton, Grant, & Atatoa Carr, 2013). Moreover, policy that only targets women *planning* a pregnancy will have fundamentally limited efficacy, because around half of all pregnancies are unplanned (Oakley & Tulchinsky, 2010). Equality of access is also a concern: In NZ, Māori, Pacific Islanders, Asian and Latin American women, as well of those of low education, low socioeconomic status, younger age or increased parity, are less likely to achieve peri-conceptual supplementation (Morton, Grant, & Atatoa Carr, 2013). Widespread supplementation also requires behavioural change, which is costly and often ineffective (Oakley & Tulchinsky, 2010).

An alternative to supplementation is the fortification of the food supply with folic acid. Currently 82 countries worldwide have mandated folic acid fortification of at least one industrially milled cereal grain, primarily milled flour (Food Fortification Initiative, 2014). Since 1998, the US has implemented mandatory fortification of flour, at a level of 140µg folic acid per 100g. This alone provides 100-200µg of folic acid per day to women of childbearing age. Mandatory fortification in the US has proven effective at reducing NTD prevalence by 28% as of 2011, giving an annual saving of $508 million in lifetime costs of prevented cases of NTD (Williams et al., 2015). Canada, South Africa, Costa Rica, Chile, Argentina and Brazil have also reported declining NTD rates following mandatory fortification, with reductions ranging from 19 to 55% (Crider, Bailey, & Berry, 2011).

Voluntary fortification (on the part of manufacturers) of selected foods with folic acid has been permitted since 1996 in New Zealand. In 2007, after several years of planning, the Labour Government announced the *(Mandatory Fortification of Bread with Folic Acid) Food Standard 2007*, a joint program with Australia, mandating fortification of commercial breads (Ministry for Primary Industries, 2012a). However, in 2009, at the time this standard was due to take effect, newly voiced industry and consumer concerns following a change of Government led to significant media attention and public debate. In response, the then Minister for Food Safety Kate Wilkinson and the Ministry for Primary Industries (MPI) announced a delay until 2012, awaiting completion of an MPI review of the standard.

At completion of the review in 2012, The MPI called for submissions on whether NZ should enforce mandatory fortification. Of 134 submissions, 29 supporting mandatory fortification and 88 supporting continued voluntary fortification (MPI, 2012d). Despite the report finding that folic acid levels were inconsistent between bread products under the current voluntary scheme, and confirming previous evidence that uptake of per-conceptual supplements was limited (MPI, 2012a), the 2007 standard was replaced by the *New Zealand (Permitted Fortification of Bread with Folic Acid) Food Standard 2012* (MPI, 2012e), and fortification of bread with folic acid has remained voluntary in NZ ever since (Houghton, 2014).

Following the 2012 standard, the New Zealand Association of Bakers (NZAB; now known as BIANZ) set an end-2014 goal of fortifying a minimum of 25% and a maximum of 50% of all bread produced (Borman & Poynter, 2014; MPI, 2012a). As of 2013, only 14.4% of bread produced is fortified (Baking Industry Research Trust, 2014), and the deadline has been moved to 2015. A survey of consumers commissioned by the NZAB suggested that 32% of customers would move away from fortified products (Wilkinson & MPI, 2012), which, together with industry estimates of revenue loss of $500 million per 1% decline in sales per annum, is likely to discourage industry efforts to further increase fortification levels (Wilkinson & MPI, 2012).

Concerns over adverse effects of folic acid have included a role in the progression of colorectal cancer, and potential masking of B12 deficiency. Current evidence suggests that these concerns are not

warranted (Keum & Giovannucci, 2014). The MPI report concluded that folic acid has had no significant effect on overall cancer incidence (MPI, 2012b) and that doses the NZ population would receive as a result of mandatory fortification are well below the doses studied in meta-analyses of cancer risk, as well as being insufficient to mask B12 deficiency (MPI, 2012b; Vollset et al., 2013). Nevertheless, adverse effects of long term supplementation or fortification are unknown; there is a need for ongoing research, particularly in those at elevated risk for colorectal cancer (Choi, Yates, Veysey, Heo, & Lucock, 2014; Miller & Ulrich, 2013).

The average cumulative cost to the healthcare system for each child affected by an NTD, from birth to 21 years, is estimated at $944,000 (Bowkett & Deverall, 2012), due to the high number of hospital admissions and multiple surgeries required. This is much higher than a previous estimate of $355,000 from FSANZ (FSANZ, 2006). These costs continue to climb into adulthood, and when combined with the cost of loss of life, disability, and suffering, the total economic burden per NTD case is estimated at $4M (Bowkett & Deverall, 2012). The industry cost of mandatory fortification is estimated at $4 million annually with an additional $2 million annual contribution from government (FSANZ, 2006). These figures include set-up and maintenance costs. There would be an additional cost to the consumer of approximately 0.5 cents per loaf (MPI, 2012c). Modelling by the Ministry for Primary Industries suggests that voluntary fortification to the level of 30% could prevent 4 to 9 NTD cases per year, as opposed to the 1 to 2 cases prevented at current levels (Wilkinson & MPI, 2012). In contrast, mandatory fortification could prevent 14 to 20 cases each year (MPI, 2012c).

The debate over mandatory versus voluntary fortification is ongoing in NZ, with proponents of the former citing the potential prevention of 14-20 NTD cases per year, and healthcare costs saved (MPI, 2012c). Arguments for continued voluntary fortification include preservation of consumer choice; the varied costs to manufacturers associated with implementation a mandatory fortification scheme; risk of lost revenue if consumers avoid fortified products; unknown effects on health; or simply a belief that the prevalence of NTDs in NZ does not warrant a costly and demanding response (Wilkinson & MPI, 2012).

2.1. Ethical analysis

When considering a transition from voluntary to mandatory fortification of bread, key ethical issues must be considered. The United Nations' *Universal Declaration on Bioethics and Human Rights* (UNESCO, 2005) serves as a useful reference point. The major ethical issues are *social responsibility and justice*; *autonomy and informed consent*; *equity*; and *beneficence and non-maleficence*.

Social responsibility and justice: The healthcare system has a duty to facilitate better health outcomes for all, particularly the socio-economically disadvantaged (Fuller-Deets & Dingwall, 2007). Mandatory fortification presents a tension between mass-medicating the entire population so that a minority may benefit, and the consequences voluntary fortification and its associated lower fortification rates. Maintaining the current voluntary system may constitute withholding a treatment of known efficacy from at-risk groups.

Autonomy and informed consent: Individuals have the right to be autonomous and make conscious, informed decisions about their own healthcare. Mandatory fortification violates these principles because, by fortifying all breads, every bread consumer becomes a participant by default (Fuller-Deets & Dingwall, 2007). Informed consent will not be obtained from all bread consumers and there will be few non-fortified options for those who do not want fortified bread. Voluntary fortification allows consumers to maintain their autonomy and freedom of choice because they can choose between fortified and non-fortified breads.

Equity, improving inequalities: There is also the issue of equity and the possibility of exacerbating inequality by making participation harder for disadvantaged groups. For example, the implementation of voluntary fortification may not be as easily accessible to certain groups, such as bread consumers who can only afford to buy white bread. Multigrain and wholemeal breads are more likely to be fortified than white bread, which puts white bread consumers at a disadvantage because they cannot afford the more commonly fortified breads (Ministry for Primary Industries, 2012a).

Beneficence and non-maleficence: An important underlying ethical principle is beneficence and non-maleficence. The potential benefits of folic acid and also the potential harms must be considered. The outcome should ideally maximise the benefits whilst minimising the harms. One must consider the possibility that, without mandatory fortification, the healthcare system is failing to prevent an identified harm (Fuller-Deets & Dingwall, 2007). However, it is also important to consider the implications of medicating a large proportion of the population for whom it is not necessary.

3. Methods

In this section, methods are outlined for each of the four elements of this research: analysis of fortified bread packaging (Section 3.1), assessment of manufacturer viewpoints via interview and existing documents (Section 3.2), online screening for public opinion (Section 3.3), and the consumer survey (Section 3.4).

3.1. Analysis of packaging

A list of fortified breads available in NZ as of May 2014 was obtained from the Baking Industry Association of New Zealand website (BIANZ, 2014). Investigators visited supermarkets across the greater Wellington region to observe the breads. Packaging was assessed according to whether folic acid/folate/vitamin B9 was mentioned on the packaging, and if so, where (e.g. front-of-pack, ingredients list, nutritional information panel). Photographs were also taken to illustrate where folic acid was mentioned on the packaging, if at all.

Because we were only able to search supermarkets in the Wellington region, we were unable to observe loaves available only outside the region (for example, some bread varieties are only sold in the South Island). We sampled supermarkets from both Foodstuffs Ltd. and Progressive Enterprises Ltd., including New World, Pak' n Save, Four Square, and Countdown. Appendix 1 shows a complete list of fortified bread varieties available in NZ, including those available in the Wellington region, sorted by manufacturer and brand.

3.2. Manufacturer viewpoints

Manufacturers of bread in NZ were identified from the list of fortified breads (BIANZ, 2014). Brands of bread manufactured in NZ (both fortified and non-fortified) fell predominantly under two manufacturers: Goodman Fielder and George Weston Foods Limited. A literature review of existing publications, press releases, and position statements was conducted, and key manufacturer concerns around the issue of fortification were identified.

In an effort to expand on information gained from the above, Goodman Fielder and George Weston Foods Ltd., as well as Yarrows and Couplands (to expand the breadth of opinion), were contacted by email with a list of questions intended to reveal the viewpoints of bread manufacturers, identify perceived barriers to both uptake of fortification and delivery of bread to the target market, and understand the likely economic impact of fortification on the baking industry (the questions are shown in Appendix 2). The email also included a consent form, to be signed and returned with responses. Manufacturers were given the opportunity to respond via a structured phone interview, provided prior consent was given.

3.3. Online opinion screening

We sought public opinions on voluntary and mandatory fortification in New Zealand. Qualitative screening was performed, by searching for published research via Google Scholar, popular press articles (via the NZ Herald and Stuff.co.nz websites), as well as the comment sections of these websites, for public opinion. Relevant articles were identified by searching for the keywords *folic acid*, *folate*, *fortification*, *Neural Tube Defects*, *NTDs*, and *bread*. We then categorised the opinions expressed into 'for' or 'against' folic acid fortification and continued until no new themes were being discovered. At this point, data collected were distilled down to a handful of underlying themes, opinions, and concerns. The results can be found in Section 4.3. These results informed the choice of questions in the bread consumer survey (Section 3.4; Appendix 3).

3.4 Consumer survey

A standardised survey (Appendix 3) was administered by pairs of students to verbally consenting adult customers (those appearing 21 or over) in the bread aisles of supermarkets across the greater Wellington region. A total of 18 supermarkets were purposively selected to capture a range of geographical areas and socioeconomic deciles (as measured by NZ Deprivation Index (University of Otago, 2013). Supermarkets were also chosen in order to provide a balance between Foodstuffs Ltd. (New World and Pak'nSave) and Progressive Enterprises Ltd. (Countdown). Duty managers of supermarkets were contacted and asked for permission to conduct the survey. Fifteen supermarkets accepted and three declined. The locations of the 15 supermarkets are shown in Figure 1.

Investigators visited each supermarket in pairs, for around one hour, aiming to obtain approximately 30 respondents per supermarket. An effort was made to distribute survey gathering times across a variety of times of the day and days of the week, so that the data were not biased for or against particular subgroups (e.g. weekend shoppers, or those who shopped during office hours).

Survey data were recorded on paper forms (Appendix 3), and later entered into a Google Docs spreadsheet. Data were analysed, and figures were produced, all within Google Docs.

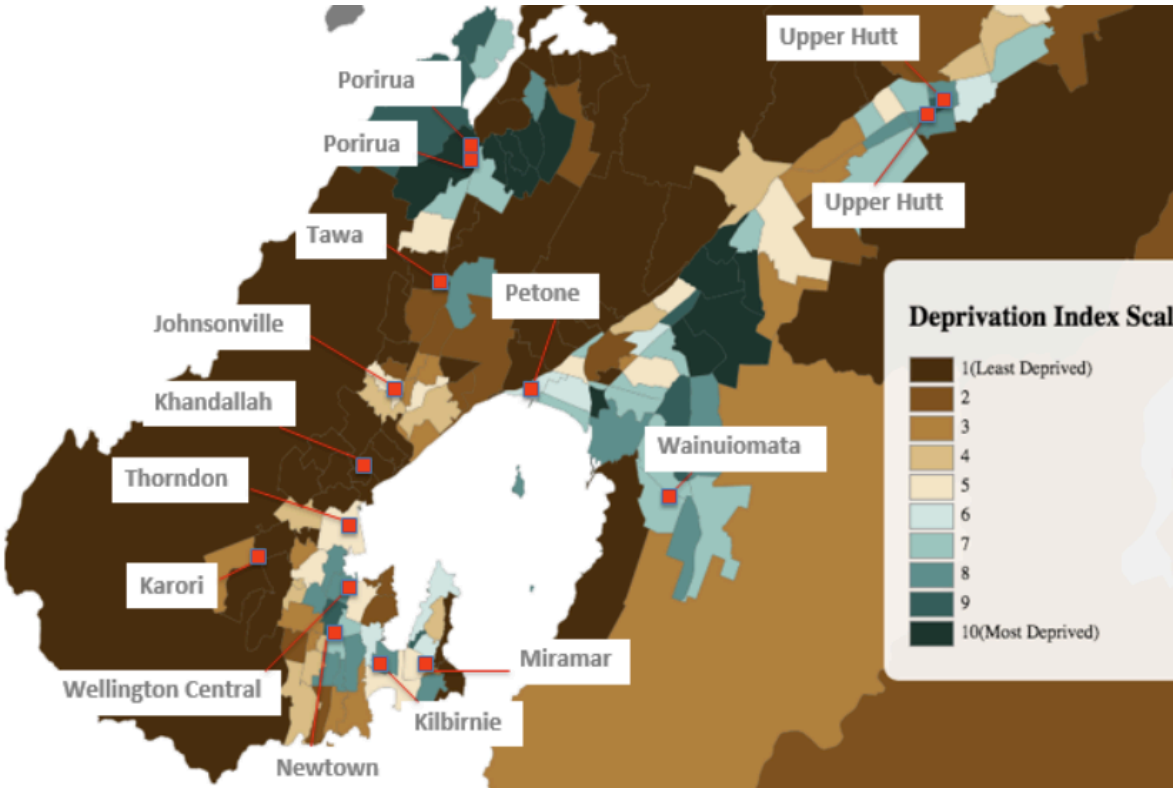


Figure 1: Map of supermarkets surveyed in the greater Wellington region, along with NZ Deprivation Indices (University of Otago, 2013). A total of 7 Countdowns, 3 Pak'nSaves, and 5 New Worlds were included.

4. Results

4.1. Analysis of packaging

The list of fortified breads obtained from the BIANZ website indicated that there are 45 distinct fortified loaves available in NZ (Appendix 1). Two of these breads were available in the South Island only, and two were available only on in Gisborne, Wairoa and the east coast of the North Island. This left 41 varieties that would potentially be available for analysis in the Wellington region.

The 41 breads were compared according to type of bread. With the exception of two white breads available only in the lower North Island, all other fortified breads were mixed grain, wholemeal or wheatmeal varieties. No gluten free or organic breads are currently fortified (MPI, 2012a).

We visited supermarkets across the greater Wellington region and searched for the 41 fortified breads, in order to analyse packaging. We observed 19 of the 41 breads. We first assessed the packaging as to whether folate/folic acid/vitamin B9 was mentioned at all. Of the 19 observed varieties, 15 mentioned folate as an ingredient on the packaging. The four loaves which did not mention folate or folic acid were all from the *Pam's* brand.

The 15 labelled varieties were then assessed according to where folate was mentioned on the packaging. The results are shown in Figure 2. All 15 featured folate in the ingredients list. Of these, 9 also mentioned folate in the nutritional information panel (typical examples can be seen in Figure 3, and Table 1 lists the other 5 varieties). None of the breads had any mention of folate on the front of the packaging. The "Goodness Grains" range from Tip Top were the only varieties which were actively marketed as "High in Folate", in a special panel on the back of the pack, alongside other nutrients (Figure 3, c).

Fortified breads with no labelling of folate/folic acid content	**Fortified breads labelled in ingredients but not in nutritional information panel**
Pams multigrain sandwich 700g	Sunny Crust multigrain toast 600g
Pams multigrain toast 700g	Burgen Pumpkin & Chia 700g
Pams wheatmeal sandwich 700g	Burgen Mixed Grain sandwich 700g
Pams wheatmeal toast 700g	Burgen Mixed Grain toast 700g
	Burgen Mixed Grain long slice 700g

Table 1: Breads of interest following packaging analysis.

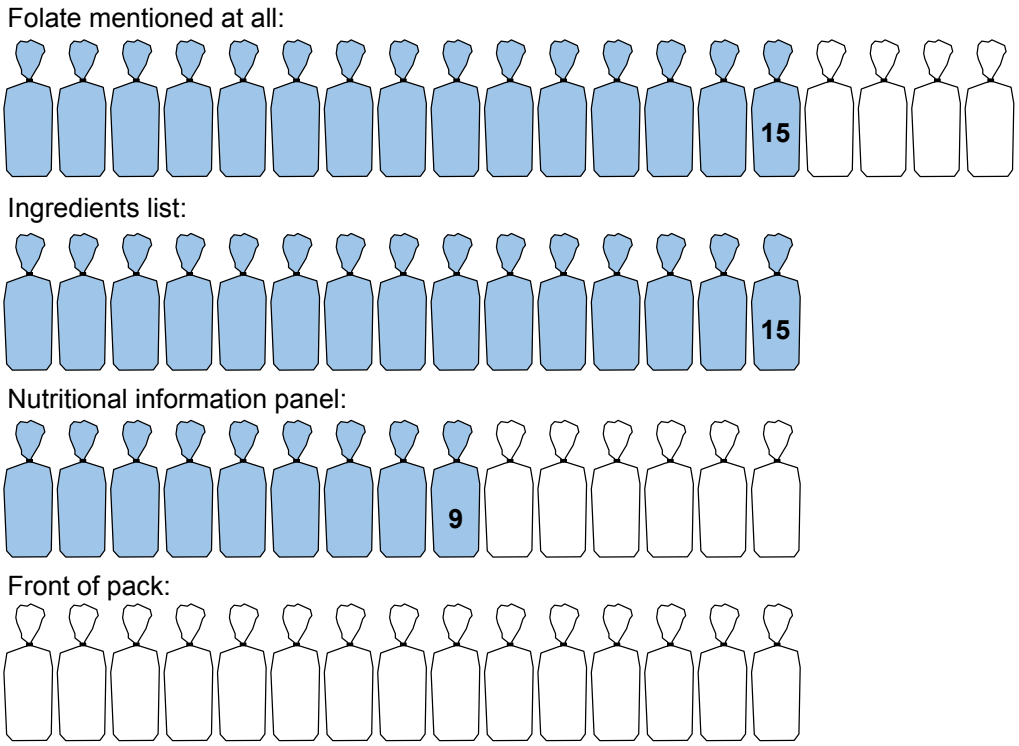
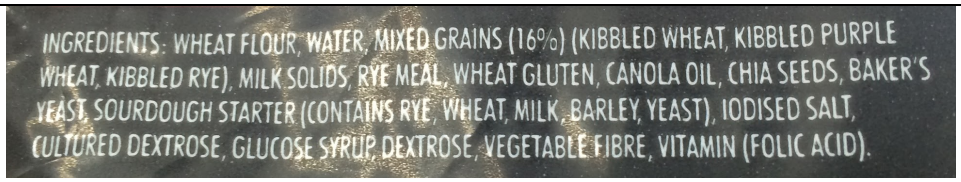
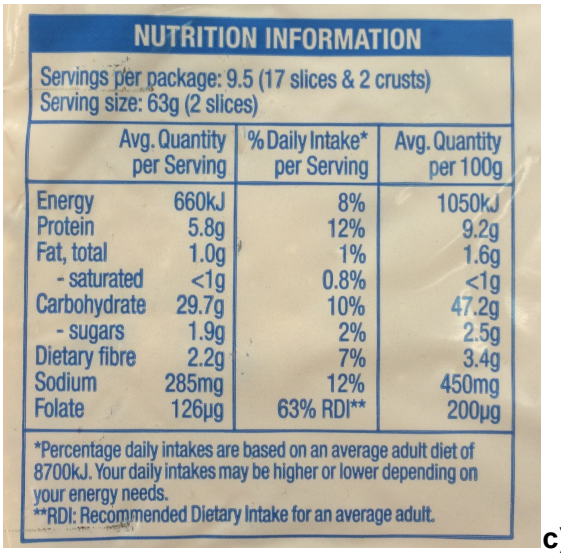


Figure 2: Results of packaging analysis for the 19 fortified varieties that were observed.

a)



b)



NUTRITION INFORMATION

Servings per package: 9.5 (17 slices & 2 crusts)
Serving size: 63g (2 slices)

	Avg. Quantity per Serving	% Daily Intake* per Serving	Avg. Quantity per 100g
Energy	660kJ	8%	1050kJ
Protein	5.8g	12%	9.2g
Fat, total	1.0g	1%	1.6g
- saturated	<1g	0.8%	<1g
Carbohydrate	29.7g	10%	47.2g
- sugars	1.9g	2%	2.5g
Dietary fibre	2.2g	7%	3.4g
Sodium	285mg	12%	450mg
Folate	126µg	63% RDI**	200µg

*Percentage daily intakes are based on an average adult diet of 8700kJ. Your daily intakes may be higher or lower depending on your energy needs.
**RDI: Recommended Dietary Intake for an average adult.

c)

Figure 3: a) A typical ingredients list featuring folic acid. **b)** A typical nutritional information panel showing folate, along with quantitative information on RDI and quantity per serving. **c)** Panel on the back of pack of Tip Top "Goodness Grains" varieties, actively marketing high folate content.

4.2. Manufacturer viewpoints

Of the four manufacturers we contacted, two declined to be interviewed, and the remaining two did not respond to the initial email. One of the former stated that due to them being a private company, no information further than that already hosted on their website would be made available.

Our assessment of manufacturer viewpoints therefore relied on information gained from existing publications, press releases, and position statements. We identified the following documents as key sources of information on manufacturer viewpoints.

Fortification of Bread with Folic Acid: Regulatory Impact Statement (Ministry for Primary Industries, 2012c)

Following consultation with the baking industry, this document discusses (among other things), the likely impact of mandatory fortification on the industry, in terms of costs, risks, and benefits.

New Zealand Food and Grocery Council submission to MPI, 2012 (NZ FGC, 2012a)

The NZ FGC represents the major manufacturers and suppliers of food, beverage, and grocery products in NZ, the most relevant of which to the current topic are George Weston Foods and Goodman Fielder. This submission to MPI therefore represents NZ's major bread manufacturers' position on folic acid fortification.

Folic Acid Fortification of Bread, 2012 Cabinet Summary (Wilkinson & MPI, 2012)

This document summarises the intention of the Minister for Food Safety, following public consultation in 2012, to replace the mandatory standard with a voluntary standard. In this document, the minister "weighs up" the costs and benefits of mandatory fortification, including an assessment of bread manufacturers' responsibility for public health initiatives and likely costs faced. The minister also mentions that she has consulted with the industry. Therefore, this document provides a proxy assessment of the viewpoint of bread manufacturers, based on which of their concerns are expressed by the Minister.

August 2012 Press release, NZ Food and Grocery Council (NZ FGC, 2012b)

This press release followed MPI's decision to mandate continued voluntary fortification. The author is unclear, however most of the FGC's press releases have been written by their CEO, Katherine Rich. In this document, the FGC praise the Government's decision.

Analysis of documents

Analysis of these documents revealed a range of manufacturer concerns regarding mandatory fortification. The key argument against mandatory fortification was that it imposed unreasonable costs on manufacturers. These costs comprise set-up costs, operational costs, compliance costs and loss of revenue due to loss of sales; the latter apparently based on a survey result of 32% of consumers saying they would move away from fortified products (MPI, 2012c). Other arguments included in the submission and the press release were descriptions of the potential risks to the entire "exposed" population and the lack of clarity of current scientific evidence (NZ FGC, 2012b). The FGC documents framed folate as a medication, rather than a vitamin supplement. New Zealand's proposed mandatory fortification to similar programmes in place internationally, emphasising that, like NZ, no European countries have mandatory fortification. This was presented as a justification for not switching to mandatory fortification, as countries comparable developmentally and economically have not instigated such an initiative (NZ FGC, 2012a). Other arguments included that New Zealand's current rate of folate-sensitive NTDs is at a "floor level", thus any additional benefit will be minimal (NZ FGC, 2012a). The impact on the general population and on consumer groups was also discussed, as well as the financial, legislative and ethical implications, especially those pertaining to human rights and the preservation of consumer choice.

4.3. Online opinion screening

Our qualitative screening of public opinion through online search methods yielded strong views both for and against fortification of breads in New Zealand. A small subset of the online community strongly supported fortification, while the majority of online commentary was opposed to fortification. Through this research, we also discovered that there was a lot of misinformation on the internet, as well as a considerable amount of public misunderstanding.

There were three main reasons that people were in support of fortification; they had personally been affected by neural tube defects in their own lives, they agreed with and trusted governmental decisions, or they believed in the scientific evidence (Espiner, 2009a; Newton, 2010; Watts, 2014). In addition to members of the public, key groups, such as the New Zealand Organisation for Rare Disorders and Spina Bifida New Zealand, publicly came out in support of fortification (Bennett, 2012).

The underlying ethical concerns that we identified in those opposed to fortification were the concept of 'mass medication' by the Government, and the interference with individual freedom of choice (Bennett, 2012; Boock, 2012; Watts, 2014). There were also concerns in the general public about potential adverse health effects of dietary folic acid. Most prominent was the supposed risk of cancer, and others believed that there had not been enough research done on potential risks (Espiner, 2009a; Watts, 2014). Still others disliked the idea of "artificial" ingredients being added to bread (Rowland, Dugbaza, & House, 2010; Watts, 2014).

Among the online material screened, there was a relatively high rate of misunderstanding of the intended effects of folic acid fortification, as well as misunderstanding of why there was a need for it to be added to bread (Espiner, 2009b). The importance of adequate folate levels in the pre-conceptual period was not well understood by some individuals, and neither was the issue of unplanned pregnancies accounting for a large proportion of births in New Zealand. This is highlighted by the following example:

> *"It is just plain ridiculous, let pregnant women take responsibility for their own health. What percentage of the population is pregnant at any one time? I guess less than 2%. Does anyone know? So why should all the population be forced to get this supplement?" South Islander #13 (08:49 pm Jul 13 2009)* (Espiner, 2009b).

It remains unclear what has been the biggest influence on public opinion. It is likely, however, that government indecisiveness and weak stance on fortification (particularly the current voluntary scheme) has led to some public scepticism (Macakasy, 2009). Furthermore, some health professionals have demonstrated opposition to fortification (Espiner, 2009a), which may have further contributed to public uncertainty and confusion.

Our research highlighted the comparisons drawn between folic acid fortification and other mandatory fortification schemes - most particularly, the iodisation of salt and bread, and fluoridation of the water supply (Ministry of Health, 2014). While there is vocal public opposition

to fluoridation (Fluoride Action Network NZ Inc., 2014), there appears to be little public opposition to iodisation of salt and bread (Ministry of Health, 2014).

Table 2 summarises the key arguments detected in the online screening process.

For fortification	Against fortification
• **Health benefits:** general health benefits to the individual or population • **Reduction of NTDs/birth defects:** early maternal folic acid supplementation has been shown to significantly reduce the risk of neural tube defects • **Trust scientific evidence:** some consumers have faith in the existing evidence regarding the health benefits of folic acid	• **Impingement of freedom of choice:** mandatory fortification removes the consumer's right to choose between fortified and non-fortified breads • **Mass medication:** issues with medicating the entire population for the benefit of a minority • **Not necessary/ineffective:** the primary benefits of fortification do not apply to a large proportion of the population; some doubt surrounding the effectiveness of fortification • **Adverse health effects:** not enough scientific research exists regarding the safety of folic acid • **Artificial/processed:** some opposition to the addition of artificial ingredients to bread

Table 2: Summary of main themes in online public debate around fortification of bread in NZ.

4.4. Consumer survey

4.4.1. Data validation

Day of collection

We aimed to collect survey data at a variety of days and times throughout the week, so that the results were not biased towards particular subgroups (e.g. weekend shoppers, or those who shopped during office hours). Figure 4 shows the distribution of data across the days of the week. Data were collected over three weeks; data from the same day on different weeks are superimposed.

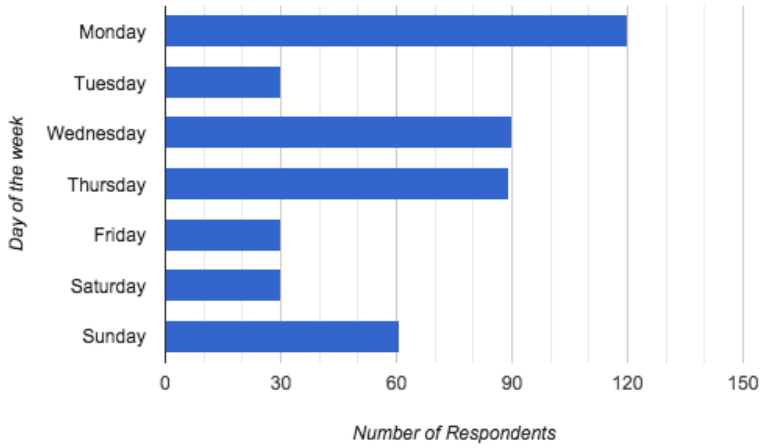


Figure 4: Distribution of data by day of the week

Response rate

We sought permission to conduct our survey in the bread aisles of 18 supermarkets across the Greater Wellington region. Three supermarkets in Central Wellington declined, leaving 15 supermarkets. We approached 561 consumers who looked over 21 years of age. Of those 561, 450 agreed to participate; a response rate of 80%.

Gender

Respondent gender was recorded as either Female, Male, or Other (unassigned, intersex etc.). 304 respondents (67.6%) were Female, and the remaining 146 (32.4%) were Male. No participants recorded their gender as Other.

Age

Respondent age was recorded in brackets 18-24, 25-39, and 40+. Only respondents appearing over 21 were approached. The distribution of respondents by age bracket is shown in Figure 5. Over half of the respondents were aged 40 or over.

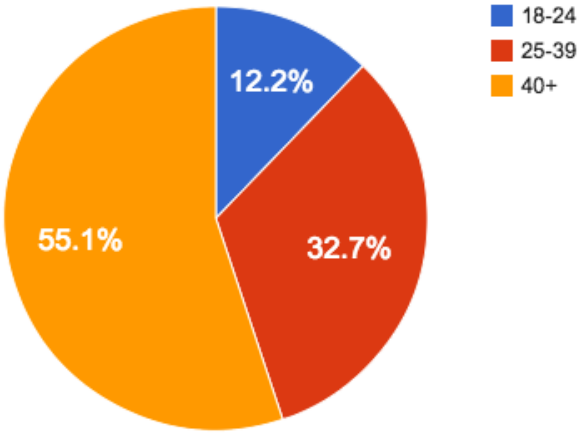


Figure 5: Respondents by age bracket.

Ethnicity

Our survey recorded self-reported ethnicity. Respondents were asked to report all the ethnic groups they identified with, resulting in some multiple responses. We assigned ethnicity in a prioritised manner (from highest to lowest priority: Māori, Pacific, Asian, NZ European). Respondents who reported none of these four main ethnicities were grouped under "Other".

Table 3 shows the results of our survey as compared with national demography data from the 2013 NZ Census (Statistics New Zealand, 2015). The closest equivalent of our "Other" category in the Census was the Middle Eastern, Latin American and African (MELAA) category.

In our survey, Māori, Pacific and Asian people were under-represented and NZ European and Other (MELAA) were over-represented. However, we obtained data from all major ethnicities, at proportions close to the national averages.

Our survey		2013 NZ Census	
Ethnicity (prioritised)	Percentage of total	Percentage of total	Ethnicity (not prioritised)
Māori	11%	15%	Māori
Pacific	4%	7%	Pacific
Asian	7%	12%	Asian
NZ European	73%	69%	European
Other	5%	1%	MELAA

Table 3: Survey demography compared with national census demography. Note that percentages measured in the 2013 Census sum to more than 100%, because multiple ethnicities were allowed to be recorded, and they were not prioritised.

4.4.2 Awareness of fortification

Of the 450 respondents, 242 (53.8%) were aware of some degree of fortification of bread with folic acid in NZ. Some of these respondents remarked that they were under the impression that *all* breads in New Zealand were fortified, although the prevalence of this response was not quantified.

Awareness by ethnicity

Figure 6 shows that those identifying as Māori or Pacific (70) were less likely to be aware of fortification than those identifying as neither (380). Around one in three (31.4%) Māori/Pacific were aware, while over half (57.9%) of all other participants were aware.

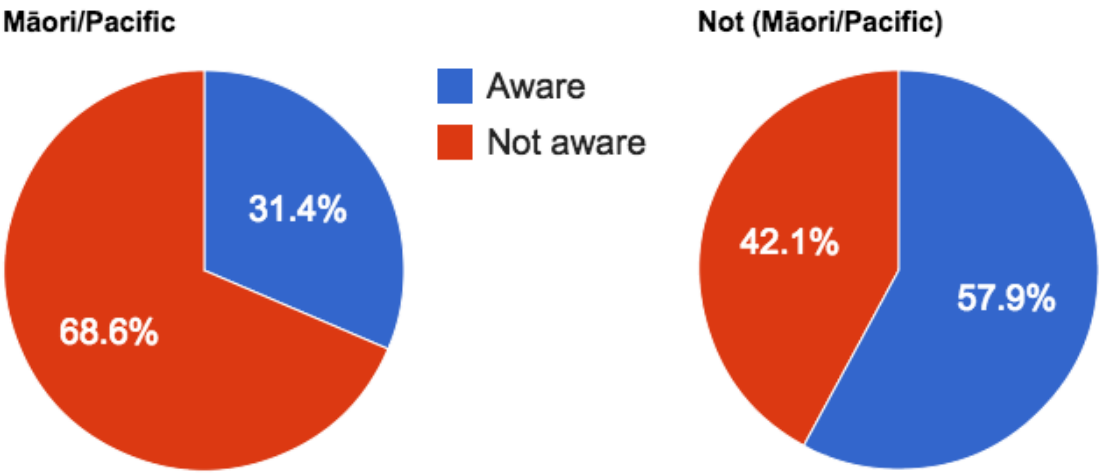


Figure 6: Awareness of fortification by ethnicity.

Awareness in women of reproductive age

Because wide age brackets, rather than specific respondent ages, were recorded, we were unable to perform an accurate subgroup analysis of women of reproductive age. However, our bottom two age brackets (18-24 and 25-39) contain peak reproductive years and so serve as an approximate subgroup.

Of 137 female respondents aged 18-39, 66 (48%) were aware of fortification of breads in NZ. This was lower than the average for the entire sample (54%). Further analysis revealed that while women aged 25-39 (n=105) were 53% aware, those aged 18-24 (n=32) were only 31% aware. While the sample size of the latter subgroup is relatively small, this level of awareness is significantly lower than other women, and of the total sample.

Because even women aged 25-39 fell slightly below the total sample in levels of awareness, we analysed awareness levels in women aged 40+. Of a total of 167, 110 (66%) were aware of

fortification, representing a much higher level of awareness than any other subgroup, which may mask poor awareness in young women.

4.4.3 Opinion on fortification

Those who reported being aware of folic acid fortification in NZ (n=242) were asked for their opinion on the issue (Figure 7). Around 1 in 10 respondents were opposed to fortification, 1 in 10 were unsure, and the remaining 8 of 10 either supported or were neutral towards fortification.

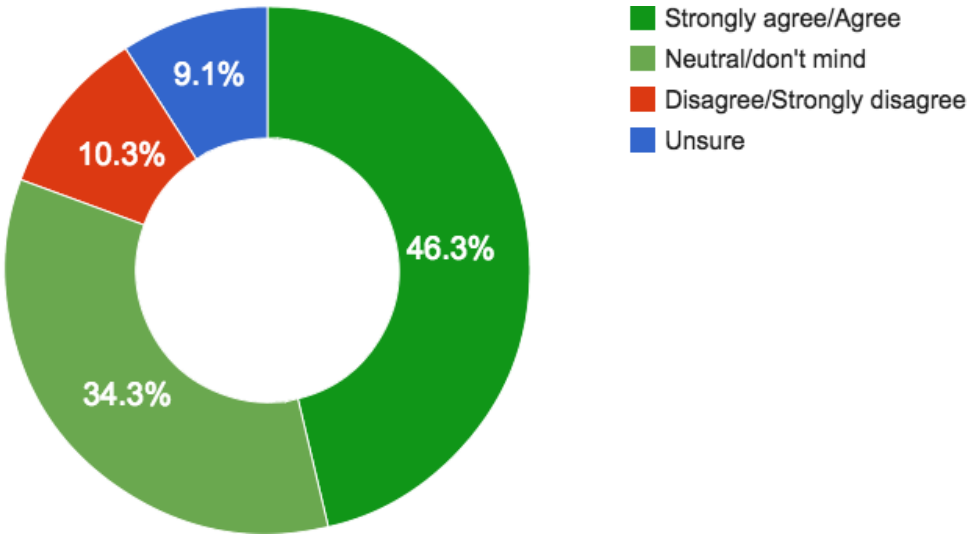


Figure 7: Opinion on fortification.

For those who either agreed or strongly agreed with fortification (n=110), Figure 8 shows their supporting reasons. The survey allowed participants to select multiple responses. The responses “prevention of NTDs” and “health benefits” were prioritised equally over “trust scientific evidence”, because the latter almost always occurred in combination with at least one of the former. This left the respondents split roughly into thirds, citing either prevention of NTDs, health benefits (for themselves and/or society) as their reason for supporting folic acid fortification. One respondent reported “trust scientific evidence” as the sole reason for support.

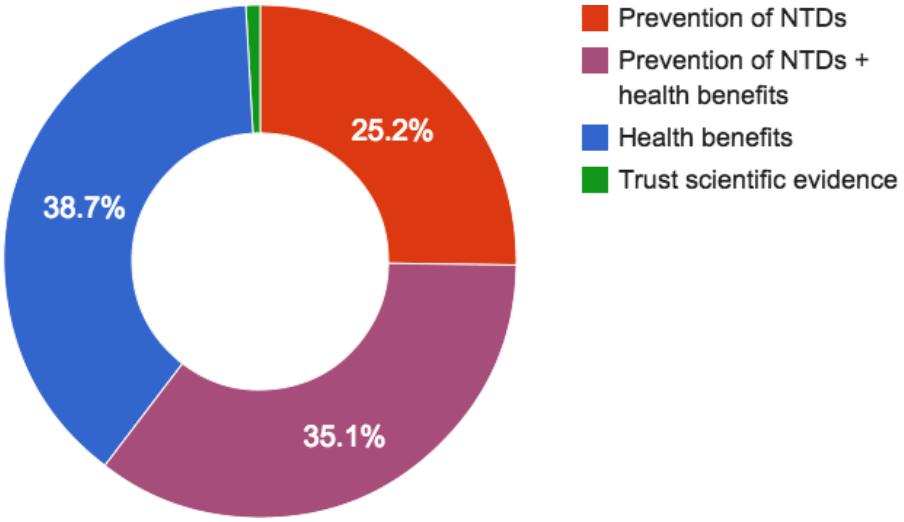


Figure 8: Reasons for supporting fortification

Those who either disagreed or strongly disagreed with fortification (n=25) were asked for their reasons. The primary reasons for opposition were folic acid being “artificial” or “processed”, loss of freedom of choice, or that fortification was ineffective or simply unnecessary. Multiple responses were allowed.

Of the remaining survey options (price increase concern, or concerns about the safety of folic acid), the former was reported only once, and the latter only twice. Furthermore, in both cases safety concerns occurred along with artificial/processed concerns. Hence, we ignored one respondent’s sole concern of price increase, and absorbed safety concerns into artificial/processed concerns, leaving 24 respondents. The results are shown as a Venn diagram in Figure 9.

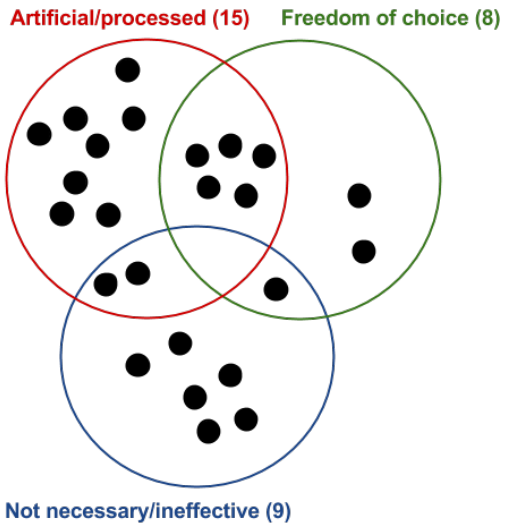


Figure 9: Reasons for opposing fortification. Respondents are represented by black dots, and are placed according to their responses (multiple responses were allowed).

Several of the respondents who believed fortification was unnecessary elaborated on their opinion by stating that this was because pregnant women already receive supplements.

In respondents who were aware of fortification but unsure of their opinion, eight expanded on their concerns and gave reasons for, against, or both. The most significant concern was around folic acid being artificial or processed.

Other concerns that were raised by respondents, although not quantified in our results, included effects on bread quality. For example, one respondent remarked, “They’re already adding things to bread anyway. Would it make the bread softer or harder?”

4.4.4 Effect of fortification on purchasing behaviour

All respondents, regardless of knowledge or opinion on fortification, were asked what they would most likely do if they learned that their usual variety of bread contained folic acid (if price remained the same). We used this question as a gauge of their likely response to increased levels of fortification: i.e., would they avoid fortified breads.

The results are shown in Figure 10. The large majority (74%) reported they would not change their purchasing behaviour or would be more likely to purchase the bread (indicating a neutral or supportive opinion of fortification), and around 10% indicated they would move away from fortified breads (perhaps indicating a negative opinion of fortification). Rates of each response correlated closely with opinions on fortification (Figure 7).

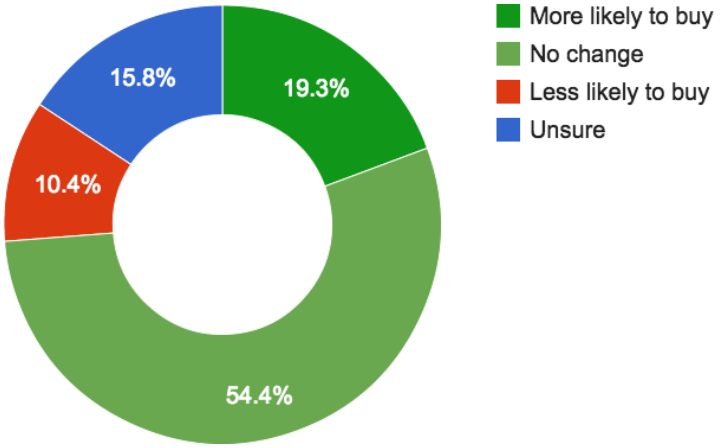


Figure 10: Likely response to learning a loaf contains folic acid.

Anecdotally, the respondents who answered that it would not affect their decision to buy their normal bread often making comments along the lines of: “Bread is bread,” “I always buy your bog standard budget white bread, always have,” “I buy the cheapest bread,” or “Taste is most important for me.” Folic acid content seemed to play a minor role in determining purchasing behaviour, while other factors such as taste, price and brand loyalty appeared to be more important.

Effect on purchasing behaviour by awareness

Figure 11 shows the likely response to learning a loaf contains folic acid as a function of awareness of fortification. This assesses the public's reaction to the idea of folic acid being added to bread, given no prior information.

Of the 242 respondents who were aware of fortification, over 80% reported they would be more likely to buy fortified bread, or that it would not change their behaviour. 11% suggested they would move away from fortified breads. This is close to the proportion of the whole sample opposed to fortification (Figure 7). Only a small number of respondents were unsure of how their purchasing behaviour might change. This is consistent with those more aware having had more time to consider their reaction to fortification.

Of the 208 respondents who were unaware of fortification, the proportions reporting no change, and less likely to buy, were similar to those in the aware subgroup. Therefore, being more aware of fortified breads did not seem to reduce the proportion of opposition. However, a much higher proportion reported being unsure, and a much lower proportion reported being more likely to buy, than in the aware subgroup.

Taken together, these results suggest that increasing awareness converts uncertainty into support for fortification, but has little effect on opposition (in either direction). This suggests that increasing awareness would likely result in higher consumer uptake of fortified breads.

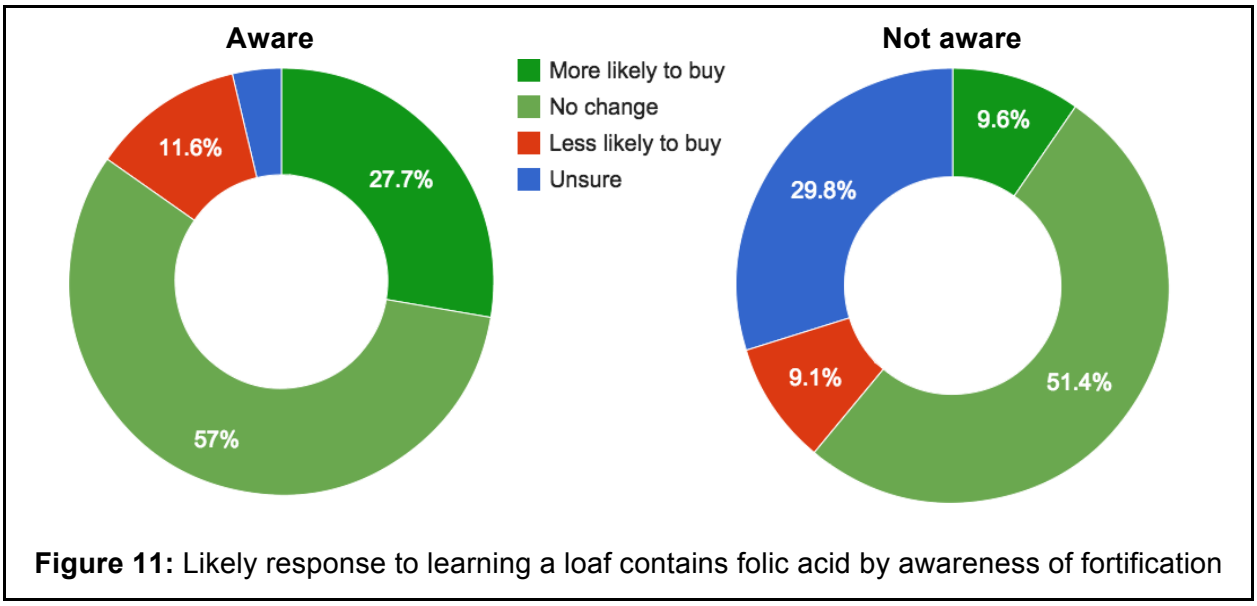


Figure 11: Likely response to learning a loaf contains folic acid by awareness of fortification

Effect on purchasing behaviour by ethnicity

Figure 12 compares the response to learning a loaf is fortified with folic acid between Māori/Pacific respondents (n=70) and the rest of the sample (n=380). The result are overall very similar, however a higher proportion of Māori/Pacific respondents were unsure, and a lower number were more likely to buy. These differences, while smaller, are analogous the differences seen between the aware and unaware subgroups. Hence, they are consistent with other results showing that Māori/Pacific are less aware of fortification (Figure 6).

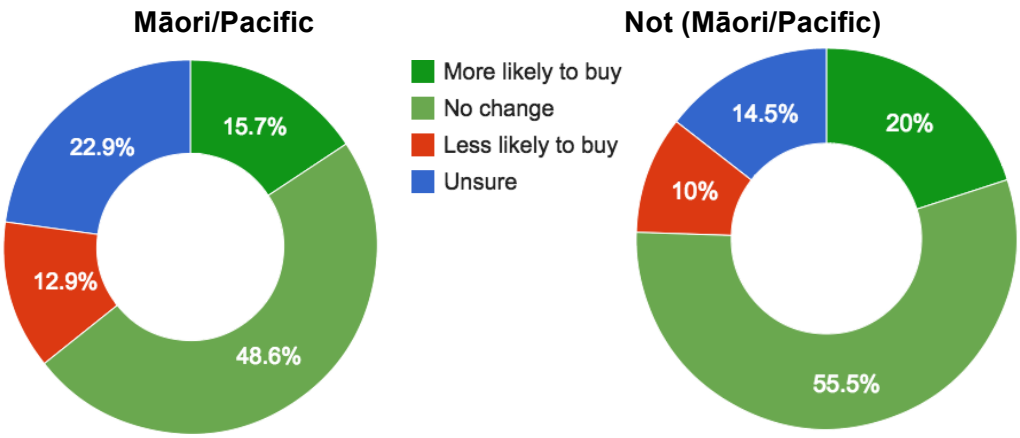


Figure 12: Likely response to learning a loaf is fortified by ethnicity

Effect on purchasing behaviour in women of reproductive age

As with prior analysis, we used female respondents aged 18-39 (n=137) as a subgroup closest to "women of reproductive age". Comparing these results with those of the entire sample (Figure 10) shows that women 18-39 do not differ greatly in their likely purchasing behaviour (Figure 13). Again, around 10% reported they would move away from fortified bread. A higher proportion reported being more likely to purchase fortified breads (27% of women aged 18-39 vs 19% of the total sample).

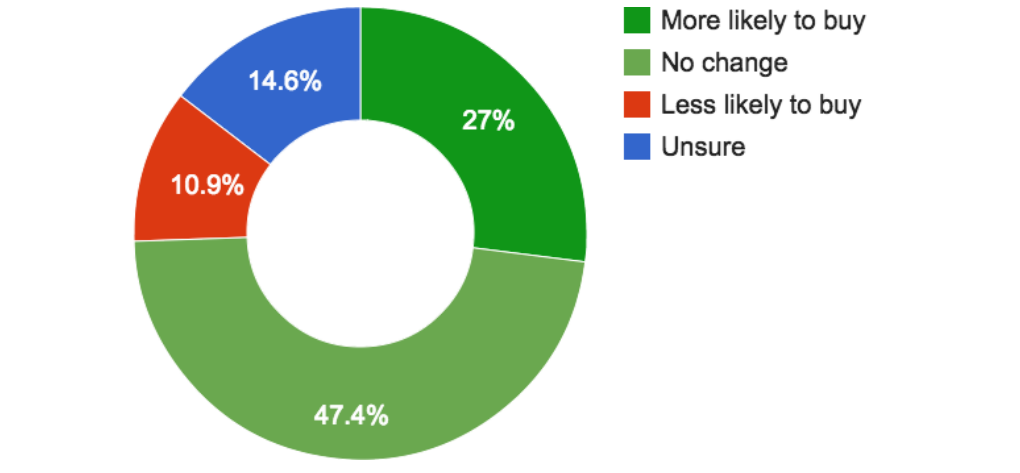


Figure 13: Likely response to learning a loaf is fortified, in women aged 18-39.

Summary of Section 4.4.4

Around 10% of respondents indicated they would move away from fortified bread, and this figure appears to be independent of awareness of fortification, ethnicity, and gender. Being more aware of fortification was however associated with increased levels of support for, and decreased levels of uncertainty around fortified bread, suggesting that while increased awareness may have no effect on the level of opposition, it nonetheless may improve consumer uptake in the remainder of the population.

4.4.5 Preferred sources of information on fortification and folic acid

Finally, respondents were asked how they would prefer to receive information on fortification and folic acid. Multiple responses were allowed. Responses were not prioritised, instead they were pooled (i.e. there are more responses than the number of respondents) and are displayed in Figure 14. “Online” (e.g. search engine) was the most preferred method of folic acid education (185 respondents), followed closely by television advertisements and awareness campaigns (159 respondents). A moderate number of responses favoured social media, health professionals and printed advertisements or posters, and a small number of respondents said they were not interested in more information.

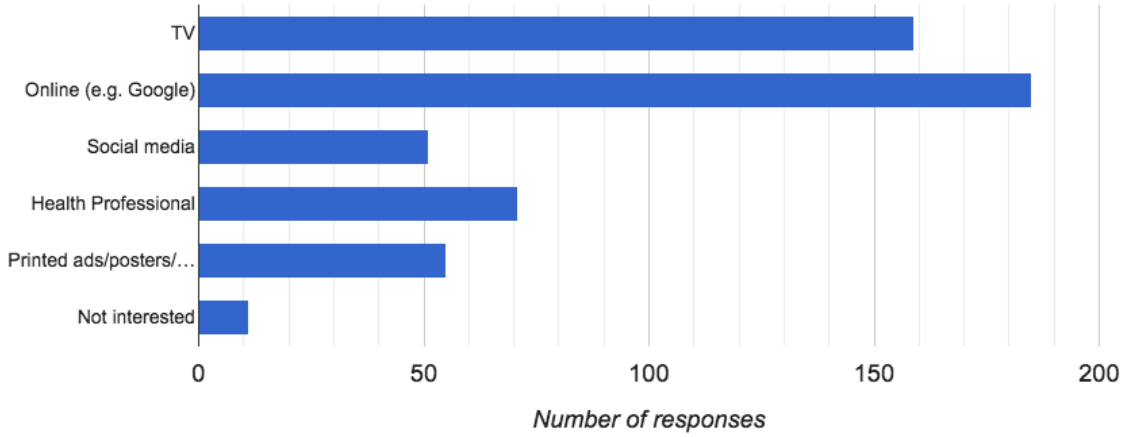


Figure 14: Preferred sources of information on fortification and folic acid.

Preferred sources of information by ethnicity

Figure 15 shows preferred sources of information as a function of ethnicity, as a percentage of the total number of responses from each ethnicity. For both groups, TV and online were the preferred sources, with Māori/Pacific respondents showing a higher preference for TV, and other respondents preferring online sources.

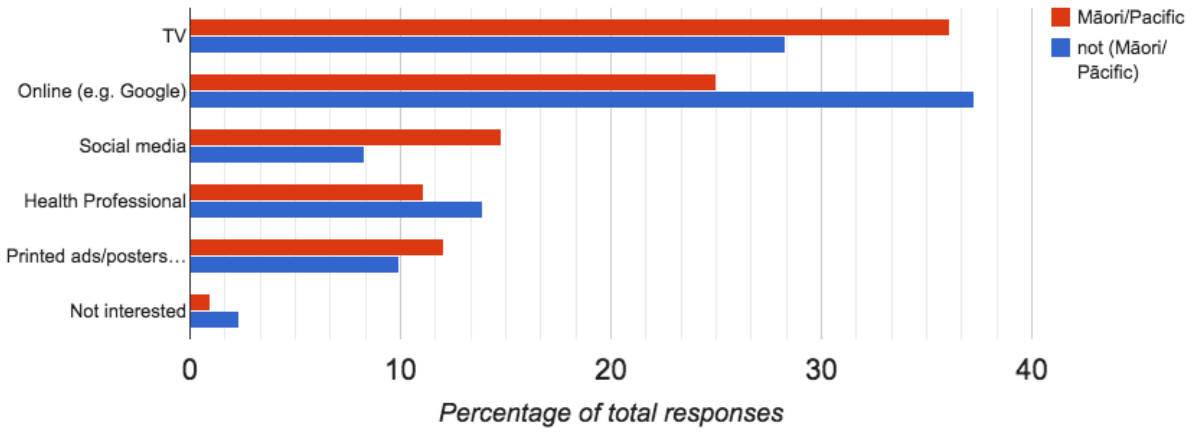


Figure 15: Preferred sources of information on fortification and folic acid by ethnicity

4.5. Summary of results

Packaging analysis

- Almost no white breads are fortified in NZ.
- Most fortified breads mentioned folate in the ingredients list.
- Folate was less commonly featured in the nutritional information panel.
- No fortified breads mentioned folate on the front of pack.
- Portrayal of folate as a “positive” ingredient is very uncommon.

Manufacturer viewpoints

- Manufacturers, like all businesses, want to avoid costs and maintain revenue.
- Manufacturers currently estimate the level of public opposition to fortification at 32%.
- Current scientific evidence on the safety of folic acid is equivocal and the risks to the general population are not known.
- Current NTD prevalence does not justify “dosing” the entire population for the benefit of a small number.
- Mandatory fortification would be ineffective because NTD prevalence is already at a floor level.

Online opinion screening

- There are a wide range of public opinions on fortification available on the internet most of which focus on the ethics, safety, or necessity of fortification.
- Misinformation about the purposes of fortification and the safety of folic acid is prevalent on the internet.

Consumer survey

- Of 450 respondents, 54% were aware of some level of fortification of bread with folic acid in NZ. Māori/Pacific respondents, and young women, were less aware than others.
- Around 80% of respondents aware of fortification either supported or had a neutral view of it, with a further 10% unsure. Around 75% of all respondents indicated they would continue to buy bread if it were fortified, with a further 15% unsure.
- 10% of those aware of fortification were opposed, and 10% of all respondents were less likely to purchase fortified breads. The latter figure was independent of awareness of fortification, ethnicity, age, and gender.
- Increased awareness of fortification was associated with lower levels of uncertainty and higher levels of confidence in buying fortified breads. There was no association with any reduction in the level of opposition.
- The primary reason given for supporting fortification was a belief that folic acid offered health benefits. Slightly fewer respondents supported fortification for the purposes of preventing NTDs.
- Opposition to fortification was primarily due to concerns about folic acid being “artificial” or “processed”, associated with health concerns in some respondents. Concerns around freedom of choice, or a belief that fortification was ineffective or simply unnecessary, were secondary to this.
- Consumers seeking information of fortification or folic acid were most likely to go online. Television was also a popular choice, particularly among Māori/Pacific respondents.

5. Discussion

From the results presented in Section 4, we were able to identify several barriers to, and enablers of, uptake of bread fortification in New Zealand, for both manufacturers and consumers. Some of these barriers are due to an underlying misalignment between manufacturer and consumers positions. In this section we discuss these barriers and enablers and how our results provide evidence for them, as well as suggesting how they could inform future interventions (i.e. interventions that avoid barriers and use existing enablers as leverage). We also discuss the strengths and weaknesses of the study.

5.1. Manufacturer barriers

Uninformative labelling

One consequence of the low proportion of breads which are fortified is that it implicitly requires consumers (women of reproductive age in particular) to seek out fortified bread, to which packaging and marketing are highly relevant. The labelling and marketing of bread products are significant considerations for bread manufacturers (alongside the actual production of bread), and it is their responsibility to ensure that labelling and marketing are accurate, informative, and empowers consumers to make informed choices.

The results of packaging analysis (Section 4.1) reveal that while most (15) of the 19 fortified varieties observed mentioned folate or folic acid in the ingredients list, fewer (9) quantified folic acid content in the nutritional information panel, and none displayed front-of-pack advertising for folic acid content. The four varieties that did not mention folic acid at all were all of Goodman Fielder's Pam's brand, sold in Foodstuffs supermarkets. It is unclear whether the list of fortified breads obtained from BIANZ (BIANZ, 2014), last updated May 2014, is out of date or inaccurate, or whether these varieties are improperly labelled.

These results are significant. Nutritional information panels provide quantitative information on folate content: specifically, the amount of folate per 100g and per serving, as well as the percentage of recommended daily intake (RDI). These features would obviously be useful for individuals seeking to ensure they reach the recommended dose, for example, women planning a pregnancy, or other women of reproductive age following recommendations. Featuring folate on the ingredients list alone only informs consumers that the bread is fortified.

More generally, regardless of whether or not folate was featured in the nutritional information panel, bread packaging typically presented folate as a "neutral" ingredient and confined mention of it to the back of the pack. Tip Top's Goodness Grains range were the only varieties we observed that actively promoted folate content as a beneficial feature (Figure 3, c), with a back-of-pack panel saying "High in Folate", providing information on the utility of folate in the diet, alongside similar information for other nutrients. These findings are interesting when compared with cereal packaging in NZ. Many cereals promote folate content as a positive feature

alongside that of iron and other B vitamins, often with a front-of-pack label, and information on the benefits of these nutrients (Sanitarium & New Zealand Health Association Limited, 2015; Borman, Brown, & Oakley, 1999).

Overall, the clarity of packaging of fortified breads with regard to folate content is poor. In order to determine which varieties are fortified, consumers are required to pick up each loaf and examine the small print of the ingredients list. We suggest that this is unrealistic for many bread consumers, for example those with little time to spare, a lack of education, or simply those who do not know where to look. This is inconsistent with the main concern of the cabinet summary in favour of continuing the voluntary standard, which was to preserve consumer choice (Wilkinson & Ministry for Primary Industries, 2012). While current packaging informs basic consumer choice *in principle* (by including folate in the ingredients list), it does not actively support them to make informed choices, because information is confined to small print on the back of the pack. Furthermore, truly informed choice requires information on dosage, which would be possible if folate was featured in the nutritional information panel.

Few white breads fortified

It is concerning that almost no white bread varieties are fortified, because of the risk of establishing inequalities. Women who purchase only white bread are unlikely to benefit from the fortification program as it currently stands. White breads tend to be cheaper than other varieties, so a lack of fortified white breads is likely to result in poor delivery of folic acid to women of lower-income.

White bread varieties represent a significant portion of sales, hence avoiding fortifying white varieties places a fundamental limit on the proportion of bread (by production/sales volume) that can be fortified. We suggest that if the major manufacturers were to begin fortifying white varieties, it would help to prevent the establishment of the inequality mentioned above, as well as significantly increase the proportion of fortified breads, assisting manufacturers to reach the 25-50% target.

Costs of fortification

Despite manufacturers declining interviews, we were able to learn about their viewpoints from the variety of press releases, position statements, and published articles listed in Section 4.2. A major barrier for manufacturers is the cost of fortification. These included initial set-up costs, ongoing maintenance costs, and compliance costs (the cost of ongoing monitoring to ensure levels of folic acid are consistent).

These costs are all due to a program, mandatory or not, which fortifies bread at the bakery level. There are many bakeries in NZ, and requiring each factory to fortify independently is an inefficient use of resources, leading to duplicate (and therefore excessive) costs. It also allows inter-manufacturer variability in processes, leading to inconsistent folic acid levels between different varieties of fortified bread (Baking Industry Research Trust, 2014).

In contrast, a fortification program at the milled flour level (which is necessarily mandatory), as conducted in the US, may reduce overall costs by utilising economies of scale. There are a small number of flour millers in NZ, which collectively supply the large majority of bakeries. While installation of a fortification program at these factories would still involve the same kind of costs as the current voluntary system does, they would likely be proportionally smaller. Furthermore, folic acid levels would be more likely to be consistent (due to fewer fortification processing sites) and far less monitoring would be required due to the lower number of sites at white fortification would take place.

5.2. Manufacturer enablers

Overestimate of consumer opposition

Results of a BIANZ-commissioned consumer survey indicate that 32% of consumers would move away from fortified products (Wilkinson & MPI, 2012). Our study suggests that this is a significant overestimate: we found that around 10% of the population were opposed to fortification and indicated that they would move away from fortified products. Hence our results suggest that a large majority of bread consumers would be unaffected in their consumption if more bread was fortified, and that manufacturer concerns over consumer response to fortification are therefore overstated.

The source of these manufacturer estimates was an industry commisioned survey, however we were unable to obtain the survey content. In contrast, our methods are transparent and well-documented, and a conscious effort was made to ask survey questions in a neutral manner. For these reasons, we contend that our figure of 10% is likely to be more accurate than the industry figure.

This overestimate is likely to create inflated estimates of lost revenue by manufacturers, obviously discouraging them from taking proactive steps toward increased fortification levels. If the level of opposition measured in this study is accurate, then informing manufacturers of this lower figure may encourage more action on fortification. In the context of the current overestimation, Our figure of 10% opposition could act as an enabler for manufacturers in the future, particularly if corroborated by further research.

Awareness does not create opposition

Figure 11 shows that awareness of fortification was not associated with any change in the proportion of respondents avoiding fortified breads. We suggest that this represents an enabler for manufacturers to play a role in increasing awareness of fortification (or at least, not oppose initiatives that increase awareness), because it indicates that increased awareness is unlikely to affect sales of fortified products in a negative way.

First, manufacturers could improve the clarity of labelling of currently fortified breads. Section 4.1 shows that there is room for drastic improvement. As discussed under manufacturer barriers (Section 5.1), more prominent labelling would enable consumers to more readily identify fortified breads, and inclusion of folic acid content in the nutritional information panel for every fortified variety would empower consumers to make truly informed choices. More prominent labelling may also normalise fortification. We are not aware of any opposition to fortification of breakfast cereals, despite the fact that folate content is heavily advertised on the packaging of those products.

Second, marketing initiatives to encourage awareness of fortified breads by women of reproductive age could be undertaken. Figure 11 suggests that this would increase uptake of fortified products by this population (thus achieving the primary goal of fortification), and at the same time not affect the proportion of the population moving away from fortified products. Manufacturers could initiate or play an active role in such campaigns without risking loss of revenue. At the very least, these data show that manufacturers need not oppose public health campaigns from other sources (e.g. Government) aimed at increasing awareness.

5.3. Consumer barriers

Low awareness of fortification

54% of respondents were aware of some level of fortification of bread with folic acid in NZ. This is consistent with data from Food Standards Australia New Zealand, showing that awareness of fortification in NZ was generally low, except for in women who had previously been pregnant (FSANZ, 2010). Low awareness of the availability of fortified breads, particularly in the current context of a minority of bread varieties being fortified, is a clear barrier to consumer uptake: consumers who do not actively seek fortified bread are less likely to consume it, and consumers who are unaware are, in turn, clearly unlikely to seek it. The barrier of poor labelling of fortified breads (Section 5.1) can be seen as working together with this barrier to prevent consumers learning about the availability of fortified breads.

Māori and Pacific respondents were less likely to be aware of folic acid fortification (Figure 6). This finding is supported by a 2012 study which found information on folic acid and fortification failed to reach Māori, Pacific and Asian people (Mallard & Houghton, 2012). Reduced awareness among Māori/Pacific respondents may explain them being more unsure of how fortification might impact on their purchasing behaviour (Figure 12). In combination with results showing that awareness increases uptake of fortified bread (Figure 11), these results suggest that Māori and Pacific people are less likely to purchase fortified breads. Current data are unclear on whether NTDs are more or less prevalent among Māori than Pākeha (New Zealand Child and Youth Epidemiology Service, 2012). Nonetheless, these results suggest that improving levels of fortification may create, or worsen, inequalities between these groups in NTD prevalence. Health promotion initiatives should therefore focus primarily on raising awareness in Māori and Pacific people.

Women aged 18-39 years old were slightly less aware (48%) of fortified breads than the sample as a whole (54%). These findings can be compared to those of a 2012 study of 707 post-partum women in NZ, showing 50% awareness (Mallard & Houghton, 2012). However, we discovered that younger women (18-24) were significantly less likely to be aware (31%). Despite the small sample size, these results are concerning, given that the rate of unplanned pregnancies is high in this age group (Statistics NZ, 2003). Fortification aims to increase folate intake in all women of childbearing age, particularly groups at higher risk of not being supplemented such as younger age of conception (Morton, Grant & Atatoa Carr, 2013), and low awareness in the latter groups therefore represents a barrier to these goals. If fortification is to remain voluntary, it is critical that health promotion activities aim to raise awareness in young women.

One in ten consistently opposed

Survey results suggest that 10% of the population would move away from fortified breads (Figure 10). This figure was also found to be independent of ethnicity (Figure 12). Of particular concern was its consistency even in young women of reproductive age, at whom the fortification program is directed (Figure 13). Also notable was the finding that this 10% persists independent of awareness of the issue; that is, 10% of respondents indicated that they would avoid fortified breads at the time of being surveyed, regardless of whether this was the first time they had heard about folic acid fortification of bread (Figure 11).

In the initial planning stages of the survey, there was some concern that, for people unaware of fortification or what folic acid is, asking them about how their purchasing behaviour would depend on folic acid content might introduce a bias by generating the appearance of controversy over the safety of folic acid, leading to more people reporting they would avoid fortified breads. To mitigate this effect, we ensured that questions were posed in a neutral way. The fact that opposition was consistent throughout the sample at around 10%, and no higher in the unaware subgroup, suggests that this was effective and that minimal bias was introduced.

For those who reported being less likely to purchase a bread if it was fortified, we did not ask for reasons. However, the 10% figure correlates well with a similar level of opposition (Figure 7) (in fact Figures 7 and 10 correlate well in general) and for the latter group reasons were investigated. The primary reason for opposition was a belief that folic acid was artificial or processed (see below). While our results show that the level of opposition is independent of awareness, it is not clear whether opposition is resistant to change following provision of information on the nature and role of folic acid.

This consistent 10% opposition poses a significant barrier to uptake of fortification for two reasons. First, and most obviously, fortification is less likely to reduce risk of NTDs in this population, regardless of how widespread it becomes. While our results suggest that simply making people aware of fortification is not enough to reduce this level of opposition, it is unclear whether people being more informed about the purposes of fortification, and the safety of

dietary folic acid, might reduce opposition. Second, despite this level of opposition being much lower than current estimates (Section 5.2), it may still represent a significant risk of lost income for manufacturers, if they are to increase fortification levels. For both of these reasons, it is essential to reduce this level of opposition by any reasonable means. If fortification is to become mandatory, consultation with manufacturers on the availability of alternative products may be necessary.

Negative perception of folic acid

The main reason given for opposition to fortification was a concern over folic acid being artificial or processed. While the sample size was small (25 respondents), these results are interesting when contrasted with the main topics of discussion in media coverage and political discourse. The debate has been framed as a libertarian one: freedom of consumer choice; opposition to mass medication; and the question of whether pregnant women should be responsible for their own nutritional requirements. While this framing is telling of the politicisation of the issue following a change to centre-right Government in 2008, our results suggest that it is not representative of the general public's concerns and is therefore missing the mark.

These results also differ from those of online opinion screening (Section 4.3). Most discussion online was around freedom of choice, and health concerns. While the latter featured in a small subset of the 25 respondents we found to be opposed, it was not common. It is likely that discussions visible online (primarily press articles and blog posts) reflect the political framing of the debate, and not the concerns of the general public.

This concern over artificial, processed, or "unnatural" ingredients must be understood in the context of the current trend towards unprocessed foods, with many food manufacturers marketing their products as "natural", "chemical-free", etc. This may shed some light on the reluctance of manufacturers to display folic acid prominently on packaging (Section 4.1); once again, any action that risks loss of sales in obviously unpalatable to manufacturers.

In the context of folic acid, these concerns are not grounded in any scientific fact, since synthetic folic acid is identical in chemical structure to one of the many forms of folate that occurs naturally in food. However, it is not clear how amenable such concerns are to information and education.

Political and media discussion of fortification has encouraged these ideas by tending to frame folic acid as a synthetic additive, as opposed to an essential vitamin (the latter was found to be rarely mentioned in media coverage). If folic acid were reframed as an essential B vitamin, it may help to mitigate some of the negative perception discussed above. During packaging analysis (Section 4.1), we noted that some brands listed folic acid in the ingredients list as "vitamin (folate)", which may indicate that manufacturers are aware of negative perception of folic acid, and may be looking for alternative ways to label products so as to avoid loss of sales resulting from this negative perception. A similar technique could be used

5.4. Consumer enablers

Awareness promotes uptake

Figure 11 suggests that awareness of fortification is an enabler of uptake of fortified breads: of those aware, 85% indicated they would continue to purchase bread if it was fortified, in contrast to 60% of those unaware. This increase in support was accompanied by a decrease in the level of uncertainty (rather than in the level of opposition, which was not significantly different between the two groups). These results suggests that efforts to increase public awareness of fortification, and understanding of its goals, would increase the level of support for and uptake of fortified breads.

The current level of awareness is fairly low, however if awareness is indeed an enabler of uptake, this means there is significant room for improvement of uptake. If the 46% of the population currently unaware became aware, our results suggest that the proportion of them who would confidently continue to purchase bread if it was fortified would rise from 60% to 85%, representing 12% of the total population who would otherwise have been unsure of their position.

Our survey assessed level of support for “fortification” (as opposed to more specific support for mandatory or voluntary fortification), however it is possible to draw some comparisons with existing data. Public submissions to the MPI in 2012 comprised a minority of responses in favour of mandatory fortification (29 of 134 submissions) (Wilkinson & MPI, 2012). We found that 80% of those aware of fortification were in support of it, and 75% of all respondents would continue to buy bread if it were fortified. Therefore, the 2012 submissions do not appear to be representative of public opinion. Submissions tend to represent the extreme or strongly held viewpoints, and it is possible that opponents of mandatory fortification were overrepresented in these submissions.

Preferred sources of information

Our survey found that online sources, such as the Google search engine, were the preferred method of receiving information about folic acid and fortification, closely followed by television advertisements (Figure 14). The latter was the most popular choice among the Māori/Pacific subgroup (Figure 15).

These data represent enablers to improved uptake because they can serve to inform future attempts to raise awareness, and we have already seen that awareness of fortification is an enabler to better uptake. However, the results of Section 4.3 revealed that misinformation is highly prevalent on the internet. Public preference for the internet as a source of information therefore poses a risk of propagating misinformation and lending weight to it as greater numbers

of people are subjected to it. Websites from authoritative sources, with a high search engine ranking, which describe the facts clearly in plain English, could help to mitigate this effect.

5.5. Summary of barriers and enablers

Manufacturer barriers	*Consumer barriers*
• Uninformative labelling • Few white breads fortified • Costs of fortification	• Low awareness of fortification • One in ten consistently opposed • Negative perception of folic acid

Manufacturer enablers	*Consumer enablers*
• Overestimate of consumer opposition • Awareness does not create opposition	• Awareness promotes uptake • Preferred sources of information

5.6. Limitations of the study

This study is subject to various limitations which may affect the internal and external validity of the results.

Analysis of packaging

19 of the 45 breads known to be fortified in New Zealand were able to be located in the Wellington supermarkets we visited. A large number of supermarkets from both Foodstuffs and Progressive Enterprises were visited to gain a representative view on what was available to the average consumer. Therefore the results from this analysis are representative of what the majority of the public can expect to find in the Wellington region.

Our analysis could be improved by locating the other 26 breads, in case they differ significantly from the 19 we found. Furthermore, we could improve our analysis by looking for breads in other regions of the country. Some varieties are only available in the South Island or East Coast of the North Island. Obtaining this extra data would be important for generalising our results on labelling to the country as a whole. However, as the majority of well-known bread brands with fortification were able to be located, it is unlikely that the smaller brands that we could not locate would substantially alter our results. Further, as these breads were not in the 16 major supermarkets we visited from a representative sample of the wider Wellington region, it is unlikely that packaging of these breads significantly influences consumer choice.

Manufacturer viewpoints

Because manufacturers declined our requests for interviews, our analysis of manufacturer beliefs and opinions were ascertained from previously published sources (Section 4.2). While these may have changed since publication and may not accurately reflect current opinions, they are the most accurate information we had access to. These sources are unlikely to accurately represent the true concerns of manufacturers - in particular, the 2012 Food and Grocery Council submission to MPI. The content of such a submission from an industry lobby group is more likely to be carefully calculated so as to best influence the political process, than to accurately summarise manufacturer concerns.

There was little incentive for bread manufacturers to respond to our questions. A study likely to gain more media attention, or involving central Government may have been more successful in eliciting a response. Furthermore, with such a short timeframe for requesting a response, combined with the serious implications that any response may have for their public image, it is understandable that the companies chose not to participate.

Online opinion screening

Online searches in articles, blogs, and other public forums were conducted to inform us of the breadth and scope of reasons for and against in New Zealand and major topics of debate. However, we acknowledge that views expressed in the internet and media are likely to represent extreme views on either side of the debate. Online sources were screened until no more new themes could be uncovered, which may bias the results towards those which appear earlier in search engines. We were unable to quantify the proportion of people who were for or against fortification (the prevalence of each argument), therefore we could not conclude that this was representative of the general public opinion. However, the online searches were integral in shaping the development of our consumer survey, and this was their main purpose.

Consumer survey

We chose to survey supermarket shoppers in the bread aisle as this was likely to indicate bread purchasers and thus the primary group of interest to manufacturers. We believe this represents a strength of our study, because previous studies have focussed on women of reproductive age. Our study is therefore uniquely posed to assess the population of most interest to manufacturers. The response rate was 80%, which may be due to how short the survey was, allowing it to be performed in under two minutes. Our sample size of 450 respondents was significant, given the very short window allowed for data gathering. We believe our results can be generalised to bread consumers in the greater Wellington region, although it is unlikely that they can be generalised to the entire NZ population. A larger sample, with more geographic and ethnic diversity, would be required for the results to be truly representative of the general New Zealand population.

The selected supermarkets were located in a wide range of geographic regions to obtain a sample population that included many demographics (Section 3.4, Figure 1). The dates and times of data collection were also varied to better represent the bread consumer population of New Zealand (Section 4.4.1, Figure 4). Our baseline characteristics vary considerably from the overall demographics of New Zealand, for example two thirds of respondents are female. However, while consumption of bread seems likely to be equally common in men and women, it is unlikely that the same holds for supermarket consumers (shoppers), which our data support.

Although efforts were made to standardise the questions in order to minimise response bias by questioning methods, some inconsistencies would still have occurred due to multiple interviewers. Questions were formulated to be as neutral as possible, and investigators were required not to give any information about folic acid to participants until after the survey, so as not to influence their responses. However, investigators did disclose that they were medical students at the University of Otago, which may influence respondents in their answers to reflect positively on health, thus introducing measurement bias through social desirability bias. Selection bias may have also been introduced with investigators likely to avoid shoppers who appeared rushed or ‘intimidating.’ In addition, investigators used their judgment to only approach shoppers who appeared 21 years or above to ensure informed consent in

participation which may have been inaccurate and biased against the younger end of the study population.

Responses were recorded using tick boxes to facilitate a more objective method of data collection, and opinions outside of the given tick boxes were noted in the ‘comments’ or ‘other’ section of each question. Some responses that emerged from respondents that were not included in the survey form were difficult to quantify and feature in our results as anonymous quotes.

Our initial survey was deployed at 3 supermarkets as a pilot study, however in the pilot study, Question 5 (regarding the best means of conveying information about fortification) was not a mandatory question. This was subsequently changed to be a compulsory question for the remaining 13 supermarkets. However this change in study design was considered minor and unlikely to change the results as it simply reduced the number of responses to our question. It is likely the information from the other 400 respondents was representative of preferences for how to receive information about folic acid fortification.

Despite asking all respondents how their purchasing behaviour may change if they knew the bread they normally purchased was fortified with folic acid, we did not gather reasons for any change in purchasing behaviour. Because the proportion of respondents who stated they would avoid fortified breads correlated well with the proportion of those aware who were opposed (for whom we did ask reasons), we have considered these groups to be related. This seems a reasonable assumption, however we note that for individuals who oppose fortification on libertarian grounds of freedom, continuing to purchase fortified bread is not inconsistent with their views.

6. Recommendations

Following extensive review of the literature (Appendix 4) and the research presented above, we strongly recommend that New Zealand implements mandatory fortification. The primary reason for this is that the current voluntary fortification programme is not reaching all pockets of society. Voluntary fortification relies on awareness of the requirement for folic acid with pregnancy, an active choice to choose breads containing folic acid and adequate labelling of breads containing folic acid. The results from our study show that none of the above requirements for successful voluntary fortification criteria are currently being met. There is a lack of awareness of fortification, and breads with folic acid are not adequately labelled. Results of the last audit of fortified breads (industry initiated and led) indicated only 14% of breads in New Zealand currently contain folic acid (Baking Industries Research Trust, 2013).

Mandatory fortification would give better reach of folic acid fortification thereby eliminating the requirement for improved awareness of folic acid in bread. In turn, this would reduce the disparities we observed in awareness of folic acid fortification between Māori/Pacific respondents and the remainder of the respondents. Problems with labelling would be less of a concer, since all breads produced by major bread manufacturers would contain folic acid. Breads without folic acid (especially organic breads or breads from smaller bakeries) could have folic acid added at the manufacturer's discretion, meaning that not *all* breads would contain folic acid. This would maintain freedom of choice for individuals who truly prefer to avoid folic acid.

The other major benefit of mandatory fortification is that it reaches all women of reproductive age, half of whose pregnancies will be unplanned. With the current voluntary fortification programme, many women who are not planning a pregnancy may not consider choosing a folic acid-containing bread as pregnancy-related health complications may not be as important to them as taste, price, or brand loyalty. This is an especially important consideration given that folic acid is required in the first 28 days following conception (embryogenesis) to ensure full closure of the neural tube, thereby preventing a NTD affected pregnancy. Mandatory fortification would ensure that blood folate stores are adequate *before* a pregnancy, which in turn would ensure blood folate stores were adequate during embryogenesis - the critical window for NTDs.

Mandatory folic acid fortification would also reduce the cost to bread manufacturers as they would not require special equipment to monitor folic acid levels in their bread as folic acid would likely be added at earlier stages of flour milling. This cost could be distributed among flour millers, government, and consumers. These costs have been estimated by both independent research groups and industry and vary widely. The estimated cost to consumers seem fairly consistent at approximately 0.5 cents per loaf.

Mandatory fortification is in line with the consensus position of the World Health Organization, the Food and Agricultural Organisation of the United Nation (FAO), the United Nations Children's Fund (UNICEF), Global Alliance for Improved Nutrition (GAIN), the Micronutrient Initiative, and the Flour Fortification Initiative (World Health Organization et al., 2009). The

position statement was “intended for a wide audience including food industry, scientists and governments involved in the design and implementation to flour fortification programs as public health interventions” (WHO et al., 2009). Our recommendations are also in line with recommendations from a 2012 report by the Flour Fortification Initiative (Luopa, L., Handforth, B., & Flour Fortification Initiative, 2012) and 82 other countries who have adopted some level of mandatory folic acid fortification of milled cereal products (usually milled wheat flour) (Food Fortification Initiative, 2014).

Mandatory fortification should run alongside an educational campaign to improve awareness of the role of folic acid in reducing the risk of NTD affected pregnancies. Our study has highlighted consumer concerns over ‘artificial and processed foods’. Educational interventions should focus on debunking these theories and informing the public of the benefits (and possible risks) of folic acid fortification. Ideally, the public should be equipped to understand health information that is disseminated via media, however this is difficult given the framing of certain topics and the inaccessibility of scientific evidence to the lay public. Informative advertisements and campaigns for folic acid fortification and awareness of NTDs should be delivered through TV and online mediums as our customer respondents identified these mediums as preferred tools for dissemination of information.

Alongside mandatory fortification of milled flour in New Zealand, we recommend that the folate status of women of reproductive age is continually monitored, to ensure that the intervention is reaching the target group. Further, we suggest that *all* NTD-affected pregnancies (including elective terminations, stillbirths, and live births) are reported in order to evaluate outcomes and the effectiveness of the intervention. Given the short history of folic acid fortification, long term effects are unknown. Therefore long term effects of folic acid exposure should be monitored to minimise adverse events in our population. Critical review of international evidence should be kept current in order to ensure evidence-based practice is maintained.

To address customer concerns over additives and processed foods (a concern that was highlighted as the most prevalent reason for opposition in our study), the government should implement more stringent food labelling laws. This would also increase customer awareness, which in turn would improve health literacy across the population, empowering individuals to take more control over their health outcomes.

Pragmatically speaking, if fortification is to remain voluntary, a greater understanding of the role of folic acid in reducing the risk of NTDs may lead to better delivery to women of childbearing age. This could be achieve through targeted interventions to educate women of childbearing age. Such interventions should target Māori and Pacific women to reduce health disparities (as they had lower rates of awareness of folic acid fortification in our study). It should also target young women, in whom our study showed low levels of awareness of fortification.

Given that the voluntary fortification programme is industry-driven, regular manufacturer audits should be conducted to ensure manufacturers adhere to predefined targets of 25-50% fortification. This should be monitored by central Government, potentially the Ministry of Health

or the Ministry for Primary Industries. Educational campaigns should go ahead regardless of whether fortification remains voluntary or becomes mandatory. The results from our study highlight the alarmingly low levels of awareness of this major public health issue. Given the overwhelming scientific evidence in favour of mandatory fortification, proponents should continue to campaign for a change to mandatory fortification.

Further research could follow from our findings that the main reason for consumer opposition was the perception folic acid was artificial or processed, and into the labelling of fortified bread products. Investigations into alternative ways to market folic acid (perhaps as "vitamin B9" or as "an essential B vitamin", and investigations of the effect of clearer labelling on bread consumption, would be useful. Further research should also monitor the prevalence of NTDs in New Zealand in order to assess the efficacy of voluntary fortification in achieving the ultimate goal of reduced NTD prevalence. Such research could also identify possible disparities that may arise due to the unequal distribution of folic acid under the voluntary standard.

7. Conclusion

This research was motivated by the present state of folic acid fortification of bread in New Zealand. Under the current voluntary system, manufacturers have failed to achieve pre-defined targets for fortification volumes, and there are no data available showing the effect of voluntary fortification on the prevelance of Neural Tube Defects. If voluntary fortification is to continue, then it is of interest to ask how NZ can make the best of the current situation. To that end, this research aimed to identify barriers and enablers to uptake of voluntary fortification in NZ, in order that future efforts are well-informed.

Unsurprisingly, the major barrier to manufacturer uptake was found to be cost, including concerns over lost revenue through reduce demand post-fortification. Manufacturers claim the prevalence of public opposition to fortification at 32%, however this is not consistent with our major finding of 10% opposition. Give the significance of cost to manufacturers, this much lower prevalence seems highly relevant to their choices in future fortification efforts. We also found that the primary reason for public opposition is a concern over folic acid being artificial or processed, and not over adverse health effects, or libertarian concerns around freedom of choice. This is in contrast to the key focuses of recent political discourse and media coverage of the issue.

Fortified breads available in NZ were found to be poorly labelled, many without quantitative information on folic acid content. We have argued that this represents a failure of manufacturers to fulfil their responsibilities to consumers, and, moreover, that this is inconstent with supposed industry concerns over preservation of consumer choice - it is very difficult for consumers to make informed choices without informative labelling.

On the consumer side, we found that awareness of fortification was generally low, and that improved awareness, while unlikely to reduce the level of opposition, is likely to increase confidence in fortified products and therefore promote consumer uptake. This finding suggests that educational campaigns are likely to improve the delivery of folic acid to women of reproductive age.

We recommend that New Zealand implements mandatory fortification of milled flour to improve the folate status of women of childbearing age across the population, and prevent the creation of inequalities. This is of particular importance given the low levels of awareness of folic acid fortification identified in this study and the poor state of labelling of currently fortified breads, factors which work in tandem to obstruct consumer uptake of currently fortified breads. If fortification is to remain voluntary, efforts to incease consumer awareness of fortification should target those who are currently least aware: Māori and Pacific people, and young women.

Appendix 1: Fortified breads available in New Zealand

Manufacturer	Brand	Varieties
Goodman Fielder	Rivermill	Wheatmeal Sandwich Wheatmeal Toast Natures Grain Toast
	Giant	Multigrain Sandwich Multigrain Toast Wheatmeal Sandwich Wheatmeal Toast
	Sunny Crust	Multigrain Toast Wholemeal Toast
	Golden Bake	Wheatmeal Sandwich* Wheatmeal Toast*
	Budget	Multigrain Sandwich Multigrain Toast Wheatmeal Sandwich Wheatmeal Toast
	Export	Wheatmeal Toast Grain Toast
	Pams	Multigrain Sandwich Multigrain Toast Wheatmeal Sandwich Wheatmeal Toast Mixed Grain Traditional Mixed Grain Toast Soy and Linseed Toast
George Weston Foods Ltd.	Burgen	Pumpkin & Chia Soy and Linseed Toast Soy and Linseed Sandwich Mixed Grain Toast Mixed Grain Sandwich Mixed Grain Long slice
	Tip Top Supersoft	Honey Grain Toast Honey Grain Sandwich Multigrain Toast
	Tip Top Goodness Grains	Sunflower and Chia 9 Grains Toast Original Swiss Toast Original Swiss Sandwich Soy and Linseed
	Norths	Multigrain
Yarrows	Salba	White Toast White Sandwich
Walter Findlay Ltd.	Eastlander	Multigrain Toast**
	Plain Pack	Multigrain Toast**

*Available in the South Island only.
**Available in Gisborne, Wairoa, and the East Coast of the North Island only.
Source: Baking Industry Research Trust, 2013 Annual Report (BIRT, 2014)

Appendix 2: Questions for manufacturers

1. What is your opinion on voluntary fortification of bread with folic acid in NZ?

2. What do you think is the prevailing public opinion (in general) regarding fortification of bread with folic acid?

3. Can you identify any barriers to NZ reaching the 50% fortified target set by the Baking Industry Research Trust? Why do you think the 25% target by the end of 2014 was not reached?

4. Are there any barriers preventing your company from fortifying more (or all) of your breads with folic acid?

5. What actions/changes do you think need to be made in order to remove these barriers?

6. If these barriers were removed, would it change your fortification practices? How?

7. Do you have any plans to improve the delivery of fortified bread to the target market (women of child bearing age)? If so, what are they?

8. For your breads that are fortified we were wondering why you choose not to advertise this on the front of the packet, as some cereals do? Is this due to labelling regulations or other reasons?

9. What impact has fortifying some of your breads had on the company? (e.g. additional costs, changes in sales etc.)

Appendix 3: Consumer survey

Date:	Time:	Location:	Supermarket:

Gender:
- ☐ Male
- ☐ Female
- ☐ X

Age (approach only if person looks over 21):
- ☐ 18 — 25
- ☐ 25—40
- ☐ 40 +

Ethnicity (multiple options can be ticked):
- ☐ NZ European
- ☐ Maori
- ☐ Pacific Island
- ☐ Asian
- ☐ Other……..

1) In NZ some breads have folic acid in them, were you aware of this?
- ☐ Yes
- ☐ No—go to question 4

2) What is your opinion on folic acid being added to bread, do you:
- ☐ Strongly agree
- ☐ Agree
- ☐ Neutral/ Doesn't mind
- ☐ Disagree
- ☐ Strongly Disagree
- ☐ Unsure

3) Reasons?

Pros (multiple options can be ticked, circle main reason):
- ☐ Health benefits (population or self)
- ☐ Neural tube/birth defects
- ☐ Trust scientific evidence

Cons (multiple options can be ticked, circle main reason):
- ☐ Freedom of choice
- ☐ Not necessary/ ineffective
- ☐ Artificial/processed
- ☐ Price increase concern
- ☐ Adverse health effects/safety*:

*Specific health concerns, if any:
……

4) If you knew the bread you normally buy had folic acid in it and was still the same price would you be:
- ☐ More likely to buy that bread
- ☐ Less likely to buy that bread
- ☐ Wouldn't affect my decision
- ☐ Unsure

Note: with current knowledge

5) Ask everyone (multiple options can be ticked):

Which of the following options would you choose to receive information about folic acid in bread?
- ☐ Television
- ☐ Poster/printed ads
- ☐ Online
- ☐ Social media
- ☐ Health professional

Any comments/other answers—if referring to a specific question write question number:

Appendix 4: Literature review

Folic Acid and Neural Tube Defects

Neural tube defects (NTDs) are a group of severe congenital abnormalities resulting from failure of the neural tube to close completely during embryogenesis, the most common of which are spina bifida and anencephaly (Frey & Hauser, 2003). NTDs as a group affect around 300,000 births globally each year (Centers for Disease Control and Prevention National Centre on Birth Defects and Developmental Disabilities, 2013). In 2008, New Zealand (NZ) had 64 NTD affected pregnancies, comprising 23 live births, 11 stillbirths and 30 terminations at a rate of almost 1 per 1,000 total births (Ministry for Primary Industries, 2012a). NTD prevalence varies internationally, from as low as 0.5 to as high as 10 per 1000 total births (Greene & Copp, 2014). NTDs are a public health concern in NZ given their extremely high (and ongoing) emotional, physical, and financial burden on the individual and their family. The economic cost has been valued at around $5.5 million per case with the majority of this burden attributed to the loss of life and disability associated with the disease (Access Economics Pty Limited, 2006).

The etiology of NTDs is known to be multifactorial, with various genetic, metabolic and environmental risk factors identified over the past 40 years (Greene & Copp, 2014). The identification of low serum folate (vitamin B9) levels in mothers of NTD foetuses (Hibbard & Smithells, 1965; Smithells, Sheppard, & Schorah, 1976) led to interest in the role of folate in the etiology, pathogenesis, and prevention of NTDs.

Folate is essential for proper cell division due to its role in nucleic acid synthesis. Although its precise role in NTD pathogenesis remains unclear, maternal serum folate level is known to be an independent risk factor for NTDs (Kirke et al., 1993), and many studies have since shown that maternal folic acid supplementation significantly reduces the risk of occurrence and recurrence of NTDs. While early studies investigated supplementation at 4mg/day (Laurence et al., 1981; Wald, Sneddon, Densem, Frost, & Stone, 1991), further research indicated that a lower dose was effective (Czeizel & Dudás, 1992). Due to the multifactorial etiology, dietary supplementation of folic acid alone is unlikely to prevent all occurrences of NTDs, however current evidence from interventional studies indicates that intake of 400µg/day can reduce NTD prevalence by 20-80% (Czeizel, Bánhidy, Dudás, & Paput, 2011; Castillo-Lancellotti, C., Tur, J.A., & Uauy, R., 2012).

International Implementation of Folic Acid Fortification

1992 was a pivotal year in Public Health. On 11 September the Centers for Disease Control and Prevention (CDC) in the USA made the following recommendation: 'All women of childbearing age in the United States who are capable of becoming pregnant should consume 0.4mg of folic acid per day' (CDC, 1992). This recommendation was based on evidence from two robust clinical trials showing that increasing a woman's folic acid intake significantly decreased the risk of giving birth to a baby with an NTD (Czeizel & Dudás, 1992; Wald et al., 1991). This recommendation prompted many countries to adopt similar policies on folic acid supplementation, including NZ in 1993. The current recommendation in NZ is that women planning a pregnancy take 800µg folic acid for four weeks prior to conception and for 12 weeks after conceiving, with a higher dose in women at higher risk (Ministry of Health, 2003). Those at higher risk include those with a family history of NTD, or those who have previously had an NTD-affected pregnancy.

Because NTDs occur in the early stages of pregnancy, and because pregnancy is often not confirmed until several weeks post-conception, supplementation with folic acid must begin before a woman

becomes pregnant in order to prevent NTDs. However, policy that only targets women *planning* a pregnancy will have fundamentally limited efficacy in reducing the prevalence of NTDs (Oakley & Tulchinsky, 2010), because around half of all pregnancies are unplanned. This is reflected in studies both internationally and in NZ which show that government recommendations around peri-conceptual supplementation alone fail to improve consumption of folic acid or improve trends in incidence of NTDs (Botto et al., 2005). In a study of over 6000 postpartum women in NZ, only 39% had taken folic acid prior to conception (Morton, Grant, & Atatoa Carr, 2013). Furthermore, certain population groups are at greater risk of not being supplemented. These groups include Māori, Pacific, Asian and Latin American women, women of lower socioeconomic status, lower education, younger age or increased parity (Morton, et al., 2013). This differential intake of folic acid across ethnic and social backgrounds may contribute to inequitable disparities in NTD incidence. Unfortunately, it is not known whether or not this has occurred in NZ, due to limited reporting on NTD prevalence since 2008.

Because of concerns around the limited efficacy of peri-conceptual supplementation, Government-mandated fortification of staple foods with folic acid was suggested as the most effective public policy to reduce NTD prevalence across society (Thurston 2009; Berry et. al 2010). Unlike targeted supplementation and partial fortification of the target food source, mandatory fortification is less likely to generate inequities (Thurston 2009). The United States Food and Drug Administration (FDA) enforced mandatory fortification of flour in 1998, setting a standard for the international community. It is estimated that mandatory fortification in the United States has saved $508 million annually in prevention of lifetime costs associated with NTDs (J. Williams et al., 2015). Prevalence of live births with NTDs in 45 US states dropped by 19% after one year following mandatory fortification (Honein, Paulozzi, Mathews, Erickson, & Wong, 2001). A study of long term rates of NTDs in South Carolina showed a 58% decline in prevalence between 1992-2009, with the steepest decline coinciding with the introduction of mandatory fortification over 1996-1998. However, it has been noted that supplement use also increased four-fold over the study period, which may be a confounding factor (Collins, Atkinson, Dean, Best, & Stevenson, 2011). An updated estimate from the CDC found that NTD prevalence decreased by 28% following mandatory fortification: this represents 1,300 births annually, which is higher than previously estimated. This was calculated using pre-fortification (1995-1996) and post-fortification (1999-2011) data on NTD cases from 19 surveillance programs, and thus estimates US national incidence which may not be accurate. The CDC confirmed the greatest decrease coincided with mandatory fortification, and that prevalence has remained stable since.

A definitive endorsement of worldwide mandatory flour fortification was made by the World Health Organisation (WHO) in April 2009 (Thurston, 2009; World Health Organization, et al., 2009). This statement reflected the consensus position of the WHO, the Food and Agricultural Organisation of the United Nations (FAO), The United Nation's Children's Fund (UNICEF), Global Alliance for Improved Nutrition (GAIN), The Micronutrient Initiative and Flour Fortification Initiative (WHO, et al., 2009). The position statement was "intended for a wide audience including food industry, scientists and governments involved in the design and implementation of flour fortification programs as public health interventions" (WHO, et al., 2009).

The WHO recommendation led to many more countries implementing mandatory fortification programmes, primarily through wheat- or grain-based products. Currently 82 countries worldwide have mandated folic acid fortification of at least one industrially milled cereal grain (Food Fortification Initiative, 2014), including Australia since 2009 (Oakley & Tulchinsky, 2010).

Canada, South Africa, Costa Rica, Chile, Argentina and Brazil have also reported significant declines in NTD prevalence following mandatory fortification, ranging from 19% to 55%. The magnitude of decline

depended on different outcome measures (live births or pregnancies), surveillance systems, consumption of the fortified food, folate status and prior NTD prevalence (Crider, Bailey, & Berry, 2011). Countries with the highest baseline rates, such as Chile, showed the largest decline (De Wals et al., 2007; López-Camelo, Castilla, & Orioli, 2010; Sayed, Bourne, Pattinson, Nixon, & Henderson, 2008). Data from Chile are shown in Figure 16.

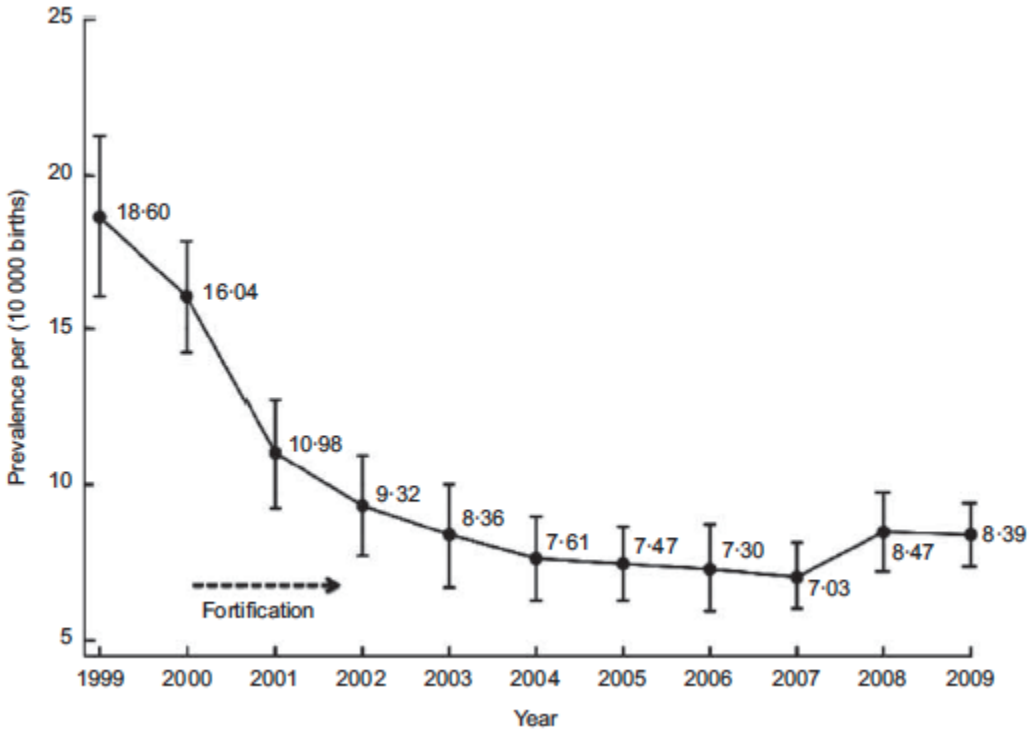


Figure 16: Birth prevalence of NTDs in Chile post-fortification between 1999-2009. Adapted from Castillo-Lancellotti, Tur, & Uauy (2012).

NZ began the process of implementing a mandatory fortification programme after the signing of Standard 2.1.1 of the Australian and New Zealand Food Standards Code in 2007 (Luopa, Handforth, & Flour Fortification Initiative, 2012). This was preceded by years of coordinated efforts by the voluntary, government, disability and private sectors (Luopa et al., 2012), including support from all political parties for mandatory fortification of bread or flour in 2001 (Thurston, 2009). Ultimately New Zealand decided to voluntarily fortify bread at bakeries instead of flour at mills. This has posed ongoing logistical barriers to achieving the recommended delivery of fortified folic acid to New Zealand women (Luopa et al., 2012). It was proposed that implementation at the flour milling stage would affect international trade (Wilkinson & MPI, 2012) and the decision was made despite both fortification of bread and voluntary fortification not being recommended by the WHO or the FDA (Luopa et al., 2012). Ireland took the same stance, permitting “voluntary fortification of foods without mandating flour fortification”. A publication endorsed by the Flour Fortification Initiative uses a review of proceedings in both aforementioned countries as a learning point to assists nations considering mandatory fortification in avoiding the same mistakes (Luopa et al., 2012).

Perceived Risk of Fortification

In 2007, a study was published that disproved the firmly held hypothesis that folate is a protective factor for the development of colorectal cancer (Cole et al., 2007), instead generating suspicion that folate may in fact *contribute* (albeit in a minor way) to the development of colorectal cancer (Miller & Ulrich, 2013). It was theorised that there exists a complex interaction between certain risks genotypes and folate metabolism in subjects with established cancer, but this was less clear with respect to the progression of precancerous lesions (Kim, 2007). A mechanism of carcinogenesis concerning the timing of folate exposure, its doses and form had yet to be well defined (Kim, 2007; Sanderson et al., 2007).

Consequently, further in depth studies and meta-analyses were carried out: to date there is insubstantial evidence for the role of supplemented folate in the etiology of colorectal and other cancers (Clarke et al., 2010; Houghton, 2014; MPI, 2012b; Vollset et al., 2013). Furthermore, FSANZ expects that doses to the general population following mandatory fortification in NZ would fall well below those used in the MPI meta-analysis (MPI, 2012b). Similarly these levels are not expected to result in harmful masking of B12 deficiencies (another potential adverse effect), nor is there evidence to suggest risk for any other complications brought to the attention of the Ministry for Primary Industries (MPI, 2012a).

In particular, trends in colorectal cancer in the US and Canada following the introduction of mandatory fortification have lent weight to suspicion that increased folic acid intake may be involved in disease progression (Miller & Ulrich, 2013). However, a recent study concluded fortification was unlikely to be the cause of these trends (Keum & Giovannucci, 2014). Scientific consensus in NZ is that folic acid supplementation or fortification has no significant effect on overall cancer incidence (MPI, 2012b).

Notwithstanding contemporary concerns, the implementation of fortification in several countries has successfully reduced the incidence of NTDs (Choi, Yates, Veysey, Heo, & Lucock, 2014). Beause no definitive conclusions about risks to non-target populations can be made with available evidence, it has been suggested that there should be ongoing research and monitoring with longer follow up (supplementation of greater than three years), particularly in those considered to be at a higher risk for colorectal cancer (Choi et al., 2014; Miller & Ulrich, 2013). One paper with longer follow-up time found a borderline statistically significant increase in prostate cancer incidence (RR 1.09 95% CI 1.00-1.18) (Wien et al., 2012). This evidence must be treated with caution; the research found no association between folic acid intake and increased mortality, and the study addressed supplementation with high doses of folic acid (greater than expected with fortification of food goods). The limited number of inconclusive studies prompted the Cancer Society (NZ) to take a precautionary stance in a recent position statement, recommending “that people with existing bowel adenomas and those with an increased risk of developing bowel adenomas should avoid taking nutritional supplements that contain high dose (greater than 1 mg (1000 µg) per day) folic acid” (Cancer Society of New Zealand, 2011). This is also the globally recognised tolerable upper level for daily intake in order to mitigate masking of vitamin B12 (Luopa et al., 2012).

The History of Fortification in New Zealand

New Zealand’s attempts to change fortification practices began in the early 1990s and were driven by Lyall Thurston, president of New Zealand CCS Disabilty Action and parent of a child with spina bifida (Luopa et al., 2012). His advocacy work involved the disability, commercial and political sectors (Luopa et al., 2012). In 1994 the National Health and Medical Research Council (NHMRC) released a position statement, recommending that fortification of flour with folic acid would be a beneficial measure for the reduction of NTD rates (Food Standards Australia New Zealand, 2007). During the following year NZ

introduced voluntary fortification based on these recommendations, in keeping with FSANZ (Luopa et al., 2012). An amendment made to the regulation in 1996 allowed folic acid to be added to breads, breakfast cereals, juices and some other foods (Borman, Brown, & Oakley, 1999).

In 1997 the Folate Replenishment-Plus Committee was formed, with the aim of promoting flour fortification (Luopa et al., 2012). A revision of their proposal was considered by the Ministry of Health in 1998, in which the recommendation shifted from fortification of flour at the milling stage, to bread at the manufacturer level (Luopa et al., 2012). The Minister for Food Safety's Cabinet report suggested that bread was chosen as the vector for delivery in 2007 because of the "(minimal) effects on international trade for the small number of flour millers in NZ" (Wilkinson & MPI, 2012). The Baking Industry Association of New Zealand (BIANZ; formerly known as the New Zealand Association of Bakers) opposed voluntary fortification due to concerns they had around consumer opposition and accrued costs of establishing a fortification process (Luopa et al., 2012).

The New Zealand Food Standard for Mandatory Fortification was drawn up in 2002 (Luopa et al., 2012). From 2004 FSANZ monitored evidence for the safety and feasibility of mandatory fortification, resulting in the final FSANZ proposal for mandatory fortification of bread being accepted in 2007. A transition period of two years was allowed before implementation in 2009 (MPI, 2012a; New Zealand Food Safety Authority, 2009). However, the change in government following the 2008 general election proved to be a major barrier to the progression of fortification in NZ. The newly incumbent National Party proved more sympathetic to the industry's concerns than the Clark-led Labour Government, and in 2009, the Minister for Food Safety Kate Wilkinson proposed postponement of the Standard until 2012, awaiting review. This followed an extensive, sudden, and aggressive media campaign (Rich, K. 2009), which exaggerated negative health effects, causing widespread doubt in the public.

The 2012 review, conducted by the Ministry for Primary Industries, resulted in bread fortification remaining voluntary in NZ. In 2014 a code of practice was signed by BIANZ with the aspirational goal of fortifying a minimum of 25% and a maximum of 50% of all bread by the end of 2014 (Borman & Poynter, 2014; MPI, 2012a). However, this has not been achieved as of 2015, with most recent data indicating that only 14% (by production volume) of packaged and sliced breads are fortified (BIRT, 2014).

2012 Cabinet Summary

Where not otherwise referenced, all of the following is taken from the MPI cabinet report 2012 as proposed by the NZ Minister for Food Safety (Wilkinson & Ministry for Primary Industries, 2012).

In 2012 the *Australian and New Zealand (mandatory fortification of bread with folic acid) Joint Food Standard (2007)* was replaced by a standard permitting voluntary fortification (MPI, 2012e). NZ can be made exempt from joint standards under section 8F or 8N of the New Zealand Food Act (1981). At this time plant bakeries (excluding small bakeries) made a commitment to fortify a minimum of 25% and up to 50% of bread by volume at higher concentrations (200µg-250µg/100g finished bread product) of folic acid. A conservative approach was taken in case of unknown vulnerabilities in non-target consumers. MPI was commissioned to work with the baking industry to monitor fortification levels alongside blood folate status in women of childbearing age. The cabinet paper outlined that 134 submissions were made during the public consultation held between the 22nd of May and 16th of July 2012 before the enforcement of this standard (from 30th September 2012), with 39 supporting 100% mandatory fortification and nearly all of the remainder (88) supporting continuation of voluntary fortification.

Submissions in support of 100% mandatory fortification were issued for the following reasons:
The implementation of the joint standard should result in a reduction to baseline rates of neural tube defect affected pregnancies (cases not associated with folate deficiency would persist). It is appropriate given the high percentage of unplanned pregnancies. There are highly significant emotional and financial costs to families and the community respectively. There is widespread lack of awareness about the requirements around folic acid intake with respect to pregnancy and low rates of folic acid supplement use. Fortification of bread is safe and mandatory fortification has been seen to be effective in other countries including Australia, the United States and Canada (Wilkinson & MPI, 2012).

The new standard was issued for the following reasons:
Although mandatory fortification would prevent the majority of NTDs, evidence suggests that fortifying a percentage of breads while increasing folic acid concentration still has a significant impact on reducing NTD incidence. The standard was estimated to reduce the annual incidence of approximately 80 NTDs by between 9 and 13 compared with a reduction of between 14 and 20 under mandatory fortification. This approach was designed to be complementary to additional public health initiatives (i.e. education, consumption of other folate fortified products and subsidized prescription supplements), while maintaining consumer choice and avoiding compliance costs to manufacturers imposed by a mandatory scheme. Consumer choice was deemed important because of concerns expressed during public consultation. Since the release of the joint agreement in 2007 women's blood cell folate levels had risen as a consequence of voluntary fortification. The 2008/09 NZ Adult Nutrition Survey (ANS 08/09) estimated that 26% of women had levels associated with a very low risk for an NTD pregnancy compared with 59% in 2011 (University of Otago & Ministry of Health, 2011). Other reasons for opposing the mandatory standard included a belief that the response was disproportionate to the small number of pregnancies affected, increased costs to consumers were expected, an objection to "mass medication" (a right to refuse medical treatment), and a perception of increased risk to the general population of adverse effects, with an associated drop in sales for the NZ bread industry.

The Cabinet summary quotes an industry-commissioned survey suggested that 32% of customers would move away from fortified products, as well as MPI data suggesting that 19% of consumers were concerned by a lack of choice with mandatory enforcement. Industry estimated a loss of revenue of $500 million for each 1% loss in sales per annum because of consumer opposition to fortification.

The revised standard recognises that a proportion of NTD affected pregnancies are not related to folate deficiency and therefore will not benefit from the scheme. It also appreciates that fortified food will provide an additional source of folate to those women at risk and who have an unplanned pregnancy or do not know about folate requirements prior to pregnancy. Bread fortification alone was deemed insufficient to reduce risk of NTD-affected pregnancies. The Minister noted in 2012 that the bread industry does not directly contribute to the problem and that it is unlikely to benefit from fortification of its products.

Bread Fortification

The New Zealand Association of Bakers (NZAB) set an "aspirational goal" of fortifying a minimum of 25% and a maximum of 50% of all packaged and sliced breads by the end of 2014 (Borman & Poynter, 2014; MPI, 2012a). However as of 2013, 14.4% of New Zealand production volume was folate fortified (Baking Industry Research Trust, 2013). The Baking Industry Research Trust 2014 annual report and audit recorded that marketing plans had been set in place to meet the 25-50% target outlined in the revised standard (BIRT, 2013). At the time of writing (April 2015), the 2015 annual report is yet to be released.

Awareness of folate's nutritional and medical benefits is quite low, especially among younger males for whom pregnancy is of little personal interest (Mallard & Houghton, 2012). The most knowledgable group are women who are currently or have been recently pregnant, with most of these women informed by their doctor. Mallard, Gray, and Houghton (2012) found that while only half of all women surveyed knew that some breads were fortified with folic acid, the rates of awareness were lower in some subgroups, including ethnic minorities (Māori, Pasifika, and Asian women), younger women, women with larger families, and women of low socioeconomic status.

Even among individuals who are aware of folic acid fortification of bread, there is still a lack of basic understanding at all levels of the clinical benefits of folic acid. It is thought that this is partly due to unclear explanations and misinformation (Food Standards Australia New Zealand, 2010). Some circles view fortification as a form of 'artificial processing' or as a 'marketing strategy' rather than improving health. Others feel mandatory fortification impinges on their consumer choice or freedoms (FSANZ, 2010). A recent survey found that 61% of postpartum women felt comfortable with the mandatory fortification scheme or held no opinion on the matter. A further 35% agreed with voluntary fortification, and 4% were strongly opposed to folic acid fortification (Mallard & Houghton, 2012). This contrasts with concerns from the baking industry, following a consumer surey, that fortification would cause 32% of consumers to move away from fortified breads (Wilkinson & MPI, 2012).

Early on in the development of New Zealand's fortification story, flour millers were hesitant to conform to fortification plans. They claimed it was not only costly, but technologically infeasible to adhere to a standard with such a tight margin for folic acid concentration. FSANZ estimated the start up cost to be $7.9 million, with an additional $1.1 million/year. On the other hand, the industry estimated a much higher financial burden, at $28.6 million for the initial year and $12.1 million for each subsequent year, attributed to the costs of equipment to monitor levels of folic acid in bread (FSANZ, 2007). FSANZ had estimated that the cost would be passed to the consumer, at approximately 0.5 to 1 cent per loaf of bread (Flour Millers' Council of Australia, 2008).

Subsequently, bread was chosen as a vehicle for folic acid fortification. This was followed by submissions by the baking industry regarding concerns over the ability to produce bread with uniformly distributed folic acid concentrations without exceeding the upper limit (guidelines of 100-170µg/100g bread) (Access Economics Limited, 2006; Flour Fortification Initiative, 2012). However this argument was countered as any effects of differences in concentrations of folic acid in bread should balance over time. Further, the industry argued that they may be sued if future studies show folic acid to be associated with adverse health outcomes. However this should not be a concern as under the Public Finance Act 1989 the Minister of Finance may offer indemnity "if it appears to the Minister to be necessary or expedient in the public interest to do so." The baking industry have also put forward a report listing all possible benefits and harms of folic acid, including increased risk of colorectal cancer, prostate cancer, and epigenetic effects (Smith & Refsum, 2012), most of the evidence for which is unconvincing or has been refuted. Unfortunately, these messages provoke fear and uncertainty amongst the public, which may account for much of the public feeling on unease around folic acid.

Bread was chosen as a vehicle for fortification because it is consumed by most women ensuring equitable coverage across New Zealand women of reproductive age (Green, Newton, & Bourn, 2003). Bread was found to be preferable over fortification of wheat flour and liquid milk, for three main reasons. Firstly, bread fortification levels can be easily monitored with 90% of all bread in New Zealand produced from two companies. Secondly, bread also is only one food group so will leave consumers with choice as opposed to flour which is involved in production of many food groups. Finally, higher intakes of liquid milk may expose certain groups to excessive levels of folic acid (children, for example) (Green, Newton, &

Bourn, 2003). Finally, the fact that New Zealand bread is not traded internationally means there would be a minimal impact on export food markets (MPI, 2012a).

The cabinet summary noted that Ireland was thought to be more successful with voluntary fortification because of the wider range of folic acid fortified products available. This was identified as a potential public health strategy for reaching fortification targets in New Zealand (Wilkinson & MPI, 2012). It is interesting to note that many breakfast cereals in NZ are already fortified with folic acid, and furthermore that their folate content is actively marketed (Sanitarium & New Zealand Health Association Limited, 2015; Borman, Brown, & Oakley, 1999).

The Current Status of Fortification in New Zealand

Following the release of the joint agreement in 2007, the 2008/09 NZ Adult Nutrition Survey (ANS 08/09) found that blood cell folate levels in NZ women had risen, likely as a consequence of voluntary fortification (University of Otago & Ministry of Health, 2011). Although mandatory folic acid fortification was revoked, there appear to be low levels of biochemical folate deficiency among NZ women of childbearing age. The most recent information from the ANS 08/09 shows that mean red blood cell folate (a measure of long-term folate status) of women above 15 years of age was 901 nmol/L (95% CI: 870-932 nmol/L) (University of Otago & MOH, 2011). 2% of the survey population was found to be biochemically folate deficient (under 315 nmol/L). The mean serum folate concentration (a measure of short-term folate status) in the same study population was 31.1 nmol/L (95% CI 29.4-32.8 nmol/L). There was no significant difference between Māori/Pacific and European women (Ministry of Health, 2012a, 2012b). However, despite the low prevalence of folate deficiency (Bradbury et al., 2014), the threshold for reducing the risk of NTDs is much higher, at 906 nmol/L (Daly, Kirke, Molloy, Weir, & Scott, 1995). Therefore it is highly likely that some women who are not folate deficient nonetheless have an increased risk of an NTD-affected pregnancy. The proportion of potentially affected women (maternal RBC folate below 906 nmol/L) has not been reported in these studies but is likely to be far higher than 2%.

The most recent serum folate information comes from the 2011 Folate and Women's Health Survey (Bradbury, 2013) and is similar to the findings from the ANS 08/09. Mean serum and erythrocyte folate concentrations were found to be 30 nmol/L and 996 nmol/L, respectively. Bradbury found that consumers of folic acid fortified bread had 25% higher serum folate concentrations compared with women who did not consume fortified bread. However, this study was conducted in a relatively small sample of 288 women of reproductive age. Results from the ANS 08/09 are in agreement with these findings. Furthermore, participants who ate breakfast regularly had higher serum folate concentrations (University of Otago & Ministry of Health, 2011).

While folate status in 2008/2009 and in 2011 (Bradbury, 2013) appears adequate to avoid biochemical deficiency, the proportion who may be at risk of an NTD affected pregnancy is less clear as data from the ANS 08/09 has been reported in strata of age and ethnicity rather than blood folate concentration (University of Otago & Ministry of Health, 2011). Furthermore, it is difficult to know if serum folate concentrations have changed in recent times, especially given that in 2013 only 14% of breads by volume were fortified (Borman & Poynter, 2014). A recent audit revealed the average folic acid levels of fortification breads was 182µg/100g (Baking Industry Research Trust, 2013), falling below the target level of 200µg/100g and maximum threshold of 250µg/100g under the New Zealand Food Standard 2012 (MPI, 2012e).

The most recent data on NTD prevalence in NZ (live and stillbirths) is from 2001-2008 and shows 5.4 cases per 10,000 total births. However, it is impossible to tell whether voluntary fortification has had any influence on this rate, because there has been no new data on dietary folic acid intakes or rates of NTDs in New Zealand since 2009 (MPI, 2012a). Studies in the US have found reductions in the risk of NTDs between 19 and 32% following mandatory fortification (Boulet, et al., 2008; Honein, et al., 2001; Mathews, 2009). Even larger reductions have been reported where prenatal information, including elective terminations, have been reported (Williams, et al., 2002). Some academics have praised folic acid fortification as being one of the most successful public health interventions in the past 75 years (Berry, Mulinare, & Hamner, 2010; Crider, Bailey, & Berry, 2011).

It is also difficult to ascertain whether voluntary folic acid fortification has influenced cancer rates in New Zealand. However, all relevant literature was accumulated in the Monitoring report (Ministry for Primary Industries, 2012b) and it was concluded that folic acid does not appear to have an adverse effect on overall cancer incidence. In fact, age-standardised incidence and mortality rates of colorectal cancer have decreased between 1994 and 2008. There also appears to be no indication of risk of site-specific cancers (including breast, colorectal, and prostate cancer) due to folic acid. However, overall, given the long latency period for the development of some cancers, it is difficult to draw explicit conclusions (Houghton, 2014).

Costs and Benefits of Folic Acid Fortification

The average cumulative cost for each NZ child affected by an NTD from birth to adolescence (up to 21 years) is $NZ944,000. This is due to the high number of hospital admissions and extended cumulative stays involving surgical procedures (Bowkett & Deverall, 2012). Even with treatment, quality of life is severely diminished with interventions aiming only to prevent deterioration rather than restore function (Bowkett & Kelly, 2009). These hospital costs when compared to a previous estimate of $355,000 by FSANZ (FSANZ, 2006) indicating the true hospital costs are higher than previous thought. These costs continue to climb past adolescence with screening, monitoring, and treatments adapted all the time for these patients adding to the significant comorbidity and economic cost (Bowkett & Deverall, 2012). The majority of the economic burden of disease is attributed the ‘value of life and suffering’ which has been estimated at a cost of over $4 million per case (MPI, 2012d). Costs include set-up and maintenance costs to industry, costs to consumers (estimated at one cent per loaf) as well as maintenance and monitoring costs to the Government (Ministry for Primary Industries, 2012d).

Table 4 summarises the benefits and costs of mandatory and voluntary fortification. Whilst mandatory fortification clearly includes additional costs for all parties, (industry, consumers, and Government), the benefits of preventing 14-20 NTD cases per annum (as opposed to preventing 1-2 NTD cases with voluntary fortification) and better reaching the target population to reduce disparities outweigh these costs (Ministry for Primary Industries, 2012a, 2012c).

Option1 – Full mandatory		Option 2 – Limited mandatory		Option 3 – Mandatory reporting only		Option 4 - Voluntary	
Benefits	**Costs**	**Benefits**	**Costs**	**Benefits**	**Costs**	**Benefits**	**Costs**
• Between 14 and 20 NTD cases prevented per annum. • Better reach to target population - will increase folic acid intake of women with unplanned pregnancies or who do not know about the importance of folic acid.	Industry • Increased costs of production: - One-off $1.5m; - On-going $1.9m p.a. • Increased compliance costs $50 -100,000 p.a. • Possible decrease in demand for products: @1% = $5m p.a. @5% = $25m p.a. • Reduced competitiveness Consumers • Increased price @ 1c/loaf = $1.8m p.a. • Lack of choice Government • Additional administration and enforcement ($100,000/year) • Adverse reaction from consumers to idea of "mass medication" of food supply.	Between 3 and 11 NTD cases prevented per annum	Industry • Increased costs of production. - One-off $0.2m -0.4m - Ongoing $0.6m-$1.1m p.a. • Increased compliance costs – higher than mandatory due to more complex record keeping and testing regimes. Consumers • Increased price – but may be able to avoid this depending on industry pricing policies. • Reduced choice (but more than under option1) Government • Additional administration and enforcement – likely to be around the same as for full mandatory.	Between 1 and 2 NTD cases prevented per annum. Consumers Choice preserved	Industry Increased compliance costs Government Monitoring costs to ensure reporting requirements complied with.	Between 1 and 2 NTD cases prevented per annum. Industry Any increased costs will be a business decision (retain control of marketing and pricing strategies) Consumers Choice preserved	Industry - Consumers - Government Adverse reaction from health professionals and disability groups.

Table 4: Summary of costs and benefits of the various fortification options considered in (and reproduced from) the Ministry for Primary Industries Regulatory Impact Statement (MPI, 2012c).

Summary

Despite industry commitment to increasing the proportion of fortified breads available to consumers (Watson & Baking Industry Research Trust, 2014), there has been only a marginal increase in folate intakes in New Zealand during this period (Baking Industry Research Trust, 2013). Increased voluntary bread fortification has led to a marginal increase in folate intakes (394 µg dietary folate equivalents/day) and an improvement in dietary folate adequacy from 63% to 71% (Evans, Mygind, Peddie, Miller, & Houghton, 2014). Overall, it appears voluntary fortification at the current levels is not sufficient to meet the needs of the population whilst mandatory fortification appears to be an effective and safe option.

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