

ROADBLOCKS TO PROGRESS:
A LOOK AT WHY IRELAND AND NEW ZEALAND
HALTED MANDATORY FLOUR FORTIFICATION WITH FOLIC ACID



Sheep blocking a road on the South Island in New Zealand symbolize the roadblocks faced in attempting to implement mandatory flour fortification in Ireland and New Zealand.

Photo by James Harrison



Flour Fortification Initiative
A Public-Private-Civic Investment in Each Nation

Table of Contents

Table of Contents	2
Summary	3
Acronyms	4
Acknowledgements	4
Introduction	5
Folic Acid: A Vital Micronutrient	5
Ireland	6
<i>Formation of Recommendation the Implementation Group</i>	6
<i>Findings of the Implementation Group (2008)</i>	7
<i>Postponing Mandatory Fortification</i>	8
New Zealand	8
<i>Political Support</i>	9
<i>Continued Concerns Halt Mandatory Fortification</i>	10
<i>Renewed Efforts</i>	12
Recommendations from the Flour Fortification Initiative (FFI):	13
Conclusion	14
References	15

Summary

In 2009, mandatory flour fortification with folic acid was progressing from idea to implementation in Ireland and New Zealand. Years prior, both countries recognized the devastation and costs incurred by neural tube defects (NTDs), and they wanted to curb the consequences of these disabling or fatal birth deformities. Each country followed its own path towards fortifying flour with folic acid, but ultimately both countries permitted voluntary fortification of foods without mandating flour fortification.

In 2006, Ireland methodically set up an Implementation Group on Folic Acid Fortification to assess the folate status of the population, estimate the country's rate of births affected by NTDs, evaluate current voluntary fortification practices and review data regarding health risks and benefits of fortification. Based on the group's findings, Ireland decided to postpone mandatory fortification indefinitely. In 2009, Ireland felt voluntary fortification alone enabled the country to both increase its population's folate status and decrease the occurrence of NTDs to levels comparable to other regions of the world.

In New Zealand, years of coordination between the civic, governmental and private sectors led to the signing of Standard 2.1.1 of the Australia and New Zealand Food Standards Code in 2007. The standard called for mandatory addition of folic acid to bread at bakeries rather than to flour during the milling process. This was partially due to the fact that the New Zealand Flour Millers argued the expense of equipping their mills for fortification and monitoring folic acid levels at the required range would put them out of business.

The standard permitted a lag period of two years for implementation. Similarly to 60 other countries, Australia committed to fortification of flour rather than bread and initiated the program as planned in 2009. Shortly before mandatory fortification with folic acid was scheduled for implementation in New Zealand, however, the mandate was postponed. Factors that impacted the 2009 decision to delay included a change of government leadership, strong concerns about folic acid fortification from industry members, and a powerful media campaign that cast a negative light on mandatory fortification with folic acid. Another review of mandatory fortification with folic acid will take place in 2012. In the meantime voluntary fortification is still permitted, and some companies, including Goodman Fielder, George Weston Foods, Yarrows and Couplands offer certain products that are fortified with folic acid. (see <http://www.bianz.co.nz/industry-news/folic-acid-fortified-breads-list.html> for complete list).

Despite the fact that both Ireland and New Zealand unexpectedly halted progress towards mandatory fortification with folic acid, their experiences provide insight into the steps countries take when assessing their need for fortification. The following document provides a glimpse into what prompted New Zealand and Ireland to assess the feasibility and benefits of mandatory flour fortification and subsequently, the factors that eventually led them to postpone mandatory fortification. By understanding the obstacles that arose in these two countries, advocates of fortification on the civic, corporate and government level can garner lessons on how to work around or address similar obstacles that may arise in future efforts.

Acronyms

FFI	Flour Fortification Initiative
FSAI	Food Safety Authority Ireland
FSANZ	Food Standards Australia New Zealand
g	Gram
µg	Microgram
mg	Milligram
MAF	Ministry of Agriculture and Forestry (New Zealand)
ng/ml	Nanograms per milliliter
NHMRC	National Health and Medical Research Council (New Zealand)
NTD	Neural tube defect
NZFSA	New Zealand Food Safety Authority
NZORD	New Zealand Organisation for Rare Disorders
RBC	Red blood cell

Acknowledgements

This document was compiled by Becky Handforth, a candidate for a master's degree at the Emory University Rollins School of Public Health and a Research Assistant at the Flour Fortification Initiative (FFI). Information was gathered through periodical research and correspondence with professionals residing in Ireland and New Zealand who have knowledge and experience regarding the mandatory flour fortification debates.

Introduction

By the 28th day of pregnancy, a flat neural plate has formed a tube which will become the baby's central nervous system. The top part of the tube will develop into the child's brain while the lower part will form the spinal cord. If the tube fails to close properly, the resulting deformity is a neural tube defect (NTD). Spina bifida and anencephaly are two of the most common NTDs. In mild cases, spina bifida causes limited sensation or movement. Severe cases cause paralysis or varying degrees of continence management problems. Some spina bifida symptoms can be treated with surgeries and therapy, but they cannot be cured. In anencephaly cases, the brain and skull do not properly form. This causes the infant to die shortly after birth.

Folic acid helps the neural tube form correctly. Women who take folic acid before conception and early in pregnancy decrease their risk of giving birth to a child with a NTD by 50-70 percent.¹ The United States, Canada and Chile are just a few countries that instituted mandatory flour fortification programs in the late 1990s and early 2000s to reduce the number of these birth defects.

By 2004, public and private entities in Ireland and New Zealand were discussing mandatory fortification policies as a means to reduce NTD-affected pregnancies. They recognized that moving beyond the status quo could reduce the emotional turmoil faced by parents and decrease health care costs. A study conducted with six NTD-affected teenagers at New Zealand's Wellington Hospital found that direct surgical and hospital costs to date had amounted to roughly NZ\$ 944,000 per individual.²

The following paper reviews the importance of folic acid, the history of Ireland and New Zealand's progress towards fortification with this nutrient, and the reasons mandatory fortification was ultimately postponed in both countries. While there are similarities between the countries' approaches, differences are obvious as well.

Folic Acid: A Vital Micronutrient

Folate is the natural form of vitamin B₉ found in a variety of foods, such as liver, collards, asparagus, lentils, beans, spinach and broccoli. However, women rarely get enough folate from these foods to prevent NTDs. This can be partially explained by three factors: diet quality, folate bioavailability, and folate loss during food processing and cooking.^{3,4} Foods rich in natural folate may also be cost-prohibitive to some consumers. Folic acid, the synthetic form of vitamin B₉, provides the same benefits as naturally occurring folate, but it is more bioavailable to the human body.⁵ Folic acid is often found in vitamin supplements and fortified foods.

Vitamin B₉ plays a role in red blood cell (RBC) development, supports other cell production, removes homocysteine from the blood, and helps the nervous system work properly. The symptoms of folate deficiency vary by individual, but may include fatigue, weakness, depression, headaches or in severe cases, anemia.

Women of child-bearing age should be especially mindful of their folic acid and folate intake. Vitamin B₉ is necessary before conception and in the early stages of pregnancy because the neural tube forms within

days after conception. Women who may become pregnant should consistently take folic acid because pregnancy is often unplanned, and by the time some women realize they are pregnant, it may be too late to take folic acid for NTD prevention.

Fortification is an inexpensive and effective way to increase folic acid levels among the general population. Fortifying wheat flour is an obvious strategy to consider given that foods made with wheat flour are widely consumed in many countries. The World Health Organization offers guidelines on recommended levels for fortifying wheat and maize flours with folic acid.⁶

Ireland

Ireland, which does not allow termination of pregnancies, historically had one of the highest rates of NTDs in Europe.^{7,8} In 1980, the NTD rate in Ireland was roughly 5 per 1000 births while the rest of Europe had rates around 1.2 per 1000 births.⁷ By 2004, Ireland's NTD rate had decreased to 1-1.5 per 1000 births, which is comparable to many other European countries.⁹ The positive change in NTD rate has been correlated to the increasing production of voluntarily fortified foods, a process which began in the early 1980's.⁹ One may also suggest that the Folic Acid Flash Labelling Scheme, which was implemented in 2001 by the Food Safety Authority Ireland (FSAI), increased the visibility and consumption of foods rich in folic acid. The labels, shown at right, vary based on the level of folic acid provided by the "amount of the product likely to be eaten in one day."¹⁰



Formation of Recommendation the Implementation Group

In 2004, the Minister of Health and Children established the National Committee on Folic Acid Food Fortification to get a better understanding of the feasibility and impact of fortification. The Food Safety Authority of Ireland (FSAI) acted as secretariat for the committee. After reviewing technical parameters, along with health benefits and risks linked to fortification, the committee provided policy recommendations to the Minister for Health and Children in July 2006. A key recommendation of the committee was to mandate fortification for the majority of Ireland's bread at a level of 120 micrograms (μg) of folic acid for every 100 grams (g) of bread.¹⁰ Whether to add folic acid during the flour milling or bread making process was left open for discussion.¹⁰ The Minister subsequently set up an Implementation Group in October 2006. The Implementation Group established working groups, each of which was chaired by a member of the Implementation Group. Goals set forth by the Implementation Group included:

1. Estimate the prevalence of voluntarily fortified foods in Ireland and their fortification levels.
2. Determine the point at which folic acid should be added during the bread-making process and the proper quantity of fortificant to use.
3. Survey Ireland's population to determine the population's current blood folate status.
4. Create a National Congenital Birth Defects Register.

- Evaluate scientific developments regarding health costs and benefits in relation to folic acid consumption and food fortification.

Findings of the Implementation Group (2008)

In 2008, the Implementation Group released a report with the following findings:

Access to Fortified Foods but Inaccurate Labeling: The Implementation Group conducted two surveys, one to estimate the number of voluntarily fortified products on the market and another to test folic acid levels in fortified bread. A product survey of major grocery store chains in Ireland showed that 211 food products were fortified with folic acid.⁹ It was determined that consumers had access to a sufficient amount of voluntarily fortified foods to reach their recommended daily intake of folic acid.⁹ Many of the fortified products were breakfast cereals and fat spreads.

The bread survey estimated that 25% of bread in Ireland was voluntarily fortified.⁹ However, in many instances, actual levels of fortification exceeded those declared on the packaging by 23% to 224%.⁹ A few sample breads labeled as fortified even tested negative for folic acid content.⁹

Folate Status: Given that folate is of utmost importance for women of child-bearing age, it was critical for the study to focus its efforts on this group. Folate status was determined by measuring each participant's plasma and RBC folate. Plasma folate reveals recent folate intake, while RBC folate is an indicator of folate stores (Table 1). Deficiency for women between the ages of 16 to 40 was defined as ≤ 2 nanograms per milliliter (ng/ml) of plasma folate or ≤ 150 (ng/ml) of RBC folate.⁹ Using those parameters, the study showed no more than 2.3% of the female population age 16-40 was folate deficient.

A 1995 study conducted in Ireland, however, found that women whose RBC folate levels were ≥ 400 ng/ml had the lowest risk for birthing a child with an NTD.¹¹ Their risk was only 0.8 per 1000 births while women whose levels were ≤ 150 ng/ml had a risk of 6.6 per 1000 births.¹¹ Using RBC as an indicator and ≥ 400 ng/ml as the adequate level, the Implementation Group's tests show that roughly 52 % of women age 16-40 had optimum folate status to prevent NTDs.

Table 1

Red Blood Cell Folate	Women Aged 16-40 (n=259)	Plasma Folate	Women Aged 16-40 (n=259)
Deficient ≤ 150 ng/ml	0.8%	Deficient ≤ 2 ng/ml	1.5%
Possibly Deficient 151-200 ng/ml	5.4%	Possibly Deficient 2-3 ng/ml	5.4%
Low-Adequate 201-400 ng/ml	41.3%	Low-Adequate 3-10 ng/ml	54.0%
Adequate-High 401-1000 ng/ml	51.0%	Adequate-High 10-20 ng/ml	32.0%
High >1000 ng/ml	1.2%	High >20 ng/ml	6.9%

Preferred Fortification Location: Voluntary fortification of bread in Ireland is largely based on the addition of an improver mix that is added to flour at the bakery-level. Given the varied findings regarding actual fortification levels in bread loaves, it was determined that adding folic acid to flour during the milling process would prove safer and more effective than adding the fortificant at the bakery-level. Also, the Implementation Group felt it would be more feasible and efficient to monitor a relatively small group of millers in comparison to the larger baking industry.

Inconsistent Fortification: Ireland's voluntary fortification program permits companies to alter their fortification levels at any time and discontinue fortification without notifying the consumer. Companies may also choose to fortify certain food products to a greater extent than others.⁹

Unclear Labeling: As the law stands, food packages must be labeled with the amount of folic acid per 100g of the product. Providing information to the consumer about the amount of folic acid per serving of the product is not required.⁹ This causes confusion among consumers.

*NTDs in Ireland-*The Implementation Group monitored birth defects between January 2005 and December 2006. During that time, 116 babies were born with NTDs, and 44 cases did not come to term (including 29 terminations).⁹ Data available in 2001 suggest that NTDs affected between 0.8 and 1.5 per 1000 births.⁹ However, this rate did not include terminations and is therefore an underestimate. If the proportion of terminations (25%) from the 2005-2006 monitoring data is applied to the 2001 data, one could surmise that NTD rates dropped from 1.25-1.88 to 0.93.⁹

Subsequent Findings: During the time that the Implementation Group was meeting, studies were published questioning whether high levels of folic acid intake could be linked to negative health consequences. The group reviewed this literature and found mixed results regarding folic acid's role in heart disease, cancer, and masking B₁₂.⁹

Postponing Mandatory Fortification

In March 2009, mandatory flour fortification was deemed unnecessary in Ireland. This decision was based on results of the Implementation Group's surveys along with monitoring and research.¹² Inconclusive study results regarding the link between excess folic acid in certain populations and negative health outcomes played a role in the decision to delay mandatory fortification indefinitely.¹² Also, voluntary fortification of an array of foods helped drop NTD rates to a level comparable with other countries.¹²

New Zealand

New Zealand's attempt to scale up fortification began in the early 1990s and involved civic, commercial and political groups. The process was championed by Lyall Thurston, Deputy Board Chairman of the Lakes District Health Board and the parent of a child with spina bifida. Mr. Thurston was committed to mandating fortifying flour with folic acid, and much of New Zealand's progress towards this goal can be attributed to his advocacy work.

A 1994 report by the National Health and Medical Research Council (NHMRC) concluded that fortifying flour with folic acid would be a beneficial measure for the reduction of NTDs.¹³ In 1995, a report proposed a Folate Replenishment-Plus Program to fortify flour with folic acid.¹⁴ The following year, New

Zealand introduced voluntary fortification based on the NHMRC recommendations.¹³ A 1997 nutrition survey established that mean dietary folate intake in the New Zealand population was 242µg, with males consuming more than females.¹⁵ Also during this year, the Folate Replenishment-Plus Committee was formed to promote flour fortification.¹⁶ Members of the scientific, research and industry sectors were included in the committee.¹⁷

In 1998, the committee began talks with the Ministry of Health and also revised its proposal to recommend the fortification of bread instead of flour. Subsequently, talks began with the Baking Industry Association of New Zealand.¹⁶ Also in 1998, the Australia New Zealand Food Authority (later renamed Food Standards Australia New Zealand or FSANZ) implemented a pilot program which permitted folate health claims on food packages or labels if the item contained at least 40µg of folate per serving. To use this label, these products were also required to contain no more than 500 milligrams (mg) of sodium, 10 g of sugar and 14 g of fat per serving.^{18,19} The recommended claim to be used by approved food manufacturers was “This food contains folate. A diet rich in folate may help prevent birth defects like spina bifida”.¹⁹ A logo (right) was created for promotion purposes and designed to advertise the nutrition quality of products. However, it was not widely embraced by industry members.¹⁹ The health claim is still voluntarily permitted.²⁰



In 1999, a report titled *Voluntary Fortification of Bread with Folic Acid* was presented to the Ministry of Health and the Baking Industry Association of New Zealand. Despite endorsement from the Ministry of Health in 2000, the Baking Industry Association of New Zealand did not embrace voluntary fortification. They feared reprisal from people who wanted only “pure” food, meaning food without additives.¹⁶ In August 2001, Folate Awareness Day was launched by the Honorable Annette King, Minister of Health. During her speech, she stated that the number of children born with spina bifida was on the decline. In 2000, there were 27 cases (including 10 stillbirths).²¹

Political Support

All political parties announced support of fortifying with folic acid in January 2001.¹⁶ A cross-party letter was sent to the Baking Industry Association of New Zealand and the New Zealand Flour Millers Association announcing support of fortification.¹⁶ Yet bakers argued that if 98% of bread were fortified, consumers who do not want fortified bread would not have a suitable number of product choices.

In 2002 a New Zealand Food Standard for mandatory fortification was created.¹⁶ In 2004, FSANZ released a proposal with four options for managing the folate intake of New Zealand’s population. These included maintaining the status quo, extending permission for voluntary folic acid fortification, executing a mandatory folic acid fortification program, and increasing health promotion and education regarding folate intakes.¹³

Throughout 2005 and early 2006, FSANZ continued to seek advice to ensure that mandatory fortification would be cost-effective and safe.¹³ It appeared that fortification was progressing as a high priority in the government.

While the 2004 proposal included four options, FSANZ refined the approach in October 2006 to require mandatory fortification of bread.¹³ The next month, the Ministerial Council requested a first review of the draft variation to the *Australia New Zealand Food Standards Code* and allowed FSANZ six months to complete the review.¹³

In June 2007, the Final Assessment Report was released by FSANZ. After a review, which focused on technical feasibility, international experience, health risk factors and a cost benefit analysis, the report confirmed that mandatory fortification of bread with folic acid was a worthwhile policy change. Acting on the FSANZ report, the council affirmed the draft standard for mandatory fortification with an allowable two-year transition period. Mandatory fortification nationwide would start on 27 September 2009 with the exemption for organic and unleavened bread.¹⁶

The campaign for folate fortification was a well-coordinated effort by leaders including Lyall Thurston in New Zealand and Fiona Stanley, Carol Bower, and Mike Daube in Australia. Most advocacy activities aimed to generate change through ministerial and health promotion groups along with FSANZ, a bi-national agency of Australia and New Zealand.²² Although the *Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System* has been in place since December 5, 1995, only Australia succeeded in achieving mandatory fortification.

Continued Concerns Halt Mandatory Fortification

As the deadline for mandatory fortification drew near, the popular and political climate in New Zealand changed to disfavor fortifying bread with folic acid. In 2009, fanned by a well-orchestrated media campaign, country leaders postponed mandatory fortification by amending the 2007 standard. A change in political leadership also gave rise to concerns about costs to the industry, unconfirmed negative health effects, and whether the NTD prevalence in New Zealand justified mandatory fortification. The next review of mandatory fortification is scheduled for 2012. The following sections provide more information about the factors that contributed to the decision to postpone national scale fortification:

Media Campaign: On 12 July 2009, a widespread commercial campaign was initiated, predominantly supported by the New Zealand Food and Grocery Council, a group that opposed mandatory fortification. Proponents of fortification were alarmed by the sudden onset of the campaign. Many fortification advocates felt the statistics presented were taken out of context or failed to provide supporting evidence. For example, fortification opponents claimed women would have to eat 11 slices of bread a day to get the amount of folic acid recommended to prevent NTDs.²³ This became a popular quote in media coverage even though fortified foods are meant to augment a person's folic acid intake, not act as the sole supply.

The advocates who wholeheartedly supported fortification for years were disheartened by the media's portrayal of fortification. After the campaign, complaints were made to broadcasting companies, citing a breach in their standards. These government regulations require media networks to give fair representation of controversial issues, seek accuracy in relation to points of fact and defer from presenting issues that may cause panic or unnecessary stress.¹⁶ However, after conducting an investigation of the complaints, the Broadcasting Standards Authority ruled that coverage of the debate surrounding folic acid fortification did not breach broadcasting standards.²⁴

Political Environment: In the November 2008 elections, New Zealand's National Party overtook the Labour Party. New leaders made the ultimate decision to postpone fortification, siding with industry arguments and emphasizing that Ireland's voluntary program has shown positive benefits while still providing consumers with choices.²⁵ Professor Fiona Stanley, Director of the Telethon Institute for Child Health Research in Australia, noted that in addition to stopping fortification, New Zealand's new government wanted to retract many of the former government's public health interventions, such as healthy school lunches.²⁶

The New Zealand Organisation for Rare Disorders (NZORD) filed a complaint against Kate Wilkinson to the Regulations Review Committee of Parliament in December 2009. NZORD claimed the 2009 amendment was not in accordance with the original intentions of the Food Act to protect public health and align with international food recommendations. The complaint also asserted that the amendment did not uphold New Zealand's obligations to the Australia-New Zealand Joint Food Standards Agreement.²⁷ It suggested that Wilkinson acted outside the authority given to her under the Food Act and that her decision was not made in compliance with the consultation procedures specified by the Food Act.^{27, 28} Ultimately, The New Zealand Food Safety Authority (NZFSA) found no fault with the minister's actions, thereby failing to accept that the 2009 amendment was in breach of standing orders.²⁷

Industry: From the beginning, the flour milling industry was hesitant to conform to fortification plans. Millers claimed it would be costly if not technically infeasible to adhere to a standard that only allowed for a 1 mg/kg upper and lower level margin.²⁹ FSANZ estimated the start-up costs to be \$7.9 million with another \$1.1 million per subsequent year.¹³ The industry, however, estimated the financial burden to be much higher at \$28.6 million for the initial year of mandatory fortification, followed by \$12.1 million each successive year.¹³ The higher industry estimates are derived from costs of equipment to tightly control the amount of folic acid in fortification and analytical testing that would be frequently necessary to ensure compliance with the mandatory range of folic acid.²⁹ According to FSANZ, costs related to fortification would be passed along to the consumer at a cost of 0.5% to 1.0% of a loaf of bread (using price data from Australia).²⁹

When the proposal was altered to promote fortification at the bakery-level, concerns were raised by the bakers regarding uniform distribution of the fortificants and the ability to meet fortification guidelines (100-170 µg per 100g of bread³⁰). Although NZFSA worked with the industry when developing the standard and the proposed levels appeared achievable, further research indicated difficulties in ensuring all slices of bread had uniform amounts of folic acid.³¹ NZFSA remarked that the most important factor was for each *loaf* of bread to meet standards.³¹ They argued that people are likely to eat multiple slices from the same loaf and would therefore obtain expected intake over time.³¹

The industry was also adamant that it could be sued if future studies determined folic acid is associated with poor health outcomes. However, NZFSA noted that this should not be a concern because 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".³¹

Unconfirmed Health Effects: Medical and research communities worried that mandatory fortification would put some populations at risk of consuming too much folic acid. One document published by

FSANZ estimated that mandatory fortification could result in high levels of folic acid in 9% of 2-3 year olds and 4% of 4-8 year olds.¹³ The *New Zealand Medical Journal* also raised concerns by reminding the population that high levels of folic acid may mask clinical signs of vitamin B₁₂ deficiency in the elderly. The globally recognized tolerable upper level of daily folic acid intake among adults is set at 1000µg to mitigate the possibility of the masking effect. Also, people rarely consume such high levels of folic acid unless they are taking a high-dose supplement.^{32, 33} Similar to Ireland, the lack of consistent findings regarding the relationship between cancer and folic acid had an impact on the final decision to forgo mandatory fortification.

NTD Rates: The most recent report from the International Clearing House for Birth Defects Surveillance and Research indicates New Zealand's NTD incidence is roughly 0.6 per 1,000 births.³⁴ However, the report did not account for stillbirths or terminations of pregnancy due to NTDs. The United States saw a 19% reduction in NTD birth prevalence from the pre-fortification period of 1995-1996 to the post fortification period of 1998-1999.³⁵ Applying this percent reduction to New Zealand's NTD rate in 2001, one author concluded that fortification would only reduce NTD births by four cases per year.³⁶ A FSANZ report suggested that mandatory fortification would decrease NTD rates in New Zealand by up to 20% which translates to between four and fourteen NTD births per year.¹³ To many New Zealanders, these small numbers were insufficient evidence for mandatory fortification, especially since flour fortification could not be guaranteed to reach all women who might become pregnant. Some argued that encouraging women of childbearing age to take folic acid supplements makes more sense. However, supplements are only effective for women who consistently take the supplement while they are planning their pregnancy. Fortification, on the other hand, does not rely on consumer behavior changes. In general, 50% of pregnancies are unplanned.³⁷ This means a high proportion of mothers may not take folic acid supplements at the opportune time.

Renewed Efforts

New Zealand continues to study the value of fortifying bread with folic acid, and a policy decision is expected in April 2012.³⁸ A study by the Ministry of Agriculture and Forestry (MAF), commissioned by NZFSA, evaluated women's knowledge of the role of folic acid. The results, published in 2011, show that 54% of the women mentioned (unprompted) that folic acid was necessary to take before or during pregnancy, but their knowledge about specific benefits was limited.³⁹ Also, the importance of folic acid and folate are rarely considered outside of pregnancy.³⁹ The majority of participants knew about the availability of folic acid in supplemental form, and 75% could list a specific food or drink known for high folate content.³⁹ There was no strong consensus in the population about adding folic acid to bread products.³⁹ Individuals who expressed concern about mandatory fortification felt such a policy would limit their choice of bread products (19% of all respondents).³⁹

New Zealand has also begun a project to monitor the effect of voluntary fortification on blood folate status of women of child-bearing age.³⁸ Final results are expected by December 2011. A new public discussion paper will be written by MAF by the end of 2011. Public input will be welcomed from December 2011 to February 2012.

Recommendations from the Flour Fortification Initiative (FFI):

In both Ireland and New Zealand, fortification advocates worked tirelessly to drive their countries towards mandatory flour fortification as a means to reduce the rates of children born with preventable birth defects. Based on insight from the experiences of these two countries and the efforts of fortification advocates, FFI shares these recommendations for future leaders of fortification movements:

1. **Mandatory fortification is recommended because voluntary fortification may not distribute folic acid benefits evenly throughout society.** Ireland credits the voluntary fortification of numerous food options to the reduction of NTDs. However, with an increasing variety of fortified foods on the market, some individuals might consume large amounts of folic acid while others may consume hardly any. If fortification is required for a limited number of the most commonly eaten food products, consumer intake is in turn more evenly distributed, quality is better ensured, and costs are normalized across the industry.
2. **Mandatory fortification is recommended because voluntary fortification leads to inconsistent fortification levels.** When fortification is voluntary, a cereal company may fortify one product at 100µg/100g and another with twice as much folic acid. The level of folic acid in products may be altered at anytime, according to the manufacturer's discretion. Consumers may fail to notice any changes made. In addition, fortification levels are not consistent from company to company. For instance, a corn flakes cereal made by one company may be fortified while the same type of cereal made by another company may not be fortified. Under a voluntary approach, fortification may not occur at all.
3. **Fortification of bread is not recommended.** Monitoring issues in New Zealand could have been easily addressed had the country proposed fortifying flour at mills rather than fortifying bread at bakeries. All countries that currently require mandatory fortification with folic acid, including Australia, add the fortificant as part of the flour milling process. Most flour is milled in centralized locations where routine monitoring is conducted. Many modern mills already have the equipment to add flour improvers, and testing standards are well-established for flour fortification. In contrast, the fact that bakeries are prevalent and often small inherently inhibits consistent monitoring efforts due to cost and time.
4. **Food labeling laws should be consumer friendly.** In Ireland, the current food labeling laws make it difficult for the consumer to understand how much folic acid is in a serving of food. At the present time, folic acid content does not have to be listed per serving size but rather as content per 100g of the product. If the food package only lists the second option, consumers must have patience, math skills and knowledge about serving size to track their intake properly.
5. **Critical review of continued research is needed.** Some research studies associate folic acid with multiple health benefits in addition to reducing NTDs, but other studies raise concerns about health risks that may be linked to high doses of folic acid. While folic acid's role in preventing NTDs is clear, advocates should be prepared to critically review future studies to address concerns voiced by the public, medical community and those in academia. The article "Reporting and Interpretation of Randomized Controlled Trials With Statistically Nonsignificant Results for

Primary Outcomes” in the January 2010 issue of the *Journal of the American Medical Association* provides insight into how the interpretation and reporting of study findings can be inconsistent with the study results.⁴⁰

6. **Monitoring a population’s folate status is vital.** Without consistent monitoring, it is difficult to assess a population’s baseline nutrition status before fortification and consequently understand fortification’s impact. Ireland conducted a nutrition survey among its population as part of the Implementation Group’s goals. The results pointed to the fact that voluntary fortification was positively impacting NTD rates. In New Zealand, the 1997 National Adult Nutrition Survey was the only source of folate data available to inform the fortification talks.¹⁵ In the Initial Assessment Report, FSANZ acknowledged a lack of information regarding the prevalence of folate deficiency in New Zealand.⁴¹ For the 2008/2009 Adult Nutrition Survey, blood samples were drawn to assess folate status of the population.⁴² This updated information will be available June 2011 from the New Zealand Ministry of Health.⁴²
7. **Groups engaged in the policy-making process for mandatory flour fortification should be prepared to engage media outlets.** In the fortification advocacy process, a few people with strong communication and persuasion skills, along with political finesse, should be responsible for media relations. These advocates can proactively suggest positive fortification stories to the media and have solid facts to back up negative responses with a unified voice. For example, supporters of flour fortification in New Zealand were ultimately blindsided by negative industry campaigns that were prominently displayed in the media after the standard was approved.
8. **New individuals coming to government offices must be educated about fortification.** Even though Standard 2.1.1 of the Australia and New Zealand Food Standards Code was passed in 2007, political support shifted when a new party came to power. Until any food standard or law is enforced nationwide, fortification proponents cannot back down. In countries where fortification comes to fruition, advocates need to monitor program effectiveness and compliance. Results from effectiveness studies should be disseminated among government leaders to ensure continuation of the program.

Conclusion

Individuals and organizations in Ireland and New Zealand worked extremely hard to promote mandatory flour fortification legislation as a means of delivering additional folic acid to people in their countries. Their efforts raised awareness of folic acid’s health impact and increased voluntary fortification activities. While mandatory flour fortification in both countries has been postponed, lessons can be gained from reviewing and assessing their experiences. By understanding the evolution of Ireland’s and New Zealand’s diverted plans, other countries will be better equipped to anticipate obstacles to the successful implementation of mandatory fortification food standards.

References

1. Centers for Disease Control and Prevention. Recommendations for the Use of Folic Acid to Reduce the Number of Cases of Spina Bifida and Other Neural Tube Defects, MMWR. 1992;41:(No. RR-14). <http://www.cdc.gov/mmwr/preview/mmwrhtml/00019479.htm>.
2. Newton K. \$1 million per child sparks folate call. *The Dominion Post*. 11 September 2010.
3. McKillop DJ, Pentieva K, Daly D, McPartlin JM. The effect of different cooking methods on folate retention in various foods that are amongs the greatest contributors to folate intake in the UK diet. *Br. J. Nutr.* 2002;88:681-688.
4. Han Y, Yon M, Hun T. Folate intake estimated with an updated database and its association to blood folate and homosysteine in Korean college students. *Eur. J. Clin. Nutr.* 2005;59:246-254.
5. Bailey LB. Dietary Reference Intakes for Folate: The Debut of Dietary Folate Equivalents. *Nutr. Rev.* 1998:294-299.
6. World Health Organization. *Recommendations of Wheat and maize Flour Fortification Meeting Report: Interim Consensus Statement*. Geneva 2009. http://www.who.int/nutrition/publications/micronutrients/wheat_maize_fort.pdf.
7. Abramsky L, Busby A, Dolk H. Promotion of periconceptional folic acid has had limited success. *The Journal of the Royal Society for the Promotion of Health.* 2005;125(5):206-209.
8. Araceli Busby et al. Preventing neural tube defects in Europe: A missed opportunity. *Reprod. Toxicol.* 2005;20:393-402.
9. *Report of the Implementation Group on Folic Acid Food Fortification to the Department of Health and Children*. Dublin: Food Safety of Ireland;2008. http://www.fsai.ie/uploadedFiles/folic_acid.pdf.
10. *Report of the National Committee on Folic Acid Food Fortification*. Dublin: Food Safety Authority of Ireland;2006. http://www.fsai.ie/uploadedFiles/folic_acid.pdf.
11. Daly L, Kirke P, Molloy A, Weir D, Scott J. Folate Levels and Neural Tube Defects: Implications for Prevention. *JAMA.* 1995;274(21):1698-1702.
12. Folic Acid Today and Everyday. Currently No Need for Mandatory Fortification-Increased Folate Status Negates Mandatory Folic Acid Fortification at This Time. 2009. http://www.folicacid.ie/press/press_20090311.html Accessed December 13, 2010.
13. Food Standards Australia New Zealand. *P295 Consideration of Mandatory Fortification with Folic Acid*: Food Standards Australia New Zealand;2007. <http://www.foodstandards.gov.au/srcfiles/P295%20Folate%20Fortification%20FR%20+%20Attach%201%20FINAL.pdf>.
14. Singh S, Elliot R. Prevention of Spina Bifida in New Zealand Auckland: Department of Paediatrics: University of Auckland; 1997.
15. Russell D, Parnell W, Wilson N. *NZ Food: NZ People: Key Results from the 1997 National Nutrition Survey*: Ministry of Health;1999. [http://www.moh.govt.nz/moh.nsf/0/8f1dbeb1e0e1c70c4c2567d80009b770/\\$FILE/nns.pdf](http://www.moh.govt.nz/moh.nsf/0/8f1dbeb1e0e1c70c4c2567d80009b770/$FILE/nns.pdf).
16. Thurston L. Submission to the Proposed Amendment to the New Zealand Folic Acid Standard, NZFSA Public Discussion Paper; no. 10/09 22 July 2009: Coalition of Parents of Children with Spina Bifida; 2009.
17. Barber F, Sell B. Staff of life...with a boost. *New Zealand Herald*. 2000. http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=108605. Accessed 23 November 2010.

18. Bourn DM, Newton R. Estimated dietary folic intakes and consumer attitudes to folate fortification of cereal products in New Zealand. *Australian Journal of Nutrition and Dietetics*. 2000;57(10-17).
19. *Evaluating the Folate-Neural Tube Defect Health Claim Pilot: Outcome Evaluation*: Australia New Zealand Food Authority;2000.http://www.foodstandards.gov.au/scienceandeducation/publications/evaluatingthefolateneuraltubedefecthealthclaimipilot/evaluatingthefolaten1039.cfm#_ackn.
20. *Final Assessment Report Proposal P293: Nutrition, Health and Related Claims*: Food Standards Australia New Zealand;2008.<http://www.foodstandards.gov.au/srcfiles/P293%20Health%20Claims%20FAR%20and%20Att%201%20&%202%20FINAL.pdf>.
21. King A. Launch of Folate Awareness Day. 2001. <http://www.beehive.govt.nz/node/11615>. Accessed 23 November 2010.
22. Daube M. Lessons learned in Ireland and New Zealand - for your review. In: Zimmerman S, ed2010.
23. New Zealand Parliament: House of Representatives. Questions for Written Answer:8126. 2009. http://www.parliament.nz/en-NZ/PB/Business/QWA/a/5/8/QWA_08126_2009-8126-2009-Sue-Kedgley-to-the-Minister-for-Food-Safety.htm. Accessed December 7, 2009.
24. Radich P, Misa T, Shanahan MA, Pearson L. Complaint under section 8(1B)(b)(i) of the Broadcasting Act 1989. In: Broadcasting Standards Authority, ed2010.
25. New Zealand Parliament: House of Representatives. Questions for Oral Answer: Folic Acid in Bread-Commencement of Mandatory Requirement. 2009. http://www.parliament.nz/en-NZ/PB/Business/QOA/3/e/9/49HansQ_20090721_00000007-7-Folic-Acid-in-Bread-Commencement-of-Mandatory.htm. Accessed 18 March 2011.
26. Stanley F. Your thoughts about fortification in New Zealand. In: Handforth B, ed2009.
27. Regulations Review Committee. *Complaint regarding the New Zealand (Mandatory Fortification of Bread with Folic Acid) Amendment Food Standard 2009*: Parliament;2010.http://www.parliament.nz/NR/rdonlyres/325EAF90-042F-46A2-852B-3717607ABC32/155212/DBSCH_SCR_4849_Complaint_7751_9.pdf.
28. New Zealand House of Representatives. Complaint regarding the New Zealand (Mandatory Fortification of Bread with Folic Acid) Amendment Food Standard 2009. *Regulations Review Committee*. Vol 2010.
29. Flour Millers' Council of Australia. *Productivity Commission-Regulatory Burdens-Manufacturing & Distributive Trades*2008.http://www.pc.gov.au/data/assets/pdf_file/0007/78406/sub12.pdf.
30. Access Economics Pty Limited. *Fortification of Bread with Folic Acid*2006.<http://www.accesseconomics.com.au/publicationsreports/getreport.php?report=112&id=148>.
31. New Zealand Food Safety Authority. Folic Acid-New Zealand Food Safety Authority Response: Key Issues. <http://www.nzfsa.govt.nz/consultation/folic-acid/nzfsa-response/index.htm>.
32. Yang Q, Cogswell ME, Hamner HC, et al. Folic acid source, usual intake, and folate and vitamin B-12 status in US adults: National Health and Nutrition Survey (NHANES) 2003-2006. *Am. J. Clin. Nutr.* 2010;91:64-72.
33. Bailey RL, Dodd KW, Gahche JJ, et al. Total folate and folate intake from foods and dietary supplements in the United States: 2003-2006. *Am. J. Clin. Nutr.* 2010;91:231-237.
34. The Center of the International Clearinghouse for Birth Defects Surveillance and Research. *Annual Report 2008 with data for 2006*. Roma, Italy2008

35. Honein M, Paulossi L, Mathews T, Erickson J, Wong L. Impact of fortification of the US food supply on the occurrence of neural tube defects. *JAMA*. 2001;285:2891-2896.
36. Skeaff M, Green T, Mann J. Mandatory fortification of flour: Science, not miracles, should inform the decision. *Journal of New Zealand Medical Association*. 2003;116(1168).
37. Lawrence M. Challenges in translating scientific evidence into mandatory food fortification policy: an antipodean case study of the folate-neural tube defect relationship. *Public Health Nutrition*. 2005;8(8):1235-1241.
38. Folic Acid Working Group. *Quarterly Report-March*. New Zealand 2011
39. Kalafatelia E, Fryer K. *Awareness and Knowledge of Folate and Folic Acid: A Survey of New Zealand women of child-bearing age*. Wellington: Ministry of Forestry and Agriculture; 2011. <http://www.foodsafety.govt.nz/elibrary/industry/folate-NZ-women.pdf>.
40. Boutron I, Dutton S, Ravaud P, Altman D. Reporting and Interpretation of Randomized Controlled Trials With Statistically Nonsignificant Results for Primary Outcomes. *The Journal of the American Medical Association*. 2010;303(20):2058-2064.
41. Food Standards Australia New Zealand. *Initial Assessment Report: Proposal P295: Consideration of Mandatory Fortification with Folic Acid*. Wellington 2004. http://www.foodstandards.gov.au/srcfiles/P295_Folate_fortification_IAR_FIN_AL.pdf.
42. Stefanogiannis N. New Zealand Adult Nutrition Survey 2008/2009 and Folate Status. In: Handforth B, ed Auckland: Health and Disability Intelligence Unit, Ministry of Health; 2010.