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Policy Group
New Zealand Food Safety Authority
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Proposed Amendment to the New Zealand Folic Acid Standard

The New Zealand Food and Grocery Council's (NZFGC) preferred option is to revoke the standard and for industry to make commitments to undertake a voluntary fortification programme for some breads.

We believe that given New Zealand's dramatic decrease in births affected by neural tube defects (NTDs) over the last 30 years that there is little evidence that mandatory fortification will deliver significant further reductions.

Academic research suggests that the benefits to New Zealand are small, while the unknown and known risks to/effects on other parts of the New Zealand population are potentially significant - easily outweighing such benefits.

In the event that the Government rejects this option, NZFGC supports the Government's "preferred option" to defer the Folic Acid Standard until 2012.

Our comments on the discussion document are structured around the document's headings which are listed in bold.

2. Background:

The Food Standards Australia New Zealand (FSANZ) guidelines for mandatory fortification are listed in the document. We argue that mandatory fortification of folic acid in bread does not meet all of FSANZ's own guidelines.

“Mandatory fortification of the food supply should only be introduced in response to a demonstrated significant population health need”.

Campaigners for fortification regularly state that they have lobbied for more than 20 years to get the New Zealand Government to dose bread. Such long term dedication to a cause is to be respected, but what they fail to acknowledge is that much has changed since the debate began.

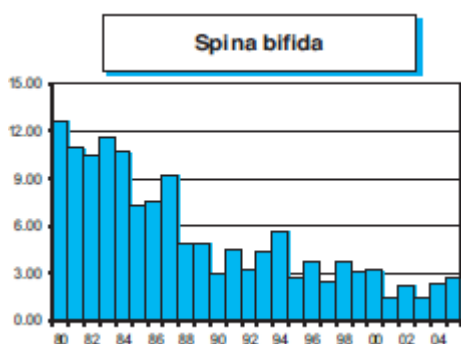
This might have been a timely policy idea in 1980 when NTD rates in New Zealand were high.

However, since that time there has been outstanding progress in reducing NTDs all without any government-mandated fortification programme.

See New Zealand data for Spina Bifida is below¹:

New Zealand

Time trends 1980-2005 (Birth prevalence rates per 10,000)



The incidence of NTDs in New Zealand has dramatically reduced due to better diets, better scanning, awareness of the importance of folic acid during pregnancy, and the voluntary fortification of many foods already widely available.

New Zealand already has a very low birth prevalence of neural tube defects (5/10,000).

Many supporters are unaware of how much the rate has come down in recent years and do not understand that even with mandatory fortification the gains in New Zealand are likely to be small - around 3-4 cases saved per year^{2 3}.

¹ International Clearing House for Birth Defects Surveillance and Research Annual Report 2007, World Health Organisation. <http://www.icbdsr.org>

² Mandatory Fortification of Flour? Science, not miracles, should inform the decision. Murray Skeaff, Tim Green and Jim Mann. The New Zealand Medical Journal 24 January 2003 Vol 116 No 1168

³ Page 10 FSANZ paper Scientific Evidence of Benefits and Risks of an increase folic acid intake in Australia and New Zealand. http://www.foodstandards.gov.au/_srcfiles/Health%20benefits%20and%20risk%20-%20part%201.pdf

Some academics have raised the concern that the effectiveness of folic acid in preventing neural tube defects may be diminished in populations with low incidence⁴.

It is worthwhile noting that while dosing all men, children and the elderly, even some of the target - women of childbearing years - will not gain any benefit because their folate levels are already within the low risk range.

Because of the folate status of New Zealand women “it is likely that a considerable proportion of women in New Zealand will derive no additional benefit” from mandatory fortification⁵.

It is the most effective public health strategy to address the problem;

The Government’s stated aim for the Standard is to reduce the incidence of NTDs in New Zealand.

To reduce the risk of neural tube defects (NTDs), women planning to or who may become pregnant should consume at least 400 micrograms of folic acid every day. Women who have a family history of NTDs may require more folic acid⁶.

We do not believe that dosing bread is the most effect public health strategy to address the problem. There are many other strategies that could be employed.

For example, it has been argued that if half of all New Zealand women planning a pregnancy took folic acid supplements at the correct time, the reduction in incidence of NTDs would be equivalent to that achieved by mandatory fortification⁷.

Greater use of supplements by women has the potential to exceed the effectiveness of any mandatory fortification programme⁸.

When the aim is to reduce neural tube defects in babies, targeting women through health services, public health campaigns, free folic acid supplements and through general practitioners

⁴ Mandatory Fortification of Flour? Science, not miracles, should inform the decision. Murray Skeaff, Tim Green and Jim Mann. The New Zealand Medical Journal 24 January 2003 Vol 116 No 1168

⁵ Mandatory Fortification of Flour? Science, not miracles, should inform the decision. Murray Skeaff, Tim Green and Jim Mann. The New Zealand Medical Journal 24 January 2003 Vol 116 No 1168

⁶ FSANZ <http://www.foodstandards.govt.nz/newsroom/factsheets/factsheets2008/mandatoryfolicacidfo3931.cfm>

⁷ Mandatory Fortification of Flour? Science, not miracles, should inform the decision. Murray Skeaff, Tim Green and Jim Mann. The New Zealand Medical Journal 24 January 2003 Vol 116 No 1168

⁸ Mandatory Fortification of Flour? Science, not miracles, should inform the decision. Murray Skeaff, Tim Green and Jim Mann. The New Zealand Medical Journal 24 January 2003 Vol 116 No 1168

would be more effective than dosing the entire country to reach a few hundred women at risk during their first few months of pregnancy.

If the Government was adamant about reaching all women, bread is arguably not the best vehicle. Statistically women are not major bread eaters and many do not eat bread at all.

Arguably water is a more effective vehicle, but as officials are well aware the politics around water are even more vigorous and controversial.

According to FSANZ dosing every New Zealander through bread could prevent approximately three New Zealand children from being born with an NTD⁹.

For those families being saved from a lifetime of disability this is no doubt priceless. However, the issue is the potential risk (and costs) to all other New Zealanders, some 4.4 million citizens who face the unknown potential effects.

The impact on other New Zealanders from this mass-medication programme seems to have been either generally dismissed as insignificant or ignored while some academics accept that such an intervention represents “an uncontrolled clinical trial with all New Zealanders as participants”.¹⁰

It is consistent with the nutrition policies of Australia and New Zealand

NZFSA aims to keep New Zealand food safe and the Ministry of Health aims to protect public health of all New Zealanders. Given there are unknown effects on some parts of the New Zealand population from artificially increasing folic acid intakes, it's hard to see how this policy can be consistent with nutrition policies of New Zealand.

Take for example the recommended daily intake of folic acid for children. NZFSA has confirmed that some children will regularly consume more than their recommended daily intake of folic acid as a result of mandatory fortification. This is certainly not consistent with nutrition policies of New Zealand.

⁹ Page 10 FSANZ paper Scientific Evidence of Benefits and Risks of an increase folic acid intake in Australia and New Zealand. http://www.foodstandards.gov.au/_srcfiles/Health%20benefits%20and%20risk%20-%20part%201.pdf

¹⁰ Mandatory Fortification of Flour? Science, not miracles, should inform the decision. Murray Skeaff, Tim Green and Jim Mann. The New Zealand Medical Journal 24 January 2003 Vol 116 No 1168

It will not result in detrimental excesses or imbalances

Mandatory fortification of folic acid should have failed on this point because expert opinions range from it will result in detrimental excesses and imbalances to a blunt “don’t know”.

Officials are aware that some parts of the New Zealand population (children, elderly in particular) could be negatively affected.

However, as mentioned earlier, this NZFSA discussion document is surprisingly silent on potential negative health effects to the New Zealand population eg. The long term effects on children, prostate cancer concerns for men and anaemia concerns particularly in the elderly.

Ignoring all these issues in the document is of concern at a time when academics in Canada, Ireland, the United Kingdom, Norway and the United States are raising such issues.

The omission is also unusual when NZFSA has previously raised certain health concerns.

In papers in 2005 and 2006 NZFSA raised concerns for some New Zealand children who will regularly consume more than their recommended daily intake of folic acid and also concerns about the effects on the elderly.

What’s the point of officials making recommendations to its citizens about recommended daily intakes if through a national dosage programme the government ensures some citizens regularly consume above that level?

While seen as a wonder vitamin of the 1980’s and 90’s, some academics are increasingly concerned about whether too much folic acid might have a detrimental effect on health in some pockets of the community. Such concerns, which have been raised around the world in the United States, Canada, the United Kingdom and Ireland, should not be ignored.

New Zealand officials have raised concerns about public health and have previously acknowledged that there are risks to the wider population (i.e. some 99.9% of New Zealanders not in their first months of pregnancy):

- a. The Government has been made aware that as a result of mandatory fortification some children will eat more than their recommended daily intake of folate/folic acid and that there could be long term effects to them.

In advice to the Minister NZFSA noted:

“There are also unknown risks that may not become apparent for one or two

generations. Children will be exposed to much higher levels of folic acid than in previous generations. It may not be until this generation of children has their own children that adverse effects become apparent.”¹¹

Other advice from NZFSA noted: *“We continue to have concerns that 13.8% males aged 5 – 8 years and 8.2% of New Zealand females are going to exceed the upper level intake (UL) for folic acid...”¹²*

Most New Zealand parents would not be happy to read this. Officials respond by stating that the effects are unknown but as academics point out *“the lack of toxicity of folic acid should not be offered as proof that folic acid is not toxic”.*¹³

A suggestion that New Zealand need only to monitor mandatory fortification over years does little to dispel the concerns of New Zealand parents.

- b. Recent academic research links increased folic acid intake to increased incidence of prostate cancer in men and also colon cancer. The results are not conclusive but are making many decision-makers and academics around the world wonder whether too much folic acid in a diet could fuel certain cancers^{14 15}.

According to some researchers folic acid may be *“a double edged sword. It was meant to prevent neural tube defects, and it did a wonderful job. [But] for people with pre-cancerous cells, or undiagnosed colon cancer tumours, giving high-dose folic acid or having high folate levels might actually make their condition worse”¹⁶.*

Such results were part of the decision by Ireland and the United Kingdom to

¹¹ NZFSA Proposal P295 – Consideration of Mandatory Fortification with Folic Acid – Draft Assessment Report <http://www.nzfsa.govt.nz/labelling-composition/publications/submissions-to-fsanx/2006/p295dar.htm>

¹² NZFSA Proposal P295 – Mandatory Fortification with Folic Acid – Issues Paper, 18 April 2007. <http://www.nzfsa.govt.nz/labelling-composition/publications/submissions-to-fsanx/2007/web-version-p295-issues-paper-april-07.htm?print>

¹³ Mandatory Fortification of Flour? Science, not miracles, should inform the decision. Murray Skeaff, Tim Green and Jim Mann. The New Zealand Medical Journal 24 January 2003 Vol 116 No 1168

¹⁴ Is folic acid good for everyone? A David Smith, Young-In Kim, and Helga Refsum *Am J Clin Nutr* 2008;87:517–33. Printed in USA.

¹⁵ Too much folic acid may trigger cancer. Tom Blackwell. National Post. Canada. Monday, August 25, 2008 <http://www.nationalpost.com/life/story.html?id=747892>

¹⁶ Too much folic acid may trigger cancer. Tom Blackwell. National Post. Canada. Monday, August 25, 2008 <http://www.nationalpost.com/life/story.html?id=747892>

place plans for mandatory fortification on hold until further research is conducted and clarified. The recent Irish paper “Report of the Implementation Group on Folic Acid Fortification to the Department of Health and Children” noted that “emerging issues in cancer risk were significant” to warrant a watching brief¹⁷.

- c. Recent academic research linking increased folic acid intake to increased incidence of colon cancer.

More recently, researchers noticed that rates of colorectal cancer went up in North America around the same time that fortification began. One study, published by Mason and colleagues in 2007 in the journal Cancer Epidemiology Biomarkers & Prevention, acknowledged that the link could be a coincidence. But according to another study published this year, the same thing happened in Chile after fortification began there in 2000¹⁸.

- d. Medical concerns about vitamin B12 deficiencies particularly for the elderly (another reason the United Kingdom recently chose to delay its plans for mandatory fortification).

As Dr Murray Skeaff pointed out in The New Zealand Medical Journal, folic acid at certain doses “can mask haematological signs of vitamin B12 deficiency allowing irreversible neurological damage to occur because of delayed diagnosis”.

- e. This concern is most pronounced in older people who are at the greatest risk for vitamin B12 deficiency range from 7 – 23%¹⁹.

This is probably one of the reasons that Grey Power chose to speak out so publicly against mandatory fortification.

- f. Folic acid is a synthetic form of folate. Many use the terms folic acid and folate interchangeably. They are different. NZFSA has previously noted the concern

¹⁷ Food Safety Authority of Ireland 2008 “Report of the Implementation Group on Folic Acid Fortification to the Department of Health and Children” page 39

¹⁸ Folic Acid Might be losing its sheen by Emily Sohn – Los Angeles Times May 11 2009
<http://www.latimes.com/features/health/la-he-folate11-2009may11,0,4656570.story>

¹⁹ Mandatory Fortification of Flour? Science, not miracles, should inform the decision. Murray Skeaff, Tim Green and Jim Mann. The New Zealand Medical Journal 24 January 2003 Vol 116 No 1168

that:

“mandatory fortification will expose the bread eating population to higher than what is currently considered [a] normal intake of folic acid. In addition the population will be exposed to the synthetically manufactured folic acid rather than the naturally occurring folate. The long term effects of this exposure is [sic] unknown therefore it is vital that the monitoring framework takes this into account.”²⁰

It will deliver effective vitamins to the target population to meet the health objectives

It will deliver more folic acid to some women, but as a public health policy it is a sledgehammer to crack a walnut.

Because the rate of NTDs in New Zealand has diminished by 75% since 1980 to its lowest level some academics suggest that miraculous further decreases may not be forthcoming.²¹

Already the stated gains to the initiative are small. In terms of meeting health objectives FSANZ believes that the Food Standard could reduce babies born with an NTD by 3²².

Rather than dosing 4.4 million New Zealanders to reach a few women at risk, it would be better to target those women through health professionals and offer folic acid supplements.

Mandatory fortification also does not guarantee that the target population (women who might get pregnant and who are low on folate) will actually receive a dose which makes a difference to their folate status. Women statistically are not big bread eaters and some do not eat bread at all.

Bread was chosen as a vehicle because it was consumed by most people and very little is traded internationally.

When so little bread is traded internationally, it begs the question why having a joint standard between Australia and New Zealand was so important in the first place.

²⁰ NSFSFA Proposal 295 – Mandatory Fortification with folic acid – issues paper 18 April 2007

²¹ Mandatory Fortification of Flour? Science, not miracles, should inform the decision. Murray Skeaff, Tim Green and Jim Mann. The New Zealand Medical Journal 24 January 2003 Vol 116 No 1168

²² Page 10 FSANZ paper Scientific Evidence of Benefits and Risks of an increase folic acid intake in Australia and New Zealand. http://www.foodstandards.gov.au/_srcfiles/Health%20benefits%20and%20risk%20-%20part%201.pdf

Fresh bread is not exported to or imported from Australia. Only a small amount of par-baked / frozen bread is exchanged.

While the focus is on this being a trans-Tasman agreement it is one of the few food products where there is little/no benefit of having a joint standard.

If the aim is to select a vehicle that was consumed by all New Zealanders then water would have been a better option. We suspect bread was chosen because it was seen as being less political.

Cost Benefit Analysis:

The Minister for Food Safety has stated: *“I am not persuaded that the public health argument in support of the requirement for mandatory fortification of bread with folic acid is compelling enough to justify the costs industry have indicated they will incur in order to comply with the standard”*²³. We agree.

The cost benefit analysis offered by NZFSA in this section appears skewed because it appears to understate the costs and overstates likely benefits.

For example it does not seem to include the costs to New Zealanders of increased bread prices, potential health costs to the wider community or other unintended consequences of mandatory fortification eg. Increased rates of colon cancer or prostate cancer.

There could be increased costs associated with late diagnosis of anaemia²⁴ which is unlikely to have been factored in to this cost benefit analysis.

We agree that there are significant costs to industry – changing packaging alone has been estimated to cost plant bakers \$3million, but there are also considerable costs to New Zealanders who will face a significant price increase in bread.

²³ Issues Concerning the Mandatory Fortification of Bread with Folic Acid: Paper to Cabinet Economic Growth and Infrastructure Committee; Office of the Minister for Food Safety. Undated.

²⁴ Mandatory Fortification of Flour? Science, not miracles, should inform the decision. Murray Skeaff, Tim Green and Jim Mann. The New Zealand Medical Journal 24 January 2003 Vol 116 No 1168

NZFSA²⁵ and industry have estimated that the cost of mandatory fortification could equate to a 5c increase per loaf.

Even if we include only plant bakers who produce around 4 million loaves per week, this is an extra \$200,000 per week or \$10.4 million per year. Such an increase to New Zealand consumers does not currently appear in the cost benefit analysis.

“The savings in reducing the incidence of NTDs in New Zealand were assessed at \$4.8million each year ongoing based on a reduction in live births affected by an NTD or \$41.2million each year ongoing based on a reduction in all pregnancies affected by an NTD (including all births and terminations”

These figures appear inflated, but it is impossible to check because this statement is not referenced and the workings to reach these figures are not included in the document and the work which underpinned these figures referenced.

In terms of live NTD births FSANZ estimated that 3 per year would be prevented as a result of mandatory fortification in New Zealand²⁶.

This then assumes that each live birth costs New Zealand \$1.6 million per year? This seems very high indeed.

In terms of terminations FSANZ estimated that 10 infants would be spared an NTD (7 terminations and 3 births) each year if the intake of folate increased by 0.2mg daily²⁷.

The figure of \$41.2million per year, begs the questions of how many NTDs does NZFSA assume will be reduced by the initiative and what costs have been included.

Again without reviewing the analysis and seeing what assumptions have been made it is impossible to critique this section in detail except to say that the figures are unexplainably high.

²⁵ NZFSA Briefing Meeting with the New Zealand Food and Grocery Council and the Bakers Association re: Folic Acid. April 2009.

²⁶ Page 10 FSANZ paper Scientific Evidence of Benefits and Risks of an increase folic acid intake in Australia and New Zealand. http://www.foodstandards.gov.au/_srcfiles/Health%20benefits%20and%20risk%20-%20part%201.pdf

²⁷ Page 10 FSANZ paper Scientific Evidence of Benefits and Risks of an increase folic acid intake in Australia and New Zealand. http://www.foodstandards.gov.au/_srcfiles/Health%20benefits%20and%20risk%20-%20part%201.pdf

3. Problem Definition

“The New Zealand Government is concerned that the New Zealand folic acid standard may be inconsistent with Government policy because it may place an unnecessary cost burden on industry and limits consumer choice”.

Agreed. However, with consumer choice, not only does it limit consumer choice for New Zealanders, it virtually removes it.

Unlike the United States and other countries which have a mandatory requirement, New Zealand is opting to put folic acid in 99% of all bread.

A mother concerned about her child’s exposure will have to consider baking her own bread unless she can afford to buy organic or unleavened bread. The option to buy organic bread is not a genuine choice for New Zealanders.

At about 1% of total bread sales it’s a tiny part of the market and about twice the price. While wealthier New Zealanders might be able to buy it, most New Zealanders, currently struggling to make ends meet, will not have the option of this luxury, and will resent it.

There are other reasons that this standard is inconsistent with Government policy.

The National Party in particular campaigned on reducing red tape, regulatory reform and diminishing the “nanny state”.

A policy that increases red tape, regulation and that extends the “nanny state” is hard to reconcile with the intentions of a National-led Government.

“There are also concerns about whether or not folic acid can be evenly distributed within a loaf of bread.

Bakers have repeatedly told the Government and officials that they can’t technically meet the standard consistently i.e. they can’t dose the bread accurately. The standard reads:

“Bread must contain no less than 0.8 mg/kg and no more than 1.8 mg/kg of folic acid”.

However, for the major plant bakers the folic acid is added into large batches of up to 300kg.

Bakers have no current method of ensuring a consistent spread of folic acid through individual loaves.

Clinical trials on behalf of the Baking Industry Research Trust and carried out at NZ Bakels Ltd and sent to various laboratories showed major inconsistencies (especially grain breads) across a wide range of breads reinforcing our current view that commercial bakers cannot meet the guidelines in the mandated standard.

Some loaves will have too little and, more concerning, some loaves will have too much.

Likewise it will be impossible to gauge actual folic acid intake of New Zealanders accurately and this will prove difficult for expectant mothers who might be consuming bread thinking they are receiving an accurate dose.

“It is also noted that mandatory fortification will not provide maximum protection against NTDs as the established level of folic acid required for protection against NTDs is higher than that likely to be derived from consuming fortified bread alone”.

Agreed. As confirmed in Parliamentary Questions by the Minister for Food Safety a woman would need to consume 11 slices of bread per day²⁸ to consume the amount of folic acid required to reduce the likelihood of an NTD.

We are concerned that some who support mandatory fortification of bread see this intervention as a miracle cure for NTDs. It isn't. NZFSA and successive Ministers of Food Safety confirm that supplements will still need to be taken.

5. Options

“There are advantages and disadvantages to all three options...and this is not an exhaustive list”.

Once again we note that it is interesting that NZFSA has chosen not to mention any health concerns whatsoever.

It is a glaring omission in the discussion of mandatory fortification of folic acid when there are concerns growing internationally about the effects of consuming too much folic acid.

²⁸ Parliamentary Questions for Written Answer. 8126 (2009). Sue Kedgley to the **Minister for Food Safety** (22 Jun 2009):

While certain academics in New Zealand are content to pronounce mandatory fortification of folic acid “safe”, advice we have received is in contrast to this view and recommends that the New Zealand Government show caution before opting to dose every New Zealander.

Emeritus Professor A. David Smith, Professor of Pharmacology at Oxford University, in his paper “Is Folic Acid Good for Everyone” published last year in the Journal of Clinical Nutrition noted:

“Folate has a dual effect on cancer, protecting against cancer initiation but facilitating progression and growth of preneoplastic cells and subclinical cancers, which are common in the population. Thus, a high folic acid intake may be harmful for some people. Nations considering fortification should be cautious and stimulate further research to identify the effects, good and bad, caused by a high intake of folic acid from fortified food or dietary supplements. Only then can authorities develop the right strategies for the population as a whole”²⁹.

NZFSA has admitted that “FSANZ is aware that research into the health effects of folic acid, both positive and negative, is a rapidly developing area³⁰”

This being the case, as Professor Smith recommends caution as a prudent measure.

In other writing on the subject of the United Kingdom’s intention to implement mandatory fortification he noted that *“Fortifying all flour with folic acid is potentially a national health disaster”* which could lead to new cases of colon cancer, a rise in prostate cancer and increase the risk of anaemia in the elderly³¹.

In an article for a UK newspaper he explained: *“While folic acid can protect you against cancer, once a tumour has already started growing, it can switch sides. Cancer cells are greedy for folic acid; it helps them to keep reproducing. Knowing that, now consider the fact that 20 per cent of middleaged people have pre-cancerous cells in their colon and that most middle-aged men have them in their prostate, too. Forcing them to eat something that is likely to encourage those cells to grow suddenly doesn't seem such a bright idea. Indeed, when we look at what has happened in the U.S. and Canada, it seems positively reckless”³².*

²⁹ Is folic acid good for everyone? A David Smith, Young-In Kim, and Helga Refsum *Am J Clin Nutr* 2008;87:517–33. Printed in USA.

³⁰ NZFSA Briefing Meeting with the New Zealand Food and Grocery Council and the Bakers Association re: Folic Acid. April 2009.

³¹ Profess David Smith 27 September 2007 Daily Mail. <http://www.dailymail.co.uk/health/article-484229/Adding-folic-acid-diets-recipe-disaster.html>

³² Profess David Smith 27 September 2007 Daily Mail. <http://www.dailymail.co.uk/health/article-484229/Adding-folic-acid-diets-recipe-disaster.html>

5.1. Status Quo

Advantages:

- **Maximizes the opportunity to reduce NTDs**

It does not “maximize” opportunities because there are other strategies the Government could employ to reduce NTDs and women are not major bread eaters - some don’t eat bread at all.

There are a number of other public health initiatives which could achieve this goal which the Ministry of Health could consider. If one considers the 75% reduction in NTDs since 1980 (refer graph included earlier), this has occurred without mandatory fortification.

There are other ways to “maximize” the reduction of NTDs.

For example, it has been argued that if half of New Zealand women planning a pregnancy took folic acid supplements at the correct time, the reduction in incidence of NTDs would be equivalent to that achieved by mandatory fortification³³.

Greater use of supplements by women has the potential to exceed the effectiveness of any mandatory fortification programme³⁴.

- **Is consistent with the intention of the standard as developed by FSANZ under the joint system.**

It is consistent with the treaty, but for little practical benefit to either signatories as there is no trade in fresh bread and only a tiny amount of frozen product trans-Tasman. While developed under a joint system they were already separate standards.

- **Maintains maximum alignment with Australia.**

Although alignment with Australia might look visually “tidy” from a regulatory perspective, there is little practical point in this instance as New Zealand plant bakers do not export fresh bread to New Zealand and neither do they import fresh bread from Australia. The trans-Tasman trade of bread products is small.

³³ Mandatory Fortification of Flour? Science, not miracles, should inform the decision. Murray Skeaff, Tim Green and Jim Mann. The New Zealand Medical Journal 24 January 2003 Vol 116 No 1168

³⁴ Mandatory Fortification of Flour? Science, not miracles, should inform the decision. Murray Skeaff, Tim Green and Jim Mann. The New Zealand Medical Journal 24 January 2003 Vol 116 No 1168

Disadvantages:

- **Not supported by many consumers**

The Minister has publicly said "Advice showed that 87 per cent of New Zealanders did not want it [folic acid in bread].³⁵

Research by NZFSA clearly showed that New Zealanders don't like the idea of being mass-medicated through bread, one of their favourite staples.

NZFSA commissioned market research on this issue in 2005 which concluded,

"84% of consumers interviewed, even after providing information on the reasons for fortification did not support mandatory fortification" for either folic acid or iodine.

This is also confirmed in NZFSA's briefing to the Minister 2009³⁶.

The topic has received much coverage in the media and has been the subject of much public discussion.

Major newspapers showed near unanimity in publishing editorials urging the Government not to go ahead with or reconsider mandatory fortification

Spare Us Our Daily Folate – Dominion Post 16/7/09

Bread Additive Unwanted – The Press 11/7/09

Give us this day our daily folic acid? - The Nelson Mail 13/7/09

Folic Acid debate far from over – The Marlborough Express 14/7/09

A lot riding on bread call – The Timaru Herald 16/7/09

Common sense vs. the common good – Taranaki Daily News 11/7/09

Let's make our own daily bread – Herald on Sunday 12/7/09

Don't tinker with our daily bread – NZ Herald 10/7/09

The daily loaf – Otago Daily Times 16/7/09

Folic acid fallout – The Gisborne Herald 14/7/09

³⁵ **Minister for Food Safety Press Release Wednesday, May 20, 2009**

<http://www.katewilkinson.co.nz/index.php?/archives/119-Minister-looks-at-science-on-folic-acid-fortification-in-bread.html>

³⁶ NZFSA Briefing Meeting with the New Zealand Food and Grocery Council and the Bakers Association re: Folic Acid. April 2009.

Because it's good for us – The Southland Times 17/7/09

- **Reduces consumer choice**

Agreed. However, it doesn't reduce choice; It eliminates it for many New Zealand families.

Unlike the United States, frequently used as evidence for why New Zealand should fortify, the New Zealand standard is to fortify all bread except organic or unleavened bread.

Organic bread, currently around 1% of the New Zealand market, is outside the price range of many New Zealand families and not accessible in many areas.

In the United States choice is preserved. What was planned for New Zealand does not.

- **Uncertainty that the mandatory fortification would deliver the desired outcome.**

Mandatory fortification has been presented by supporters as a miracle intervention designed to rid New Zealand of all NTDs. Sadly this is not the case.

The dosage rate is set too low to make a major difference to women who will still require supplements (but still too high for some New Zealand children who will consume more than their recommended daily intake).

The method of dosage will be inaccurate and bakers have regularly stated that the standard is written in such a way with a narrow min / max band, that they will find it impossible to meet the standard consistently and accurately.

Some academics have raised the wider issue of whether mandatory fortification of folic acid is as effective in preventing NTDs in a population with low incidence³⁷.

³⁷ Mandatory Fortification of Flour? Science, not miracles, should inform the decision. Murray Skeaff, Tim Green and Jim Mann. The New Zealand Medical Journal 24 January 2003 Vol 116 No 1168

- **Imposes costs on industry**

Correct, as mentioned earlier in the discussion document.

More importantly, there should be a disadvantage listed “Imposes Costs on Consumers” because the standard imposes costs on New Zealanders of up to 5 cents a loaf extra.

NZFSA has noted “In developing the standard, FSANZ estimated that the cost to consumers of mandatory fortification would be likely to be less than two percent of the price of bread...On average, a two percent increase in the price of bread would equate to about five cents³⁸ .

Industry representatives had done a separate cost analysis and came to a similar conclusion of around 5 cents.

When approximately 4 million loaves are produced each week by the major factory bakers, a five cent increase costs New Zealanders an extra \$200,000 per week or an extra \$10.4 million per year.

Many New Zealanders are struggling to make ends meet during this recession. While an extra five cents a loaf might not seem much to some people, it will be an unwelcome increase for many families and also politically unpopular.

- **May be difficult to comply with due to difficulties associated with getting an even spread of folic acid to the required level.**

“May” is an understatement. Bakers have been clear that it “will” be difficult to comply; in fact some bakers will find it impossible to consistently meet the standard accurately.

Bakers have no current method of ensuring a consistent spread of folic acid through individual loaves.

The standard reads,

“Bread must contain no less than 0.8 mg/kg and no more than 1.8 mg/kg of folic acid”.

³⁸ NZFSA Briefing Meeting with the New Zealand Food and Grocery Council and the Bakers Association re: Folic Acid. April 2009.

However, for the major plant bakers the folic acid is added into large batches of up to 300kg.

The Bakers have had formal research trials conducted and the variability in results concerns them. Clinical trials on behalf of the Baking Industry Research Trust and carried out at NZ Bakels Ltd and sent to various laboratories showed major inconsistencies across a wide range of breads reinforcing our current view that commercially bakers cannot meet the guidelines in the mandated standard.

To state clearly bakers do not have the processes to accurately dose the bread to ensure that they meet the standard consistently and accurately on a per loaf basis.

They seek no comfort from officials telling them that this is not a problem and that all they have to do is guarantee that the right amount is going into a 300kg batch.

Some loaves will have too little and, more concerning, some loaves will have too much.

From a consumer perspective it will be impossible to gauge actual folic acid intake of New Zealanders accurately and this will prove difficult for expectant mothers who might be consuming bread thinking they are receiving an accurate dose.

- **Other disadvantages not mentioned.**

Costs to New Zealanders from increased bread prices – mentioned above

Some New Zealand children will regularly consume more than their recommended daily intake of folic acid as a result of this initiative. This was raised as a concern in previous NZSFA submissions to FSANZ.

Potential personal, social and financial costs to the New Zealand public as a result of new cases of colon cancer, increased incidence of prostate cancer and anaemia in the elderly.

Officials acknowledge that there are significant unknowns with mandatory fortification which some academics have described as “an uncontrolled clinical trial with all New

Zealanders as participants”.³⁹

5.2 Amendment to Commencement Date

Advantages:

- **Allows voluntary fortification to continue**

Agreed, but this is an administrative problem for officials to fix. Voluntary fortification currently occurs and will continue. It will be politically embarrassing if bakers who in good faith wish to voluntarily fortify some parts of their range are told they can't.

- **Less costly to the industry over the next two years.**

Agreed, but the important point here is that it is also less costly to New Zealanders who will save because bread prices won't rise as a result of the mandatory standard. This is estimated to save more than \$10.4 million per annum.

- **Provides greater choice to consumers over the next two years.**

Whether it is the next two years or beyond that New Zealanders have made clear they want choice. There have been a number of polls conducted on this subject over the years and all of them have concluded that New Zealanders do not want mandatory fortification of all bread.

- **Allows new evidence to be considered.**

As NZFSA has noted research into the health effects, both positive and negative is a “rapidly developing area”. Like the United Kingdom and Ireland, we believe it's prudent for the Government to postpone the standard while research positions are clarified.

It gives NZFSA time to review academic concerns which have been raised in Canada, United States, United Kingdom, Ireland and Norway. While officials keep pointing out that cancer risks “were thoroughly researched” at the time the standard was developing

³⁹ Mandatory Fortification of Flour? Science, not miracles, should inform the decision. Murray Skeaff, Tim Green and Jim Mann. The New Zealand Medical Journal 24 January 2003 Vol 116 No 1168

academic thinking has moved on in the last 4 years and such concerns should not be ignored.

- **Other advantages.**

It recognizes widespread public concern and lack of support for mandatory fortification. New Zealanders don't want their bread dosed.

Concerns about increased rates of prostate and colon cancer as a result of mandatory fortification are reduced.

Concerns about the unknown effects on New Zealand children from consuming too much folic acid are reduced.

Disadvantages

- **Would reduce the impact on addressing the folate deficiency in the New Zealand diet and reducing the number of NTD affected pregnancies.**

New Zealand's NTD rate is already at an historic low and it's questionable what the "impact" of mandatory fortification might be given New Zealand's current low incidence⁴⁰.

If one considers the 75% reduction in spina bifida since 1980 (refer graph included earlier), this has occurred without mandatory fortification.

There are a number of other public health initiatives which could achieve the goal to reduce NTDs which the Ministry of Health could consider.

For example, it has been argued that if half of all New Zealand women planning a pregnancy took folic acid supplements at the correct time, the reduction in incidence of NTDs would be equivalent to that achieved by mandatory fortification⁴¹.

Greater use of supplements by women also has the potential to exceed the effectiveness of any mandatory fortification programme⁴².

Supporters of mandatory fortification give the impression that dosing bread will rid New Zealand of birth defects. This is sadly not the case, particularly when some women do not consume large amounts of bread and others will be unaffected by the folic acid due to the fact they already have an adequate folate level.

- **Would not remove the uncertainty that mandatory fortification may still occur.**

Correct. Potentially it just postpones further debate where the industry is unlikely to

⁴⁰ Mandatory Fortification of Flour? Science, not miracles, should inform the decision. Murray Skeaff, Tim Green and Jim Mann. The New Zealand Medical Journal 24 January 2003 Vol 116 No 1168

⁴¹ Mandatory Fortification of Flour? Science, not miracles, should inform the decision. Murray Skeaff, Tim Green and Jim Mann. The New Zealand Medical Journal 24 January 2003 Vol 116 No 1168

⁴² Mandatory Fortification of Flour? Science, not miracles, should inform the decision. Murray Skeaff, Tim Green and Jim Mann. The New Zealand Medical Journal 24 January 2003 Vol 116 No 1168

change its position and New Zealanders are unlikely to change their minds about governments tampering with their bread.

- **Implementation no longer aligned between Australia and New Zealand**

This disadvantage is so small it's negligible. In fact implementation was never aligned with Australia in the first place given that Australia was putting folic acid in flour and New Zealand opted out of doing this.

Australia and New Zealand don't trade fresh bread. NZ and Australia benefit from many joint standards but the benefits are minute here as the two countries run virtually separate industries trading only a small amount of frozen product.

5.3 Revocation of New Zealand Folic Acid Standard

Advantages:

- **Provides certainty for industry and consumers**

Agreed. It provides certainty to Government that this political issue will not be raised again. It encourages a voluntary regime which bakers have already committed to.

- **Ensures maintenance of consumer choice over the long term.**

Agreed and this should not be underestimated as being important to New Zealanders. It's doubtful that New Zealanders will change their minds about tampering with their bread over the next two years.

- **Concerns about increased rates of prostate and colon cancer as a result of mandatory fortification are reduced.**

- **Concerns about the unknown effects on New Zealand children from consuming too much folic acid are reduced.**

Disadvantages:

- **Would reduce the impact of addressing the folate deficiency in the New Zealand diet and reducing the number of NTD affected pregnancies**

This assumes public health authorities do nothing else.

Through folic acid awareness and work by health professionals New Zealand has achieved a massive reduction in NTDs without mandatory fortification e.g. a 75% reduction in spina bifida since 1980 (refer graph included earlier). All this occurred without mandatory fortification.

There are a number of other public health initiatives which could achieve the goal to reduce NTDs which the Ministry of Health could consider.

For example, it has been argued that if half of New Zealand women planning a pregnancy took folic acid supplements at the correct time, the reduction in incidence of NTDs would be equivalent to that achieved by mandatory fortification⁴³.

Greater use of supplements by women also has the potential to exceed the effectiveness of any mandatory fortification programme⁴⁴.

Supporters of mandatory fortification give the impression that dosing bread will rid New Zealand of birth defects.

This is sadly not the case, particularly when some women do not consume large amounts of bread and others will be unaffected by the folic acid due to the fact they already have an adequate folate level.

- **Would be inconsistent with the joint standards as developed with Australia**

The effect of this is negligible given there is so little exchange of bread across the Tasman.

⁴³ Mandatory Fortification of Flour? Science, not miracles, should inform the decision. Murray Skeaff, Tim Green and Jim Mann. The New Zealand Medical Journal 24 January 2003 Vol 116 No 1168

⁴⁴ Mandatory Fortification of Flour? Science, not miracles, should inform the decision. Murray Skeaff, Tim Green and Jim Mann. The New Zealand Medical Journal 24 January 2003 Vol 116 No 1168

- **Would not provide for voluntary fortification.**

Revoking the mandatory standard potentially removes the ability of bakers to add folic acid to some parts of their ranges only because of the way NZFSA had set up the mandatory standard. This is an administrative issue and can be easily solved.

Thank you for the opportunity to submit on this subject. If there are any issues that need to be raised with me I am contactable through my office.

Katherine Rich
Chief Executive