



Proposed Amendment to the New Zealand Folic Acid Standard

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Submissions

NZFSA is inviting submissions from all interested parties on any aspect of the proposal to amend the New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007 (the New Zealand folic acid standard) – the Government’s preferred option being to delay its commencement date until 31 May 2012 and to maintain the permission to voluntarily fortify bread with folic acid.

The following points may be of assistance in preparing comments:

- wherever possible, comment should be specific to a particular section of the document. All major sections are numbered and these numbers should be used to link comments to the document.
- omissions should be clearly and separately indicated.
- comments should be to the point and, where possible, reasons and data to support comment are requested.
- the use of examples to illustrate particular points is encouraged.
- as a number of copies may be made of your comments, please use good quality type, or make sure the comments are clearly hand-written in black or blue ink.

Please include the following information in your submission:

- the title of the discussion document;
- your name and title (if applicable);
- your organisation’s name (if applicable);
- your address;
- the number(s) of the sections you are commenting on.

Please submit your response by 5:00pm on 12 August 2009

Your comments should be sent to:

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The Official Information Act 1982 (OIA) states that information is to be made available unless there are grounds for withholding it. The grounds for withholding information are outlined in the OIA.

Submitters may wish to indicate any grounds for withholding information contained in their submission.

Reasons for withholding information could include that information is commercially sensitive or that the submitters wish personal information such as names or contact details to be withheld. NZFSA will take such indications into account when determining whether or not to release information. Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman.

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1 Introduction

The purpose of this discussion paper is to consult on a proposal to amend the New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007¹ (the New Zealand folic acid standard). The Government's preferred option is to delay the commencement date from 27 September 2009 until 31 May 2012 and to maintain the permission to voluntarily fortify bread with folic acid.

The commencement date in clause 2 of the New Zealand folic acid standard is set at 24 months after gazettal. This means the standard will come into force on 27 September 2009 if it is not amended. Given the limited time available, submitters are encouraged to give this matter urgent consideration in order to allow analysis of submissions to be undertaken and a decision to be made before the current commencement date.

2 Background

New Zealand and Australia signed the '*Agreement Between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System*' (the Food Treaty) in 1995. Joint food standards covering composition and labelling for Australia and New Zealand are set out in the Australia New Zealand Food Standards Code (the Food Code). Food Standards Australia New Zealand (FSANZ) maintains and updates the Food Code. FSANZ has no policy role and is purely responsible for scientific risk assessments, evaluations and the risk management decisions necessary for the development of standards.

The joint food standards system is governed by the Australia and New Zealand Food Regulation Ministerial Council (the Ministerial Council). The Ministerial Council is responsible for setting the policy direction for standards development and for making the final decision on whether a FSANZ-approved standard should be adopted.

¹ [New Zealand \(Mandatory Fortification of Bread with Folic Acid\) Food Standard 2007](#)

The New Zealand folic acid standard was developed by FSANZ under the joint food standards system but was ultimately adopted into New Zealand law by a separate New Zealand standard in 2007. The New Zealand standard included a two-year transition period.

Folic acid is the synthetic version of the naturally occurring B-vitamin, folate (Vitamin B₉). Folate is commonly found in leafy green vegetables such as broccoli, spinach, salad greens, citrus fruit, and wholegrain breads and breakfast cereals. Chickpeas, nuts, dried beans and peas are also high in folate, although cooking can reduce the level of folate in these foods.

It is recommended that New Zealand adults consume around 400 micrograms of folate from food each day. Adults get about 250 micrograms of folate from food each day, which is well below the recommended intake.

The consumption by women of an adequate amount of folate (and folic acid) immediately prior to and during the first trimester of pregnancy is scientifically proven to reduce the risk of having a neural tube defect (NTD) affected pregnancy. The permission to voluntarily fortify products with folic acid has been available in New Zealand since 1996.

In 2004 the Ministerial Council asked FSANZ to give high priority to the investigation of mandatory folic acid fortification as a means of reducing NTDs in Australia and New Zealand. The policy principles that were agreed by the Ministerial Council for the development of the standard stated that mandatory fortification of the food supply should only be introduced in response to a demonstrated significant population health need, and where:

- it is the most effective public health strategy to address the problem;
- it is consistent with the nutrition policies of Australia and New Zealand;
- it will not result in detrimental excesses or imbalances; and
- it will deliver effective vitamins to the target population to meet the health objectives.

In developing the folic acid standard FSANZ prepared seven assessment reports including three cost benefit assessments². Bread was chosen as the vehicle because it is consumed by most people and very little is traded internationally.

² The FSANZ assessment reports are available at:

<http://www.foodstandards.govt.nz/standardsdevelopment/proposals/> under proposal P295

The excerpts below have been taken from the cost-benefit assessments commissioned by FSANZ between 2006 and 2007 (for full details of these analyses refer to the FSANZ website identified at note 2 above).

Consumers:

- the actual cost of the Standard in terms of the price of bread to consumers was assessed in the June 2006 *Cost Benefit Analysis of Fortifying the Food Supply with Folic Acid* as very low – between 3 and 5 cents a loaf.
- the cost to consumers in terms of loss of choice was assessed in the 13 April 2007 *Cost Effectiveness Analysis of Options* report as significant

Industry (from the June 2006 *Cost Benefit Analysis of Fortifying the Food Supply with Folic Acid*):

- the annual costs to New Zealand industry assessed by FSANZ included upfront costs: labelling, packaging write-offs and equipment totalling approximately \$1million; and
- the annual ongoing costs for New Zealand industry: premix, analytical testing, and administration totalling approximately \$4.15 million.

Public Health (from the June 2006 *Cost Benefit Analysis of Fortifying the Food Supply with Folic Acid*)

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

Towards the end of the standard development process differences emerged in the implementation requirements. Australia preferred to add folic acid at the flour milling stage, while New Zealand preferred the addition of folic acid to bread itself, giving industry the flexibility to add folic acid at any point in the manufacturing process. This difference necessitated the development of a separate regulatory mechanism for New Zealand to give effect to the mandatory fortification policy developed under the joint system.

The Australian fortification requirement is located in the Food Code under Standard 2.1.1³, Cereals and Cereal Products. Standard 2.1.1 notes that the New Zealand folic acid fortification requirements are set out in a separate standard made under the New Zealand Food Act 1981. The Australian standard in the Food Code and the separate New Zealand standard were planned to come into force within a month of each other.

When the folic acid fortification requirements were approved, the Ministerial Council agreed that 'a comprehensive and independent review of mandatory fortification with folic acid will be initiated two years after the implementation. The review will consider health impacts and the effectiveness of the initiative, the actual cost effects on the food industry, and the adequacy of the monitoring framework'.

It should be noted that at the same time that bread is to be fortified with folic acid, bread will also be fortified with iodised salt to address the re-emergence of mild to moderate iodine deficiency in the New Zealand population. The preferred option outlined in this paper to extend the commencement date for the folic acid standard does not apply to the fortification of bread with iodised salt.

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

The effectiveness of folic acid in reducing NTDs is established. However, the target group for the mandatory fortification is limited to women of child-bearing age and the application of the measure is broad. It is also noted that mandatory fortification alone 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.

³ [Australian Standard 2.1.1, Cereals and Cereal Products](#)

In light of the level of public resistance for the measure, and questions about its effectiveness relative to cost and effect on consumer choice, the Government is considering whether it is prudent to delay commencement of mandatory fortification until 31 May 2012.

Such a delay would require a further amendment to the standard to provide permission for manufacturers to voluntarily fortify bread with folic acid. This is because the current voluntary permission in Standard 1.3.2, *Vitamins and Minerals*, of the Food Code will be consequentially revoked on the commencement of the mandatory requirements under Standard 2.1.1 (Australia only).

A delayed commencement date would allow new evidence to be considered (including the planned 2011 independent review of the standard) before making decisions in 2012 regarding commencement of, revocation, or further amendments to, the standard. An amendment enabling folic acid to be added to bread in New Zealand would ensure the continued permission for bread to be voluntarily fortified with folic acid.

4 Legislative Framework

The New Zealand folic acid standard was issued pursuant to Section 11C of the Food Act. All food standards, whether they are incorporating a joint food standard by reference or a New Zealand only standard, are ultimately given lawful effect in New Zealand under section 11C of the Act. Sections 11B through to 11L of the Food Act also contain criteria relevant to the issuing of a food standard. Section 11E contains a number of statutory preconditions that need to be taken into account by the Minister when issuing a food standard, and when amending a food standard.

5 Options

There are advantages and disadvantages to all three options and the following section provides possible examples to aid discussion. This is not an exhaustive list and submitters may well identify other impacts or hold an alternative view on the examples that have been provided. Comment is sought from interested parties on the impacts (actual or potential) of each option.

5.1 Status Quo

Under this option the folic acid standard would commence on 27 September 2009. On this date it would be mandatory for bread to be fortified with folic acid.

Advantages

- maximises the opportunity to reduce NTDs
- is consistent with the intention of the standard as developed by FSANZ under the joint system
- maintains maximum alignment with Australia

Disadvantages

- not supported by many consumers
- reduces consumer choice
- uncertainty that the mandatory fortification would deliver the desired outcome
- imposes costs on industry
- may be difficult to comply with due to the difficulties associated with getting an even spread of folic acid in bread to the required level.

5.2 Amendment to Commencement date (preferred option)

The commencement date would be changed from 27 September 2009 to 31 May 2012. The standard would be amended to provide for the continuation of voluntary fortification in New Zealand but it would not be mandatory to fortify bread with folic acid until 2012.

Advantages

- allows voluntary fortification to continue
- less cost to industry over the next two years (would not be subject to verification and auditing)
- provides greater choice to consumers over the next two years

- allows new evidence to be considered (including the planned 2011 independent review of the standard) before making decisions in 2012 regarding commencement of, revocation, or further amendments to, the standard.

Disadvantages

- would reduce the impact on addressing the folate deficiency in the New Zealand diet, and reducing the number of NTD affected pregnancies
- would not remove the uncertainty to industry that mandatory fortification may still occur
- implementation no longer aligned between Australia and New Zealand

5.3 Revocation of the New Zealand Folic Acid Standard

Under Section 11L of the Food Act, the Minister for Food Safety may revoke a standard having met the preconditions set out under Section 11E. The voluntary permission to fortify other foods with folic acid, as provided under the Food Code in Standard 1.3.2, *Vitamins and Minerals*, would continue to apply, but the permission for bread would no longer be available as it would have been removed as a consequence of the Food Code mandatory permission coming into effect.

Advantages

- provides certainty for industry and consumers about future regulatory requirement for folic acid fortification
- Ensures maintenance of consumer choice over the long term

Disadvantages

- would reduce the impact on addressing the folate deficiency in the New Zealand diet, and reducing the numbers of NTD affected pregnancies
- would be inconsistent with the joint standard as developed with Australia
- would not provide for voluntary fortification

6 Cost implications

NZFSA seeks comment on the cost impacts of the three options described above that were not covered in the FSANZ assessments in 2005-2007⁴.

6.1 Industry

NZFSA is aware that many bakers have already invested in the capacity to implement the New Zealand folic acid standard. Delaying the commencement date may create inequities between those businesses that have invested and those that have not. Comment is sought from industry on the actual or potential cost implications arising from each of the options.

Examples of costs that have already been incurred may include:

- verification and auditing costs
- equipment costs
- cost of folic acid supplies
- labelling changes

Examples of costs that may be anticipated that were not covered in the FSANZ assessments may include:

- redundancy of investment already made
- reduced demand for product

⁴ The FSANZ assessment reports are available at:

<http://www.foodstandards.govt.nz/standardsdevelopment/proposals/> under proposal P295

6.2 Consumers

The impending commencement date may have influenced consumer purchasing decisions. Comment is sought on the impact to date and the anticipated impact of folic acid fortification on consumer purchasing decisions.

Examples may include:

- plans to purchase organic bread
- plans to reduce the amount of supplements purchased

6.3 Public health

The purpose of mandatory fortification is to reduce the incidence of NTDs. Comment is sought on the impact of each of the three options on public health.

Examples may include:

- the cost of enhancing the existing education programme to increase the intake of folic acid
- the impact on planned monitoring activities, including additional or reduced costs and any redundant expenditure

7 Next Steps

7.1 Consultation

Analysis of submissions will be given the highest priority to ensure that the Minister for Food Safety receives the information necessary as soon as possible to allow time for a considered decision to be made.

NZFA appreciates the demands that the short timeframe places on submitters and wishes to assure all those seeking to make submissions that each submission will be given full consideration in preparing advice for the Minister. NZFA undertakes to publish a summary of submissions on the NZFA website five working days after submissions have closed.

The Government is aware of the high level of public interest in this issue and in order to achieve meaningful consultation (i.e. that the issues are discussed and a decision is made prior to the current commencement date) a shortened timeframe is necessary.

7.2 Indicative timeline

Notice of proposal to amend standard	22 July 2009
Consultation period	22 July – 12 August 2009 (3 weeks)
Submissions considered	12 August – 26 August 2009 (2 weeks)
Notice of any amended standard in <i>Gazette</i>	28 August 2009
Effective date of any amended standard	25 September 2009
Laid before the House of Representatives	Not later than 16 th House sitting day following the date on which standard is made