



Folic Acid Fortification: Extension to the commencement date

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1 Executive Summary

1.1 PURPOSE AND SCOPE OF CONSULTATION

Purpose of this document

This document discusses options for the commencement date of the New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007 (as amended in 2009) (the Standard).

Scope of proposals

The Standard provides for the voluntary fortification of bread with folic acid (for bread products within the scope of the Standard¹) until the end of 30 May 2012 and mandatory fortification if required on and after 31 May 2012.

This document considers a proposal to extend the commencement date for mandatory fortification from 31 May 2012 until late September 2012, a period of four months. The extension is to provide more time to review the Standard.

The options being consulted on in this document are to:

- maintain the current commencement date; and
- to extend the date by four months.

This paper does not consider any issues around the substantive content of the Standard such as whether fortification of bread should be mandatory or voluntary, or if bread should be fortified at all. Feedback is not sought on the content of the Standard at this time. This will be the subject of separate consultation.

1.2 REASONS FOR CONSIDERING AN EXTENSION OF THE COMMENCEMENT DATE

The Standard was introduced in 2007 with mandatory fortification to come into effect in 2009. In 2009, in response to concerns raised by industry and consumers, the Minister for Food Safety deferred the date for the start of mandatory fortification to 31 May 2012. The extension was to permit study of the impact of voluntary fortification and ensure a robust review of the Standard was conducted before mandatory fortification commenced.

The Minister for Food Safety created a Folic Acid Working Group in 2009 to contribute to the development and assessment of information relating to folic acid fortification. The Working Group includes representatives from the baking industry, government departments, health professionals, academics and groups who represent families affected by neural tube defect pregnancies.

The Minister committed the government to working with the baking industry to develop and progress voluntary folic acid fortification initiatives. The baking industry volunteered to fortify some breads with folic acid, focusing on breads thought to be more likely to be

¹ Bread products that are within the scope of the Standard are described in *The addition of folic acid and iodised salt to bread: New Zealand User Guide on implementing the requirements*. It is available at http://www.foodsafety.govt.nz/elibrary/industry/Addition_Folic-Manufacturers_Retailers.pdf. Bread that is represented as "organic" is an example of a bread product that is not included in the Standard.

consumed by women. The Baking Industry Research Trust now lists more than thirty breads fortified with folic acid on its website.

Government also undertook to take into account the impact of the voluntary fortification initiatives, new research, and the outcome of the planned review of the Australian mandatory fortification of wheat flour Standard. The Ministry of Agriculture and Forestry (MAF) commissioned New Zealand research into voluntary fortification of bread and published the results on 22 December 2011. MAF also published research into New Zealand women’s awareness and understanding of folate in March 2011.

MAF considers that the current commencement date of 31 May 2012 does not allow sufficient time for a full review of the new research and for robust public consultation to take place prior to mandatory fortification.

1.3 MAF’S PROPOSED OPTIONS

MAF has identified two options for the commencement of the Standard on 31 May 2012:

Option 1: Mandatory fortification takes effect 31 May 2012 (status quo)
All bread (except for “organic” bread) would be legally required to have folic acid added to it from 31 May 2012. There would be a short consultation period on options for the Standard’s future.
Option 2: Amend the Standard so that mandatory fortification takes effect late September 2012 (Preferred option)
The requirement for all bread (except for “organic” bread) to have folic acid added to it would be extended until late September 2012. Until then bread could have folic acid added to it voluntarily but would not be legally required. There would be a review of the Standard conducted with an eight (8) week public consultation during that period to inform the Minister of Food Safety’s decision on the future of the Standard.

1.4 INDICATIVE TIMELINE

This consultation runs from 2 February to 24 February 2012.

Key dates for this consultation:

Consultation period	2 – 24 February 2012 (15 working days)
Submissions considered	27 February – 16 March (3 weeks)
Formal processes if an amended commencement date is to proceed	19 March – 1 May
Effective date of any amended standard	31 May 2012

2 Consultation

Written submissions on the issues raised and the two options presented in the consultation paper are invited from all interested parties.

The closing date for submissions is 24 February 2012.

Submissions should be sent to:

Folic Acid Fortification: Extension to the commencement date.

Food Policy Team

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Ministry of Agriculture and Forestry

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Please include your name and address on your submission. If you are making comments on behalf of an organisation, also include your title and the name of the organisation.

Please make sure your comments can be clearly read as a number of copies may be made of your submission.

Submissions backed by evidence and argument will carry more weight than statements of opinion.

Information on the timing of this consultation will be posted on MAF's website and sent to interested parties.

2.1 OFFICIAL INFORMATION ACT

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. MAF 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.

2.2 PROCESS AFTER SUBMISSIONS

Once the consultation period has closed, MAF will analyse submissions and make recommendations to the Minister for Food Safety. A summary of submissions and analysis will be sent to all submitters and posted on MAF's website.

3 Introduction

The New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007 (as amended in 2009) (the Standard) is due to commence on 31 May 2012. On that date, bread products within the scope of the Standard must be fortified with folic acid (or *L-methyltetrahydrofolate, calcium*) unless it is “represented as organic”.²

MAF is consulting on extending the commencement date for the mandatory requirement in the Standard to late September 2012 to enable a fuller and more robust review of the Standard than would be possible in the time available before 31 May 2012. Extension of the commencement date requires a formal amendment of the Standard.

3.1 AMENDING THE STANDARD

The Standard was issued pursuant to Section 11C of the Food Act 1981 (the Act). All food standards are given lawful effect in New Zealand under the Act.

Section 11L of the Act permits the Minister to amend a food standard and stipulates that requirements under sections 11E to 11K of the Act apply to amendments as well as issuing a 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, including appropriate consultation.

The consultation period for amending the Standard will run from 2 February 2012 until 24 February 2012, a period of 15 working days, to enable interested parties to submit comments on the merits or otherwise of extending the commencement of the Standard by four months until late September 2012.

MAF will analyse the submissions received on this document and will make recommendations to the Minister for Food Safety who will make a final decision on the extension of commencement date of the Standard. Any extension to the commencement date of the Standard would occur before the mandatory standard comes into effect on 31 May 2012.

² Details of which bread products must be fortified and information on how that can be done is contained in *The addition of folic acid and iodised salt to bread: New Zealand User Guide on implementing the requirements*. 18 September 2009. http://www.foodsafety.govt.nz/elibrary/industry/Addition_Folic-Manufacturers_Retailers.pdf

4 Background

4.1 THE CURRENT SITUATION

The New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007 (as amended in 2009) (the Standard) was introduced with mandatory fortification to take effect on 25 September 2009 to allow time for bakers to prepare for mandatory fortification.

Following concerns expressed by both industry and consumers about mandatory fortification prior to September 2009 and after a short public consultation period, the Standard was amended. The amendment extended the date of commencement to 31 May 2012 and explicitly permitted the continuation of voluntary fortification of bread in New Zealand.³ The extension was to allow the results of further research into the effectiveness of voluntary fortification to inform decisions about mandatory fortification.

Commencement of the requirement for mandatory fortification will occur automatically on 31 May 2012 unless the Standard is amended to further extend its commencement.

4.2 FOLIC ACID SUPPLEMENTATION

The introduction of folic acid fortification of foods in New Zealand and Australia was in response to scientific research that demonstrated a link between low levels of blood folate in early pregnancy and an increased frequency of pregnancies affected by neural tube defects. Neural tube defects are major congenital abnormalities involving the brain and spinal cord, for example, spina bifida, which can result in death or lifelong disabilities. Folic acid is an internationally accepted form of supplementation used to raise blood folate⁴ levels.

Because it can be difficult to obtain the necessary amounts of folate from a natural diet alone, the Ministry of Health recommends that women take folic acid supplements (tablets) for four weeks before and 12 weeks after conception. Supplements are also available over the counter and by prescription for women who are pregnant or who plan to become pregnant. The Ministry of Health provides educational material for women, their doctors and midwives on natural sources of folate and the need for folate supplementation.

Folic acid fortification of bread is part of a third arm of a holistic approach to improving the blood folate status of women. Fortified bread provides an additional source of folic acid to protect women who do not intend to get pregnant or who do not realise that they may already be pregnant from pregnancies affected by neural tube defects. The Food Code also permits fortification of other foods with folic acid, including breakfast cereals, fruit and vegetable juices, and yeast and meat extracts.

4.3 THE 2009 EXTENSION TO COMMENCEMENT OF THE STANDARD

In 2009, the New Zealand Food Safety Authority⁵ issued a public consultation document on extending the commencement date until 31 May 2012⁶. That document acknowledged public

³ The commencement of mandatory folic acid fortification in Australia in September 2009 automatically revoked the permissions for voluntary fortification in the Australia New Zealand Food Standards Code that applied in both Australia and New Zealand. Therefore, specific provisions to permit voluntary fortification in New Zealand were required in the New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007.

⁴ Also known as vitamin B₉.

⁵ NZFSA was merged with the Ministry of Agriculture and Forestry on 1 July 2010.

⁶ Proposed Amendment to the New Zealand Folic Acid Standard. NZFSA Public Discussion Paper; no.10/09 22 July 2009

<http://www.foodsafety.govt.nz/library/industry/proposed-amendment-nz-folic-acid-standard/folic-acid-discussion-paper-22-july-09.pdf>

concern around mandatory fortification and proposed a delayed commencement in order to allow new evidence to be considered in any future decision about the Standard. It also proposed that the Standard be amended to explicitly permit bakers to voluntarily fortify bread with folic acid to encourage voluntary fortification of bread.

Concerns raised by industry about mandatory fortification included the costs involved in preparing for the new process (equipment, staff training, new recipes, new packaging, and new sources of ingredients/premix) and the ongoing increased costs of fortifying bread. Consumers were concerned by the reduction in choice if fortification was mandatory and the possibility of adverse effects from folic acid consumption.

The Minister for Food Safety committed to a full and meaningful review of the Standard before making a decision on its future.

5 Developments since the 2009 extension of commencement of the Standard

5.1 COOPERATIVE ACTIVITIES

In 2009, the Minister for Food Safety established an advisory committee known as the Folic Acid Working Group with representatives from the baking industry, government departments, health professionals, academics and groups who represent families affected by neural tube defect pregnancies.

Since then, MAF has worked with industry representatives on the Working Group to encourage voluntary fortification of bread with folic acid. The Baking Industry Research Trust now lists more than thirty breads voluntarily fortified with folic acid on its website.⁷

MAF also commissioned research into New Zealand women's awareness and understanding of folate and its role in foetal health, and more recently, research into folic acid levels in bread and into blood folate levels in women.

5.2 RESULTS OF RESEARCH

MAF has funded several research projects into blood folate levels and folic acid fortification of food. Those project reports are on the website at <http://www.foodsafety.govt.nz/science-risk/project-reports/food-composition/nutrients/folic-acid.htm>. Research New Zealand conducted a study into New Zealand women's awareness of folate and folic acid.⁸ The results were published in March 2011. Otago University studied folic acid in bread and blood folate levels of women.⁹ MAF released the report into these research projects on 22 December 2011.

The Australian Institute of Health and Welfare is conducting a major study into neural tube defects in Australia. In December 2011, the Institute published the final report¹⁰ on its work to establish baseline levels for neural tube defects during the period when voluntary fortification was permitted but before the introduction of mandatory fortification of flour with folic acid (i.e. 1998-2008). The next phase of that research will look at the incidence of neural tube defect affected pregnancies since the introduction of mandatory fortification of wheat flour with folic acid in Australia.

Australia is also in the process of reviewing its mandatory fortification of wheat flour standard. The review will be completed in two tranches, with the impact of mandatory fortification on industry due to be completed July 2012, and the impact on public health by 2013/2014.

⁷ <http://www.bakeinfo.co.nz/Hot-Topics/News/Companies-Respon-To-Voluntary-Fortification-of-Folic-Acid>

⁸ Awareness and knowledge of folate and folic acid: A survey of New Zealand women of child-bearing age. MAF Technical Paper No: 2011/8. Prepared for FSA by Research New Zealand March 2011 <http://www.foodsafety.govt.nz/elibrary/industry/folate-NZ-women.pdf>

⁹ Monitoring voluntary fortification of bread with folic acid. MAF Technical Paper No: 2011/103. December 2011.

<http://www.foodsafety.govt.nz/elibrary/industry/monitoring-fortification-of-bread-folic-acid.pdf>

A scientific interpretive summary is also available at <http://www.foodsafety.govt.nz/elibrary/industry/monitoring-fortification-of-bread-folic-acid-sis.pdf>

¹⁰ AIHW National Perinatal Statistics Unit 2011. Neural tube defects in Australia: prevalence before mandatory folic acid fortification. Cat. no. PER 53. Canberra: AIHW. <http://www.aihw.gov.au/publication-detail/?id=10737420864&tab=2>

5.3 REASONS FOR EXTENDING THE STANDARD'S COMMENCEMENT

By permitting voluntary fortification of bread, the Standard has provided an opportunity to assess the effectiveness of public health education efforts and the voluntary fortified bread on raising blood folate levels in New Zealand women. It also allows recent international research results to inform any decisions on the future of the Standard.

When the Minister for Food Safety issued the Standard in 2009, she stated the government would consider the impact of voluntary fortification and other research before making a decision on mandatory fortification prior to May 2012. She also intended to include consideration of the Australian research mentioned above to be part of that review.

MAF considers that the current commencement date of 31 May 2012 does not allow sufficient time for the new research to be fully reviewed and for meaningful public consultation to take place prior to mandatory fortification. It is therefore proposing an extension of the commencement date to enable a full public consultation on the options for the future of the Standard to be considered by interested parties and the public and for the Minister to make an informed decision.

6 Options

There are advantages and disadvantages to each of the options presented. The following section discusses the two options and the advantages and disadvantages of each.

6.1 STATUS QUO

Under this option, the Standard will commence on 31 May 2012. On this date, it would be mandatory for bread to be fortified with folic acid.

Status Quo Advantages	Status Quo Disadvantages
<ul style="list-style-type: none"> • It is consistent with the intention of the Standard as developed by Food Standards Australia New Zealand. • It does not further delay a decision since the Standard was delayed in 2009. • The Standard could be amended to permit a transition period from voluntary to mandatory. 	<ul style="list-style-type: none"> • It allows only a very brief period for a review of the Standard including any public consultation before fortification becomes mandatory. • It assumes a better result from mandatory fortification.

6.2 EXTENSION OF COMMENCEMENT DATE TO SEPTEMBER 2012 (PREFERRED OPTION)

Under this option, the Standard would commence in late September 2012. At that time, it is expected that a full and meaningful review of the Standard will be complete and available to inform any decision on the future of the Standard.

Extension Advantages	Extension Disadvantages
<ul style="list-style-type: none"> • It permits a full review of the Standard including an eight-week public consultation before mandatory fortification comes into effect. • It permits voluntary fortification of bread to continue. • It allows stakeholders more time to respond to the research on folic acid levels in bread and women's blood folate levels. 	<ul style="list-style-type: none"> • The Australian report on the impact of mandatory fortification may not be available in time to be considered in the review.

7 Next steps

7.1 CONSULTATION

This is a short consultation focused solely on the extension of the commencement date of the Standard and not on the substance of the Standard itself. MAF undertakes to publish a summary of submission on the food safety website (www.foodsafety.govt.nz) after submissions have closed.¹¹

7.2 INDICATIVE TIMELINE FOR THIS CONSULTATION

Consultation period	2 – 24 February 2012 (15 working days)
Submissions considered	27 February – 16 March (3 weeks)
Notice of any amended standard in the Gazette	3 May 2012
Effective date of any amended standard	31 May 2012
Laid before the House of Representatives	Not later than 16 th House sitting day following the day on which the standard is made.

7.3 FUTURE REVIEW OF THE STANDARD

If the commencement date of the Standard is extended to late September 2012, MAF intends to use that additional time to consult on the future of the Standard. It is expected that the extended commencement will permit an eight-week public consultation as part of a full and meaningful review of the Standard. It is expected the consultation would start in late April 2012.

¹¹ Food safety consultations can also be accessed directly from MAF's main website <http://www.maf.govt.nz/>

Appendix 1: New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007 (Administrative Consolidation)

This document is an administrative consolidation of the New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007 and the New Zealand (Mandatory Fortification of Bread with Folic Acid) Amendment Food Standard 2009. It is for guidance only. For the actual law on this matter please see the wording of those standards.

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Standard

1 Title

This standard is the New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007.

2 Commencement

- (1) This standard (except Part 2) comes into force on 25 September 2009.
- (2) Part 2 of this standard comes into force on 31 May 2012.

Part 1

Preliminary provisions

3 Purpose

This standard provides for—

- (a) the voluntary fortification of bread with folic acid (and Lmethyltetrahydrofolate, calcium) until the end of 30 May 2012; and
- (b) the mandatory fortification of bread with folic acid on and after 31 May 2012.

3A Meaning of bread

In this standard, **bread** has the meaning given to it in Standard 2.1.1 - Cereals and Cereal Products of the Australia New Zealand Food Standards Code.

Part 2A

Permitted addition of folic acid to bread (temporary)

4 Expiry of part

This Part expires at the end of 30 May 2012.

5 Addition of folic acid to bread permitted

Folic acid or L-methyltetrahydrofolate calcium may be added to bread.

Part 2

Mandatory addition of folic acid to bread

6 Mandatory addition of folic acid to bread

- (1) Bread must contain no less than 0.8 mg/kg and no more than 1.8 mg/kg of folic acid.
- (2) Subclause (1) does not apply to bread that is represented as organic.

Part 3

Relationship to the Australia New Zealand Food Standards Code

7 Applicable standards in the Australia New Zealand Food Standards Code

<p>This standard does not affect any additional obligations or restrictions relating to the manufacture and sale of bread specified in the Australia New Zealand Food Standards Code that are applicable in New Zealand.</p>
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