

# **Australian User Guide**

## **Mandatory Folic Acid Fortification**

**Implementing the Requirements**

**of the**

**Mandatory Fortification with Folic Acid under  
Standard 2.1.1 – Cereals and Cereal Products**

**February 2009**

## Background

The mandatory folic acid fortification Standard was accepted by Food Ministers in June 2007 and requires that all wheat flour for making bread (except organic) be fortified with folic acid. The mandatory Standard provides a two year implementation period, becoming enforceable in September 2009. During the two-year phase-in period, industry can add folic acid prior to the commencement date under the existing voluntary permissions, noting however this would require labelling changes. Mandatory folic acid fortification is in addition to the existing requirement for flour for making bread to contain added thiamin.

This User Guide, unlike the Standard itself, is not legally binding. If you are in any doubt about interpreting the Standard, FSANZ recommends that you seek independent legal advice.

In addition to the Food Standards requirements, it is also necessary to comply with other legislation, including the *Trades Practices Act 1974*, *Imported Food Control Act 1992* and State and Territory fair trading acts and food acts.

## Purpose of the Guide

Food Standards Australia New Zealand (FSANZ) has developed this User Guide, in consultation with government and industry representatives, to help manufacturers, retailers and food enforcement officers interpret and apply the mandatory folic acid fortification requirement under Standard 2.1.1 – Cereals and Cereal Products of the *Australia New Zealand Food Standards Code* (the Code).

### **Disclaimer**

FSANZ disclaims any liability for any loss or injury directly or indirectly sustained by any person as a result of any reliance upon (including reading or using) this guide. Any person relying on this guide should seek independent legal advice in relation to any queries they may have regarding obligations imposed under the standards in the *Australia New Zealand Food Standards Code*.

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## Part 1 The Standard

### 1.1 What is the mandatory folic acid fortification Standard?

Standard 2.1.1 – Cereals and Cereal Products requires that all wheat flour for making bread, with the exception of flour represented as organic, must be fortified with folic acid from 13 September 2009.

The level of fortification required is between 2 and 3 milligrams of folic acid per kilogram of wheat flour for making bread. Folic acid is the only permitted form of folate that can be used to meet these requirements.

### 1.2 Where can I find a copy of Standard 2.1.1 – Cereals and Cereal Products?

Standard 2.1.1 – Cereals and Cereal Products can be found in Chapter 2 – Food Product Standards. All the standards and subsequent amendments to the Code are available from the FSANZ website in html or PDF format: ([www.foodstandards.gov.au](http://www.foodstandards.gov.au)). Hard copies of the Code and User Guides can be purchased from Anstat Pty Ltd, phone 61 3 9278 1144 or on-line: <http://anzfa.anstat.com.au>.

## Part 2 Responsibilities of industry

### 2.1 What are the responsibilities of flour millers?

It is the responsibility of flour millers to ensure all wheat flour for making bread contains the required amount of folic acid as specified in the mandatory folic acid fortification Standard.

### 2.2 What foods are expected to contain wheat flour fortified with folic acid?

Bread and bread products are required to contain wheat flour fortified with folic acid. Bread is defined in the Code as *the product made by baking a yeast-leavened dough prepared from one or more cereal flours or meals and water*. Therefore, the following products are required to contain folic acid:

- plain white, white high fibre, wholemeal and multigrain bread loaves, buns and rolls
- yeast-containing flat breads (e.g. pita bread, naan bread)
- focaccia and pide (Turkish bread)
- bagels (white, wholemeal, sweet)
- topped breads, buns and rolls (e.g. cheese and bacon rolls)
- baked English-style muffins (white, white high fibre, multigrain, wholemeal and fruit)
- sweet buns
- fruit breads and rolls.

Current industry practice indicates that wheat flour for making bread may also be used in the manufacture of other foods; these include crumpets, pizza bases, scones, pancakes, pikelets, crepes, croissants and doughnuts. While the voluntary use of wheat flour fortified with folic acid is permitted under Standard 1.3.2 – Vitamins and Minerals, suppliers of these products must adhere to labelling requirements (refer to Part 4 of this Guide or Standard 1.2.4 - Labelling of Ingredients).

Bread made from other flours e.g. rye, rice, corn, will not be required to contain folic acid provided it does not contain any wheat flour. Where bread is made from a mixture of cereal flours only the wheat flour component will be required to contain folic acid.

### **2.3 Can food manufacturers use wheat flour fortified with folic acid for products other than bread?**

As indicated above, the use of wheat flour fortified with folic acid in other foods (e.g. pastries and other bakery products) is permitted under Standard 1.3.2 – Vitamins and Minerals, providing suppliers adhere to labelling requirements (refer to Part 4 of this Guide or Standard 1.2.4 - Labelling of Ingredients).

### **2.4 Will breadcrumbs be required to contain folic acid?**

Purpose-made crumbing (e.g. for fish, chicken etc.) is not required to contain folic acid. By virtue of the voluntary permissions for cereal flours, manufacturers may choose to use wheat flour fortified with folic acid if they wish; however suppliers must adhere to labelling requirements. If breadcrumbs are made from returned bread they will contain folic acid and must be labelled accordingly (refer to Part 4 or Standard 1.2.4 - Labelling of Ingredients).

Breadcrumbs made for export products should comply with the specifications of the country of destination.

### **2.5 Will wheat flour for home use be required to contain folic acid?**

General purpose wheat flour for domestic home use will not be required to contain folic acid. However, manufacturers may use voluntary permissions under Standard 1.3.2 – Vitamins and Minerals to fortify flour. In these instances, suppliers must adhere to labelling requirements (refer to Part 4 of this Guide or Standard 1.2.4 - Labelling of Ingredients).

Wheat flour labelled for use in making bread will be required to contain folic acid, including retail bread-mixes for making bread at home, unless represented as organic.

### **2.6 Are there any stock-in-trade provisions?**

The two year transition period was designed to allow flour millers sufficient time to upgrade their equipment and systems to ensure all wheat flour for making bread, and prepared bread mixes, were fortified with folic acid within the required range by 13 September 2009.

Enforcement agencies have agreed to a Compliance and Enforcement Model that is focused on the compliance of flour produced within mills from 13 September 2009 (refer to Part 5).

## **Part 3 Exemptions to mandatory fortification**

### **3.1 Are there any exemptions to mandatory folic acid fortification?**

Wheat flour for making bread that is represented as organic will be exempt from mandatory folic acid fortification.

### **3.2 What is flour represented as organic?**

The Australian [Trade Practices Act 1974](#) and the New Zealand [Fair Trading Act 1986](#) prohibit traders from misleading the public as to, amongst other things, the nature, characteristics, and quality of goods. They also prohibit traders from making false or misleading representations that goods are of a particular kind, standard, quality or have had a particular history.

Therefore, if a trader wishes to represent their product as 'organic', to ensure they do not breach the respective Australian or New Zealand legislation, all of the product's ingredients must be 100% organic through the entire food chain.

To assure consumers that the foods they produce are organic, many organic food producers and manufacturers choose to have their production processes certified organic. There are a number of organic certification organisations in Australia and New Zealand. Under Australian and New Zealand fair trading legislation, mandatorily fortified foods would generally not be able to be labelled as 'organic'.

### **3.3 Will wheat flour for making bread imported into Australia be exempt from mandatory folic acid fortification?**

Imported wheat flour for making bread must comply with the mandatory folic acid fortification Standard, with the exception of flour represented as organic.

### **3.4 Is wheat flour that is exported from Australia permitted to contain folic acid?**

Wheat flour exported from Australia may contain folic acid provided it is permitted in the destination country.

## **Part 4 Labelling requirements**

### **4.1 What labelling will be required under mandatory folic acid fortification?**

The mandatory folic acid fortification Standard affects the labelling requirements of products that contain wheat flour fortified with folic acid. The labelling requirements differ depending on whether the food is for retail sale or not, or for catering purposes.

### Food not for retail sale

Food not for retail sale means *food not for sale to the public and includes food intended for further processing, packaging or labelling prior to retail sale* e.g. wheat flour for making bread provided to a bakery (this does not include for food catering purposes (see below)). These foods are not required to be labelled with a statement of ingredients. However, if requested by the purchaser or relevant authority, the flour must be accompanied by enough information for the purchaser to comply with the compositional and labelling requirements of the Code. This information must be provided in writing if requested by the purchaser or relevant authority.

### Food for catering purposes

Food for catering purposes includes food supplied to catering establishments, restaurants, canteens, schools, hospitals and institutions where food is prepared or offered for immediate consumption. Such food e.g. wheat flour sold to a restaurant, is not required to be labelled with a statement of ingredients. However, a statement of ingredients, amongst other information, must be provided in documentation. Suppliers may choose to provide this information electronically, in written documentation, or by placing it on the label. In addition, if specifically requested by the purchaser or relevant authority, the wheat flour must be accompanied by enough information for the purchaser to comply with the compositional and labelling requirements of the Code.

For further details, refer to Standard 1.2.1 - Application of Labelling and Other Information Requirements.

### Food for retail sale

Food for retail sale means food for sale to the public and includes food prior to retail sale which is not intended for further processing, packing or labelling. Suppliers will be required to list folic acid either as folic acid or folate in the statement of ingredients on foods that contain wheat flour fortified with folic acid. A declaration of folic acid/folate in the statement of ingredients will provide consumers with information about whether their product choice contains added folic acid and may assist them with making purchasing decisions.

When wheat flour fortified with folic acid is an ingredient of a food, it is classified as a 'compound ingredient'. Compound ingredients can be declared in the statement of ingredients either:

- (a) by declaring the compound ingredient by name and listing its ingredients in brackets; or
- (b) by declaring all of the ingredients of the compound ingredient separately as if they were individual ingredients of the final food.

If wheat flour fortified with folic acid is declared as outlined in (a), and the flour makes up less than 5% of the final food, the individual flour ingredients do not need to be declared, including folic acid (note: allergens and certain food additives still need to be declared).



It is a requirement, however, for all ingredients (including compound ingredients) to be declared using a name that describes the true nature of the ingredient (refer to clause 4(a) of Standard 1.2.4 – Labelling of Ingredients).

For further detail on the labelling of compound ingredients refer to clause 6 of Standard 1.2.4 – Labelling of Ingredients and clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations.

In some situations, products are exempt from the requirement to label with a statement of ingredient lists. These include:

- unpackaged food
- food made and packaged on the premises from which it is sold
- food packaged in the presence of the purchaser
- food in a small package<sup>1</sup>.

For further details, refer to clause 2 of Standard 1.2.4 – Labelling of Ingredients and clauses 1 and 2 of Standard 1.2.1 – Application of Labelling and Other Information Requirements. For these products, consumer information about the presence of folic acid may be made available from the food outlet upon request; however this is not a requirement.

#### **4.2 Will nutrition and health claims be permitted in relation to mandatory folic acid fortification?**

Yes, nutrition and health claims can be made for foods containing folic acid; however certain compositional requirements must be met and a declaration made in the nutrition information panel (NIP). For further details on:

- nutrition claims, refer to Standard 1.2.8 – Nutrition Information Requirements and Standard 1.3.2. –Vitamins and Minerals
- health claims, refer to Standard 1.1A.2 – Transitional Standard – Health Claims.

FSANZ is developing a new Standard to regulate nutrition, health and related claims under Proposal P293 – Nutrition, Health and Related Claims. The conditions for making claims about the presence of vitamins or minerals and associated health claims are being considered under this Proposal. The new Standard, when gazetted, may therefore impact on the current information on nutrition and health claims.

#### **4.3 What about use of 'natural' claims?**

The Australian Competition and Consumer Commission (ACCC) considers that 'natural' claims imply the product is made up of natural ingredients, i.e. ingredients nature has produced, not man made or interfered with by man. Folic acid is not a natural substance; therefore 'all natural' claims for foods containing folic acid may not be used, although the product may be labelled as 'contains natural ingredients'. Care should be taken however when labelling a product as 'contains natural ingredients' to avoid giving the impression that all the ingredients in the product are natural.

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<sup>1</sup> Small package is defined in Standard 1.2.1 and means a package with a surface area of less than 100 cm<sup>2</sup>.

For further details refer to the ACCC 'Food and Beverage Industry – Food Descriptors Guideline to the Trade Practices Act'<sup>2</sup>.

## **Part 5 Compliance/enforcement**

### **5.1 When will mandatory folic acid fortification commence?**

The mandatory Standard provides industry with two years to implement requirements and is enforceable from 13 September 2009. At this time, all wheat flour for making bread, with the exception of flour represented as organic, will be required to be fortified with folic acid. The timing is such that industry may choose to add folic acid prior to the implementation date under the existing voluntary permissions providing suppliers adhere to labelling requirements.

### **5.2 At what point does wheat flour for making bread need to meet the requirements of mandatory folic acid fortification?**

Wheat flour for making bread is required to meet the mandatory folic acid fortification Standard at the final point of production at the mill. Imported wheat flour for making bread is required to contain folic acid at the point of import into Australia.

The level of folic acid will also need to remain within the range of 2-3 mg/kg over the declared shelf-life of the product. Millers should obtain their own information to verify the shelf-life of a product; however information available from overseas indicates a maximum degradation of folic acid in flour and bread pre-mixes of 10% over 12 months<sup>3,4</sup>.

### **5.3 How will mandatory folic acid fortification be assessed for compliance?**

Assessing compliance with food standards is the responsibility of state and territory enforcement agencies. These agencies have developed a Compliance and Enforcement Model for mandatory folic acid fortification. Contact your local enforcement officers or state/territory health department for further information on this issue.

The Model is based on mills incorporating components designed to control compliance with mandatory folic acid fortification into a quality assurance arrangement (QAA), including monitoring, sampling and analysis protocols. Many mills already have a third party audited QAA in place, and in that case folic acid fortification would be an additional element. Third party audit arrangements can be applied to demonstrate the QAA is in place and achieving the stated outcomes. However, the Model does not preclude enforcement agencies from taking samples for analysis should the need arise.

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<sup>2</sup> [www.accc.gov.au](http://www.accc.gov.au)

<sup>3</sup>Source: Popper, L. from Muhlenchemie (presentation at the Australasian Milling Conference 2008)

<sup>4</sup>Source: US Aid/DSM (information paper on 'Fortification Basics: Stability')  
[http://www.dsm.com/en\\_US/downloads/dnp/51610\\_fort\\_basics\\_stability.pdf](http://www.dsm.com/en_US/downloads/dnp/51610_fort_basics_stability.pdf)

Due to the inherent analytical variability, the Model recognises that there is potential for analysed samples to be outside the required fortification range on occasions. Therefore, to determine how a mill operator is managing compliance with the Standard, sample results will be considered in conjunction with other information available at the mill.

Enforcement agencies plan to undertake compliance monitoring through the ISC Coordinated Survey Plan. This will provide a 'snapshot' of how effectively mills' have implemented the Standard and will include an assessment of mills' QAA documentation and appropriate sampling and analysis protocols for wheat flour used for making bread.

#### **5.4 Do bread and other food manufacturers have compliance requirements under mandatory fortification?**

Bread manufacturers should specify the end use of the flour when placing orders with the flour mill. Bread and other food manufacturers using wheat flour fortified with folic acid are required to adhere to the specific labelling requirements (refer to part 4 of this Guide or Standard 1.2.4 - Labelling of Ingredients).

## **Part 6 Implementing the Standard**

### **6.1 How should folic acid be added in the milling process?**

It is the responsibility of each mill to review and assess the best method for the addition of folic acid.

In general, folic acid is best added late in the process and at a point that ensures mixing, with the addition rate based on the measured/known flour production rate. The approach taken by mills to fortify wheat flour for making bread with folic acid will differ according to the set-up of each individual mill.

### **6.2 What are the suggested components to include in a quality assurance arrangement?**

Most flour mills in Australia already have a QAA in place; in those cases the components to demonstrate compliance with the mandatory folic acid Standard can be incorporated into an existing QAA.

Enforcement agencies agree that adherence to a QAA or equivalent arrangement, assessed through either third party or alternative audit arrangements, is an acceptable means of demonstrating achievement of compliance with a specific mandatory fortification Standard. Suggested components are outlined below.

#### **Folic acid addition**

1. Correct pre-mix calculations and defined addition formulas.
2. The feeder is working properly and set at the appropriate rate to deliver folic acid within the defined range.
3. The feeder is calibrated and maintained.

4. Monitoring records to demonstrate Items 1-3 above are in place and specified levels are being achieved.
5. Evidence of validation of the pre-mix delivery system.

### Verification

There are two components to verification:

1. A stocktake performed on the quantity of pre-mix added in relation to wheat flour for making bread produced. This should be on a basis that is appropriate for the amount of flour produced e.g. at the end of each shift, day, week or any other period of time that is appropriate to demonstrate the correct amount of pre-mix has been added.
2. Sampling and laboratory analysis to check that the flour contains the required amount of folic acid. Suggested sampling and analysis protocols are outlined below.

### Corrective action

A system should be in place for corrective action should routine verification procedures confirm the potential exists for a product to be out-of-specification.

## **6.3 What are the suggested sampling and analysis protocols?**

It is suggested that industry and enforcement agencies adhere to similar sampling and analysis protocols to ensure consistency between mills and enforcement agencies. Suggested protocols are outlined below.

### Quality assurance sampling: mills

The flour miller is responsible for developing and implementing QAA procedures for the collection of samples to verify that folic acid is being added to wheat flour for making bread at the required level. Mills will need a disciplined approach to sampling if they wish to use the results to demonstrate compliance. The components to be considered include frequency, location and type and the following information acts as a guide.

#### *Frequency*

The frequency of sampling may be time or quantity based depending on the mill's size and output. An example of time-based sampling is once every 1000 tonnes of flour produced which may equate to once every two days for large and monthly for small mills. The frequency may vary depending on operational performance.

#### *Location*

Samples should be drawn from a point that is a fair representation of the flour to be dispatched. It will be up to each mill to determine the position that delivers a representative sample of the flour produced.

### *Type*

Samples can either be a single 'grab sample' or a sample representative of a lot i.e. composite sample made up of a number of sub-samples. Each mill is to determine their definition of a 'lot'.

For a lot sample, sub-samples should be taken from a predetermined point or points in the milling process. It is recommended to take at least three sub-samples each of >500 g over the course of the run. These sub-samples can then be combined, mixed well and a representative sample of the composite sent for analysis. A matching sample should be retained by the mill in a sealed bag in a cool dark place.

### Compliance sampling: enforcement agencies

#### *Frequency*

Sampling may be on a scheduled basis or triggered by events, such as a mill's failure to take agreed samples, inadequate record keeping or failure to demonstrate corrective actions when problems are identified.

#### *Location*

Samples should be drawn from a point that is a fair representation of the flour to be dispatched.

#### *Type*

It is recommended for compliance monitoring that samples are representative of a lot i.e. the collection of a number of sub-samples to prepare a composite sample. Sub-samples should be taken from a predetermined point or points in the milling process.

It is recommended to take at least three sub-samples each of >500 g over the course of the run. These sub-samples can then be combined, mixed well and a representative sample of the composite sent for analysis. A matching sample should be retained in a sealed bag in a cool dark place.

Note: if enforcement agencies are sampling bakery pre-mixes as part of compliance monitoring, they need to factor in the proportion of wheat flour in the pre-mix.

### Analysis: mills and enforcement agencies

#### *Methods*

The two suggested methods for folic acid analysis are:

1. HPLC for quality assurance (QA) and compliance monitoring
2. kits (Biocore, protein binding assay and ELISA) for QA.

The method chosen should be subject to a validation process.

#### *Choice of laboratory*

All analyses should be carried out by laboratories that are accredited to test for the presence and level of folic acid in wheat flour for making bread (e.g. NATA or IANZ)

and which undertake proficiency testing. The laboratory should also maintain records of their testing coefficient of variation (CV) and provide this with the results. For routine QA testing using HPLC, single extraction and duplicate analysis i.e. 1x2 should be suitable. However for compliance monitoring by enforcement agencies, it is recommended that consideration be given to duplicate extraction and analysis i.e. 2x2.

### *Proficiency testing*

Proficiency testing for nutrient analysis is important for assessing inter- and intra-laboratory variation. NMI has commenced a proficiency testing program. This User Guide will be updated when further information becomes available.

## **Part 7 Other requirements**

### **7.1 What other requirements must be complied with that are relevant to wheat flour for making bread?**

Standard 2.1.1 also continues the requirement for thiamin to be added to flour for making bread at a minimum level.

Prior to gazettal of the mandatory folic acid fortification Standard, thiamin was required to be added to all flours for making bread e.g. not just wheat flour, and included organic flour. However, the requirement now aligns with that of folic acid in that the addition is only to 'wheat' flour for making bread and flour represented as organic is exempt.

It is also proposed that the use of iodised salt will be mandated for making bread. This standard will come into effect at the same time as the standard mandating the fortification of wheat flour with folic acid.

## **Part 8 Voluntary folic acid fortification**

### **8.1 What other provisions in the Code permit the addition of folic acid to foods?**

Voluntary fortification allows food manufacturers to choose what vitamins and minerals they add to food, providing they are permitted in the Code. Refer to Standard 1.3.2 – Vitamins and Minerals for existing voluntary folic acid fortification permissions.

### **8.2 How does mandatory folic acid fortification impact on voluntary folic acid permissions in the Code?**

The current voluntary folic acid fortification permissions will not be affected by mandatory folic acid fortification, with the exception that the voluntary permission for adding folic acid to bread is being repealed and replaced with the mandatory

requirement. Bread made from other cereal flour can be fortified under the voluntary fortification permissions (refer to Standard 1.3.2 – Vitamins and Minerals).

## **Part 9 Mandatory folic acid fortification in New Zealand**

### **9.1 What is the mandatory fortification requirement for New Zealand?**

The mandatory fortification standard in New Zealand applies to 'bread', which must contain no less than 0.8 mg/kg and no more than 1.8 mg/kg of folic acid. Bread represented as organic is exempt from mandatory folic acid fortification.

### **9.2 Why is the New Zealand Standard based on bread rather than wheat flour for making bread?**

New Zealand industry and enforcement agencies preferred compliance with a fortification standard for bread rather than flour. New Zealand does not have a history of mandatory thiamin fortification and therefore does not have existing infrastructure for mandatory fortification of wheat flour for making bread.

### **9.3 We export wheat flour for making bread to New Zealand? What are our requirements?**

Wheat flour for making bread that is exported to New Zealand is not required to contain folic acid. The flour *may* be fortified under the voluntary permissions (Standard 1.3.2 – Vitamins and Minerals); however it is important that the end user is aware of the presence of folic acid.

Because the mandatory folic acid fortification Standard in New Zealand relates to 'bread', it will be up to bread manufacturers to consider their approach to fortification which may be through the use of fortified flour or addition of folic acid through some other means, e.g. as part of a pre-mix. It is important to remember that the final bread must contain no less than 0.8 mg/kg and no more than 1.8 mg/kg of folic acid.

## **Part 10 Legal considerations**

### **10.1 What protection will flour millers, food manufacturers, bakers or others have in case of legal prosecution under common law should prosecution for public liability arise?**

FSANZ has sought advice from the Australian Government Solicitor (AGS) on potential product liability exposure for flour manufacturers under Part VA of the *Trade Practices Act 1974*. The AGS advised that millers would be protected from liability where they have complied with a mandatory standard as defined in the *Trade Practices Act 1974*.

## **Part 11 Consumer information**

### **11.1 What is folate/folic acid?**

Folate is a B group vitamin needed for healthy growth and development, especially of the nervous system. This vitamin is known as **folate** when occurring naturally in food, such as green leafy vegetables. **Folic acid** is the 'man made' form used in supplements or added to food. Folic acid is more readily absorbed than naturally-occurring folate.

### 11.2 Who needs folic acid and why?

Folic acid is important to the healthy development of babies in early pregnancy. A baby's growth is the most rapid in the first weeks of life – often before a woman is aware she is pregnant. The neural tube closes and fuses very early in pregnancy; if it doesn't close, the result is a neural tube defect (NTD) such as spina bifida. Folic acid taken at least one month before and three months after conception can prevent the occurrence of most NTDs.

### 11.3 What is mandatory folic acid fortification?

Mandatory fortification is the compulsory addition of certain vitamins and minerals to foods in response to a significant public health need. The mandatory folic acid fortification Standard requires that all wheat flour used for making bread, with the exception of flour represented as organic, must be fortified with folic acid.

This will mean most bread in Australia will contain folic acid. Bread will contain an average of 120 micrograms of folic acid per 100 grams (approximately three slices).

### 11.4 Why mandatory folic acid fortification?

For more than ten years, Australia and New Zealand have introduced a number of initiatives to increase the folic acid intake of women planning to or who may become pregnant to reduce the risk of their babies developing NTDs. These have included health claims on food labels, education programs, voluntary folic acid fortification of foods - such as breakfast cereals and bread - and encouraging women to take folic acid supplements. Despite these initiatives, most women of child-bearing age are still not consuming enough folic acid. Mandatory fortification is being introduced to provide additional protection against NTDs.

Mandatory folic acid fortification is expected to reduce the number of NTD affected pregnancies by 14-49 (or up to 14%) each year in Australia.

### 11.5 Why was wheat flour for making bread chosen for fortification?

Bread was chosen as the appropriate food vehicle for fortification as it is consumed regularly by a large proportion of women of child-bearing age across different socio-economic sub-groups. However, women of child bearing age will still need to take a folic acid supplement to ensure that they achieve the recommended amount of folic acid.

The addition of folic acid to wheat flour for making bread was selected as the preferred route to add folic acid to bread. Under Standard 2.1.1 – Cereals and Cereal Products, Australian manufacturers are already required to add thiamin to flour used for making bread.



## 11.6 What choice do consumers have who want to avoid folic acid?

Wheat flour for making bread represented as organic will be exempt from folic acid fortification. This will provide some choice for consumers who do not wish to consume bread with added folic acid. Bread made from other cereal grains e.g. rice, corn and rye, provided they do not contain any wheat flour, will not be required to be fortified with folic acid. However, manufacturers may choose to add folic acid, by virtue of the voluntary permissions that exist for flours from other cereal grains. In these instances, suppliers must declare the addition of folic acid as part of ingredient labelling (refer to Part 4 of this Guide or Standard 1.2.4 – Labelling of Ingredients).

## Part 12 Further information

### 12.1 Will the mandatory folic acid fortification Standard be monitored and reviewed?

The Ministerial policy guidelines for mandatory fortification of food products state that:

*Any agreement to require fortification should require that it be monitored and formally reviewed to assess the effectiveness of, and continuing need for, the mandating of fortification.*

When making their decision to implement mandatory folic acid fortification, Food Ministers directed that a thorough, comprehensive and independent review of the Standard be initiated two years after implementation. The review is expected to consider improvements in dietary folic acid intakes and folate status, particularly in women of child-bearing age, and effectiveness in reducing the incidence of neural tube defects (NTD) within the Australian and New Zealand populations. It will also assess any adverse health effects and the adequacy of the monitoring framework.

### 12.2 Who is responsible for monitoring?

Monitoring the impacts of mandatory folic acid fortification is the responsibility of health and regulatory agencies at the Commonwealth and state/territory levels in Australia and New Zealand. The Australian Institute of Health and Welfare (AIHW) has been given overall responsibility for the monitoring program and reporting on progress.

FSANZ will contribute directly to some elements of the monitoring program as part of its on-going work and may also be involved indirectly in other fortification monitoring program activities.

### 12.3 Is there any further consumer education material available?

FSANZ has developed a list of Consumer Frequently Asked Questions (FAQs) for mandatory folic acid fortification that are available on the FSANZ website ([www.foodstandards.gov.au](http://www.foodstandards.gov.au)).

## 12.4 Where can I get more information?

Enforcement of mandatory folic acid fortification will be the responsibility of state and territory enforcement agencies. Contact your local enforcement officers or State/Territory health department for further advice regarding this issue.

FSANZ can provide assistance with navigating the Code. However FSANZ does not provide approval of labels, or food compliance of any type. FSANZ is limited to providing information about the Code only and does not provide legal advice on or interpretation of the Code. The onus is upon suppliers including food companies to ensure compliance with relevant food legislation. You may wish to engage a food compliance consultant or your own legal counsel for further advice.

For access to the Code, go to FSANZ website: [www.foodstandards.gov.au](http://www.foodstandards.gov.au)

Additional user guides are available on the FSANZ website:  
[www.foodstandards.gov.au](http://www.foodstandards.gov.au)

- Overview of Food Labelling
- Legibility Requirements for Food Labels
- Information Requirements for Foods Exempt from Bearing a Label
- Ingredient Labelling
- Nutrition Information Labelling