

# **Mandatory Folic Acid Fortification**

**A short guide to the development of a food standard  
for Australia and New Zealand**

**July 2006**

# Summary

*FSANZ is developing a new food standard for mandatory fortification of food with folic acid. This is a complex issue, requiring wide consultation throughout the community.*

## **Our proposed approach seeks to...**

### **Reduce the incidence of neural tube defects (NTDs) in Australia and New Zealand through mandatory fortification of the food supply with folic acid**

We have been asked by the Australia and New Zealand Food Regulation Ministerial Council to consider how mandatory folic acid fortification of the food supply can be achieved to further reduce the incidence of NTDs, such as spina bifida, in Australia and New Zealand. We want to reduce the incidence of NTDs to the maximum extent possible by increasing dietary folic acid intakes in women of child-bearing age, without jeopardising the safety of the food supply.

Each year, 300-350 pregnancies in Australia are affected by NTDs. In New Zealand there are approximately 70-75 cases per year. Women can reduce the risk of having a baby with a NTD by consuming 400 micrograms of folic acid a day before and during the first three months of pregnancy. However, there is evidence that pregnant women are not getting sufficient folic acid, either from food that has been fortified voluntarily by food companies or naturally occurring folate. Although women planning pregnancies often take folic acid supplements, nearly half of all pregnancies are unplanned.

## **The new measure...**

### **Mandates fortification of all bread-making flour with folic acid**

Our preferred approach is mandatory fortification of all bread-making flour with folic acid in Australia and New Zealand to further reduce the incidence of NTDs. The proposed level of mandatory fortification is 230-280 micrograms of folic acid per 100 grams of bread-making flour, to achieve an average residual level of approximately 200 micrograms folic acid in bread and bread products.

### **Recommends folic acid supplementation and education in addition to mandatory fortification**

The average folic acid intake from mandatory fortification combined with folic acid intake contributed by foods voluntarily fortified with folic acid, is less than the 400 micrograms folic acid recommended for women of child-bearing age. Folic acid supplementation and education for women planning to, or capable of, becoming pregnant will therefore continue to be an important strategy in reducing NTDs.

## **And includes...**

### **Labelling requirements to guide and inform consumers**

Consumers will be informed about the addition of folic acid to bread-making flour through general labelling requirements that require all ingredients of a product to be identified in the ingredient list. Additionally, if manufacturers choose to do so, or where a claim is made about a product and its folate content (naturally-occurring and/or added), folate will be declared in the Nutrition Information Panel. This information will enable consumers to either select products fortified with folic acid or to avoid those products.

### **Continuation of support for existing strategies to reduce the incidence of NTDs**

We acknowledge the useful role of current strategies in reducing the incidence of NTDs. These strategies include the promotion of increased folate intakes in women of child-bearing age through education, voluntary fortification and supplement use. Optimal reduction in NTDs depends on these strategies continuing, including a commitment to the ongoing promotion of folic acid supplements.

### **Monitoring the effectiveness and safety of mandatory folic acid fortification**

Monitoring will form an essential component of implementing this proposed new standard. It will provide a basis to gauge both the ongoing effectiveness and safety of mandatory folic acid fortification, particularly in further reducing the incidence of NTDs. Monitoring the ongoing need for fortification at the recommended level will also be required, given some uncertainties associated with mandatory fortification. We have developed a proposed plan for this activity, which is attached to the Draft Assessment Report.

Responsibility for establishing and funding a monitoring system to assess the impact of mandatory fortification on the population extends beyond our responsibilities under the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), and will require the involvement of health and regulatory agencies at the Commonwealth, State and Territory level in Australia and the New Zealand Government.

### **Communication and education**

We have prepared a strategy to guide communication and education initiatives to raise awareness and understanding of the proposed standard for mandatory folic acid fortification and its implementation. In implementing this strategy, we will collaborate with other organisations that play an important role in providing information and education to consumers, industry and other key stakeholders.

### **A phase-in period**

To give industry time to make the required changes to manufacturing and labelling, and to alert consumers to the new rules, we are recommending a **12-month transition period** for implementation after the standard becomes law.

# Guide to the proposed food standard

Food Standards Australia New Zealand (FSANZ) is an independent bi-national agency responsible for setting food standards for Australia and New Zealand, which appear in the *Australia New Zealand Food Standards Code*.

This Guide provides individuals and organisations with an interest in fortification of food with information on the approach being proposed by FSANZ and our recommendations for the content of the standard.

Underpinning this document is a report that sets out in detail the reasons why new regulations are needed, options that we considered during the development of the standard and a draft standard for incorporating into the Code. You can access this information from the FSANZ website at [www.foodstandards.gov.au](http://www.foodstandards.gov.au).

The report also includes the policy guidelines that we received from the Australia and New Zealand Food Regulation Ministerial Council to be taken into account in developing the standard.

It also contains our responses to issues raised by the public, industry, government and public health groups during our first period of public consultation in October to December 2004. We have carefully considered these views. We now invite the community to examine the rationale and content of the proposed food standard and to comment on our approach.

This second period of consultation will operate from **3 July 2006** until **31 July 2006**. If you would like to make a written submission, please see the FSANZ website on how to do this.

Your views are important to us.

They will help shape new regulations for the fortification of food in Australia and New Zealand.

We invite you to let us know what you think by **31 July 2006**.

## Background

In May 2004, the Australia and New Zealand Food Regulation Ministerial Council (the Ministerial Council) asked Food Standards Australia New Zealand (FSANZ) to investigate mandatory fortification with folic acid as a possible means of reducing the incidence of neural tube defects (NTDs) which are serious birth defects.

FSANZ released its Initial Assessment Report in October 2004 and presented four options, namely: maintenance of the *status quo*; extension of permissions for voluntary folic acid fortification; mandatory folic acid fortification; and increased health promotion and education strategies to increase folate intakes.

On the basis of Ministerial advice received in 2005 that mandatory folic acid fortification is an effective strategy, FSANZ reduced the number of regulatory options considered in this Draft Assessment Report to: maintenance of the *status quo* and mandatory folic acid fortification.

Internationally, a number of countries have reported successful mandatory folic acid fortification programs as an equitable and sustainable means of increasing the folic acid intake of women of child-bearing age (the target population) to reduce the incidence of NTDs. Wheat flour is the most commonly chosen food vehicle.

FSANZ drew on this international experience and selected bread-making flour as the food vehicle for mandatory folic acid fortification in Australia and New Zealand. From a practical perspective, it considered bread-making flour as a feasible vehicle due to the existing mandatory fortification requirement with thiamin in Australia.

The report focuses on consideration of mandatory folic acid fortification as a means of reducing the incidence of NTDs in Australia and New Zealand and includes:

- an assessment of the health benefits and risks of increased dietary intakes of folic acid by the Australian and New Zealand populations;
- identification of a preferred food vehicle and level of folic acid concentration to achieve the desired health outcome;
- management of any identified risks;
- cost-benefit analysis;
- associated communication and education;
- monitoring and implementation issues; and
- presentation of a preferred regulatory approach.

This report also addresses issues arising from public submissions and targeted stakeholder consultation. The current approach gives particular consideration to folic acid intake from voluntary fortification and reported trends in NTDs.

The report describes our preferred regulatory option and a draft food standard for inclusion in the Code. We will carefully assess comments received on the second report before producing final recommendations for consideration by the FSANZ Board and, if approved, by the Ministerial Council.

## Regulatory options

The Draft Assessment Report presents two regulatory options: maintenance of the *status quo* and mandatory folic acid fortification. We canvassed both these options during our first round of public consultation.

### Preferred Approach

Mandatory fortification of all bread-making flour with folic acid is the preferred approach in Australia and New Zealand to further reduce the incidence of NTDs.

The proposed level of mandatory fortification is 230-280 micrograms of folic acid per 100 grams of bread-making flour, to achieve an average residual level of approximately 200 micrograms folic acid in the flour component of the final food.

The approach maintains current voluntary folic acid permissions except for bread which will be changed from a voluntary permission to a mandatory requirement.

### Reasons for Preferred Approach

The reasons for the preferred approach are:

- fortifying flour with folic acid, in this case bread-making flour, is consistent with international experience of mandatory fortification to reduce the incidence of NTDs;
- bread-making flour is an effective and technically feasible food vehicle for mandatory folic acid fortification;
- bread-making flour (as bread and bread products) is a staple food consumed widely, consistently and regularly by the target population of women of child-bearing age;
- fortification of bread-making flour will deliver a mean increase in folic acid intake in the target population of 100 micrograms and 131 micrograms in Australia and New Zealand respectively, resulting in an estimated reduction of between 14-49 pregnancies in Australia and 4-14 pregnancies in New Zealand affected by an NTD;
- on the available evidence, including overseas experience, the proposed level of fortification does not pose a risk to public health and safety. The level has been set to minimise any potential health risks as a degree of uncertainty exists, particularly for the non-target population from increased folic acid intakes over the longer term;

- the cost-benefit analysis indicates that the benefits from the projected reduction in NTDs will exceed the costs of mandating fortification:
  - a) in Australia, the net benefits would be \$23.9 million each year ongoing for live NTDs reduced, or \$124.5 million each year ongoing for all NTDs (including still births and terminations) reduced by fortification; and
  - b) in New Zealand, the net benefits would be \$4.8 million each year ongoing for live NTDs reduced, or \$41.2 million each year ongoing for all NTDs (including still births and terminations) reduced by fortification.
- the cost to consumers is likely to be small, probably less than 1% of the price of a loaf of bread;
- consumers will be provided with information through ingredient labelling to identify the presence of folic acid in products containing bread-making flour; and
- it is consistent with Ministerial policy guidance on mandatory fortification.

This consideration acknowledges the useful role of current strategies in reducing the incidence of NTDs. These strategies include the promotion of increased folate intakes in women of child-bearing age through education, voluntary fortification and supplement use. Optimal reduction in NTDs depends on these strategies continuing, including a commitment to the ongoing promotion of folic acid supplements.

There are some uncertainties associated with mandatory fortification, particularly chronic exposure to increased folic acid intakes beginning in childhood. As a result, a conservative approach to the level of fortification has been adopted.

Monitoring will form an essential component of implementing this Proposal. It will provide a basis to gauge both the ongoing effectiveness and safety of mandatory folic acid fortification, particularly in further reducing the incidence of NTDs and ongoing need for fortification at the recommended level. A proposed plan is provided as an attachment to the Draft Assessment Report.

Responsibility for establishing and funding a monitoring system to assess the impact of a mandatory fortification on the population extends beyond FSANZ's responsibilities under the FSANZ Act 1991, and will require the concomitant involvement of health and regulatory agencies at a Commonwealth, State and Territory level in Australia and the New Zealand Government.

FSANZ will undertake ongoing monitoring of any changes in voluntary fortification of foods, as well as any changes in consumption of fortified foods and consumers' attitudes and behaviour towards these foods.

## **How mandatory folic acid fortification will work**

Following completion of a Final Assessment for the Proposal and approval of the proposed draft variations to the Code by the FSANZ Board, the Ministerial Council will be notified. Subject to any request from the Ministerial Council for a review, the proposed draft variations to the Code are expected to come into effect upon gazettal. Once gazetted, it is proposed that the normal 12-month transitional period for amendments to the Food Standards Code will apply to the proposed mandatory fortification of bread-making flour with folic acid.

FSANZ has prepared a strategy to guide communication and education initiatives to raise awareness and understanding of the proposed standard for mandatory folic acid fortification and its implementation. In implementing this strategy, FSANZ will collaborate with other organisations that play an important role in providing information and education to consumers, industry and other key stakeholders.

## Commonly Asked Questions

### What is folate/folic acid?

Folic acid is a B group vitamin that is needed for healthy growth and development. This vitamin is known as **folate** when it is found naturally in food, such as green leafy vegetables, and as **folic acid** when it is added to food, such as bread and breakfast cereals, or used in dietary supplements.

### Who needs folic acid and why?

Folic acid is important for everyone but is especially important for women of childbearing age particularly those planning a pregnancy. This vitamin is crucial 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 knows that she is pregnant. Folic acid taken at least one month before pregnancy and for the first three months of pregnancy will substantially reduce the risk of birth abnormalities called NTDs in babies.

### What are NTDs?

NTDs are severe congenital malformations of the central nervous system which may occur during early development of the baby in the womb. The two major types of NTDs are anencephaly and spina bifida. There is more information about NTDs on the Australian Spina Bifida & Hydrocephalus Association (ASBHA) website at <http://www.asbha.org.au/SpinaBifidaandHydrocephalus.htm>

### How much folic acid do women need?

In Australia, women of child bearing age are advised to take folic acid (a synthetic form of folate) as a supplement or consume fortified foods at a level of 400 micrograms a day to minimise the risk of their unborn child being affected by a NTD such as spina bifida. In New Zealand, women are recommended to consume a tablet containing 800 micrograms of folic acid a day. These recommendations are in addition to the normal diet which contains naturally-occurring folate.

### Why can't women get enough folate in their diet?

A woman needs to consume large quantities of food with high levels of naturally-occurring folate to obtain the recommended daily dose. Foods naturally high in folate include: green leafy vegetables, nuts, orange juice, some fruits and dried beans. Although the naturally-occurring folate in these foods also contributes to protecting against NTDs, naturally-occurring folate is not as easily absorbed by the body as folic acid found in supplements and fortified foods. For example, to obtain the equivalent of 400 micrograms of folic acid, a woman would need to eat daily nearly ½ kilogram of cooked spinach or raw broccoli!

### **Are there education programs in place throughout Australia to encourage women to take folic acid supplements?**

Yes. Since the early 1990s, Australian women of child-bearing age have been encouraged to take folic acid supplements at the daily recommended dose of 400 micrograms. Similar health messages have been promoted in New Zealand. However, well-resourced supplement promotion programs encouraging women to take folic acid, such as in Western Australia, have only achieved about 1 in 3 women obtaining an average of 200 micrograms per day or more from supplements. In addition, as many pregnancies are unplanned (estimated to be more than 50% of all pregnancies) reliance on supplements alone is not an effective strategy.

### **Voluntary fortification is already in place. Why isn't that enough?**

Voluntary fortification of foods (flour, savoury biscuits, bread, cereal flours, breakfast cereals, pasta, yeast extracts and fruit and vegetable juices) with folic acid has been in place since 1995 but not all of the food industry has taken up this option. Despite this and the fact that not all women are taking sufficient folic acid supplements, some Australian States have reported a fall in NTD rates. So it is possible that there can be further reductions in NTD cases if there is a rise in folic acid intake.

### **How does Australia and New Zealand compare with overseas countries?**

Rates of NTDs in Australia are still much higher than in similar overseas countries that have introduced mandatory fortification such as Canada and the United States. Data on the number of NTDs in New Zealand are incomplete, but the rates are likely to be comparable with Australia.

### **What food will folic acid be added to?**

Bread making flour has been recommended as it is a common food that is consumed by most women of childbearing age. Overseas projects, where folic acid has been added to flour, have proven successful in reducing the rate of NTDs. The proposed FSANZ standard balances the need for pregnant women to get sufficient folic acid, while ensuring that some segments of the population, such as small children, do not get too much.

Bread is consumed by over 80% of the target population and surveys conducted in the 1980s and 1990s have shown that this level of consumption has remained stable. Bread products containing bread-making flour that will also be fortified include muffins, buns, crumpets etc.

After modelling for higher and lower concentrations of folic acid in bread-making flour, the preferred concentration is a residual 200 micrograms folic acid per 100 grams of flour in bread and bread products.

### **What about women who do not consume bread?**

FSANZ has recognised that some women may not consume bread, for example they may be gluten intolerant or for cultural or other reasons bread is not a major component of their diet. In this case it will be important for these women to consume folic acid from other sources such as voluntary fortified foods and/or supplements.

### **What about people who may object to mandatory fortification of food?**

Folic acid is a naturally occurring B group vitamin that is essential part of the diet. Based on current scientific evidence and overseas experience, the levels of folic acid fortification recommended by FSANZ don't pose a risk to public health and safety. The added folic acid will be listed in the ingredient list on the product. FSANZ is interested in any views that some people may want to avoid fortified products and, if so, suggestions on allowing for some consumer choice.

### **What will be the expected reduction in NTDs?**

Consuming enough folic acid substantially reduces the risk of NTDs but it won't prevent all cases.

**Australia:** Mandatory fortification of bread-making flour is expected to **increase** the folic acid intake of Australian women of child-bearing age by an average of **100 micrograms a day**. This is estimated to decrease the number of NTDs by 14-49 unborn children. About 300-350 pregnancies in Australia are affected with a NTD each year, with the majority of these (about 70%) terminated.

**New Zealand:** Mandatory fortification of bread-making flour is expected to **increase** the folic acid intake of New Zealand women of child-bearing age by an average of **130 micrograms a day**. This is estimated to decrease the number of NTDs by 4-14 unborn children. In New Zealand, about 70-80 pregnancies are affected with a NTD each year, with the proportion of these terminated similar to Australia.

### **Are there other benefits from increasing the population's intake of folic acid?**

The potential positive effect of increased folic acid on several other diseases and conditions (such cardiovascular disease, cancer and cognitive function) has been investigated. However, the additional adult intake of folic acid from mandatory fortification (averaging 100-130 micrograms a day) is unlikely to produce any other discernible health benefits.

### **Are there any potential adverse effects from taking folic acid?**

High doses of folic acid are not known to have any adverse effects on healthy individuals. The US and Canada have had mandatory fortification of flour with folic acid since 1998 and have found this to be a successful and effective means of reducing the rate of NTDs.

### **Will voluntary fortification continue if mandatory fortification is implemented?**

FSANZ is not proposing to amend the permissions for voluntary addition of folic acid to the current range of foods except that voluntary fortification of breads with folic acid will be replaced with the new mandatory standard. We will, however, closely monitor changes in the number of foods voluntarily fortified as part of the broader monitoring and review of mandatory fortification to assess changes in potential effectiveness or health risk.

### **What does industry have to do to implement this proposal?**

Mandatory fortification of bread-making flour with thiamin already occurs in Australia. Extending this fortification to folic acid should be possible for flour millers. It is technologically feasible to add folic acid to bread-making flour at the preferred concentration. Food labels, however, would need to be changed to reflect the addition of folic acid.

Addition of thiamin to flour in New Zealand is not mandated. As a result, affected industries have been consulted and FSANZ will continue to actively work with these industries in finalising this Proposal.

## Having your say

We welcome your views on the issues and approaches outlined in this guide to the development of a food standard for mandatory folic acid fortification of the food supply. You can find other documents relating to this standard on our website at [www.foodstandards.gov.au](http://www.foodstandards.gov.au), including:

- Draft Assessment Report for Consideration of Mandatory Fortification with Folic Acid (Proposal P295). This report contains a summary of submitters' comments from the first round of consultation.
- Ministerial Policy Guideline Fortification of Food with Vitamins and Minerals.
- Information for individuals and organisations intending to make a submission.

We must receive your submission by **6pm Monday 31 July 2006**.

### Anticipated Timeline for the Mandatory Folic Acid Fortification Standard

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|--|---------------|
| Draft Assessment Report completed              | July 2006     |
| Final Assessment Report completed              | August 2006   |
| Consideration by the Ministerial Council       | October 2006  |
| Fortification Standard gazetted                | November 2006 |
| Transition arrangements for industry finalised | November 2007 |