# EXPLANATORY STATEMENT

# PROPOSAL P300

# FOLATE/NEURAL TUBE DEFECT HEALTH CLAIM – EXTENSION OF TIMEFRAME 3

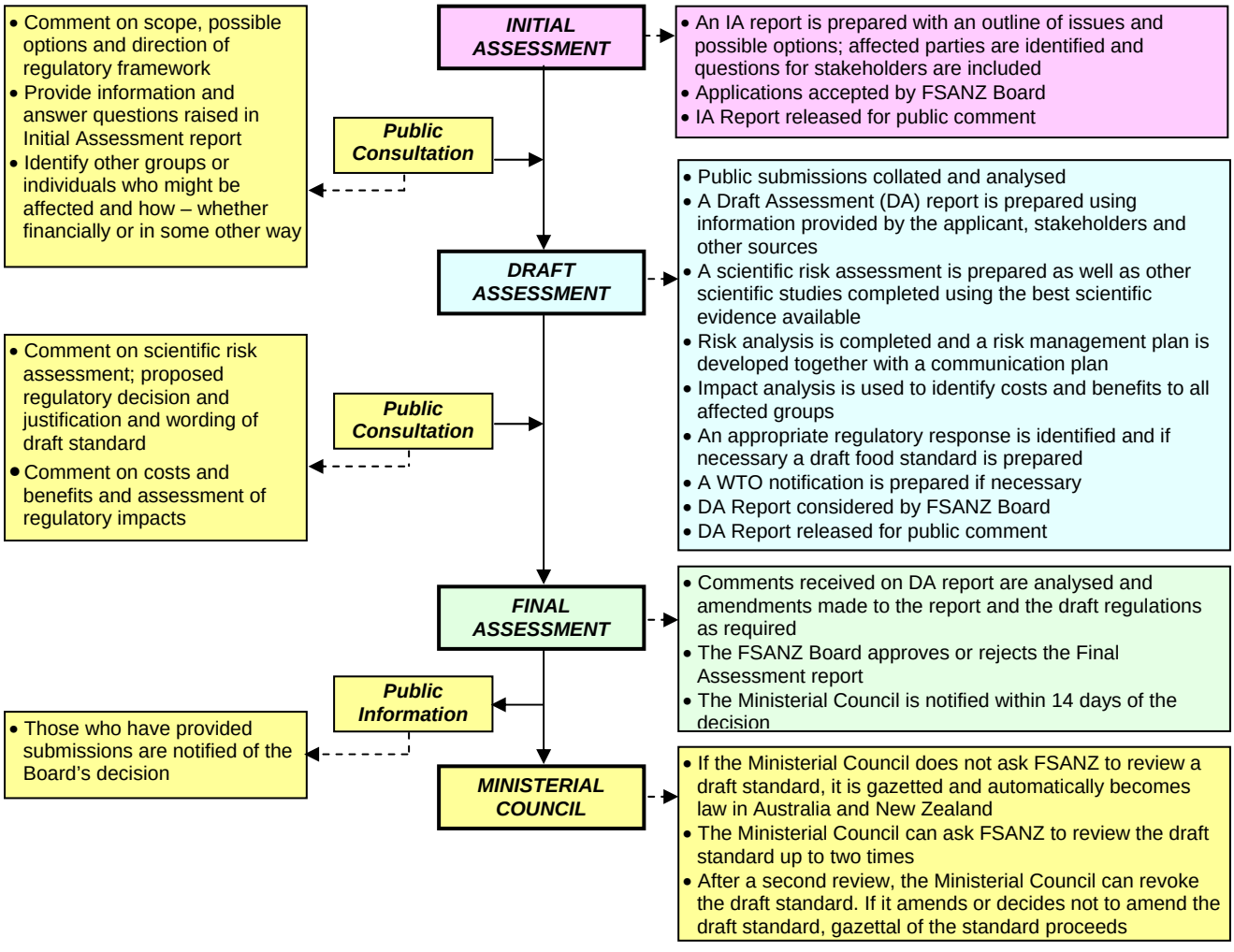
## FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Australian Government; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Australian Government, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Australian Government, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



**Final Assessment Stage (s.36)**

FSANZ has now completed the assessment of the Proposal and held a single round of public consultation under section 36 of the FSANZ Act. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Ministerial Council.

If the Ministerial Council does not request FSANZ to review the draft amendments to the Code, an amendment to the Code is published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under Australian State and Territory food law.

In New Zealand, the New Zealand Minister of Health gazettes the food standard under the New Zealand Food Act. Following gazettal, the standard takes effect 28 days later.

**Further Information**

Further information on this Proposal and the assessment process should be addressed to the FSANZ Standards Management Officer at one of the following addresses:


**Food Standards Australia New Zealand**
**PO Box 7186**
**Canberra BC ACT 2610**
**AUSTRALIA**
**Tel (02) 6271 2222**
**www.foodstandards.gov.au**

**Food Standards Australia New Zealand**
**PO Box 10559**
**The Terrace WELLINGTON 6036**
**NEW ZEALAND**
**Tel (04) 473 9942**
**www.foodstandards.govt.nz**


Assessment reports are available for viewing and downloading from the FSANZ website www.foodstandards.gov.au or alternatively paper copies of reports can be requested from FSANZ's Information Officer at info@foodstandards.gov.au including other general inquiries and requests for information.

# CONTENTS

## Executive Summary and Statement of Reasons

### Regulatory Problem

The temporary provision allowing a folate/neural tube defect (NTD) health claim on approved products is due to expire on 13 February 2006. In December 2003, the Australia and New Zealand Food Regulation Ministerial Council (the Ministerial Council) agreed to a Policy Guideline on Nutrition, Health and Related Claims (the Policy Guideline). Proposal P293 is the vehicle by which FSANZ will develop a standard and an appropriate management system for the regulation of nutrition, health and related claims. The Draft Assessment Report for Proposal P293 was released for public consultation in late November 2005. It is anticipated that a new Standard will be in place by the end of 2006.

### Objective

The objective of this Proposal is to minimise avoidable disruption to current practice until such time as Proposal P293 is finalised.

### Options

*Option 1*. Do nothing, with the effect that the folate/NTD claim would no longer be permitted to be made after 13 February 2006.

*Option 2*. Amend Standard 1.1A.2, so that the folate/NTD claim is permitted to be made and will cease to have effect two years from the commencement of Standard 1.2.7, that is, the new health claims standard. The omission of clause (1C) negates the requirement to continue to extend the folate/NTD health claim.

### Consultation

FSANZ is satisfied that this matter raises issues of minor significance or complexity only and, pursuant to section 36 of the FSANZ Act, conducted one round of public consultation on this Proposal, from 28 November to 5 December 2005. A total of five submissions were received. All submissions supported the Proposal to extend the permission allowing the folate health claim (Option 2).

### Conclusion and Statement of Reasons

The preferred approach is to continue the permission to make the folate/NTD health claim under certain conditions until two years from the commencement of Standard 1.2.7 (Option 2). This approach is preferred in order to:

- avoid consumer confusion;
- minimise disruption to products on the marketplace currently approved to carry the folate/NTD health claim; and
- avoid the cost to governments of avoidable enforcement measures and public education.

# 1. Introduction

## 1.1 Nature of Proposal

FSANZ has prepared a Proposal to extend the current permission to allow folate/NTD health claims to be made on products listed in the Code.

FSANZ is satisfied that this Proposal raises issues of minor significance or complexity only. FSANZ therefore decided to combine the Initial Assessment and Draft Assessment and have one round of public consultation only, as provided for by section 36 of the FSANZ Act.

# 2. Regulatory Problem

## 2.1 Current Standard

The temporary provision in Standard 1.1A.2, subclauses 3 (e), (f), (g), (h) and (i) of the Code, allowing a folate/NTD health claim on listed food products, will, due to subclause 1C, cease to have effect on 13 February 2006. This temporary provision was originally expected to be in place until such time as the review of nutrition, health and related claims under Proposal P293 was finalised and the subsequent commencement of a new health claims standard.

The Draft Assessment Report for Proposal P293 was released for public consultation in late November 2005 and is not expected to be finalised until late 2006. If permission to make the folate/NTD health claim expires in the interim, food manufacturers using the voluntary temporary provision will no longer be legally permitted to make such claims, resulting in disruption to industry and potential consumer confusion.

# 3. Objective

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and

- any written policy guidelines formulated by the Ministerial Council.

The specific objectives for this Proposal are to minimise:

1. avoidable disruption to industry;

2. avoidable cost to Governments; and

3. potential consumer confusion that might result if permission to make the folate/NTD health claim was removed in the absence of a final outcome of the review of nutrition, health and related claims under Proposal P293.

# 4. Background

## 4.1 Historical Background

As a result of a Ministerial Direction in 1998, the (then) Australia New Zealand Food Authority (ANZFA) developed a Proposal (Proposal P170) to consider a folate/NTD health claim pilot as a matter of urgency and to truncate its usual assessment processes. The main aim of the pilot was to inform the review of health claims being conducted under Proposal P153 at that time. Following recommendations to the (then) Australia New Zealand Food Standards Council (ANZFSC), the variation to the Code to facilitate the pilot was gazetted. The variation permits voluntary use of the folate/NTD health claim on listed food items as a temporary exemption to the general prohibition on health claims.

The original timeframe for the pilot was from November 1998 – November 1999, with the majority of pilot education and monitoring activities undertaken from November 1998 – May 1999. When ANZFA was unable to complete Proposal P153 by the end of 1999 as originally anticipated, ANZFSC agreed in late 1999 to extend the temporary permission for the folate/NTD claim until February 2001. The complexity of Proposal P153 caused further delays, and in July 2000, ANZFSC agreed to again extend the expiry date for the folate/NTD health claim, this time by 18 months to August 2002. It was anticipated that Proposal P153 would be completed, and a decision made by Ministers within that time.

ANZFA finalised its advice on Proposal P153 to ANZFSC in June 2001. ANZFSC met on 31 July 2001 to consider the issue. ANZFSC decided to refer the matter of health claims to FRSC to coordinate the development of policy advice, which was also to take account of the review of nutrient content and related claims being undertaken by ANZFA at that time.

In December 2003, the Ministerial Council agreed to a Policy Guideline on Nutrition, Health and Related Claims (the Policy Guideline). The Policy Guideline provides the policy principles to underpin the regulation of nutrition, health and related claims including the elements of a regulatory system.

Proposal P293 is the vehicle by which FSANZ will develop a standard and an appropriate management system for the regulation of nutrition, health and related claims. The Draft Assessment Report for Proposal P293 was released for public consultation in late November 2005. It is anticipated that the new Standard will be in place by the end of 2006.

The temporary provision allowing the folate/NTD health claim was extended by the Ministerial Council in May 2002 and again in October 2003, pending finalisation of the new health claims standard. The current temporary provision expires on 13 February 2006.

## 5. Relevant Issues

FSANZ conducted one round of public consultation on this Proposal, from 28 November to 5 December 2005. A total of five submissions were received. All submissions supported the Proposal to extend the permission allowing the folate/NTD health claim for a period of two years from the commencement of Standard 1.2.7.

## 6. Regulatory Options

There are two options for this Proposal:

*Option 1*. To maintain the *status quo*, thus permission to make the folate/NTD health claim would cease on 13 February 2006.

*Option 2*. Amend Standard 1.1A.2, to omit clause (1C) and amend clause (1B) so that the Standard ceases to have effect two years from the commencement of Standard 1.2.7, that is, the new health claims standard. The omission of clause (1C) negates the requirement to continue to extend the folate/NTD health claim.

## 7. Impact Analysis

### 7.1 Affected Parties

Those parties with potential to be affected by this Proposal include:

- those sectors of the food industry with products listed in the table to subclause 3(e) of Standard 1.1A.2 of the Code, making or preparing to make folate/NTD health claims at this time;
- those sectors of the food industry intending to make folate/NTD health claims who are not yet listed in the table to subclause 3(e) of Standard 1.1A.2 of the Code;
- consumers accustomed to a range of products carrying folate/NTD health claims; and
- government agencies charged with the responsibility of enforcing the Code and educating consumers about food regulatory provisions.

### 7.2 Data Collection

FSANZ is not aware of any information available to determine the impact of this Proposal and no information has been provided by submitters to previous Proposals to extend the temporary folate/NTD health claims provision.

The temporary provision allowing folate/NTD health claims is also voluntary, and there is no mechanism in place to know which of the foods listed in the table to subclause 3(e) of Standard 1.1A.2 of the Code are making folate/NTD health claims at any point in time. It is therefore not possible to obtain an exact cost of the impact of this Proposal.

## 7.3 Impact Analysis

Precise quantification of the impact of this Proposal is not possible.

### *7.3.1 Option 1 – maintain status quo*

#### 7.3.1.1 Advantages

None identified.

#### 7.3.1.2 Disadvantages

- Food industry currently utilising the provision would be forced to revise their product labels and marketing arrangements. If the folate/NTD health claim was later reinstated, another set of changes would need to be made to labels.

- If the folate/NTD health claim was removed without explanation from products that have been carrying the claim, consumers familiar with the labelling and marketing of those products may become confused.

- Governments would need to educate consumers about the outcome, reinforcing the message that public health advice about increasing folate intakes to reduce the risk of having a child with a neural tube defect is unchanged. Governments would have to inform consumers that the change was an amended regulatory measure, not a change to the widely accepted public health advice.

- Government enforcement agencies would need to monitor removal of prohibited folate/NTD health claims from food products after 13 February 2006, taking action where necessary.

### *7.3.2 Option 2 – removal of expiry date.*

#### 7.3.2.1 Advantages

- Disruption to industry will be avoided;

- Consumer confusion, due to removal of the folate/NTD health claim from product labels, will be avoided.

- If the final outcome of the review of health, nutrition and related claims results in removal of permission to make folate/NTD health claims, industry currently making the claims will only need to change their labels and marketing practices once.

- There will be no increased burden on enforcement agencies in regard to folate/NTD health claims. To this point in time, there have been no problems reported regarding compliance with the temporary provisions for the folate/NTD health claim.

- There will be no requirement to continue to extend the folate/NTD health claim provision until the new health claims standard is implemented.

7.3.2.2 Disadvantages

None identified.

# 8. Consultation

FSANZ is satisfied that this matter raises issues of minor significance or complexity only. Pursuant to section 36 of the FSANZ Act, FSANZ conducted one round of public consultation on this Proposal following Draft Assessment, from 28 November to 5 December 2005. A total of 5 submissions were received. All submissions supported the Proposal to extend the permission allowing the folate health claim (Option 2).

## 8.1 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

This Proposal is aimed only at extending the period allowed for the folate/NTD health claim pilot. It continues the existing voluntary permissions in the Code and will not give rise to a new regulatory measure. Therefore FSANZ did not notify the WTO under either the Technical Barriers to Trade (TBT) or the Sanitary and Phytosanitary Measures (SPS) Agreements.

# 9. Conclusion and Recommendation

The preferred option is **Option 2.**

In order to avoid consumer confusion, minimise disruption to products on the marketplace currently approved to carry the folate/NTD health claim, and avoid the cost to governments of avoidable enforcement measures and public education, permission to make the folate/NTD health claim under certain conditions should continue until two years from the commencement of Standard 1.2.7. Therefore, the following action is recommended:

Amend Standard 1.1A.2 to omit clause (1C) and amend clause (1B) to state ‘this Standard ceases to have effect two years from the commencement of Standard 1.2.7’. In this way, the existing provisions for making folate/NTD health claims in subclauses (3)(e), (f), (g), (h) and (i) are not linked to an expiry date and therefore will not need to be extended pending completion of Proposal P293.

## ATTACHMENTS

1. Draft variation to Standard 1.1A.2 of the *Australia New Zealand Food Standards Code.*
2. Summary of submissions.

**Attachment 1**

## *Draft Variation to the Australia New Zealand Food Standards Code*

To commence: on gazettal

**[1]** ***Standard 1.1A.2*** *of the Australia New Zealand Food Standards Code is varied by omitting clauses (1B) and (1C), substituting –*

(1B) This Standard ceases to have effect two years from the commencement of Standard 1.2.7.

(1C) Deleted.

## Attachment 2

## Summary of Submissions

| | |
|---|---|
| Department of Human Services Victoria | • Supports Option 2, thereby achieving consistency with the stock in trade provisions of draft Standard 1.2.7. |
| Food Technology Association of Victoria | • Supports Option 2. |
| New Zealand Food Safety Authority | • Supports Option 2. |
| Queensland Health – Environmental Health Unit | • Supports Option 2.<br>• Believes this approach will avoid consumer confusion, minimise disruption to products in the marketplace currently approved to carry the folate/neural tube defect health claim, and avoid the burden which would be placed on government to initiate costly measures and public education. |
| SA Department of Health | • Supports Option 2. |