

9-05

24 November 2005

## **INITIAL/DRAFT ASSESSMENT REPORT**

### **PROPOSAL P300**

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

**DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 5 December 2005**

**SUBMISSIONS RECEIVED AFTER THIS DEADLINE  
WILL NOT BE CONSIDERED**

*(See 'Invitation for Public Submissions' for details)*

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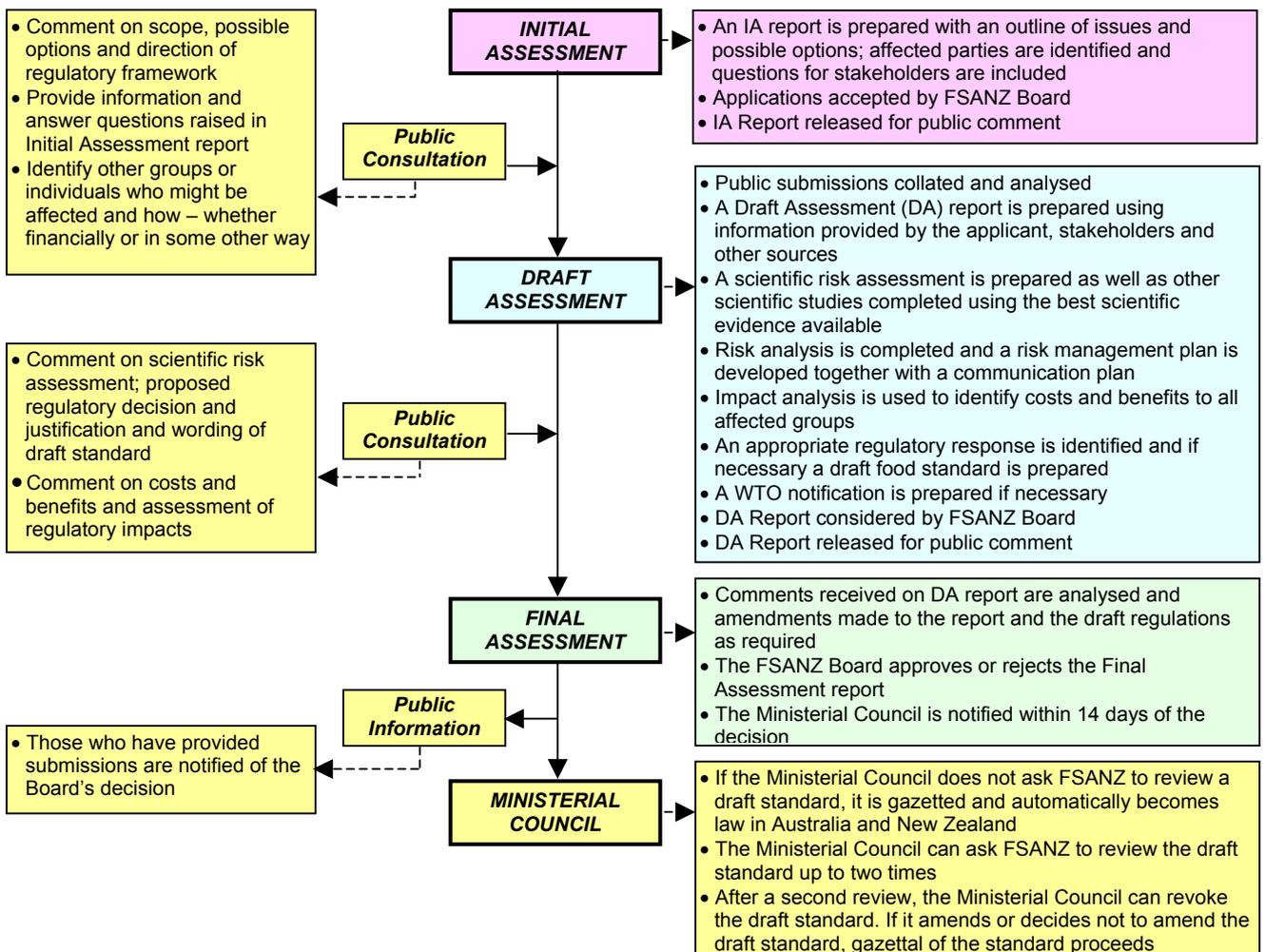
## FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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.



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### INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial / Draft Assessment Report of Proposal P300 and prepared a draft variation to the *Australia New Zealand Food Standards Code* (the Code).

FSANZ invites public comment on this Initial / Draft Assessment Report based on regulation impact principles and the draft variation to the Code for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Final Assessment for this Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to 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](http://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](http://www.foodstandards.govt.nz)**

**Submissions need to be received by FSANZ by 6pm (Canberra time) 5 December 2005.**

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

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While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing [slo@foodstandards.gov.au](mailto:slo@foodstandards.gov.au).

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing [info@foodstandards.gov.au](mailto:info@foodstandards.gov.au).

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## **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 will be released for public consultation at the end of 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 has therefore decided to combine the Initial Assessment and Draft Assessment and only have one round of public consultation.

### **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.

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### **1. Introduction**

#### **1.1 Nature of Proposal**

FSANZ is preparing a Proposal to extend the current permission to allow folate / NTD claims to continue 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.

Proposal P293 is currently at Draft Assessment 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

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- 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 and 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 Steering Committee (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 will be released for public consultation at the end of November 2005. It is anticipated that the new standard will be in place by the end of 2006.

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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

The most recent extension to the folate/NTD health claim was considered under Proposal P275. While the majority of submitters supported an extension, two submitters raised concerns in relation to permitting the folate health claim in the absence of policy guidance, and that an extension would further delay the introduction of a health claims standard. One submitter presented an additional option, that is, to provide permission to use the folate health claim on a permanent basis without specifying an end date.

Given the progress made to date regarding the implementation of a new health claims standard, FSANZ does not envisage that any major issues are likely to be raised through additional public consultation in relation to this Proposal. Additionally, as FSANZ is proposing to remove the expiry date, there will no longer be a requirement to continue to extend the folate claim, should the implementation of P293 be delayed.

### 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 compliance with the Code and educating consumers about food regulatory provisions.

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### 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.

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

##### 7.2.1.1 Advantages

None identified.

##### 7.2.1.2 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.

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

##### 7.2.2.1 Advantages

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

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- 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.
- No requirement to continue to extend the folate/NTD health claim provision until the new health claims standard is implemented.

### 7.2.2.2 Disadvantages

None identified.

## 8. Consultation

There will be one round of public consultation for this Proposal. All major FSANZ stakeholders, including submitters to Proposal 293, will be advised through normal advice procedures.

FSANZ made its decision under section 36 to omit a round of public consultation because it was satisfied that the Proposal raised issues of minor significance or complexity only.

### 8.2 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. If approved it will simply continue the existing voluntary permissions in the Code and will not give rise to a new regulatory measure. FSANZ is therefore not notifying this matter to the WTO under either the Technical Barriers to Trade (TBT) or the Sanitary and Phytosanitary Measures (SPS) Agreements.

## 10. 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:

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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.

### **ATTACHMENT**

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

***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.