FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

5-05
3 August 2005

DRAFT ASSESSMENT REPORT

APPLICATION A500

FORTIFICATION OF CEREAL-BASED BEVERAGES

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 14 September 2005
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

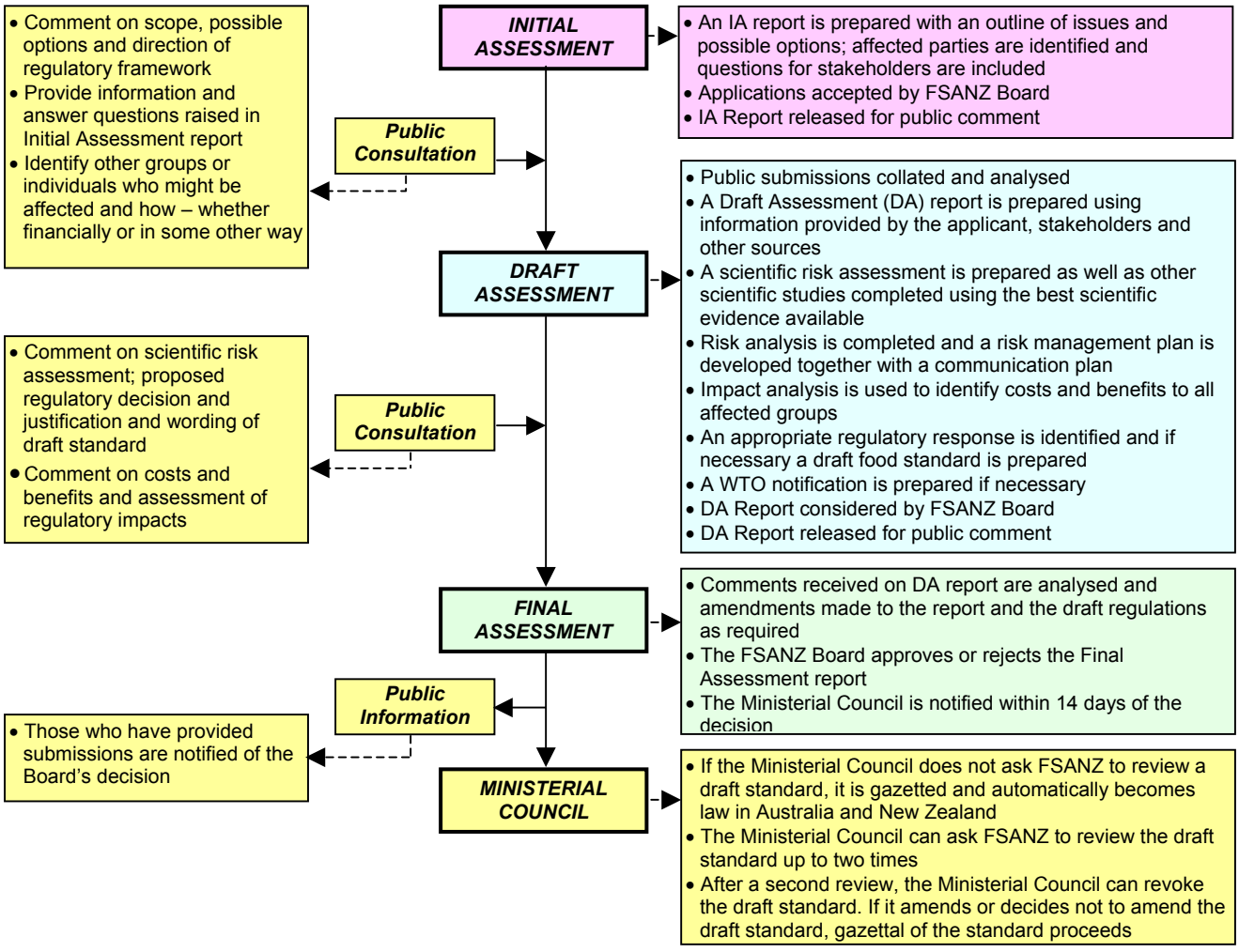
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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.



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared a Draft Assessment Report of Application A500; and prepared a draft variation to the *Australia New Zealand Food Standards Code* (the Code).

FSANZ invites public comment on this 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 Application. 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

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

Submissions need to be received by FSANZ by 6pm (Canberra time) 14 September 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.

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.

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.

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Executive Summary and Statement of Reasons

Food Standards Australia New Zealand (FSANZ) received an Application from SoNatural Foods Australia (the Applicant) on 2 May 2003 seeking to amend Standard 1.3.2 – Vitamins and Minerals of the *Australia New Zealand Food Standards Code* (the Code), to permit the addition of calcium to cereal-based beverages (e.g. rice and oat beverages) at a maximum claim level of 240 mg (30% Recommended Dietary Intake (RDI)) per 200 mL reference quantity.

This Draft Assessment Report discusses issues relating to the regulation of cereal-based beverages and proposes a preferred regulatory option. FSANZ seeks comment from stakeholders on this Draft Assessment, particularly in relation to the expected regulatory impact(s) of the proposed regulatory options, to assist in making a Final Assessment of this Application.

Regulatory Problem

The Applicant is seeking permission for the voluntary addition of calcium to cereal-based beverages. The Applicant states the purpose of their request is 'to provide a suitably nutritious milk alternative for consumers' who are allergic/intolerant to dairy and/or soy foods or those who choose not to consume dairy products for health or philosophical reasons.

Currently, the Code permits the voluntary addition of calcium, in addition to other vitamins and minerals, to certain foods such as breakfast cereals, most dairy products, and soy-based analogues of dairy products, such as soy beverages and soy yoghurts; however, there is no permission for the voluntary addition (i.e. fortification) of calcium to cereal-based beverages. However, calcium is currently added to cereal-based beverages as a food additive. Consequently, the Code does not permit the use of content claims to inform consumers of the presence of calcium in cereal-based beverages, which to some consumers, may be important information and affect their purchase decisions.

Fortified cereal-based beverages are permitted to be manufactured and/or sold in New Zealand. Although, no fortified cereal-based beverages are currently manufactured in New Zealand, fortified products are being imported into Australia via New Zealand by virtue of the Trans-Tasman Mutual Recognition Arrangement (TTMRA). Thus, an inequitable situation exists for Australian manufacturers/importers. Incorporating permissions for the addition of vitamins and minerals to cereal-based beverages in a joint standard, would provide further consistency and equity between Australian and New Zealand food standards.

Objectives

The specific objectives of Application A500 are to:

- protect the public health and safety of cereal-based beverage consumers; and
- ensure adequate information is provided to enable consumers to make informed choices.

Risk Assessment

FSANZ has undertaken two separate assessments that can inform an overall assessment of risk. These assessments are a Nutrition Assessment and a Dietary Intake Assessment; and are provided in full detail at Attachment 2. The methodology for the Dietary Intake Assessment is described in Attachment 3.

The Risk Assessment concludes that non-dairy consumers are at risk of inadequate intake of eight vitamins and minerals, which dairy milk makes a significant contribution to the diets of the general population. The evidence of risk associated with the low protein and fat intakes by non-dairy consumers was inconclusive, though it is considered that children who avoid dairy products and regularly consume cereal-based beverages have a small risk of inadequate protein intake, where protein is important for normal growth and development.

Risk Management

This Draft Assessment Report considers issues relevant to managing any identified risks associated with this Application, in particular:

- Ministerial policy guidance in relation to fortification and nutritional equivalence;
- permitting the addition of other selected vitamins and minerals to cereal-based beverages, that were not requested in the original Application;
- the low protein content of cereal-based beverages compared to dairy milk and beverages derived from legumes, such as soy beverages; and
- the inappropriate consumption of cereal-based beverages, particularly by children.

Regulatory Options and Impact Analysis

There are three regulatory options proposed for addressing this Application at Draft Assessment, these are:

Option 1 – Maintenance of the status quo; or

Option 2 – Amend Standard 1.3.2 to permit the voluntary addition of calcium to cereal-based beverages equal to the level permitted for beverages derived from legumes (which is based on cows' milk), in addition to the requirement for specific advisory labelling; or

Option 3 – Amend Standard 1.3.2 to permit the voluntary addition of selected vitamins and minerals including calcium to cereal-based beverages, being the same range and equal levels as permitted for beverages derived from legumes (which is based on cows' milk), in addition to the requirement for specific advisory labelling.

For each regulatory option, an impact analysis has been undertaken to assess the potential costs and benefits to the affected parties. This impact analysis is detailed in Section 8 of this report.

Consultation

The Initial Assessment report for this Application was released for public comment from 16 June 2004 to 28 July 2004. A total of thirteen submissions were received, nine in support of permitting the addition of calcium to cereal-based beverages, two opposed, and two which did not indicate support for either regulatory option (see Attachment 4). A number of submitters also indicated support for permitting the addition of other vitamins and minerals to cereal-based beverages. The issues raised in submissions are discussed in this report. FSANZ now seeks public comment on this Draft Assessment Report in order to proceed to Final Assessment.

Conclusion

Option 3 is the preferred regulatory option as it fulfils the specific objectives of this Application and when compared with Options 1 and 2 delivers greater net benefits to all affected parties. In the interest of protecting public health and safety, Option 3 provides consumers of cereal-based beverages with a more nutritionally equivalent substitute food for dairy milk and guidance on the appropriate use of these beverages through use of an advisory statement. In addition, this option may be advantageous for manufacturers, with respect to new markets and increasing market share.

Proposed Approach

It is recommended that:

- Standard 1.3.2 be amended to permit cereal-based beverages containing no less than 0.3% protein derived from cereals to be fortified with selected vitamins and minerals, being the same range and equal levels as those permitted for beverages derived from legumes (see table over page);

- Standard 1.2.3 be amended to require cereal-based beverages containing less than 3% protein (and no more than 2.5% fat) to carry an advisory statement to the effect that *the product is not suitable as a complete milk replacement for children under the age of twelve years*; and

- the existing advisory labelling requirement for low fat milks and beverages (no more than 2.5% fat), as per Standard 1.2.3, be extended to apply to all cereal-based beverages, including oat beverages, rather than rice beverages alone.

The proposed draft variations to the Code are at Attachment 1.

The table below outlines the proposed permissions for cereal-based beverages, and the corresponding maximum claims and maximum permitted quantity allowed per 200 mL reference quantity for each vitamin and mineral.

Table: Proposed vitamin and mineral permissions for cereal-based beverages per 200 mL reference quantity

Vitamins and Minerals	Maximum Claim per Reference Quantity (proportion RDI)	Maximum Permitted Quantity of Vitamin or Mineral per Reference Quantity
Vitamin A	110 µg (15%)	125 µg
Thiamin	no claim permitted	0.10 mg
Riboflavin	0.43 mg (25%)	
Vitamin B_6	no claim permitted	0.12 mg
Vitamin B_{12}	0.8 µg (40%)	
Vitamin D	1.0 µg (10%)	1.6 µg
Folate	no claim permitted	12 µg
Calcium	240 mg (30%)	
Magnesium	no claim permitted	22 mg
Phosphorus	200 mg (20%)	
Zinc	no claim permitted	0.8 mg
Iodine	15 µg (10%)	

Statement of Reasons

Therefore, FSANZ recommends the draft variations to the Code as detailed in Attachment 1 for the following reasons:

- the fortification of cereal-based beverages would assist in protecting the health and safety of cereal-based beverage consumers through:
  - allowing the manufacture of more nutritionally equivalent substitutes for dairy milk; and
  - use of an advisory statement to reduce the risk of inappropriate use of cereal-based beverages, particularly in the diets of children;
- is consistent with FSANZ statutory objectives including Ministerial policy guidance on voluntary fortification;
- the fortification of cereal-based beverages does not raise any safety concerns for consumers of these beverages or the general population;
- permission to fortify cereal-based beverages in a joint food standard provides uniform regulations for these beverages between Australia and New Zealand;
- a joint food standard provides regulatory certainty for industry and government enforcement agencies; and
- the regulation impact assessment concludes that the benefits from permitting the fortification of cereal-based beverages with selected vitamins and minerals outweigh any potential costs to affected parties.

1. Introduction

Food Standards Australia New Zealand (FSANZ) received an Application from SoNatural Foods Australia (the Applicant) on 2 May 2003 seeking to amend Standard 1.3.2 – Vitamins and Minerals of the *Australia New Zealand Food Standards Code* (the Code), to permit the addition of calcium to cereal-based beverages (e.g. rice and oat beverages) at a maximum claim level of 240 mg (30% Recommended Dietary Intake (RDI)) per 200 mL reference quantity.

This Draft Assessment Report discusses issues relating to the regulation of cereal-based beverages and proposes a preferred regulatory option. FSANZ seeks comment from stakeholders on this Draft Assessment, particularly in relation to the expected regulatory impact(s) of the proposed regulatory options, to assist in making a Final Assessment of this Application.

1.1 Nature of Application

1.1.1 Basis of the Application

The Applicant requested that a new food category be included under Standard 1.3.2 of the Code, to permit the addition of calcium to beverages derived from cereals. As cereal-based beverages are consumed as a substitute food for dairy milk[1] by a small subgroup of the population, the Applicant considers that enabling the addition of calcium to these beverages to an equivalent level as found in dairy milk would provide consumers with a more nutritionally similar alternative.

1.1.2 Amendments to the Original Application

During assessment of this Application, it has been proposed that the scope of the original Application be extended. Permission for the addition of calcium alone to cereal-based beverages was originally requested. This Draft Assessment considers a third regulatory option of permitting the addition of selected vitamins and minerals including calcium to cereal-based beverages, as permitted under Standard 1.3.2 for beverages derived from legumes. The concept of permitting other vitamins and minerals in addition to calcium was raised in the Initial Assessment Report. The Applicant supports this proposed third regulatory option.

As this third regulatory option is being considered at Draft Assessment, the name of the Application has been amended accordingly to more accurately reflect the nature of this Application. The original Application requested a minimum percent protein of 0.5%, whereby only those cereal-based beverages containing greater than 0.5% would be permitted to be fortified. Cereal-based beverages generally contain between 0.3-1.4% protein, noting that the Applicant's rice beverage contains 0.6% protein. Therefore, a minimum percent protein of 0.3% is more inclusive of other brands and varieties of cereal-based beverages currently available. Consequently, the Applicant has amended their original Application from 0.5% to 0.3% minimum protein.

[1] For the purpose of this report, the term 'dairy milk' refers to cows' milk and goats' milk. For comparative purposes, cows' milk alone has been commonly used, as it is the most predominantly consumed dairy milk.

1.1.3 Extension of Time

The statutory timeframe for consideration of an application is 12 months, however under the FSANZ Act, FSANZ may extend the timeframe if it is not practicable for the decision to occur within the designated time. In March 2005, the FSANZ Board agreed to extend the timeframe by six months, the maximum allowed under the FSANZ Act. This extension of time was considered necessary given the complexity of issues involved including, consideration of permissions for the addition of other vitamins and minerals to cereal-based beverages.

The current revised completion date for Application A500 is 9 December 2005.

2. Regulatory Problem

The Applicant is seeking permission for the voluntary addition of calcium to cereal-based beverages. The Applicant states the purpose of their request is 'to provide a suitably nutritious milk alternative for consumers' who are allergic/intolerant to dairy and/or soy foods or those who choose not to consume dairy products for health or philosophical reasons.

Currently, the Code permits the voluntary addition of calcium, in addition to other vitamins and minerals, to certain foods such as breakfast cereals, most dairy products, and soy-based analogues of dairy products, such as soy beverages and soy yoghurts; however, there is no permission for the voluntary addition (i.e. fortification) of calcium to cereal-based beverages. However, calcium is currently added to cereal-based beverages as a food additive. Consequently, the Code does not permit the use of content claims to inform consumers of the presence of calcium in cereal-based beverages, which to some consumers, may be important information and affect their purchase decisions.

Fortified cereal-based beverages are permitted to be manufactured and/or sold in New Zealand. Although, no fortified cereal-based beverages are currently manufactured in New Zealand, fortified products are being imported into Australia via New Zealand by virtue of the Trans-Tasman Mutual Recognition Arrangement (TTMRA). Thus, an inequitable situation exists for Australian manufacturers/importers. Incorporating permissions for the addition of vitamins and minerals to cereal-based beverages in a joint standard, would provide further consistency and equity between Australian and New Zealand food standards.

3. Objectives

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 following:

- 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 the assessment of this Application are to:

- protect the public health and safety of cereal-based beverage consumers; and
- ensure adequate information is provided to enable consumers to make informed choices.

4. Background

4.1 Current Regulation

4.1.1 Relevant Standards

The Standards in the Code of most relevance to consideration of Application A500 are:

- Standard 1.3.2 – Vitamins and Minerals - regulates the addition of vitamins and minerals to foods generally, as well as the claims that can be made about the vitamin and mineral content of foods. On the basis of nutritional equivalence, Standard 1.3.2 currently permits the voluntary addition of calcium and other vitamins and minerals to legume-based analogues of dairy products, such as soy beverages and soy yoghurts. Table 1 illustrates the current vitamin and mineral permissions for beverages derived from legumes, as permitted in Standard 1.3.2.

Table 1: Vitamin and mineral permissions per 200 mL reference quantity for beverages containing no less than 3% m/m[2] protein derived from legumes

Permitted Vitamins & Minerals	Maximum Claim per 200 mL (proportion RDI)	Maximum Permitted Quantity of Vitamin or Mineral per 200 mL
Vitamin A	110 µg (15%)	125 µg
Thiamin	no claim permitted	0.10 mg
Riboflavin	0.43 mg (25%)	
Vitamin B_6	no claim permitted	0.12 mg
Vitamin B_{12}	0.8 µg (40%)	
Vitamin D	1.0 µg (10%)	1.6 µg
Folate	no claim permitted	12 µg
Calcium	240 mg (30%)	
Magnesium	no claim permitted	22 mg
Phosphorus	200 mg (20%)	
Zinc	no claim permitted	0.8 mg
Iodine	15 µg (10%)	

- Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions - contains the Schedule of permitted forms of vitamins and minerals, which if permitted elsewhere in the Code may be added to certain foods.

- Standard 1.1A.6 – Transitional Standard for Special Purposes Foods (New Zealand only) - permits fortified cereal-based beverages to be manufactured and/or sold in New Zealand. This Standard incorporates the provisions of Regulations 237 and 239A of the former New Zealand *Food Regulations 1984* and permits the formulation of special purpose foods including amino acid modified foods. Foods manufactured to this Standard must include labelling that states the special purpose of the food. Imported fortified cereal-based beverages are currently labelled as special purpose foods. Standard 1.1A.6 is expected to be repealed upon the development of a standard regulating foods for special medical purposes and following clarification of the regulatory requirements for the addition of substances other than vitamins and minerals to foods, which is currently the subject of Ministerial policy development[3].

- Standard 1.3.1 – Food Additives - regulates the use of food additives in the production and processing of food. This standard permits some food additives to be added to cereal-based beverages for technological purposes. These food additives include calcium carbonate and calcium phosphate, which have been added to cereal-based beverages for the reported technological functions of acidity regulators and emulsifiers.

- Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations - sets out mandatory warning and advisory statements and declarations, which must be made in relation to certain foods or foods containing certain substances. Currently, milk evaporated milks, dried milks and equivalent products made from soy or rice that contain no more than 2.5% m/m fat, must carry an advisory statement to the effect that *the product is not suitable as a complete milk food for children under the age of two years*.

[2] m/m = mass per mass as per Standard 1.1.1
[3] Available at: www.health.gov.au/internet/wcms/publishing.nsf/Content/foodsecretariat-consult.htm

- Standard 1.2.8 – Nutrition Information Requirements - sets out the labelling requirements for the provision of nutrition information including nutrition claims.

4.1.2 Trans-Tasman Mutual Recognition Arrangement

The *Trans-Tasman Mutual Recognition Act 1997* gives effect to the TTMRA between Australia and New Zealand. The TTMRA came into effect on 1 May 1998 to promote closer economic relations and trade between Australia and New Zealand. Under the TTMRA, a range of products, including food, which can be produced in or imported, and be legally sold in one country, may be lawfully imported into and sold in the other country, without the necessity of compliance with further requirements imposed by or under the law of the jurisdiction.

As fortified cereal-based beverages are permitted to be manufactured and/or sold in New Zealand under Standard 1.1A.6, the current market includes fortified cereal-based beverages imported (from outside New Zealand) into Australia via New Zealand that comply with this Standard. Therefore, although fortified cereal-based beverages cannot legally be manufactured in Australia, they are being imported via New Zealand by virtue of the TTMRA.

4.2 Ministerial Policy Guidance

The Ministerial Council approved a Policy Guideline on *Fortification of Foods with Vitamins and Minerals* (the Policy Guideline) in May 2004, after FSANZ had completed the Initial Assessment for Application A500.

The Policy Guideline provides guidance to FSANZ on development of permissions for the addition of vitamins and minerals to food. The Policy Guideline includes 'High Order' Policy Principles that are supplemented by separate 'Specific Order' Policy Principles and 'Additional Policy Guidance' for both mandatory and voluntary fortification.

The 'Specific Order' Policy Principles for voluntary fortification include certain conditions for which the voluntary addition of vitamins and minerals can be permitted. The condition considered most relevant to this Application is *to enable the nutritional profile of specific substitute foods to be aligned with the primary food (through nutritional equivalence)*. This is on the basis that cereal-based beverages are consumed as a substitute food for cows' milk.

In response to the Policy Guideline, FSANZ has developed the *Fortification Implementation Framework* (FIF), an internal working document that details FSANZ's revised decision making in light of the Policy Guideline. As documented in the FIF, the 'High Order' Policy Principles restate the objectives of the FSANZ Act and therefore take precedence over the 'Specific Order' Policy Principles.

4.3 International Regulations

4.3.1 Codex Alimentarius

There is no specific Codex Standard for cereal-based beverages, although general principles exist for the addition of essential nutrients to foods[4]. These principles include guidance on the addition of nutrients for purposes of nutritional equivalence.

4.3.2 Canada

Currently, there is no provision in the *Food and Drug Regulations* to permit the addition of vitamins or minerals to beverages made from plant bases such as soy, rice and almonds. An Interim Marketing Authorisation (IMA) was issued in November 1997 to allow the sale of fortified soy and other plant-based beverages as an alternative to milk[5]. In early 2005, Health Canada released a *Proposed Policy and Implementation for the Addition of Vitamins and Minerals to Foods*[6], which includes a proposed amendment to the *Food and Drug Regulations* for the fortification of plant-based beverages. It is intended that the proposed regulatory amendments will be published in early 2006 and will reflect those fortification levels outlined in the IMA.

The IMA considered the fortification of plant-based beverages to 'enable them to be used as nutritionally adequate alternatives for milk'. Canada considers their approach is consistent with Codex General Principles. In respect to the fat and protein content of these beverages, the IMA specifies that a plant-based beverage can be fortified with vitamins and minerals to specified amounts if they contain not less than 2.5 g of protein and contain not more than 3.3 g of fat per 100 mL. However, if a beverage does not meet the protein requirement but meets all other requirements, then the product label must carry the expression 'Not a source of protein' in close proximity to and in the same size type used for the common name.

4.3.3 United States of America

At present, the United States of America (USA) Food and Drug Administration has no regulations permitting the fortification of cereal-based beverages, although a *Fortification Policy* does exist[7]. The nutrients and amounts that can be added to foods are specified in this policy. The *Fortification Policy* states that 'a nutrient(s) may appropriately be added to a food that replaces traditional food in the diet to avoid nutritional inferiority'.

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[4] General Principles for the Addition of Essential Nutrients to Foods, CAC/GL 09-1987 (Amended 1989, 1991). Codex Alimentarius. 1994 Volume 4, pages 9-12.

[5] Interim Marketing Authorization for Amendments to Plant-based Beverages. Canada Gazette, Part 1, November 1997. Available at: www.hc-sc.gc.ca/food-aliment/ns-sc/ne-en/nq-qn/e_foritfication_final_doc_app_f.html

[6] Addition of Vitamins and Minerals to Foods 2005 – Health Canada's Proposed Policy and Implementation Plans. Available at: www.hc-sc.gc.ca/food-aliment/ns-sc/ne-en/nq-qn/e_foritfication_final_doc_1.html

[7] Code of Federal Regulations – Fortification Policy. 2004. Title 21, Chapter 1, Subchapter B, Part 104.20. Available at: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=104&showFR=1&subpartNode=21:2.0.1.1.4.2

4.3.4 European Countries

The European Commission (EC), including the United Kingdom, is considering a proposed regulation on the addition of vitamins and minerals and other substances to foods[8]. FSANZ is aware of further consideration by the EC on this Proposal, with the most recent amendment[9] stating that:

> *Vitamins and minerals can be added to food by manufacturers for a number of purposes including to restore their content where this has been reduced during the manufacturing, storage or handling procedures or to provide a similar nutritional value to foods for which they are intended as alternatives.*

4.4 Current Market

4.4.1 Target Group

Cereal-based beverages, such as those made from rice and oat, are predominantly used as a dairy milk substitute either by individuals who:

- are allergic/intolerant to dairy and/or soy foods; or
- choose not to consume dairy products, either for health or philosophical reasons.

No quantitative information is available on the age groups of cereal-based beverage users, however individuals of all ages are known to use these products. It is possible that a greater number of children compared to adults consume cereal-based beverages for allergy/intolerance reasons, as dairy milk allergy and/or soy allergy is most common in young children. The majority of young children with allergy/intolerance to dairy and/or soy foods are under medical and/or dietetic supervision, and as such will have access to a subsidised hypoallergenic formula which is suitable as a complete milk substitute.

For those individuals with allergies/intolerances to dairy and/or soy foods, cereal-based beverages can be used to replace dairy milk or soy beverage as a drink and as an ingredient in baking and cooking. For those individuals wishing to avoid dairy products for other reasons, such as vegans, cereal-based beverages extend the range of dairy substitute options available to them.

4.4.2 Composition of Cereal-Based Beverages

Rice beverages generally contain filtered water, 13-15% brown rice (whole or partially milled), unsaturated oil such as safflower, canola or sunflower oil, and sea salt. The composition of oat beverage is similar to rice, with whole oats substituted for brown rice.

The nutrient profiles of unfortified cereal-based beverages differ from cows' milk, as demonstrated below in Table 2. Cereal-based beverages are naturally lower in fat and protein, and higher in carbohydrate when compared to cows' milk. In addition, cereal-based beverages generally do not contain significant amounts of vitamins and minerals that are naturally present in cows' milk.

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[8] *Proposed European Parliament and Council Regulations on the Addition of Vitamins and Minerals and certain other Substances to Foods* available at: www.food.gov.uk/multimedia/pdfs/vitsminsconsult.pdf

[9] UK Food Safety Agency Stakeholder Notification (8 June 2005).

Table 2: Key nutrients in cows' milk, oat and rice beverages (per 100 mL)

Nutrition Content	Cows' (whole milk)[#]	Oat[^]	Rice[*]
Energy (kJ)	272	179	272
Protein (g)	3.3	1.4	0.6
Fat (g)			
- total	3.8	2	1.0
- saturated	2.5	0.35	0.1
- polyunsaturated	0.1	0.73	0.3
- monounsaturated	1	0.62	0.5
Cholesterol (mg)	13	0	0
Carbohydrate (g)			
- total	4.7	5.9	13.4
- sugars	4.7	0.4	4.2
Calcium (mg)	114	N/A	8
Magnesium (mg)	11	N/A	4
Phosphorus (mg)	93	N/A	14
Zinc (mg)	0.4	N/A	0.1
Vitamin A (µg)	48	N/A	0
Thiamin (mg)	0.05	N/A	0.031
Riboflavin (mg)	0.2	N/A	0.005
Folate (µg)	6	N/A	37
Vitamin B_6 (mg)	0.04	N/A	0.018
Vitamin B_{12} (µg)	0.35	N/A	0
Vitamin D (µg)	0.03	N/A	0.01
Iodine (µg)	13.3	N/A	0

Sources of composition data:
[#] 1995 Australian National Nutrition Survey
[^] Composition of Pure Harvest 'Organic Oat Milk'
[*] Macronutrient composition of So Natural Foods 'Original Rice Milk' and micronutrient composition of 'Rice Dream Original'.
N/A = Not available

Australian manufactured rice beverages also contain calcium phosphate or calcium carbonate as food additives at levels equivalent to that permitted in Standard 1.3.2 for beverages derived from legumes (i.e. 240 mg per 200 mL reference quantity). All three product labels include content claims such as 'calcium enriched', 'calcium equal to milk' and 'high in calcium', which appear to be inconsistent with current permissions in the Code.

One imported rice beverage product contains vitamin A, vitamin B_{12}, vitamin D and calcium. in levels currently permitted for beverages derived from legumes, except for vitamin D which is added to a level that exceeds the maximum permitted quantity.

4.4.3 Product Description and Availability

Cereal-based beverages are designed to resemble dairy milk in appearance and viscosity. These products are an off-white colour and have a similar viscosity to dairy milk. Cereal-based beverages are promoted as a dairy substitute, as implied by the use of the word 'milk' in the product name of some brands of cereal-based beverages, and their appearance.

Rice beverages are widely available from supermarkets in large urban centres, but are not as readily available in some smaller towns. Many health food stores sell cereal-based beverages, including both rice and oat varieties. The cost of cereal-based beverages is greater than for cows' milk. Rice and oat based beverages made in Australia cost between 1.4-2 times the price of cows' milk.

The cereal-based beverage products available in both Australia and New Zealand are predominantly the same, with four main manufacturers supplying the market. Three of these are Australian manufacturers, and one product line is imported from the USA via New Zealand. FSANZ is not aware of any cereal-based beverages currently being manufactured in New Zealand. One of the imported products is 'enriched' with vitamin A, vitamin B_{12} and vitamin D and calcium, and is sold in New Zealand as a 'special purpose food: suitable for people with dairy allergies'. The price of this 'enriched' product is considerably higher than cows' milk at approximately 2.3 times the price.

Until recently, one Australian manufacturer produced three varieties of cereal-based beverages, being rice, oat and multigrain, however no longer manufactures the multigrain variety.

4.4.4 Sales

Australian supermarket retail sales of cereal-based beverages totalled 3,800,000 litres for the year ending April 2005[10]. The Applicant estimates the size of the Australian and New Zealand cereal-based beverage market as 5,500,000 litres, which includes sales from health food stores and New Zealand supermarkets. This compares with approximately 1.085 billion litres of cows' milk and 47 million litres of soy beverage sold in Australia in 2004[11].

4.5 Cereal-Based Beverages as a Substitute Food for Cows' Milk

At Draft Assessment, the concepts of reference food, substitute food and nutritional equivalence have been further developed, drawing on issues discussed in the Initial Assessment Report and FSANZ's Fortification Implementation Framework (FIF). For the purpose of considering these concepts, cows' milk rather than dairy milk has been used, as cows' milk is the most predominantly consumed dairy milk.

The FIF, which moved away from the Codex definition of nutritional equivalence as used in the Initial Assessment Report, outlines the following four aspects to consider when assessing nutritional equivalence:

- the nutrients in the substitute food compared to the reference food;
- distinguishing core nutrients[12], from non-core nutrients based on consideration of matters such as whether the food is a significant source of nutrient in the diet and whether there is a risk of deficiency if substitution occurs;
- the intended purpose of the substitution; and

[10] Aztec Information Systems – year ending April 2005.
[11] Retail World Australasian Grocery Guide 2004. 14th edition. Sydney, New South Wales
[12] Core nutrients are nutrients that are naturally present at a level that contributes at least 5% of the RDI in a reference quantity of the food.

- the risk of inappropriate substitution of the fortified food for a natural source of the vitamin or mineral based on product similarity or perceived use.

Cows' milk is considered to be a significant source of energy in the Australian and New Zealand diets, contributing 6%[13] and 5%[14] of total energy respectively. In addition, cows' milk contains a number of core nutrients being protein, vitamin A, riboflavin, vitamin D, vitamin B_{12} and calcium. Considering these factors, FSANZ considers cows' milk qualifies as an appropriate reference food for cereal-based beverages. This is consistent with the previous decision to use cows' milk as the reference food in order to permit addition of vitamins and minerals to beverages derived from legumes, which was considered on the basis of nutritional equivalence.

The FIF, based on the definition in the Codex General Principles, defines a substitute food as *a food which is designed to resemble a common food in appearance and texture and is intended to be used as a complete or partial replacement for the food it resembles (i.e. reference food)*. Cereal-based beverages are designed to resemble dairy milk in appearance and viscosity, and are promoted and used as dairy milk substitutes. Thus, FSANZ considers that cereal-based beverages meet the FIF definition for a substitute food, on the basis of their physical properties and use by consumers.

However, cereal-based beverages are not nutritionally equivalent to cows' milk (the reference food) and other dairy milks. As discussed in Section 4.4.2, cereal-based beverages have lower protein, fat, and vitamin and mineral contents when compared to cows' milk. In addition, cows' milk is a source of many core nutrients that are not naturally present in the same levels in cereal-based beverages.

Therefore as indicated at Initial Assessment, FSANZ considers that while cereal-based beverages are not nutritionally equivalent to cows' milk (the reference food), they are considered a substitute food.

5. Risk Assessment

FSANZ has undertaken two separate assessments that can inform an overall assessment of risk. These assessments are a Nutrition Assessment and a Dietary Intake Assessment; and are provided in full detail at Attachment 2. The methodology for the Dietary Intake Assessment is described in Attachment 3. A summary of these assessments can be found below.

Information pertaining specifically to the users of cereal-based beverages is limited to sales data and anecdotal information. It is assumed that cereal-based beverages are predominantly used as a substitute for dairy milk by people who for whatever reason do not consume dairy milk or soy-based beverages. Dairy milk is an important contributor of dietary calcium, magnesium, phosphorus, zinc, vitamin A, riboflavin, vitamin B_{12}, and iodine. Compared to whole cows' milk, the composition of cereal-based beverages is low in protein, many vitamins and minerals and lower in fat.

[13] FSANZ (2004). DIAMOND Modelling – contribution based on plain, non-flavoured dairy milks and not including dairy desserts.
[14] Russell, DG., Parnell, WR., Wilson, NC., et al (1999). *NZ Food NZ People. Key Results in the 1997 National Nutrition Survey.* Ministry of Health: Wellington.

The potential risk identified for assessment was that of inadequate vitamin and mineral intakes by those consuming cereal-based beverages. To address this risk, a question raised at Initial Assessment was to permit fortification of cereal-based beverages with vitamins and minerals to the levels found in dairy milk. The low protein content of these products and their regular consumption by some children was of concern to several submitters to the Initial Assessment Report. The general dietary risks of low protein and lower fat intake of non-dairy consumers[15] were also investigated, particularly since consumers might perceive fortified cereal-based beverages as nutritionally equivalent to dairy milk and thus not take steps to ensure adequate protein intake.

5.1 Methods for Assessing Risk

To establish the risk associated with consumption of non-fortified cereal-based beverages, the nutrient intake of cereal-based beverage consumers was investigated. However, there was extremely limited consumption of cereal-based beverages in the Australian and New Zealand National Nutrition Surveys (NNS). Consequently, consumption of soy-based beverages – fortified and non-fortified, in conjunction with the limited consumption of cereal-based beverages, was used as a proxy for consumption of cereal-based beverages for dietary modelling purposes. Consumers of dairy products were also excluded from the models, which are described in Section 2.3 of Attachment 3.

Whole of population dietary intake data (Model 1) were used to assess the importance of dairy milk as a contributor of nutrients to the diet. Five nutrient intake models were devised to represent people who did not eat dairy products on the day of the surveys. Models 2 and 4 represented non-dairy consumers: Model 2 comprised all non-dairy consumers including those who might have consumed a soy-based beverage; Model 4 was only non-dairy consumers who consumed a soy beverage. Models 3 and 5 were based on Models 2 and 4 respectively but with the composition of soy-based beverage changed to that of an unfortified cereal-based beverage.

A literature review was also conducted. No studies were found specific to consumers of cereal-based beverages and very little data related to Australia and New Zealand. Five studies were found that investigated the nutrient intake of consumers who avoided dairy or had an allergy, four of which were by young children. Only one study assessed the adequacy of nutrient intakes compared to a nutrient reference value, whereas the other four compared intakes with controls, who were assumed to have adequate intakes. Three case studies in infants under two years were found. However, apart from these case studies, all of which led to hospitalisation, no information could be found on the nutrient intake of infants and toddlers aged less than 2 years who consume cereal-based beverages.

5.2 Nutritional Risks to Consumers of Cereal-Based Beverages

5.2.1 Vitamins and Minerals

The dietary intake estimates for non-dairy consumers including a small number of consumers of unfortified cereal-based beverages indicated a considerable proportion are likely to have inadequate intakes of some vitamins and minerals ordinarily supplied by dairy foods.

[15] Non-dairy consumers are those individuals who do not consume any dairy products, including those who may not consume soy-based beverages

The most likely vitamins and minerals to be generally compromised are calcium, magnesium, zinc, vitamin A, riboflavin, vitamin B_6 and iodine as assessed by one or more subpopulation age groups not meeting 50% of their respective Estimated Average Requirement (EAR). Older consumers appear to be more at risk with respect to vitamin and mineral intakes compared with the 2-4 year age group.

5.2.2 Protein and Fat

Adequate intakes of protein and fat are particularly important in the diets of young children for growth and development, and dairy milk is a very important source of protein. Cereal-based beverages, whether non-fortified or fortified, have low concentrations of protein and lower amounts of fat than whole cows' milk. Results of the estimated dietary intake assessment and literature review do not provide conclusive evidence of the risk of low protein and lower fat intakes by consumers of cereal-based beverages, although these data sources suggest a low prevalence of protein inadequacy among young non-dairy consumers that increases with age. In contrast, the consequences of inadequate protein intakes for growth and development of children are greater than for adults. Therefore, taking account of both the likelihood and consequence of inadequate protein intakes, it is considered that children who avoid dairy products and regularly consume cereal-based beverages have a small risk of inadequate protein intakes. Consumers' possible perception of fortified cereal-based beverages as nutritionally equivalent to dairy milk may increase this risk of inadequacy, as they may not appreciate the need to ensure adequate intakes from appropriate dietary sources.

5.3 Effect of Fortifying Cereal-Based Beverages

5.3.1 Efficacy

The scenario modelling data used in Model 6 suggests that, with the exception of folate, permission to fortify cereal-based products would address to some extent the risk of inadequate intake of a variety of vitamins and minerals for cereal-based beverage consumers who are dairy avoiders. Based on the limited composition data, the natural content of folate in cereal-based beverages appears to be already higher than that found in dairy milk, therefore, permission to add folate would be useful only for beverages with lower folate amounts than dairy milk.

Due to the large number of modifiers influencing bioavailability, especially those that may confound scientific research into this area, FSANZ cannot fully assess the bioavailability of vitamin and mineral additions to cereal-based beverages. From the limited literature available, as evaluated in Attachment 2, the addition of vitamins and minerals to cereal-based beverages is likely to be comparable to the bioavailability obtained from other food sources of these nutrients.

5.3.2 Safety

Fortification of cereal-based beverages to the levels of vitamins and minerals found naturally in cows' milk poses the same risk as milk itself. This is unlikely to cause excess consumption of these micronutrients for regular consumers of cereal-based beverages because they are likely to be non-dairy consumers and thus at risk of inadequate intakes of vitamins and minerals ordinarily provided by dairy products.

5.4 Conclusion

It is difficult to describe the consumers of cereal-based beverages but it is assumed that the majority will be people who cannot or choose not to consume dairy milk or soy beverages.

The results of the estimated dietary intake assessment and literature review do not provide conclusive evidence of the risk of low protein and lower fat intakes by consumers of cereal-based beverages, although these data sources suggest a low prevalence of protein inadequacy among young non-dairy consumers that increases with age. The management of this risk is worthy of consideration.

The results of the risk assessment suggest that non-dairy consumers are at risk of inadequate intake of a variety of vitamins and minerals for which dairy milk is an important source and that use of a fortified product may aid in mitigating the risk. Fortification of cereal-based beverages to the levels of vitamins and minerals found in cows' milk poses no greater risk than cows' milk itself and is therefore considered to be safe.

6. Risk Management

6.1 Nutritional Equivalence

Nutritional equivalence is the basis for which this Application is being considered. As discussed previously in Section 4.5, FSANZ considers cows' milk is an appropriate reference food for cereal-based beverages, and that cereal-based beverages meet the definition of a 'substitute food' for dairy milk on the basis of their physical properties and how they are used by consumers. However, while cereal-based beverages meet the definition of a substitute food for dairy milk, they do not meet the criteria for nutritional equivalence due to their lower protein, fat, and vitamin and mineral content when compared to cows' milk.

In comments to the Initial Assessment Report, submitters agreed that consumers use these beverages as substitutes for dairy milk and soy beverages and that cereal-based beverages are not nutritionally equivalent when compared to cows' milk due to their lower protein and micronutrient composition.

6.2 Composition

As discussed in the Nutrition Assessment, cows' milk is a significant source of many core nutrients, such as calcium and riboflavin, which are not naturally present in the same levels in cereal-based beverages. As a result, non-dairy consumers are at risk of inadequate intake of a variety of vitamins and minerals compared with dairy consumers. This provides the basis for considering the fortification of cereal-based beverages with vitamins and minerals.

6.2.1 Fortifying Cereal-Based Beverages with Vitamins and Minerals

The Nutrition Assessment Report (Attachment 2) has identified that non-dairy consumers are at risk of inadequate intakes of seven vitamins and minerals that are naturally present in dairy milk and other dairy products.

Ten of the thirteen submitters to the Initial Assessment Report supported the addition of other vitamins and minerals including calcium to cereal-based beverages. One public health submitter, in support of maintaining the status quo, commented that they would reconsider their position if cereal-based beverages were fortified with macro- and micronutrients to the nutritional equivalence of milk. Two submitters, who supported the addition of other vitamins and minerals, did so on the condition that the protein content is equivalent to that found in milk and legume-based beverages.

To assess the likely uptake by industry of permissions to fortify cereal-based beverages, the uptake of permissions for soy-based beverages was investigated by FSANZ in 2004[16]. Five brands of fortified soy beverages were evaluated. The results showed that between two and seven vitamins and minerals were added to each soy beverage product. Seven of the twelve permitted vitamins and minerals were utilised, where five of these nutrients are permitted to make content claims. It can be assumed that there would be a similar uptake of permissions for cereal-based beverages, if they were permitted to be fortified.

Ministerial policy guidance for fortification includes a 'Specific Order' Policy Principle for voluntary fortification requires the permitted fortification to have *the potential to address the deficit or deliver the benefit to a population group that consumes the fortified food according to its reasonable intended use*. The estimated dietary intake assessment suggests that the use of a fortified cereal-based beverage would have a positive impact on the intake of the selected vitamins and minerals, with the exception of folate, which is naturally present in cereal-based beverages at a comparable level to the proposed fortification permissions. While fortification of cereal-based beverages may not correct deficiency in beverage users, it would provide consumers with a more nutritious dairy milk substitute than a non-fortified product.

The risk of excess consumption through use of fortified cereal-based beverages is considered unlikely. The proposed vitamin and mineral permissions are based on amounts found naturally in cows' milk, where cows' milk consumption is not related to safety issues. Therefore, this approach is consistent with another 'Specific Order' Policy Principle for voluntary fortification which states that permission to fortify will not have *the potential to result in detrimental excesses or imbalances of vitamins and minerals in the context of total intake across the general population*.

The proposed addition of selected vitamins and minerals addresses submitter concerns that consumers may be misled as to the nutritional quality of cereal-based beverages if calcium alone were permitted to be added, especially as consumers may associate calcium with dairy milk. Similarly, this option minimises the impact if a calcium content claim was perceived by consumers to mean nutritional equivalence to dairy milk, as the product will have the potential to be as nutritionally equivalent to cows' milk as possible with the exception of protein.

Therefore, FSANZ is proposing to permit the addition of selected vitamins and minerals including calcium to cereal-based beverages, as currently permitted for beverages derived from legumes.

[16] Voluntary Fortification Issues – a student project (2004). Not published.

6.2.2 Permitted Forms

Standard 1.1.1 of the Code contains the Schedule of permitted forms of vitamins and minerals. If a permission exists in the Code for a food to be fortified with a vitamin or mineral, the added vitamin or mineral must be in a permitted form as outlined in Standard 1.1.1. It is not proposed that any additional forms of vitamins or minerals be considered as part of this Application.

6.2.3 Macronutrients

6.2.3.1 Fat

Results from the estimated dietary intake assessment and literature review suggest that there is not a risk of inadequate fat intake for cereal-based beverage consumers. Therefore, no additional risk management measures are required specific to the fat content of these beverages.

6.2.3.2 Protein

Cereal-based beverages are low in protein compared with cows' milk. Cows' milk contains approximately 3.3 g protein per 100 mL, compared with rice beverage that contains 0.3-0.6 g/100 mL and oat beverage that contains 1.4 g/100 mL.

The low protein content of cereal-based beverages was a primary concern of many submitters to the Initial Assessment Report. Submitters considered that cereal-based beverages cannot be considered nutritionally equivalent to dairy milk because of their low protein content. In comparison, the Applicant considers that the low protein content of cereal-based beverages is not a concern for adult consumers, as mean protein intakes are higher than physiological requirements.

The Nutrition Assessment suggests that children who avoid dairy foods and regularly consume cereal-based beverages have a small risk of inadequate protein intakes. No dietary intake data is available for children under the age of two years. However, two of the three case studies identified highlight the potential risk to infants as a consequence of the low protein content of cereal-based beverages. Both case studies involved the inappropriate use of cereal-based beverages for children under the age of two years, despite advisory statements on the product labels and in one instance against medical advice. One of these cases resulted in the death of a five-month old infant, after she was fed unfortified rice beverage as the sole source of nutrition.

6.2.4 Increasing the Protein Content of Cereal-Based Beverages

Due to the potential risk, albeit small, of protein inadequacy among cereal-based beverage consumers, FSANZ has considered the practicality of a requirement to increase the protein content of cereal-based beverages, to make them more nutritionally equivalent to dairy milk.

Sources of proteins that are added to cereal foods to boost protein content include wheat gluten, milk caseins, egg albumen and soy protein isolates. All of these protein sources are known allergens and therefore are not appropriate to be added to cereal-based beverages, which are thought to be predominantly consumed by people with dairy and/or soy allergies/intolerances.

Proteins derived from cereals such as maize or lupin flour could be considered, however a considerable amount of product development would be required to provide a soluble ingredient with an acceptable appearance in the final product.

Oats or rice could be fractionated to provide more of the same protein in the form of protein isolates. Due to the relatively low protein contents of oats and rice, the starting amount of cereal required would be at least tripled and markets for the by-products would need to be developed. For this reason it is expected that cereal protein isolates would be more expensive than soy isolates. Rice protein isolates are currently available in Australia and New Zealand, however they are in an insoluble form and are therefore difficult to incorporate into a beverage product. Soluble forms, which will be more expensive, have recently been developed and are expected to be available in Australia and New Zealand in the near future. Similar soluble oat protein products may become available in the future.

Therefore, while it is feasible to increase the protein content of cereal-based beverages, it is both technically difficult and economically onerous to do so. For this reason it is proposed that cereal-based beverages will not be required to have a protein content similar to that of dairy milk or soy beverage before being permitted to contain selected vitamins and minerals. Instead, FSANZ is proposing other risk management strategies, such as labelling, to manage the small risk of protein inadequacy among cereal-based beverage consumers.

While it is proposed that cereal-based beverages will only have to contain a minimum 0.3% protein content before being permitted to be fortified with selected vitamins and minerals, manufacturers could increase the protein content of their products on a voluntary basis.

6.3 Labelling

6.3.1 Advisory Statements

Advisory statements can be used to help mitigate risk. An advisory statement is required when the general public or a sub-population are exposed to a significant potential risk to health but the risk is not life threatening, or when guidance about the use of a food is needed to protect public health and safety. For advisory statements, the specific wording is not prescribed and manufacturers may use their own words provided they convey the intended meaning and the statement is prominent and legible.

In comparison, a warning statement is required if the risk to health is life threatening and it can be reasonably assumed that the general population or the specific target group is unaware of the potential risk to their health. Both warning and advisory statements are mandatory, and the text of a warning statement is prescribed.

Nine submitters to the Initial Assessment Report supported the use of an advisory statement alerting consumers that cereal-based beverages are low in protein. The Applicant does not support the use of a statement specific to protein, commenting that the average protein intake is sufficient in the Australian and New Zealand populations. Submitter views as to whether the advisory statement should include a recommendation that consumers seek medical advice on the use of these beverages was divided. Allergy New Zealand members commented that most people using these products are knowledgeable about their needs and are seeking/have already sought advice from a doctor or dietitian.

The case studies presented in the Nutrition Assessment Report (Section 3.3.2.2 of Attachment 2) suggest that cereal-based beverages fortified with vitamins and minerals may potentially mislead some consumers as to their nutritional quality. It is important that consumers do not perceive cereal-based beverages to be completely nutritionally equivalent and/or superior to dairy milk, as inappropriate use may have adverse effects on the nutritional status and health of the consumer.

Consequently to help mitigate this potential risk, FSANZ considers it appropriate that cereal-based beverages should be required to carry an advisory statement that provides guidance to consumers about their appropriate use in order to protect public health and safety.

6.3.1.1 Current Advisory Statement for Low Fat Milks and Beverages

Currently, as prescribed in Standard 1.2.3, milk and beverages made from soy or rice that contain less than 2.5% fat are required to carry an advisory statement to the effect that *the product is not suitable as a complete milk food for children under the age of two years*. The same advisory statement is required for evaporated and dried rice products that can be reconstituted to make a beverage.

The current advisory statement was an outcome of Proposal P240 – Labelling Statements on Reduced Fat and Condensed Milks, which was gazetted in 2002. The reason for this advisory statement, as provided in the Proposal P240 Final Assessment Report, is that limited fat intake from milk in infants may interfere with optimal energy intake and hence affect growth and development. This is consistent with both the Australian and New Zealand Dietary Guidelines, which do not recommend reduced fat milks for children under 2 years of age. The wording of this advisory statement was derived from a similar statement set out in the New Zealand *Food Regulations 1984*, and was extended to identify the most at risk age group.

As rice beverages have a fat content of approximately 1% they are required to carry this advisory statement. Oat beverages and other cereal-based beverages contain less than 2.5% fat too, but unlike rice beverages they are not required to carry this advisory statement. The reason for this is unclear, however it may have been an oversight that other cereal-based beverages were not considered in Proposal P240.

All rice beverages currently available in Australia and New Zealand provide an advisory statement on their product labels. As illustrated below in Table 3, a variety of advisory statements exist with respect to the text used. Interestingly, some manufacturers voluntarily provide additional information in their advisory statements that is beyond the intent of the prescribed advisory statement, for example, an increase in the prescribed age and reference to seeking medical advice. Although not currently required to carry an advisory statement, the identified oat beverage voluntarily carries an advisory statement. The advisory statements currently used are:

Table 3: Text used by manufacturers of cereal-based beverages to convey the prescribed advisory statement

Advisory Statement	Cereal-Based Beverage
Not suitable as a complete milk food for children under the age of two years	So Natural (rice) Rice Dream – original & 'enriched' (rice)
Not suitable as a complete milk food for children under 5 years of age	Vitasoy (rice)
Unsuitable for infants except on medical advice	Pure Harvest (rice) Pure Harvest (oat)*

* Oat beverage not currently required to carry an advisory statement under Standard 1.2.3.

6.3.1.2 Proposed Advisory Statement for Cereal-Based Beverages

FSANZ is proposing that all cereal-based beverages that contain no more than 2.5% fat and less than 3% protein, or less than 3% protein only, carry an advisory statement to the effect that *the product is not suitable as a complete milk replacement for children under the age of twelve years*.

The intent of the proposed advisory statement is to prevent the inappropriate use of cereal-based beverages, especially in the diets of children. The proposed advisory statement informs consumers that these products should not be considered as a 'complete milk replacement' in the diet. This implies that while it is acceptable for people to use cereal-based beverages, additional food sources are needed to compensate for the lower levels of some nutrients, particularly protein, that would otherwise have been provided through inclusion of dairy milk in the diet. This advisory statement also informs caregivers that cereal-based beverages should not replace breast milk and/or formula in the diets of infants.

The proposed advisory statement highlights a specific age group at risk of protein inadequacy, being children under the age of twelve years. In this instance, 'children' is defined as under the age of twelve years, consistent with both the Australian and New Zealand Dietary Guidelines. The specified age has been extended from two years, as used in the current advisory statement, to twelve years of age on the basis that all children require adequate protein for normal growth, and that children under the age of two years who have allergies are generally under medical supervision and therefore consume a hypoallergenic formula to meet their nutritional requirements.

The protein content of cereal-based beverages (i.e. less than 3% protein) will act as the trigger for the proposed advisory statement, as inadequate protein intake may result in compromised nutritional status for consumers, particularly children. The protein cut-off has been established at 3% as cows' milk contains greater than 3 g protein per 100 mL, and beverages derived from soy must contain no less that 3% protein before they are permitted to be fortified with selected vitamins and minerals.

In the instance where a cereal-based beverage contains greater than 3% protein but no more than 2.5% fat, the existing requirement for advisory labelling for reduced fat milks and beverages made from soy and rice will continue to apply.

However, it is also proposed that the current advisory statement be extended to apply to all cereal-based beverages, including oat beverage, rather than rice alone, as all cereal-based beverages are naturally low in fat and thus pose the same risk to children under the age of two years.

The proposed advisory statement would apply to both fortified and non-fortified cereal-based beverages, and all forms of cereal-based beverages including ready-to-drink, evaporated and dried products.

6.3.2 Nutrient Content Claims

If cereal-based beverages were permitted to be fortified with calcium and/or selected vitamins and minerals, claims to the effect that the product is a 'source' or 'good source' of the vitamin or mineral would, in most cases, be permitted. These claims can be made if the food provides at least 10% or 25% of the RDI per reference quantity respectively, as per Standard 1.3.2.

However, Standard 1.3.2 does restrict the use of content claims for some vitamins and minerals currently permitted to be added to beverages derived from legumes. Claims are not permitted for five vitamins and minerals namely thiamin, vitamin B_6, folate, magnesium and zinc, as although these nutrients are naturally present in cows' milk they are found in levels below 10% of the RDI. Therefore on the basis of nutritional equivalence it is appropriate that manufacturers when adding these nutrients to beverages derived from legumes not be permitted to make content claims.

As FSANZ is proposing to permit the addition of selected vitamins and minerals to cereal-based beverages being the same range and equal levels as currently permitted for beverages derived from legumes (which are based on cows' milk), it is appropriate that the same permissions on claims for beverages derived from legumes also apply to cereal-based beverages.

6.4 Other Issues Raised in Submissions

6.4.1 Use of the term 'Milk'

Four submitters (2 industry, 1 public health and 1 government) to the Initial Assessment Report commented on the use of the term 'milk' in the product name of many cereal-based beverages, and the potential for this to mislead consumers. They consider that the milk-like nature of cereal-based beverages and use of the word 'milk' in the product name may mislead consumers as to the nutritional value of these beverages. The public health submitter recommended that cereal-based beverages be "forbidden" to use the word 'milk' in their product name.

Cereal-based beverages do not meet the definition of 'milk' as defined in Standard 2.5.1 – Milk of the Code, as they are not 'the mammary secretion of milking animals'. However, consumers of cereal-based beverage commonly use these products as a dairy milk substitute on breakfast cereal, in beverages, and in baking and cooking.

Although use of the term 'milk' in the product name of some cereal-based beverages does not meet the prescribed definition, it can be argued that there is a general understanding by consumers that these products are not 'milk' per se.

Other similar examples include 'coconut cream', 'soy milk' and 'vegetarian mince', where consumers understand that these foods are not the same as the conventional food. In addition, the *Representations About Foods - User Guide*[17] states that:

- *The law allows manufacturers to make voluntary representations about their products as long as the representations are not false, misleading or deceptive or likely to be misleading or deceptive to consumer;* and

- *In representing a food to consumers, manufacturers must make sure that the name of the food and the overall impression of the food is consistent with the nature of the food i.e. the food is what it says it is and the food is what it looks like.*

While it can be debated whether the use of the term 'milk' in the product names of some cereal-based beverages is misleading for consumers/caregivers, this issue is beyond the scope of Application A500. The use of the term 'milk' for products such as cereal-based beverages could be investigated by an enforcement agency under the *Trade Practices Act 1991*, if there is evidence that use of this term is misleading for consumers.

7. Regulatory Options

There are three regulatory options proposed for addressing this Application at Draft Assessment, these are:

7.1 Option 1 – Maintain status quo

Maintaining the status quo by not permitting the addition of calcium or other selected vitamins and minerals to cereal-based beverages. The existing requirements for advisory labelling would continue to apply.

7.2 Option 2 – Amend Standard 1.3.2 to permit the voluntary addition of calcium to cereal-based beverages equal to the level permitted for beverages derived from legumes (which is based on cows' milk), in addition to the requirement for a specific advisory labelling.

This would allow the voluntary addition of calcium to cereal-based beverages so that the calcium content resulting from fortification is equivalent to that permitted in fortified beverages derived from legumes, which is based on cows' milk. This option also includes the requirement for labelling with a specific advisory statement.

[17] FSANZ Representations About Foods – User Guide, August 2002. Available at www.foodstandards.gov.au/_srcfiles/Reps_about_food_0802.pdf

7.3 Option 3 – Amend Standard 1.3.2 to permit the voluntary addition of selected vitamins and minerals including calcium to cereal-based beverages, being the same range and equal levels as permitted for beverages derived from legumes (which is based on cows' milk), in addition to the requirement for a specific advisory labelling.

This would allow the voluntary addition of vitamin A, thiamin, riboflavin, vitamin B_6, vitamin B_{12}, vitamin D, folate, calcium, magnesium, phosphorus, zinc and iodine to cereal-based beverages in equal levels to that permitted in fortified beverages derived from legumes, which is based on cows' milk. In addition there would be a requirement for cereal-based beverages to be labelled with a specific advisory statement.

8. Impact Analysis

Since the Initial Assessment, the Impact Analysis has been revised on the basis of updated market and product information, submitter comments and the addition of the third regulatory option.

8.1 Affected Parties

The parties affected by the three regulatory options can be broadly divided into three groups (consumers, industry and government) and include:

8.1.1 Consumers

- specifically consumers who are allergic/intolerant to dairy and/or soy foods, or those who choose not to consume dairy products either for health or philosophical reasons.

8.1.2 Food Industry

- manufacturers/importers of cereal-based beverages who will benefit from the voluntary permissions to fortify cereal-based beverages with the selected vitamins and minerals;

- the dairy industry, which currently has a large market share of food sources of calcium and other micronutrients; and

- the dairy substitute (e.g. soy-based beverages) industry that currently provides food sources of calcium and other vitamins and minerals for those individuals who, for whatever reason, do not consume dairy products.

8.1.3 Government

- Governments of Australia, New Zealand, the States and Territories (including food regulation enforcement agencies) and the health sector.

8.2 Cost Benefit Analysis

The Cost Benefit Analysis assesses the immediate and potential impacts on the affected parties.

8.2.1 Option 1 – Maintain status quo

8.2.1.1 Consumers

Benefits

- Consumers would continue to be able to consume a calcium fortified cereal-based beverage, as these beverages are currently available in both Australia and New Zealand. Three of the four available products are manufactured in Australia, and contain calcium as a food additive with a technological function. While no products are manufactured in New Zealand, one product containing added calcium and vitamins A, B_{12} and D is imported into Australia via New Zealand.

Costs

- FSANZ has identified some subgroups of the community who are at risk of low intakes of certain macronutrients and micronutrients as a result of using cereal-based beverages as a substitute for dairy milk. The population subgroups include vegetarians, vegans and those who have an allergy/intolerance to dairy milk and/or soy. Maintenance of the status quo will see the continuation of low intakes of these nutrients in the population subgroups identified in both Australia and New Zealand.

- Consumers may be misled by the milk-like nature of cereal-based beverages to believe they are nutritionally equivalent to dairy milk and this could result in these consumers, especially young children, being nutritionally compromised. Although current advisory labelling lessens this risk
- Consumers may not be able to identify that a cereal-based beverage contains calcium, as food additives are not permitted to make content claims.

8.2.1.2 Industry

Benefits

- The Australian industry would continue its practice of adding calcium as a food additive to cereal based beverages for the local market, and hence maintaining this market niche.

Costs

- Australian industry faces a risk that government enforcement agencies will strictly enforce Standard 1.3.1 and ensure that the industry does not make any claims that are not permitted under the Code. This would involve costs of re-labelling to remove calcium content claims.

- If Standard 1.1A.6 were repealed from the Code without amendment to the Code to allow the manufacture of fortified cereal-based beverages, then this advantage would be lost for future New Zealand manufacturers and importers.

8.2.1.3 Government

Benefits

- There is no particular benefit to Government of maintaining the *status quo*.

Costs

- As fortified cereal-based beverages are currently on the market and there is consumer demand for these products, there is potential that maintaining the *status quo* will require enforcement agencies to take appropriate action to ensure compliance with Standard 1.3.1 which could increase enforcement costs.

8.2.2 Option 2 – Amend Standard 1.3.2 to permit the voluntary addition of calcium to cereal-based beverages equal to the level permitted for beverages derived from legumes, which is based on cow's milk.

8.2.2.1 Consumers

Benefits

- Amending Standard 1.3.2 to permit the voluntary fortification of calcium to cereal-based beverages would provide manufacturers with a mechanism to inform consumers as to the presence of calcium in these products. This could potentially increase the availability of calcium fortified cereal-based beverages on the market. Thus, fortification of the proposed products with calcium and the presence of calcium content claims would provide all consumers with continuing information and possibly alternative food sources of calcium.

- For individuals who have a dairy milk allergy/intolerance, the availability of calcium-fortified products provides an alternative food source of calcium to the currently fortified dairy substitutes (e.g. soy-based beverages). Currently dietary sources of calcium for this population are limited. Option 2 ensures that such consumers will continue to be informed of calcium contained in fortified cereal-based beverages, through use of content claims.

- For individuals with allergies/intolerances to both dairy milk and soy, amending the Code to permit the voluntary addition of calcium to cereal-based beverages may increase the availability and decrease the price of these products because they could be manufactured in Australia under a prescribed standard and directly imported to Australia, rather than via New Zealand. Option 2 ensures that such consumers will continue to be informed of calcium contained in fortified cereal-based beverages, through use of content claims.

- There may be potential to reduce the long-term health costs to consumers that are associated with inadequate calcium intake.

Costs

- Consumers may be further misled by the addition of calcium, in addition to the milk-like nature of cereal-based beverages, to believe they are nutritionally equivalent to dairy milk and this could result in these consumers, especially young children, being nutritionally compromised. However, the inclusion of an appropriate advisory label indicating that these products are not a complete milk replacement would lessen this risk.

8.2.2.2 Industry

Benefits

- Australian manufacturers would be permitted to voluntarily fortify cereal-based beverages with calcium and make claims. This may potentially open up new markets and increase market share both domestically and internationally.

- Option 2 would legitimise the current practice of Australian industry of making calcium content claims and avoid the risk under the status quo that these claims might be required to be removed from beverage labels.

- Australian importers would be able to import calcium-fortified cereal-based beverages directly, rather than via New Zealand, which would reduce operational costs.

- There would be no loss in export revenue for New Zealand as currently no cereal-based beverages are manufactured in New Zealand.

- Permitting the addition of calcium to cereal-based beverages would provide partial equity for Australian manufacturers compared with potential New Zealand counterparts.

Costs

- Unless Standard 1.1A.6 is repealed, NZ manufacturers could potentially have an advantage over their Australian counterparts. However, this currently is not an issue as cereal-based beverages are not being manufactured in New Zealand.

- There is a potential cost to the dairy and soy industries, as consumers may choose to substitute fortified cereal-based beverages for dairy milk and/or soy-based beverages. However, this potential cost is likely to be minimal, as cereal-based beverages are generally used by a specific population group.

- Non-dairy consumers may substitute a calcium fortified cereal-based beverage for soy-based beverages, thus potentially reducing the market share of the soy-based beverage industry.

- Manufacturers would be faced with the cost of re-labelling their products in order to comply with the proposed advisory statement.

8.2.2.3 Government

Benefits

- There may be the potential to reduce the public health costs associated with osteoporosis, fractures and other conditions associated with inadequate calcium intake.

- There is potential to reduce enforcement costs, as these products would be specifically regulated. Amending Standard 1.3.2 to permit the voluntary fortification of calcium to cereal-based beverages would avoid the inappropriate use of the food additive standard to add calcium to cereal-based beverages.

Costs

- This option may require a change in education approaches to take account of the presence of calcium in foods that are not natural sources of calcium.

8.2.3 Option 3 – Amend Standard 1.3.2 to permit the voluntary addition of selected vitamins and minerals including calcium to cereal-based beverages, being the same range and equal levels as permitted for beverages derived from legumes, which is based on cow's milk.

8.2.3.1 Consumers

Benefits

- Fortification of cereal-based beverages with the selected vitamins and minerals would provide a more nutritious substitute for non-fortified cereal-based beverages, for those who choose not to or cannot consume dairy or soy for reasons of allergy/intolerance.

- The increased levels of vitamins and minerals in cereal-based beverages may reduce the risk of nutritional deficiencies in these population subgroups.

- Fortification of cereal-based beverages with the selected vitamins and minerals would provide all consumers with additional and/or alternative food sources of these vitamins and minerals.

- Permission to fortify cereal-based beverages with the selected vitamins and minerals may increase the availability of these products because they could be manufactured in Australia and directly imported into Australia, rather than via New Zealand.

- There may be potential to reduce the direct health costs to consumers that are associated with inadequate vitamin and mineral intakes, not just inadequate calcium as per Option 2.

Costs

- There is potential that consumers/caregivers may be mislead as to the nutritional quality of fortified cereal-based beverages, with respect to protein content. Inappropriate use, especially in children, may result in the child becoming nutritionally compromised.

- Although inclusion of an advisory statement should help to mitigate this risk.

- It is unknown what costs would be added by the manufacturer and therefore it is difficult to determine the potential increase in retail price of fortified cereal-based beverages.

8.2.3.2 Industry

Benefits

- Australian manufacturers would be permitted to voluntarily add selected vitamins and minerals to the proposed products, and this may potentially open up new markets or increase market share both domestically and internationally.

- Australian importers would be able to import a range of fortified cereal-based beverages directly, rather than via New Zealand, which would reduce operational costs.

- There would be no loss in export revenue for New Zealand as currently no cereal-based beverages (fortified and non-fortified) are manufactured in New Zealand.

- Permitting the addition of vitamins and minerals to cereal-based beverages would, in principle, provide total equity for Australian manufacturers compared with their New Zealand counterparts.

Costs

- There is a potential cost to the dairy and soy industries, as consumers may choose to substitute fortified cereal-based beverages for dairy milk and/or soy-based beverages. However, this potential cost is likely to be minimal, as cereal-based beverages are generally used by a specific population group.

- There is a potential that cereal-based beverage consumers currently taking vitamin and mineral supplements may choose fortified food sources over supplements, therefore the supplement industry may be adversely affected.

- Manufacturers would be faced with the cost of re-labelling their products in order to comply with the proposed advisory statement. However the status quo includes the possibility of industry being required to re-label beverages containing calcium to comply with Standard 1.3.1, hence there is no extra cost of re-labelling under Option 3.

8.2.3.3 Government

Benefits

- There may be the potential to reduce the public health costs associated with conditions relating to inadequate vitamin and mineral intakes.

- There is potential to reduce enforcement costs, as these products would be specifically regulated.

Costs

- This option may require a change in education approaches to take account of the presence of the selected vitamins and minerals in foods that are not natural sources of these nutrients.

9. Consultation

9.1 Public Consultation

The Initial Assessment Report for Application A500 was released for public comment from 16 June 2004 to 28 July 2004. A total of thirteen submissions were received, with eight submissions from industry, two from government, two from public health and one from a consumer group.

Nine submissions supported amending Standard 1.3.2 to permit the addition of calcium to cereal-based beverages, two opposed (one industry and one public health), and two did not indicate support for either regulatory option. A number of submitters also indicated support for permitting the addition of other vitamins and minerals to cereal-based beverages. A summary of submissions is at Attachment 4.

FSANZ is now seeking further public comment on this Draft Assessment Report to assist in assessing this Application at Final Assessment.

9.2 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.

It is not expected that the proposed fortification of cereal-based beverages would have a significant effect on trade between WTO member nations. Instead, it is likely to open up both the import and export markets for member nations. While the vitamin D content of the current imported fortified rice beverage exceeds the proposed fortificant level for this nutrient, this product could be reformulated to remove this trade barrier. In addition, if fortification were approved, then similar fortified cereal-based beverages could be manufactured within Australia and New Zealand for the respective populations.

Therefore at Draft Assessment, FSANZ does not consider it necessary to notify WTO member nations of the proposed amendment to allow the addition of selected vitamins and minerals to cereal-based beverages.

10. Conclusion

As cereal-based beverages with added calcium are currently available in Australia and New Zealand, Option 2 offers few additional benefits to consumers when compared with Option 1. Although, Option 2 does provide benefits to both consumers and industry by allowing content claims to be made.

Option 3 fulfils the specific objectives of this Application and when compared with Options 1 and 2 delivers greater net benefits to all affected parties. Option 3 is preferable in the interest of protecting the public health and safety, through providing consumers of cereal-based beverages with a more nutritionally equivalent substitute food for dairy milk. Option 3 permits, in addition to calcium, the vitamins and minerals that have been identified as being inadequate in the diets of some consumers of cereal-based beverage. This approach is also consistent with existing permissions in the Code for legume-based beverages, with respect to nutritional equivalence and opportunities for fair trade. In addition, Option 3 may potentially open up new markets for manufacturers or increase market share both domestically and internationally due to the greater number of vitamin and mineral permissions.

Option 3 is considered the preferred regulatory option

11. Recommendation

It is recommended that:

- Standard 1.3.2 be amended to permit cereal-based beverages containing no less than 0.3% protein derived from cereals to be fortified with selected vitamins and minerals, being the same range and equal levels as those permitted for beverages derived from legumes (see table over page);

- Standard 1.2.3 be amended to require cereal-based beverages containing less than 3% protein (and no more than 2.5% fat) to carry an advisory statement to the effect that *the product is not suitable as a complete milk replacement for children under the age of twelve years*; and

- the existing advisory labelling requirement for low fat milks and beverages (no more than 2.5% fat), as per Standard 1.2.3, be extended to apply to all cereal-based beverages, including oat beverages, rather than rice beverages alone.

The table below outlines the proposed permissions for cereal-based beverages, and the corresponding maximum claims and maximum permitted quantity allowed per 200 mL reference quantity for each vitamin and mineral.

Table 4: Proposed vitamin and mineral permissions for cereal-based beverages per 200 mL reference quantity, as per Option 3

Vitamins and Minerals	Maximum Claim per Reference Quantity (proportion RDI)	Maximum Permitted Quantity of Vitamin or Mineral per Reference Quantity
Vitamin A	110 µg (15%)	125 µg
Thiamin	no claim permitted	0.10 mg
Riboflavin	0.43 mg (25%)	
Vitamin B_6	no claim permitted	0.12 mg
Vitamin B_{12}	0.8 µg (40%)	
Vitamin D	1.0 µg (10%)	1.6 µg
Folate	no claim permitted	12 µg
Calcium	240 mg (30%)	

Vitamins and Minerals	Maximum Claim per Reference Quantity (proportion RDI)	Maximum Permitted Quantity of Vitamin or Mineral per Reference Quantity
Magnesium	no claim permitted	22 mg
Phosphorus	200 mg (20%)	
Zinc	no claim permitted	0.8 mg
Iodine	15 µg (10%)	

The proposed draft variations to Standards 1.3.2 and 1.2.3 are at Attachment 1.

12. Statement of Reasons

Therefore, FSANZ recommends the draft variations to the Code as detailed in Attachment 1 for the following reasons:

- the fortification of cereal-based beverages would assist in protecting the health and safety of cereal-based beverage consumers through:
  - allowing the manufacture of more nutritionally equivalent substitutes for dairy milk; and
  - use of an advisory statement to reduce the risk of inappropriate use of cereal-based beverages, particularly in the diets of children;
- is consistent with FSANZ statutory objectives including Ministerial policy guidance on voluntary fortification;
- the fortification of cereal-based beverages does not raise any safety concerns for consumers of these beverages or the general population;
- permission to fortify cereal-based beverages in a joint food standard provides uniform regulations for these beverages between Australia and New Zealand;
- a joint food standard provides regulatory certainty for industry and government enforcement agencies; and
- the regulation impact assessment concludes that the benefits from permitting the fortification of cereal-based beverages with selected vitamins and minerals outweigh any potential costs to affected parties.

13. Implementation and Review

Following the second consultation period for this document, a Final Assessment of this Application will be completed. Following the preparation of the Final Assessment Report and approval by the FSANZ Board, notification will be made to the Ministerial Council.

The proposed draft variations to the Code are expected to come into effect upon gazettal, subject to any request from the Ministerial Council for a review.

ATTACHMENTS

1. Draft Variations to the *Australia New Zealand Food Standards Code*
2. Nutrition Assessment Report
3. Dietary Modelling Methodology Report
4. Summary of Submissions

Attachment 1

Draft Variations to the *Australia New Zealand Food Standards Code*

To commence: On gazettal

[1] ***Standard 1.2.3*** *of the Australia New Zealand Food Standards Code is varied by –*

[1.1] *inserting in the* Table to clause 2, Columns 1 and 2 –

Cereal-based beverages, where these foods contain no more than 2.5% m/m fat and less than 3% m/m protein, or less than 3%m/m protein only.	Statement to the effect that the product is not suitable as a complete milk replacement for children under the age of twelve years.
Evaporated and dried products made from cereals, where these foods contain no more than 2.5% m/m fat and less than 3% m/m protein, or less than 3% m/m protein only, as reconstituted according to directions for direct consumption.	Statement to the effect that the product is not suitable as a complete milk replacement for children under the age of twelve years.

[1.2] *omitting from the* Table to clause 2 –

Evaporated milks, dried milks and equivalent products made from soy or rice, where these foods contain no more than 2.5% m/m fat as reconstituted according to directions for direct consumption	Statement to the effect that the product is not suitable as a complete milk food for children under the age of two years

substituting

Evaporated milks, dried milks and equivalent products made from soy or cereals, where these foods contain no more than 2.5% m/m fat as reconstituted according to directions for direct consumption.	Statement to the effect that the product is not suitable as a complete milk food for children under the age of two years.

[1.3] *omitting from the* Table to clause 2 –

Milk, and beverages made from soy or rice, where these foods contain no more than 2.5% m/m fat	Statement to the effect that the product is not suitable as a complete milk food for children under the age of two years

substituting

Milk, and beverages made from soy or cereals, where these foods contain no more than 2.5% m/m fat.	Statement to the effect that the product is not suitable as a complete milk food for children under the age of two years.

[2] ***Standard 1.3.2*** *of the Australia New Zealand Food Standards Code is varied by –*

[2.1] *inserting in* Column 1 *in the* Table to clause 3 *the heading –*

Analogues derived from

cereals

[2.2] *inserting in the* Table to clause 3, Columns 2, 3, 4 and 5*, under the heading* Analogues derived from cereals –

Beverages containing no less than 0.3% m/m protein derived from cereals	200 mL	Vitamin A Thiamin Riboflavin Vitamin B_6 Vitamin B_{12} Vitamin D Folate Calcium Magnesium Phosphorus Zinc Iodine	110 µg (15%) no claim permitted 0.43 mg (25%) no claim permitted 0.8 µg (40%) 1.0 µg (10%) no claim permitted 240 mg (30%) no claim permitted 200 mg (20%) no claim permitted 15 µg (10%)	125 µg 0.10 mg 0.12 mg 1.6 µg 12 µg 22 mg 0.8 mg

Attachment 2

Nutrition Assessment Report

1. Executive Summary

Information pertaining specifically to the users of cereal-based beverages is limited to sales data and anecdotal information. It is assumed that cereal-based beverages are predominantly used as a substitute for dairy milk by people who for whatever reason do not consume dairy milk or soy-based beverages. Dairy milk is an important contributor of dietary calcium, magnesium, phosphorus, zinc, vitamin A, riboflavin, vitamin B_{12}, and iodine. Compared to whole cows' milk, the composition of cereal-based beverages is low in protein, many vitamins and minerals and lower in fat.

The potential risk identified for assessment was that of inadequate vitamin and mineral intakes by those consuming cereal-based beverages. To address this risk, a question raised at Initial Assessment was to permit fortification of cereal-based beverages with vitamins and minerals to the levels found in dairy milk. The low protein content of these products and their regular consumption by some children was of concern to several submitters to the Initial Assessment Report. The general dietary risks of low protein and lower fat intake of non-dairy consumers[18] were also investigated, particularly since consumers might perceive fortified cereal-based beverages as nutritionally equivalent to dairy milk and thus not take steps to ensure adequate protein intake.

1.1 Methods for Assessing Risk

To establish the risk associated with consumption of non-fortified cereal-based beverages, the nutrient intake of cereal-based beverage consumers was investigated. However, there was extremely limited consumption of cereal-based beverages in the Australian and New Zealand National Nutrition Surveys (NNS). Consequently, consumption of soy-based beverages – fortified and non-fortified, in conjunction with the limited consumption of cereal-based beverages, was used as a proxy for consumption of cereal-based beverages for dietary modelling purposes. Consumers of dairy products were also excluded from the models, which are described in Section 2.3 of Attachment 3.

Whole of population dietary intake data (Model 1) were used to assess the importance of dairy milk as a contributor of nutrients to the diet. Five nutrient intake models were devised to represent people who did not eat dairy products on the day of the surveys. Models 2 and 4 represented non-dairy consumers: Model 2 comprised all non-dairy consumers including those who might have consumed a soy-based beverage; Model 4 was only non-dairy consumers who consumed a soy beverage. Models 3 and 5 were based on Models 2 and 4 respectively but with the composition of soy-based beverage changed to that of an unfortified cereal-based beverage.

[18] Non-dairy consumers are those individuals who do not consume any dairy products, including those who may not consume soy-based beverages

A literature review was also conducted. No studies were found specific to consumers of cereal-based beverages and very little data related to Australia and New Zealand. Five studies were found that investigated the nutrient intake of consumers who avoided dairy or had an allergy, four of which were by young children. Only one study assessed the adequacy of nutrient intakes compared to a nutrient reference value, whereas the other four compared intakes with controls, who were assumed to have adequate intakes.

Three case studies in infants under two years were found. However, apart from these case studies, all of which led to hospitalisation, no information could be found on the nutrient intake of infants and toddlers aged less than 2 years who consume cereal-based beverages.

1.2 Nutritional Risks to Consumers of Cereal-Based Beverages

1.2.1 Vitamins and Minerals

The dietary intake estimates for non-dairy consumers including a small number of consumers of unfortified cereal-based beverages indicated a considerable proportion are likely to have inadequate intakes of some vitamins and minerals ordinarily supplied by dairy foods. The most likely vitamins and minerals to be generally compromised are calcium, magnesium, zinc, vitamin A, riboflavin, vitamin B_6 and iodine as assessed by one or more subpopulation age groups not meeting 50% of their respective EAR. Older consumers appear to be more at risk with respect to vitamin and mineral intakes compared with the 2-4 year age group.

1.2.2 Protein and Fat

Adequate intakes of protein and fat are particularly important in the diets of young children for growth and development, and dairy milk is a very important source of protein. Cereal-based beverages, whether non-fortified or fortified, have low concentrations of protein and lower amounts of fat than whole cows' milk. Results of the estimated dietary intake assessment and literature review do not provide conclusive evidence of the risk of low protein and lower fat intakes by consumers of cereal-based beverages, although these data sources suggest a low prevalence of protein inadequacy among young non-dairy consumers that increases with age. In contrast, the consequences of inadequate protein intakes for growth and development of children are greater than for adults. Therefore, taking account of both the likelihood and consequence of inadequate protein intakes, it is considered that children who avoid dairy products and regularly consume cereal-based beverages have a small risk of inadequate protein intakes. Consumers' possible perception of fortified cereal-based beverages as nutritionally equivalent to dairy milk may increase this risk of inadequacy such that they do not appreciate the need to ensure adequate intakes from appropriate dietary sources.

1.3 Effect of Fortifying Cereal-Based Beverages

1.3.1 Efficacy

The scenario modelling data used in Model 6 suggests that, with the exception of folate, permission to fortify cereal-based products would address to some extent the risk of inadequate intake of a variety of vitamins and minerals for cereal-based beverage consumers who are dairy avoiders.

Based on the limited composition data, the natural content of folate in cereal-based beverages appears to be already higher than that found in dairy milk, therefore, permission to add folate would be useful only for beverages with lower folate amounts than dairy milk.

Due to the large number of modifiers influencing bioavailability, especially those that may confound scientific research into this area, FSANZ cannot fully assess the bioavailability of vitamin and mineral additions to cereal-based beverages. From the limited literature available, as evaluated in Attachment 2, the addition of vitamins and minerals to cereal-based beverages is likely to be comparable to the bioavailability obtained from other food sources of these nutrients.

1.3.2 Safety

Fortification of cereal-based beverages to the levels of vitamins and minerals found naturally in cows' milk poses the same risk as milk itself. This is unlikely to cause excess consumption of these micronutrients for regular consumers of cereal-based beverages because they are likely to be non-dairy consumers and thus at risk of inadequate intakes of vitamins and minerals ordinarily provided by dairy products.

1.4 Conclusion

It is difficult to describe the consumers of cereal-based beverages but it is assumed that the majority will be people who cannot or choose not to consume dairy milk or soy beverages.

The results of the estimated dietary intake assessment and literature review do not provide conclusive evidence of the risk of low protein and lower fat intakes by consumers of cereal-based beverages, although these data sources suggest a low prevalence of protein inadequacy among young non-dairy consumers that increases with age. The management of this risk is worthy of consideration.

The results of the risk assessment suggest that non-dairy consumers are at risk of inadequate intake of a variety of vitamins and minerals for which dairy milk is an important source and that use of a fortified product may aid in mitigating the risk. Fortification of cereal-based beverages to the levels of vitamins and minerals found in cows' milk poses no greater risk than cows' milk itself and is therefore considered to be safe.

2. Consumers of Cereal-Based Beverages

There are two distinct subpopulations who could choose to drink cereal-based beverages: those who are allergic/intolerant to dairy and soy foods and those who choose not to consume dairy foods for taste preference, health or philosophical reasons, including vegans and those who wish to avoid phytoestrogens from soy.

Of the 13 858 Australians and 4 636 New Zealanders surveyed in the Australian and New Zealand NNS respectively, there was only one New Zealand respondent who consumed a rice-based beverage on the day of the NNS. Since consumption of rice beverages was extremely limited, other data pertaining to the number and profile of cereal-based beverage users were investigated including sales data, a literature search regarding prevalence of dual milk and soy allergies, information provided by submitters and personal communication with allergy specialists.

The most recent sales information supplied by the Applicant showed that Australian supermarket retail sales totalled 3,800,000 litres for the year up until April 2005[19]. With the addition of New Zealand supermarket sales as well as sales from health food stores, the size of the Trans Tasman cereal-based beverage market was estimated to be about 5,500,000 litres. This represents 0.2% of the total dairy milk market[20]. The cost of rice- and oat- beverages is 10-15% higher than soy beverages and 28-128% higher than cows' milk[21].

The *Allergy New Zealand* organisation undertook a short survey of their members' households to investigate questions raised in the Initial Assessment Report on the use of cereal-based beverages. In the 14 households that responded, 15 people less than eight years old and 8 people aged 32-60 years reported using rice-based beverages. The respondents used the rice-based beverage as a soy- and cows' milk- substitute on breakfast cereal, in beverages and in baking and cooking.

Cows' milk allergy is reported to exist in 7-8% of young children (Hill *et al.*, 1999). Personal communication with allergy specialists in both Australia and New Zealand suggests that between 14-47% of these children do not tolerate soy[22]. The large majority of them are less than 4 years of age, under professional care and consuming a special purpose product rather than cereal-based beverages.

3. Nutritional Profile of Cows' Milk and Estimated Nutrient Intake of Non-dairy Consumers

3.1 Contribution of Cows' Milk to Nutrient Intake

Cows' milk and dairy products are very important contributors of energy and nutrients in the diets of humans, and in particular the young. Milk provides more than 5% of the adult Recommended Dietary Intake (RDI) per 200 mL serve for many nutrients. The protein, vitamin and mineral composition of whole cows' milk per 200 mL is provided in Table 2 in Section 4.4.2 in the main body of the Draft Assessment Report.

According to the Australian 1995 NNS, despite a decrease in the amount consumed with increasing age, dairy milk was the second most important source of energy for children 2-11 years (25% for children 2-3 years, 16% for children aged 8-11 years). In the New Zealand Children's Nutrition Survey (CNS) milk contributed 6% of energy intake of children 5-15 years. Table 1 below indicates the percent contribution of dairy milk to the estimated dietary intake of protein, and vitamin and minerals for all respondents in Australia and New Zealand populations regardless of what they consumed on the day of the NNS.

[19] As provide by AZTEC systems to the Applicant
[20] Based on annual consumption of 1 960 million litres in Australia (Dairy Australia Website)
[21] Based on cost of goods in New Zealand as at 19.05.05
[22] Personal communication with Vincent Crump and Jan Sinclair Via email May 2006.

Table 1: Percentage contribution of dairy milk to estimated mean nutrient intakes, Australia and New Zealand

	Australia				New Zealand
Nutrient	2 years and above (n=13,858)	2-4 years (n=583)	5-14 years (n=1,844)	15 years and above (n=11,431)	15 years and above (n=4,636)
Protein	9	22	13	8	10
Calcium	33	51	38	31	37
Magnesium	9	20	13	8	8
Phosphorus	15	32	21	14	16
Zinc	8	20	12	7	8
Vitamin A	7	22	12	6	6
Thiamin	6	13	7	5	5
Riboflavin	23	38	26	21	26
Folate	4	11	6	4	4
Vitamin B_6	7	13	8	6	6
Vitamin B_{12}	16	41	25	14	15
Vitamin D	3	8	4	2	2
Iodine[#]	68	77	74	66	65

For Iodine 'Dairy milk' includes all milks, yoghurts, cheese, ice cream, butter and their use in recipes.
For all other vitamins and minerals dairy milk includes fluid milk, evaporated milk, condensed milk and milk powder (including undiluted and dry forms). Milkshakes, flavoured milks and milk used in recipes are not included.

Table 1 illustrates that cows' milk and dairy foods are nutritious foods and important contributors of many vitamins and minerals[23], particularly calcium, magnesium, phosphorus, zinc, vitamin A, riboflavin, vitamin B_{12} and iodine; and particularly for children 2-4 years of age. With the exception of the iodine results, the results in Table 1 do not include the contribution of other nutritious dairy products to nutrient intake. Unless care is taken to substitute dairy foods appropriately, people who avoid dairy foods could be more at risk of inadequate intakes of nutrients of which dairy foods are a significant dietary contributor.

3.2 Postulated Risks to Consumers of Cereal-Based Beverages

Unfortified cereal-based beverages are a poor source of protein, vitamins and minerals, and are lower in fat than whole dairy milk. It is postulated that consumers of unfortified cereal-based beverages may be at risk of inadequate intakes of vitamins and minerals usually found in dairy milk and dairy milk products. Assessment of the Application has raised the option to permit the addition of a variety of vitamins and minerals in order to achieve micronutrient equivalence with dairy milk although a fortified product's protein and fat content would remain unchanged. It is further considered that consumers of cereal-based beverages may also be at risk of low protein and/or fat intakes. The extent to which consumers of unfortified products assume that cereal-based beverages are nutritionally equivalent to dairy milk is unknown. Improved vitamin and mineral content via fortification may increase the chances of consumers believing cereal-based beverages are as nutritious as dairy milk. Thus the possibility exists that those consumers who rely on fortified rice- and oat- beverages as milk alternatives may regard them as nutritionally equivalent to dairy milk in all respects. The possible risk of protein inadequacy may be compounded because consumers may not be aware of the need to take steps to consume adequate amounts of other dietary sources of protein.

[23] Contributes at least 20% of total dietary intake of a vitamin or mineral, for one or more subpopulation age groups.

3.3 Nutrient Intakes of Non-Dairy Consumers

This section assesses the estimated intakes of protein and fat in addition to vitamins and minerals for non-dairy consumers.

3.3.1 Estimated Dietary Intake Assessment

There were 6 models used to assess this Application. Each model is described below in Table 2.

Table 2: Description of models used to assess this Application

Model Name	Model Description	Population Groups Assessed
Model 1	This model was conducted to determine baseline estimated mean protein intakes for all Australians aged 2 years and above and all New Zealanders aged 15 years and above. It was also used to determine the percent contribution of dairy milk to estimated mean vitamin and mineral intakes.	Australia: 2 years and above, n=13 858 2-4 years, n=583 5-14 years, n=1 844 15 years and above, n=11 431 New Zealand: 15 years and above, n=4 636
Model 2	This model was conducted to determine baseline estimated mean protein intakes for all non-dairy consumers and it includes those respondents who consumed a soy-based beverage (unfortified or fortified) on the day of the NNS.	Australia: 2 years and above, n=734 2-4 years, n=12 5-14 years, n=99 15 years and above, n=623 New Zealand: 15 years and above, n=205
Model 3	This scenario model was conducted to determine baseline estimated mean vitamin and mineral intakes for all non-dairy consumers and includes respondents represented as consuming an unfortified cereal-based beverage on the day of the NNS. It was also used to determine percent contribution of fat to total energy.	Australia: 2 years and above, n=734 2-4 years, n=12 5-14 years, n=99 15 years and above, n=623 New Zealand: 15 years and above, n=205
Model 4	This model was conducted to determine baseline estimated mean protein intakes for only non-dairy consumers who consumed a soy-based beverage (unfortified or fortified) on the day of the NNS.	Australia: 2 years and above, n=60
Model 5	This scenario model was conducted to determine baseline estimated mean vitamin and mineral intakes for only non-dairy consumers represented as consuming an unfortified cereal-based beverage on the day of the NNS. This model was also used to determine percent contribution of fat to total energy.	Australia: 2 years and above, n=60

Model Name	Model Description	Population Groups Assessed
Model 6	This scenario model was conducted to determine estimated mean vitamin and mineral intake for only non-dairy consumers represented as consuming a fortified cereal-based beverage on the day of the NNS. The nutrient composition of cereal-based beverages was based on Standard 1.3.2 of the Code and the Applicant's requested calcium level of 120 mg/100g.	Australia: 2 years and above n=60

Consumers of dairy milk, dairy yoghurt, cream, dairy cheese, frozen and unfrozen dairy milk desserts, dairy spreads, butter, oil/cream base sauces or pizza were excluded from the dietary intake assessment for non-dairy consumers. In addition, respondents consuming milk-based meal replacements, infant custards and yoghurts, cheese/cream dry mix sauces for Australia and roux for New Zealand were also excluded.

The results of these models are used either alone or in combination to describe the potential impact of cereal-based beverage consumption on nutrient intake. FSANZ decided previously[24] that a population of interest could be considered to have an inadequate intake of a nutrient when more than 3% of that population had adjusted nutrient intakes below the relevant EAR. The Estimated Average Requirement(s) (EAR) used in this report are those given in the National Health Medical Research Council (NHMRC) and New Zealand Ministry of Health (MoH) Draft Nutrient Reference Values (NHMRC/MoH 2004). Attachment 3 provides further information pertaining to the methodology used in the models.

3.3.1.1 Vitamins and Minerals

Given the significant contribution of dairy milk to the diet, the dietary intake of vitamins and minerals usually found in dairy milk was estimated for non-dairy consumers to assess the potential level of inadequacy. Table 3 on the next page provides the estimated vitamin and mineral intakes of all non-dairy consumers including those represented as consuming an unfortified cereal-based beverage on the day of the NNS (Model 3).
It also provides an estimate of dietary inadequacy, showing the percentage of consumers whose vitamin and mineral intakes are below the respective EAR.

The dietary intake assessments presented are estimates only and incorporate a number of assumptions and limitations. While the best available data and the assumptions deemed most appropriate have been considered, care needs to be taken in interpreting the results. Potential variation in the results (e.g. due to natural variation in the nutrient concentrations in foods) has not been incorporated in the estimates of dietary nutrient intake. Also, given that there were small consumer numbers for some groups assessed, and the fact that second day adjustments were not conducted, which means that the quoted % consumers < EAR are overestimates, care needs to be taken in the interpretation of these results as they may not accurately reflect longer-term nutrient intake. Therefore these results should be used as a guide to risk management decisions.

[24] FSANZ Fortification Implementation Framework 2005

Table 3: Estimated mean intakes (/day) and percent of consumers below the EAR for vitamins and minerals in Model 3, Australia and New Zealand

Vitamin/Mineral	Country	Population Group^	Mean intake	% of Consumers < EAR
Calcium	Australia	2 years and above	337 mg	85
		2-4 years	231 mg*	85*
		5-14 years	296 mg	85
		15 years and above	346 mg	85
	New Zealand	15 years and above	329 mg	90
Magnesium	Australia	2 years and above	251 mg	45
		2-4 years	144 mg*	15*
		5-14 years	186 mg	50
		15 years and above	264 mg	45
	New Zealand	15 years and above	245 mg	55
Phosphorus	Australia	2 years and above	1045 mg	7
		2-4 years	643 mg*	8*
		5-14 years	823 mg	10
		15 years and above	1088 mg	6
	New Zealand	15 years and above	1008 mg	15
Zinc	Australia	2 years and above	9.7 mg	45
		2-4 years	4.9 mg*	8*
		5-14 years	7.5 mg	35
		15 years and above	10.1 mg	50
	New Zealand	15 years and above	10.0 mg	50
Vitamin A	Australia	2 years and above	1010 ug	50
		2-4 years	326 ug*	50*
		5-14 years	553 ug	50
		15 years and above	1095 ug	50
	New Zealand	15 years and above	759 ug	55
Thiamin	Australia	2 years and above	1.3 mg	25
		2-4 years	1.0 mg*	8*
		5-14 years	1.2 mg	15
		15 years and above	1.4 mg	25
	New Zealand	15 years and above	1.0 mg	20
Riboflavin	Australia	2 years and above	1.2 mg	50
		2-4 years	0.8 mg*	25*
		5-14 years	1.0 mg	55
		15 years and above	1.3 mg	50
	New Zealand	15 years and above	1.0 mg	60

Vitamin/Mineral	Country	Population Group^	Mean intake	% of Consumers < EAR
Folate	Australia	2 years and above	240 ug	25
		2-4 years	160 ug*	15*
		5-14 years	181 ug	30
		15 years and above	251 ug	25
	New Zealand	15 years and above	187 ug	40
Vitamin B_6	Australia	2 years and above	1.2 mg	55
		2-4 years	0.9 mg*	35*
		5-14 years	0.9 mg	40
		15 years and above	1.3 mg	55
	New Zealand	15 years and above	1.1 mg	55
Vitamin B_{12}	Australia	2 years and above	4.1 ug	30
		2-4 years	2.2 ug*	25*
		5-14 years	2.4 ug	25
		15 years and above	4.4 ug	35
	New Zealand	15 years and above	3.7 ug	35
Vitamin D	Australia	2 years and above	1.6 ug	-
		2-4 years	0.7 ug *	-
		5-14 years	1.3 ug	-
		15 years and above	1.6 ug	-
	New Zealand	15 years and above	2.0 ug	-
Iodine	Australia	2 years and above	50 ug	90
		2-4 years	48 ug*	75*
		5-14 years	46 ug	85
		15 years and above	50 ug	90
	New Zealand	15 years and above	44 ug	90

Consumers only – This includes only the people who have not consumed any 'dairy products'.
^ Note: information regarding consumer numbers assessed for each population group can be found in Table 2
* Note: these figures are to be used as a guide only due to the small consumers in this population group (n=12).

Even allowing for overestimated percentage of consumers below the EAR, Table 3 shows a general pattern of considerable inadequacy for all vitamins and minerals ordinarily provided by dairy foods in the diets of non-dairy consumers including those who consumed an unfortified cereal-based beverage on the day of the NNS. A trend is evident that risk of inadequate intakes increases with age: compared with young children, the older age groups appear to be increasingly at risk of vitamin and mineral inadequacy. The most likely vitamins and minerals to be compromised[25] are calcium, magnesium, zinc, vitamin A, riboflavin, vitamin B_6 and iodine.

Therefore, the estimated intakes shown above indicate that a considerable proportion of non-dairy consumers are likely to have inadequate intakes of some vitamins and minerals ordinarily supplied by dairy foods. Among this group, older consumers appear to be more at risk with respect to vitamin and mineral intake compared with the 2-4 year age group.

[25] At least 50% of one or more subpopulation age groups do not meet the EAR.

Further information pertaining to the estimated dietary intake assessments can be found in Attachment 3.

3.3.1.2 Protein

Table 4 below shows the estimated mean protein intakes (g/day) and percent of consumers below the EAR in the Australian and New Zealand populations for all models assessed for this Application.

Table 4: Estimated mean protein intake (g/day) and % of consumers below the EAR for all models, Australia and New Zealand

		Protein Intake (g/day) (% Consumers <EAR)				
Country	**Population Group^**	**Model 1**	**Model 2**	**Model 3**	**Model 4**	**Model 5 and Model 6**
Australia	2 years and above	86 (8%)	72 (20%)	71 (20%)	77 (10%)	70 (15%)
	2-4 years	54 (0.7%)	44* (8%)	43* (8%)	NA	NA
	5-14 years	73 (2%)	58 (7%)	57 (7%)	NA	NA
	15 years and above	90 (10%)	75 (20%)	74 (25%)	NA	NA
New Zealand	15 years and above	87 (10%)	68 (25%)	68 (25%)	NA	NA

^ Note: information regarding consumer numbers assessed for each population group can be found in Table 2
* Note: these figures are to be used as a guide only due to the small consumers in population group (n=12).
NA - These population groups were not assessed due to the small consumer numbers.

A comparison of non-dairy consumers in Model 2 and Model 3 with the general population in Model 1 shows that dairy foods are an important contributor to protein intake for the general population. This is because the percentage of consumers below the EAR for protein was higher for non-dairy consumers across all the age groups compared to the general population. Also the extent of inadequacy increased with age from low to moderate levels, regardless of beverage preference. However, the relative impact on the ability of non-dairy consumers to consume greater amounts that exceed the EAR was most noticeable in the younger age groups. Compared to their respective general populations, the percentage of non-dairy consumers aged 2-4 years below the protein EAR was several times higher than the percentage of non-dairy consumers aged 5-14 years which in turn was slightly higher than for those aged 15 years and older.

The mean protein intake of all non-dairy consumers (Models 2-5) was lower and the prevalence of protein inadequacy higher than for the general population (Model 1). Furthermore, those who consumed soy-based beverages (Model 4) but not cereal-based beverages (Model 5) had higher mean protein intakes than non-dairy consumers generally. Also, the proportion of soy-based beverage consumers below the EAR for protein (Model 4) increased only slightly compared to the general population. Of particular interest however, is the comparison of Model 4 and Model 5 and 6 showing the overall impact on protein intakes of non-dairy consumers when lower protein cereal-based beverages replace soy-based beverages at the same level of consumption. Mean protein intake decreased 9% and the percentage of one-day intakes below the EAR worsened from 10% to 15%. These trends indicate that some cereal-based beverage consumers who also avoid dairy foods could be at greater risk of protein inadequacy than non-dairy soy beverage consumers.

3.3.1.3 Fat

Table 5 below shows the mean percentage contribution of total fat (TF) to total energy (TE) intake for Model 3. The contribution, is between 25% and 30% across all age groups, and is slightly less than the New Zealand dietary guidelines recommendation of 30-33% (New Zealand Ministry of Health, 2003) but above the lower bound of recommended contribution of fat to total energy (20% TE) in the draft Australia New Zealand report of revised nutrient reference values (NHMRC/MOH, 2004). These data indicate that consumers of cereal-based beverages are not at risk of inadequate fat intakes.

Table 5: Estimated mean intake of total fat (g/day) and percentage contribution of total fat (TF) to total energy (TE) intake for Model 3, Australia and New Zealand

Country	Population Group^	Mean Intake	% Energy from Fat
Australia	2 years and above	64 g	30
	2-4 years	44 g*	25*
	5-14 years	59 g	30
	15 years and above	65 g	30
New Zealand	15 years and above	70 g	30

^ Note: information regarding consumer numbers assessed for each population group can be found in Table 2
* Note: these figures are to be used as a guide only due to the small consumers in population group (n=12).

3.3.2 Literature Review

Due to the extremely limited consumption of cereal-based beverages in the NNS, a comprehensive literature search and review was undertaken to better assess the nutrient status of sufferers of dairy and other food allergies. Only five reports were found, including only one from Australia New Zealand. With one exception, all the available literature was based on studies in children or case studies of infants. These are now described in more detail.

3.3.2.1 Literature Review - Studies

In a study of 323 self-reported adult allergy sufferers (McGowan and Gibney, 1993), 47% of respondents avoided milk. Of these 71 respondents, a subset of 62 subjects was matched with controls and completed a 7-day diet history.

Milk avoiders had a significantly lower than average intake of calcium compared with controls and a significantly higher intake of fibre, beta carotene, vitamin E, vitamin C, folic acid, copper and zinc. The percent contribution to energy from protein was no different for milk avoiders than for controls.

Four studies were found that investigated the nutritional intake and/or status of children who were allergic to or avoided cows' milk. Table 6 below illustrates their results. The studies were of limited use in establishing the nutritional adequacy of diets of allergy sufferers. In most studies, the results were described as a relative comparison of intakes between an allergy group and a control group rather than being compared to nutrient reference values such as the EAR. By comparing two groups, authors have made the assumption that the dietary intake of the control group is a sufficient benchmark of adequate nutrient intake. One study used children with an allergy other than to cows' milk as a control.

Table 6: Results of literature search undertaken to assess the nutrient intake of children with allergies or aversions to cows' milk

Author	Numbers	Age and other characteristics	Method	Results
Christie *et al*, 2002	98 Children diagnosed skin prick or elimination diet 99 healthy controls	3.7±2.3 years Arkansas, USA	3 day diet record	>25% of children in both groups had < 67% of the Dietary Reference Intakes (DRI) for - calcium - vitamin D - vitamin E. A higher number of those with allergies exceeded 67% DRI than those that did not for - energy - phosphorus - iron - vitamin C - folate Among those with cows' milk allergy, 91% who drank an infant formula or fortified soy beverage met their DRIs for calcium and vitamin D.
Henrickson *et al,* 2000	20 children: 10 milk free; 10 milk consuming controls (all had adverse reaction to eggs)	Mean age 34 months (between 32-37 months) born in 1992 in Oslo, Norway	4 day weighed diet record	Mean macro- and micronutrient intakes with significant differences between milk and non-milk consumers: - energy - calcium - riboflavin - niacin. 2/10 children in milk free group and none in milk consuming group had a protein intake <1.5g /kg BW. Note: the EAR for protein intake by children aged 1-3 years is 0.92g/kg. 3/10 children in milk free and none in milk consuming groups had <20% energy from fat.

Author	Numbers	Age and other characteristics	Method	Results
Paganus *et al,* 1992	19 children with verified milk allergy, 12 age matched controls	Mean age 2 years (0.6-4.1 years) Sweden	Nutritional status was studied three times at three month intervals, dietary intake was recorded by 7 day diet record at second visit.	- Serum zinc most common biochemical index observed to be outside reference values (12/19 children) - Other biochemical measurements made were: serum protein, prealbumin, transferrin, ferritin, iron, calcium, phosphorus, zinc and alkaline phosphatase. Statistically lower intake between CMA and controls were: - protein g/day and g/kg bw/day - calcium - phosphorus - magnesium - zinc - riboflavin - niacin
Black *et al,* 2002	50 child milk avoiders,	3-10 years New Zealand	Food frequency questionnaire to measure calcium intake, body and bone mineral density measured by dual energy x-ray absorpiometry	- Dietary calcium intakes were low (443±230 SD mg/day) - Few children consumed substitute calcium rich drinks or supplements. Milk avoiders were: - shorter ($p<0.01$) - had smaller skeletons ($P<0.01$) - lower total body bone mineral content ($p<0.01$)

The vitamin/mineral that was most compromised across the study participants in all four studies was calcium; riboflavin intake was lower in allergy sufferers than in controls in two studies (Henrickon *et al*, 2000. Paganus *et al*, 1992).

Daily protein intake was significantly lower in children with allergies (mean 2.8g/kg body weight) compared to controls (mean 3.7g/kg body weight) in one study (Paganus *et al*, 1992), but another study found that 2 out of 10 children in the allergy group had protein intakes less than 1.5g/kg body weight compared to no children in the age matched controls (Hendrickson *et al*, 2000). No significant difference between protein intake of adult milk drinkers and avoiders was observed in the study by McGowan (1993). Christie *et al* (2002) did not report protein intake for their subjects.

The largest study was undertaken by Christie *et al* (2002). The 98 children with all types of food allergies had higher mean nutrient intakes than age-matched controls for energy, phosphorus, iron, vitamin C and folate. Moreover, a greater number of allergy sufferers exceeded 67% Dietary Reference Intakes (DRI) for these nutrients compared to controls. This suggests that allergy sufferers may take greater care with their diets to ensure a positive nutrient intake than non-allergy sufferers. This study also found that of 26 children with cows' milk allergy, 38% had calcium intakes below 67% DRI and 46% had vitamin D intakes below 67% DRI. FSANZ considers that intakes below 67% DRI are a reasonable approximation for the EAR for most micronutrients.

No other specific information about cows' milk allergy sufferers was given. Of those with cows' milk allergy who drank a fortified infant formula or fortified soy beverage, 91% exceeded their DRI for calcium and vitamin D.

3.3.2.2 Literature Review – Case Studies.

There have been several documented incidents of health complications and even death in infants inappropriately fed rice- and soy-based beverages. Three case studies have been described in the literature. One Australian infant[26] and two American infants (Carvalho *et al*, 2001) under the age of 18 months were fed cows' milk alternatives. The Australian infant died at 5 months of age after being fed rice-based beverage as its primary source of food. Of the American infants, one who drank fortified rice beverage and only small amounts of other plant foods presented to hospital with kwashiorkor, a form of severe protein malnutrition, and the other infant fed unfortified soy beverage presented with rickets.

The rice- based beverage fed to the Australian infant carried a label statement, to the effect that the product was not suitable as an infant formula[9]. Both the milk alternatives used in the American case studies also stated on the container that they were not intended for use as infant formulas. Carvalho *et al* (2001) additionally noted that neither of the products were labelled advising caution regarding use in toddlers. They reported that the well-educated parents had purchased a fortified product and incorrectly assumed because it was fortified that their infant was consuming a superior product when in fact the protein content of the rice-based beverage was low.

3.3.3 Conclusion

Milk is an important source of several vitamins and minerals. Non-dairy consumers are at increased risk of inadequate intakes of several nutrients, the extent of which appears to increase with age. The literature reports that adequate calcium intake is definitely compromised in the diets of children who avoid dairy products. Some studies also suggest that intakes of other vitamins and minerals are compromised although one study found that allergy sufferers had more adequate nutrient intakes than their age matched controls.

FSANZ previously proposed the option of permitting fortification of cereal-based beverages to the level found in dairy milk. The possibility exists that low protein cereal-based beverages might constitute a health risk for non-dairy consumers who assume that such beverages, especially fortified types, provide all the nutrients of dairy milk and thus they might not ensure adequate protein intakes from other food sources. From analysis of national nutrition surveys, average protein intakes of non-dairy consumers are lower, and prevalence of inadequate protein intakes are greater than the general population. The severity of this outcome increases with age, regardless of whether the diet includes milk alternatives, although the magnitude of the reduction in intake is relatively greater for younger age groups. Those non-dairy consumers who consume soy-based beverages but not those modelled to consume cereal-based beverages appear to have a higher average protein intake and a smaller prevalence of protein inadequacy than non-dairy consumers generally. Replacing soy-based beverages by cereal-based beverages in the diets of non-dairy consumers appears to have an adverse effect by moderately decreasing average protein intake and increasing prevalence of protein inadequacy.

[26] As quoted in the Melbourne Age, May 14, 2002.

The literature generally shows that intakes of nutrients ordinarily provided by dairy foods in the diets of non-dairy consumers were lower than for healthy controls and where measured were generally below relevant dietary reference values thus indicating inadequate intakes.

The case studies suggest that low protein intake resulting from a disproportionately high consumption of cereal-based beverages places children under 2 years of age at great risk to health.

Fat intake does not appear to be a concern for non-dairy consumers based on evidence drawn from estimated dietary intake assessment or the literature.

3.4 Nutrients Associated with Most Risk for Non-Dairy Consumers

Cereal-based beverages are a poor source of fat, protein, vitamins and minerals whereas dairy milk and other dairy foods are very important contributors of many nutrients to the diet. The following section looks at the risks of inadequate vitamin and mineral intake that could be mitigated by fortification of cereal-based beverages, and potential nutritional risks in relation to the low protein and lower fat composition of these products.

3.4.1 Calcium

The role of calcium in the diet involves: the protection of the calcium in the bones (Jones 1997); the regulation of cardiac and skeletal muscle contraction; the regulation of certain enzymes; assistance in nerve transmission (Wylie –Rosset and Swencionis, 1990).

Both the estimated dietary intake assessment and literature review showed that calcium is the micronutrient for which non-dairy consumers are most at risk of inadequacy. This is not surprising as dairy milk contributes between 33 and 51% of calcium intake as shown in Table 1. Dairy products such as cheese and yogurt are also important sources of dietary calcium.

Because calcium is not widely distributed across the food supply, and milk and other dairy foods are an excellent source of calcium, non-dairy consumers are more likely to be at risk of lower and inadequate calcium intakes than those who do consume dairy products.

3.4.2 Other Vitamins and Minerals

As discussed in section 3.1, dairy milk is a very important contributor to many vitamins and minerals in the diet. Other vitamins and minerals for which non-dairy consumers may be at risk of inadequacy are magnesium, zinc, vitamin A, riboflavin, vitamin B_6 and iodine.

Estimated dietary intakes shown in Table 3 suggests that non-dairy consumers aged 5 years and older are more at risk with respect to vitamin and mineral intake ordinarily provided by dairy foods compared with the 2-4 year age group. These results may indicate that carers of allergic children ensure that dairy food removed from the diet is replaced by nutritionally appropriate substitutes. It could also indicate that consumers in different age groups are avoiding dairy products for different reasons. As many young children grow out of dairy allergy, older non-dairy consumers could be avoiding dairy foods because they don't like them, or are vegan or perceive dairy products to be high in fat.

3.4.3 Protein

Protein is especially important in the diets of infants and children. Proteins are the basis of body tissues – cells, enzymes, antibodies and many hormones. Amino acids are the building blocks for proteins. Some amino acids can be synthesised in the body but others need to be supplied from the diet. During growth, the protein content of the body increases from about 15% at one year of age to 18% by four years of age, (Department of Health and Human Services, 1988). Protein requirements per kg body weight decreases with age until the age of 70 years when it increases. Requirements also increase during pregnancy and lactation. The major source of protein the diets of Australians and New Zealanders are meats, poultry and fish (about a 30%), cereals and cereal-based foods (about 25%), and dairy foods (about 15%).

The Applicant has requested that cereal-based beverages be permitted to contain added calcium if the protein content is higher than 0.5%. FSANZ notes however, that the protein content of these products can be as low as 0.3%. The Applicant claims that the protein content of cereal-based beverages is difficult to increase, and that low protein intake is not considered a public health problem in either New Zealand or Australia.

The Applicant considers that the lower protein levels in cereal-based beverages are unlikely to impact on the nutritional status of adult consumers considering that mean Australian and New Zealand protein intakes are significantly higher than physiological requirements (McLennan and Podger, 1999, Russell *et al*, 1999). While this is true for the general population, FSANZ needs to consider the nutritional status of those subgroups in the population who are unable to or choose not to consume dairy milk or soy-based beverages.

The Applicant considers that children who consume cereal-based beverages as a substitute for dairy milk or soy-based beverage, and thus who may be at risk of nutritional inadequacy, usually do so under dietetic or medical supervision for food allergy or intolerance.

According to the NNS, dairy milk is a very important contributor of protein for young children (Table 1). The Australian 1995 NNS shows that dairy milk contributed 22% of mean protein intake of children aged 2-4 years and 13% for children aged 5-15 years. The New Zealand NCS showed that dairy milk contributed 11% to the mean protein intakes of children aged 5-14 years.

The set of draft NHMRC EARs for protein is provided in Annex 1 to this report. The estimated dietary intake assessment in section 3.3.1.2 suggests a higher proportion of non-dairy consumers do not meet their requirements for protein compared with consumers who do eat dairy foods. Of the literature studies consulted, the results of two studies in children show a lower protein intake in dairy allergy sufferers than in controls, but none of the levels described were low enough to be of concern. The other two studies in children did not report protein intake. The study of adult milk avoiders showed no difference between their protein intake and those of controls.

Although the estimated dietary intake assessment suggests that the extent of the likely protein inadequacy is less prevalent in the younger groups, the effect of inadequate protein intake in growing children is more detrimental than inadequate protein intake in adults because of children's needs for growth and development. In addition, the avoidance of dairy products appears to have a relatively greater impact on protein intake and prevalence of inadequacy in children aged 2-14 years compared to those older than 15 years.

In addition, as discussed in section 3.3.2.2 there is case study evidence to suggest that some very young children aged under two years are being fed cereal-based beverages as a sole or primary source of food without medical or dietetic supervision and as a result have suffered severe protein deficiency or death. These cases occurred despite an advisory label statement to the effect that they were not suitable as a milk substitute for infants.

3.4.4 Fat

In infants, growth and tissue replacement requires 30% of energy intake compared to only 5% in adults. Thus, even a small energy deficit during this period of rapid growth in the first two years of life may affect growth rate. The Australian and New Zealand Dietary Guidelines suggest that reduced fat milks and skim milks with a fat content of no more than 2.5% are unsuitable as the main source of milk for children under two years of age. Because of this, FSANZ previously decided that low- and reduced-fat milk and comparable milk substitutes would be required to carry an advisory statement to enable carers of young children to make appropriate choices about the feeding of reduced-fat milks and milk alternatives to their children. As a result, Standard 1.2.3 requires milk and beverages made from soy and rice with fat contents of no more than 2.5% to carry an advisory statement to the effect that the product is not suitable as a complete milk food for children under the age of two years. The fat content of rice-based beverages ranges between 0.8 and 1.1%, which means that all rice-based beverages are required to carry the advisory statement. The fat content of oat-based beverages is 2.0% however they are a relatively new product on the market and were omitted from the labelling requirements for low-fat/fat-reduced milk and substitutes.

The estimated dietary intake assessment show that the mean percentage of energy from fat for children aged 2-4 years from Model 3 is 25%. Although this is lower than 30% suggested by dietary guidelines, a lower amount may not necessarily relate to an inadequate intake. The mean energy intake of this small group is quite high (6200 kJ) compared to an estimated energy requirement of 3200 –5500 kJ per day. The actual grams of fat provided by 25% of a higher energy intake of 6200 kJ is within the range of the grams of fat provided by 30% of the recommended energy intake of 3200 - 5500 kJ.

It is possible for diets to provide 20% energy from total fat that would meet all other nutrient requirements, but nutritional adequacy is more difficult below this level unless total energy intake is high. A lower bound for intakes of 20% energy from fat has been determined as appropriate in the draft Australia New Zealand nutrient reference values report. The average percent contribution in the estimated dietary intake assessment shows that the average contribution of energy from fat was 25-30% for all age groups.

3.4.5 Conclusion

Non-dairy consumers are at risk of inadequate intakes of protein and several vitamins and minerals provided by dairy foods. Although it appears that more care to achieve nutritional adequacy is taken with the diets of young children than older children and in turn adults, perhaps reflecting professional dietary advice, the consequences of such inadequacy are greater for the younger age groups because of the potential adverse effect on optimal growth and development. This risk is of greatest concern for young regular consumers of these products who are not under the care of a doctor or dietitian.

3.5 Risks from Consumption of Cereal-based Beverages according to Age Group

3.5.1 Infants and Toddlers Less than 2 Years of Age

Cereal-based beverages are a poor source of vitamins, minerals, protein and fat. With the exception of the case studies, there is no information pertaining to the dietary intake of children under the age of two years who do not consume dairy milk or soy-based beverages. An optimal nutrient intake including protein and fat is very important for infants and toddlers under two years of age because of growth and development needs. Risk management strategies including label advisory statements on some products, and access to dietary advice and special products are available for this group.

3.5.2 Young Children Aged 2-4 Years

There is no clear indication of the risk to non-dairy consumers and consumers of cereal-based beverages in this age group. Whilst the results of the estimated dietary intake assessment suggest that this age group has more balanced diet than older age groups (i.e. more likely to exceed the EAR for a variety of nutrients), perhaps as a result of receiving earlier dietary advice, the results of the literature review are mixed and inconclusive. The estimated dietary intake assessment suggest that while the younger age groups have more adequate protein intakes compared to those aged 15 year and older, the relative impact of avoiding dairy and soy foods is higher in children aged 2-4 years than for the older population. Protein is important for growth and development of this group. Dairy milk is a more important contributor to a variety of nutrients for this age group compared to the older groups.

3.5.3 Older Children 5-14 Years

There is little information on the risks to this age group of non-dairy consumers. The major focus of the literature is on the younger ages. Whilst information on the contribution of milk to nutrient intakes suggests that it is a less important food in this age group compared to the 2-4 year age group, the estimated dietary intake assessment in section 3.2 suggests that the vitamin and mineral intake in this age group is poorer than that of the younger group and that consumers of this age are less likely to exceed the EAR for a variety of vitamins and minerals. Older children have a more diverse diet and eat a larger variety of foods although they also have reached the age where they make some of their own dietary decisions including less nutritious foods, as perhaps indicated by the higher proportion whose protein intakes are inadequate compared with younger age groups. However, because this age group are still growing, the requirement for adequate protein to meet growth and development remains important.

3.5.4 Adolescents and Adults 15 Years and Older

Risks as a result of consuming cereal-based beverages for this age group are minimal. The more likely cause of compromised nutrient intake in this age group are overall poor dietary habits and not as a result of the consumption of a single product. Protein requirements are lower for this age group except for older adults.

Compared to the general population, all non-dairy consumers have lower intakes and greater prevalence of inadequacy of the nutrients ordinarily provided by dairy foods. Within the group of non-dairy consumers, including those who consume cereal-based beverages, the greatest risk of inadequate nutrient intake appears to be for those over the age of 15 years.

Although the nutritional quality of the diets of younger non-dairy consumers appears to be higher than for adults, the serious consequence of inadequate nutrient intakes to support growth and development is confined to the younger age groups. The replacement of dairy or soy-based beverage by cereal-based beverages has a relatively greater adverse impact on nutrient intakes of children than of adults.

Therefore children are identified as having a greater risk to health from inadequate protein, vitamin and mineral intakes, even though the likelihood of such health risks occurring is lower than for adults. The perception of fortified cereal-based beverages as nutritionally equivalent to dairy milk may heighten the risk in relation to protein.

4. Effect of Fortifying Cereal-Based Beverages

4.1 Increased Opportunity for Consumption of Vitamins and Minerals

4.1.1 Efficacy

Fortification of cereal-based beverages with either calcium alone or with other vitamins and minerals similar to the profile of dairy milk will provide individual users with a more nutritious milk replacement than a non-fortified cereal-based beverage.

Table 7 below shows the impact of fortifying cereal-based beverages with vitamins and minerals at concentrations equivalent to levels found in milk and permitted in Standard 1.3.2 for soy-based beverages (Model 6) and compared them against dietary vitamin and mineral intake of consumers of unfortified cereal-based beverage (Model 5).

Table 7: Estimated mean intakes and percent of consumers below the EAR for vitamins and minerals for Model 5 and Model 6, Australia, 2 years and older

	Model 5		Model 6	
Vitamin/Mineral	Mean	% of Consumers <EAR	Mean	% of Consumers <EAR
Calcium	407 mg	75	690 mg	35
Magnesium	347 mg	15	364 mg	15
Phosphorus	1,208 mg	3	1,426 mg	2
Zinc	9.6 mg	35	10.4 ug	30
Vitamin A	1,012 ug	25	1,170 ug	20

	Model 5		Model 6	
Vitamin/Mineral	Mean	% of Consumers <EAR	Mean	% of Consumers <EAR
Thiamin	1.7 mg	3	1.7 mg	2
Riboflavin	1.3 mg	35	1.8 mg	10
Folate	411 ug	2	333 ug	3
Vitamin B_6	1.7 mg	30	1.8 mg	25
Vitamin B_{12}	2.1 ug	45	3.2 ug	25
Vitamin D	1.5 ug	-	3.5 ug	-
Iodine	43 ug	95	46 ug	95

Note: information regarding consumer numbers assessed for each population group can be found in Table 2

The results in Table 7 indicate that consumption of a fortified cereal-based beverage would result in increased dietary intakes for all the vitamins and minerals listed above with the exception of folate where fortification appears to have a negative effect on both the mean intake and % consumers < EAR results. The explanation for this is based on the composition used for the unfortified cereal–based beverage. In Model 5, the folate concentration of the unfortified product (37 µg/100g) was based on a US product – Rice Dream, canned (USDA 2005). In Model 6, cereal-based beverages were assigned a folate concentration (6 µg/100g) based on the maximum permitted quantity of folate in Standard 1.3.2. Since a lower folate concentration was used for Model 6 than for Model 5, the estimated dietary folate intake decreased between the 'unfortified' and 'fortified' models.

4.1.2 Bioavailability

Bioavailability refers to the biological availability of a nutrient to the human body. This property can be influenced by many factors, making it a highly variable attribute of vitamins and minerals. Because of this variability, a wide variety of research techniques have been applied to the measurement of bioavailability. These techniques include balance studies of the vitamin or mineral, changes in serum or urine vitamin/mineral concentrations (where intake is reflected by these changes), the use of isotopic tracers, the effect of the vitamin or mineral on target body systems, and *in vitro* assessments (Heaney *et al*, 2001).

4.1.2.1 Bioavailability Issues Specific to Various Vitamins and Minerals

Two of the most heavily researched nutrients in respect to bioavailability are iron and calcium, and are thus perhaps two of the best examples of mineral bioavailability. These two examples show that regardless of their source, minerals cannot be fully absorbed by the intestine even during ideal conditions (Turnlund, 1991).

For example, balance and isotopic tracer studies have shown that maximum of 60% of ingested calcium can be absorbed during infancy, and this figure decreases with increasing age down to approximately 25% (excepting calcium uptake during pregnancy) (United States Institute of Medicine, 1997).

Additionally, any limitations in mineral bioavailability are unlikely to be due to the use of synthetic forms of these nutrients. In the case of iron, it is more often the quality of the overall diet that determines the bioavailability of consumed iron than the addition of iron salts to individual foods (Fairweather-Tait and Teucher, 2002). Recker *et al.* (1988) has also shown, through the use of isotopic tracers, that the use of a calcium salt in food (such as calcium carbonate) is as bioavailable as the form of calcium found in milk.

Compared to minerals, vitamins have fewer issues surrounding their bioavailability. Water-soluble vitamins are rarely affected by the food matrix, and are subject more to the physiological state of the consumer, or the presence of inhibitors and enhancers within a meal (Finglas, 2004). Fat-soluble vitamins are also affected little by the food matrix, although they do require the use of micelle carriers during digestion to be effectively available to the body. Thus, factors that can impact on the efficiency of micelle carriers (such as a low level of fat within a meal) may also have a negative effect on the bioavailability of fat-soluble vitamins (Fairweather-Tait and Southon, 2004).

4.1.2.2 The Variable Nature of Bioavailability

Current research has developed methods to account for the variable nature of vitamin and mineral bioavailability. However, a large degree of uncertainty still remains with any findings on vitamin and minerals bioavailability, as there are a wide variety of modifying factors that can confound results from scientific studies.

Confounding modifiers of bioavailability include the nutrient's release from the food matrix during digestion, physical interaction between other food components during digestion, and the form of the nutrient. There are also a number of host-related modifiers, including the host's nutritional status, developmental state, gastrointestinal secretions, mucosal cell regulation, and gut microflora (Fairweather-Tait and Southon, 2004). A major influence on bioavailability is also the interaction between foods within a meal.

Any assessment of vitamin and mineral bioavailability therefore must recognise that *in vitro* studies, and studies examining the fasting consumption of a single food, are unlikely to provide an accurate assessment of vitamin or mineral uptake and regulation within the body (Heaney 2001).

4.1.2.3 Bioavailability Specific to Cereal-Based Beverages

Only one study has been found that investigates the bioavailability of vitamins and minerals from cereal based beverages (Heaney *et al*, 2005). This study compared the bioavailability of calcium from fortified: rice beverage, soy beverages and orange juice compared to cows' milk. Fortification was evaluated by extrinsic labelling of each beverage with a calcium isotope followed by refrigeration and centrifugation. Beverages were allocated a score based on the amount of dissolved calcium and the activity of the precipitate. Milk scored the highest score of 99.5; the one rice beverage tested scored 90.1 with the three soy beverages scoring between 57.5 and 70.6.

This implies that the calcium in rice beverages fortified with tricalcium phosphate is relatively bioavailable. No studies have been undertaken to look at the bioavailability of any other nutrients in fortified cereal-based beverages.

4.1.3 Conclusion

The modelling data suggests that permission to fortify cereal-based products would address to some extent the risk of inadequate intake of a variety of vitamins and minerals for cereal-based beverage consumers who are non-dairy consumers.

Due to the large number of modifiers influencing bioavailability, especially those that may confound scientific research into this area, FSANZ cannot fully assess the bioavailability of vitamin and mineral additions to cereal-based beverages. From the limited assessment above, the addition of vitamins and minerals to cereal-based beverages is likely to be comparable to the bioavailability obtained from other food sources of these nutrients.

4.2 Safety

4.2.1 Risk of Excess Consumption

Fortification of cereal-based beverages to similar levels of vitamins and minerals found naturally in dairy milk poses the same risk as milk itself. This is unlikely to cause excess consumption of these micronutrients for regular consumers of cereal-based beverages because they are likely to be non-dairy consumers and at risk of inadequate intakes of vitamins and minerals ordinarily provided by dairy foods.

5. Conclusion

The dietary intake assessment and the studies in the literature suggest that many non-dairy consumers who also avoid soy-based beverages are at risk of nutritional inadequacy due to intakes below the EAR for those vitamins and minerals for which dairy milk makes a considerable contribution to the diets of the general population.

The fortification of cereal-based beverages to levels equivalent to dairy milk and already permitted in soy-based beverages containing at least 3% protein would give consumers of cereal-based beverages the same opportunities for vitamin and mineral intake from this beverage source as for consumers of dairy milk and fortified soy-based beverages, without likely threat to safety from higher than recommended intakes.

Dairy milk is an important dietary source of a variety of nutrients including protein for the general population. Whilst industry uptake of a permission to fortify cereal-based beverages will help increase the consumption of a variety of vitamins and minerals by those individuals who do not consume dairy foods or soy-based beverages, it will not address the potential risk of inadequate protein intake which appears to exist for a minority of non-dairy consumers and which may be heightened by promotion of a fortified cereal-based beverage. Although a greater proportion of adults appear to be at risk of inadequate protein intakes compared with children, this risk to health is more severe for the younger age groups because of their additional protein needs for growth and development.

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ANNEX

Table: Estimated Average Requirements (EAR) of protein (g/day) and (g/ kilogram body weight/ day).

Age	Sex	EAR
1-3 years	all	12 g/day (0.92g/kg)
4-8 years	all	16 g/day (0.73 g/kg)
9-13 years	boys	31 g/day (0.78 g/kg)
	girls	24 g/day (0.61 g/kg)
14-18 years	boys	49 g/day (0.76 g/kg)
	girls	35 g/day (0.62 g/kg)
19-70 years	men	52 g/day (0.68 g/kg)
	women	37 g/day (0.60 g/kg)
>70 years	men	65 g/day (0.86 g/kg)
	women[1]	46 g/day (0.75 g/kg)

[1]Additional requirements are necessary during pregnancy and lactation.

Attachment 3

Dietary Modelling Methodology Report

An Application was received from SoNatural Foods Australia requesting a new food category be included in the Code under Standard 1.3.2 – Vitamins & Minerals to enable the addition of calcium to beverages derived from cereals to a level of 240 mg per 200 mL reference quantity.

At Draft Assessment, FSANZ has proposed that the scope of the original Application be extended to consider the addition of other vitamins and minerals including calcium to cereal-based beverages, as permitted under Standard 1.3.2 for beverages derived from legumes. Application A500 is to be considered on the basis of nutritional equivalence, where cereal-based beverages are considered a substitute food for dairy milk, as determined in Section 4.5 of the Draft Assessment Report.

1. Dietary Intake Assessment Provided by the Applicant

The Applicant stated that population-based nutrition survey data have limited relevance for this Application due to considerably lower volumes of rice beverage being consumed (165,000 litres per month) in comparison to dairy milk (80 million litres per month). As such, the Applicant provided no estimates of dietary intakes for calcium, either prior to or after fortifying cereal-based beverages with calcium. Therefore, a dietary intake assessment was deemed necessary in order to determine the impact of allowing calcium and other vitamins and minerals to be added to cereal-based beverages.

2. Dietary Modelling

The dietary intake assessment was conducted using dietary modelling techniques that combine food consumption data with food nutrient concentration data to estimate the intake of the nutrient from the diet. The dietary intake assessment was conducted using FSANZ's dietary modelling computer program, DIAMOND.

Dietary intake = food nutrient concentration x food consumption

The intake was estimated by combining usual patterns of food consumption, as derived from NNS data, with existing or proposed levels of vitamins and minerals in foods.

2.1 Dietary Survey Data

DIAMOND contains dietary survey data for both Australia and New Zealand; the 1995 National Nutrition Survey (NNS) from Australia that surveyed 13,858 people aged 2 years and above, and the 1997 NNS from New Zealand that surveyed 4,636 people aged 15 years and above. Both of the NNSs used a 24-hour food recall methodology.

There was no consumption of cereal-based beverages reported in the Australian 1995 NNS, with only limited consumption of rice beverage being reported in the New Zealand 1997 NNS.

Consequently, consumption of legume-based beverages (i.e. soy beverages - unfortified and fortified), in conjunction with the limited consumption of cereal-based beverages, was used as a proxy for consumption of cereal-based beverages for dietary modelling purposes.

Consumers of dairy milk, dairy yoghurt, cream, dairy cheese, frozen and unfrozen dairy milk desserts, dairy spreads, butter, oil/cream base sauces or pizza were excluded from the dietary intake assessment for non-dairy respondents.

In addition, respondents consuming milk-based meal replacements, infant custards and yoghurts, cheese/cream dry mix sauces for Australia and roux for New Zealand were also excluded. In the context of this report, 'dairy' milk or 'dairy' products include both cow's milk and goat's milk and their products. These foods were excluded using the 4-digit number assigned to these food groups in the NNSs.

Conducting dietary modelling based on 1995 or 1997 NNS food consumption data provides the best estimate of actual consumption of a food and the resulting estimated intake of a nutrient. However, it should be noted that limitations exist within the NNS data. These limitations relate to the age of the data and the changes in eating patterns that may have occurred since the data were collected. Generally, consumption of staple foods such as fruit, vegetables, meat, dairy products and cereal products, which make up the majority of most people's diet, is unlikely to have changed markedly since 1995/1997 (Cook *et al*., 2001). However, there is uncertainty associated with the consumption of foods that may have changed in consumption since 1995 or 1997 or that have been introduced to the market since 1995/1997.

2.2 Additional Food Consumption Data or Other Relevant Data

No further information was required or identified for the purpose of refining the dietary intake estimates for this Application.

2.3 Scenarios for Dietary Modelling

Six models used for the purpose of assessing this Application.

2.3.1 'Model 1'

This model was conducted to determine baseline estimated mean protein intakes for all Australians aged 2 years and above (n=13,858) and all New Zealanders aged 15 years and above (n=4,636), regardless of what they consumed on the day of the NNS. It was also used to determine the percent contribution of dairy milk to estimated mean vitamin and mineral intakes.

2.3.2 'Model 2'

This model was conducted to determine baseline estimated protein intakes for non-dairy consumers and it includes those respondents who consumed a soy-based beverage (unfortified or fortified) on the day of the NNS and those who did not.

2.3.3 'Model 3'

This scenario model was conducted to determine baseline estimated mean vitamin and mineral intakes for non-dairy consumers and includes respondents who consumed an unfortified cereal-based beverage on the day of the NNS and those respondents who did not. It was also used to determine percent contribution of fat to total energy.

2.3.4 'Model 4'

This model was conducted to determine baseline estimated protein intakes for non-dairy consumers who consumed a soy-based beverage (unfortified or fortified) on the day of the NNS. Non-dairy consumers who did not consume a soy beverage on the day of the NNS were not included in this model.

2.3.5 'Model 5'

This scenario model was conducted to determine baseline estimated mean vitamin and mineral intakes for non-dairy consumers who consumed an unfortified cereal-based beverage on the day of the NNS. Non-dairy consumers who did not consume a cereal-based beverage on the day of the NNS were not included in this model. This model was also used to determine percent contribution of fat to total energy.

2.3.6 'Model 6'

This scenario model was conducted to determine estimated mean vitamin and mineral intake for non-dairy consumers who consumed a fortified cereal-based beverage on the day of the NNS. Non-dairy consumers who did not consume a cereal-based beverage on the day of the NNS were not included in this model. The nutrient composition of cereal-based beverages was based on Standard 1.3.2 of the Code and the Applicant's requested calcium level of 120 mg/100 mL.

2.4 Population Groups Assessed

The dietary intake assessments were conducted for the Australian and New Zealand populations. For 'model 1', 'model 2', and 'model 3', the dietary intake assessments were conducted for Australians aged 2 years and above, 2-4 years, 5-14 years and 15 years and above and those aged 15 years and above for New Zealand. Children aged 2-4 years were selected due to concerns regarding adequate protein intake to meet their growth requirements. The draft NHMRC nutrient reference values were used as a guide in selecting the other age groups to be assessed. For 'model 4', 'model 5', and 'model 6', the dietary intake assessments were conducted for Australians aged 2 years and above only.

It is important to note that, while the population groups assessed in 'model 5' and 'model 6' have been assessed as separate groups, these groups have also been assessed in the dietary intake assessments for 'model 1', 'model 2', and 'model 3'.

2.5 Vitamin and Mineral Concentration Levels

The vitamin and mineral levels in foods, as used in the nutrient intake assessments for the NNSs, were used in all models and included both naturally occurring and added levels of nutrients for the foods on the market at the time. Specific vitamin and mineral concentrations were also assigned to cereal-based beverages. The nutrient composition of unfortified cereal-based beverages was based on the US product Rice Dream, canned (USDA 2005). In the models including cereal-based beverages, only the concentrations for these products were altered from the NNS database values. All other foods retained nutrient concentrations as assigned in the NNSs.

2.5.1 'Model 1', 'Model 2' and 'Model 4'

For each of these models, each food was assigned a vitamin and mineral concentration from the NNS database.

2.5.2 'Model 3' and 'Model 5'

The macronutrient composition used for unfortified cereal-based beverages in this assessment was based on a weighted average of the composition of rice beverage to oat beverage in a ratio of 9:1, based on sales figures provided by the Applicant. The micronutrients were based on the nutrient composition of the US product Rice Dream, canned.

2.5.3 'Model 6'

The macronutrient composition used for fortified cereal-based beverages in this assessment was based on a weighted average of the composition of rice beverage and oat beverage in a ratio of 9:1, based on sales figures provided by the Applicant. Calcium was assigned a concentration of 120 mg/100 mL as requested by the Applicant. The remaining vitamins and minerals were assigned a nutrient composition based on the maximum permitted levels of vitamins and minerals in analogues derived from legumes (i.e. soy beverages) found in Standard 1.3.2 of the Code. Where maximum permitted levels were not stated, maximum claim levels were used instead.

The oat and rice beverages were matched to the most appropriate DIAMOND codes (soy-based beverages) for dietary modelling purposes. Vitamin and mineral concentrations were then assigned to some 4-digit food groups used in the Australia and New Zealand NNS (for example '1971' represents cereal-based beverages in the Australian 1995 NNS and '0861' represents cereal-based beverages in the New Zealand 1997 NNS) to take into account the nutrient composition of unfortified and fortified cereal-based beverages. This means that all soy-based beverages (unfortified and fortified) grouped under the code '1971' and '0861' were assigned the proposed vitamin and mineral concentration levels shown in Table 2.

Dietary iodine intakes were not assessed in the 1995 or 1997 NNSs. Therefore there were no iodine concentration data available for each food consumed in the NNS. However, iodine concentration data were available for a limited range of foods or food groups from survey data or food composition data. For Australia, the estimated dietary iodine intakes were based primarily on unpublished 22nd Australian Total Diet Survey (TDS) data. For New Zealand, the estimated dietary iodine intakes were based primarily on the data from the 1997/1998 and 2003/2004 New Zealand TDSs.

However, where data gaps existed in the Australian data, New Zealand data were used and vice versa. Where available, unpublished data from the Australian or New Zealand food composition program were also used. Where data gaps still existed, international food composition data (e.g. German and UK) were used. For Australia, iodine concentration data from the Application A493 – Iodine as a processing aid were also used. Dietary iodine intakes were estimated using a different methodology to that used for the other nutrients in this Application.

The vitamin and mineral concentrations used in this dietary intake assessment are listed in Table 1 below.

Table 1: Concentrations of vitamins and minerals in foods used in dietary intake assessments for the Australian and New Zealand populations

Food Group Code	Food Name	Vitamin/Mineral (Units)	Concentration Level	
			'Unfortified' Scenarios[^]	'Fortified' Scenario[↑]
1971[*], 0861[#]	Cereal-based beverages	Energy (kJ)	263	263
		Total Protein (g)	0.68	0.68
		Total Fat (g)	1.1	1.1
		Total Carbohydrate (g)	12.6	12.6
		Calcium (mg)	8	120
		Magnesium (mg)	4	11
		Phosphorus (mg)	14	100
		Zinc (mg)	0.1	0.4
		Vitamin A (µg)	0	62.5
		Thiamin (mg)	0.031	0.05
		Riboflavin (mg)	0.005	0.215
		Folate (µg)	37	6
		Vitamin B_6 (mg)	0.018	0.06
		Vitamin B_{12} (µg)	0	0.4
		Vitamin D (µg)	0.01	0.8
VD05413[@]	Cereal-based beverages	Iodine (µg)	0	0.075

[*] 1971 represents the DIAMOND food code for cereal-based beverages in the Australian 1995 NNS.
[#] 0861 represents the DIAMOND food code for cereal-based beverages in the New Zealand 1997 NNS.
[@] VD05413 represents the DIAMOND food code for cereal-based beverages in the Australian and New Zealand NNS.
^ 'Unfortified' scenarios refer to both 'model 3' and 'model 5'.
[↑] 'Fortified' scenario refers to 'model 6'.
Note: 1 milligram (mg) is equal to 1000 micrograms (µg)

2.6 How were the Estimated Dietary Exposures Calculated?

Two types of models in DIAMOND were used for the purpose of this Application. A nutrient intake model was used to estimate dietary intakes of macronutrients (energy, protein, fat and carbohydrate), calcium, magnesium, phosphorus, zinc, vitamin A, thiamin, riboflavin, folate, vitamin B_6, vitamin B_{12} and vitamin D. A chemical intake model was used to estimate dietary iodine intake.

2.6.1 All Vitamins and Minerals

Each individual's intake was calculated for each vitamin and mineral using his or her individual food records from the dietary survey. The DIAMOND program multiplies the specified concentration of the vitamin or mineral for a food by the amount of that food that an individual consumed in order to estimate the intake of the vitamin or mineral from each food. Once this has been completed for all of the foods containing the vitamin or mineral, the total intake of the vitamin or mineral from all foods is summed for each individual. Population statistics (mean) are then derived from the individuals' ranked intakes.

Where estimated intakes are expressed as a percentage of the reference health standard, each individual's total intake is calculated as a percentage of the reference health standard (using the total intakes in milligrams or micrograms per day), the results are then ranked, and population statistics derived.

2.6.2 Iodine Only

The food chemical model is based on raw commodity amounts. Food consumption amounts for each individual take into account where each food in a classification code is consumed alone and as an ingredient in mixed foods. For example, raw tomato eaten as a part of a salad, tomato in pasta sauce, and tomato paste are all included in the consumption of tomatoes. Where a higher-level food classification code (e.g. FI Tropical fruits – inedible peel) is given an iodine concentration, as well as a sub-category (e.g. FI0326 Avocado), the consumption of the foods in the sub-classification is not included in the higher-level classification code.

When a food is classified in two food groups (for example, mixed fruit juice may be entered in the apple and pear groups), and these food groups are assigned different iodine permissions, DIAMOND will assume the food is in the food group with the highest assigned iodine level to assume a worst case scenario. If the food groups have the same permitted iodine level, DIAMOND will assume the food is in the food group that appears first, based alpha-numerically on the DIAMOND food code.

In DIAMOND, all mixed foods have a recipe. Recipes are used to break down mixed foods into their raw commodity components (e.g. bread will be broken down to wheat flour, yeast, water etc). The data for consumption of the raw commodities are then used in models that assign iodine permissions to raw commodity classifications.

3. Assumptions in the Dietary Modelling

The aim of the dietary intake assessment was to make as realistic an estimate of dietary intake as possible. However, where significant uncertainties in the data exist, conservative assumptions were generally used to ensure that the dietary intake assessment did not underestimate intake.

Assumptions made in the dietary modelling include:

- where a permission is given to a food group code, all foods in that group contain vitamins and minerals at levels specified in Table 2;

- the nutrient databases from the NNSs are representative of the nutrient levels in foods that are currently on the market;
- for ‘model 3’ and ‘model 5’, cereal-based beverages have the same micronutrient composition as rice beverage regardless of whether a rice or oat beverage was consumed;
- consumption of foods as recorded in the NNS represent current food consumption patterns;
- cereal-based beverage consumers have the same food intake patterns as soy-beverage consumers, therefore soy-beverage consumption in the NNSs was used as a proxy for cereal-based beverage consumption;
- all cereal-based beverages will be fortified with each vitamin and mineral listed in Table 2 and at the concentration listed in Table 2 and that consumers always select fortified cereal-based beverages in ‘model 6’;
- consumers do not increase their consumption of foods/food groups upon foods/food groups containing added vitamins and minerals becoming available;
- all vitamins and minerals present in food are absorbed by the body;
- naturally occurring sources of vitamins and minerals and any fortified products on the market at the time of the NNSs have been included in the dietary intake assessment;
- where there were no Australian iodine data for specific food groups, it was assumed that New Zealand data were representative of these food groups, and vice versa for New Zealand;
- where there were no Australian or New Zealand data on iodine concentrations of food groups, it was assumed that overseas data were representative of these food groups;
- there are no reductions in vitamin and mineral concentrations during food preparation or due to cooking;
- for the purpose of this assessment, it was assumed that 1 millilitre is equal to 1 gram for all liquid and semi-liquid foods (e.g. milk, yoghurt);
- there was no consumption of iodine through discretionary salt use (since NNS did not measure discretionary salt use) or supplements;
- food manufacturers do not use iodised salt in their products. In a study by Gunton et al (Gunton *et al*., 1999), three major Australian food manufacturers of processed food were contacted and reported using only non-iodised salt.; and
- there was no contribution to vitamin and mineral intake through the use of complimentary medicines (Australia) or dietary supplements (New Zealand).

Most of these assumptions are likely to lead to conservative estimates for dietary vitamin and mineral intakes.

4. Limitations of the Dietary Modelling

A limitation of estimating dietary intake over a period of time associated with the dietary modelling is that only 24-hour dietary survey data were available, and these tend to over-estimate habitual food consumption amounts for high consumers. Therefore, predicted high percentile intakes are likely to be higher than actual high percentile intakes over a lifetime, and low percentile intakes are likely to be lower than actual intakes over a lifetime.

A second day of 24-hour recall food consumption data was available for approximately 10% of NNS respondents. These data can be used to adjust nutrient intakes to better estimate nutrient intakes over a longer period of time.

For second day adjusted nutrients intakes to be derived there must be an adequate number of consumers in order to derive a result that is reliable. Second day adjustments have little impact on estimated mean vitamin and mineral intakes (Rutishauser, 2000), but usually increase the estimated daily 5th percentile vitamin and mineral intakes and reduce estimated daily 95th percentile vitamin and mineral intakes. Second day nutrient adjustments were not conducted for the population groups in this assessment due to a lack of consumer numbers for some of the scenarios assessed.

There was no consumption of cereal-based beverages reported in the Australian 1995 NNS, with only limited consumption of rice beverage being reported in the New Zealand 1997 NNS. Consequently, consumption of legume-based beverages (i.e. soy beverages – unfortified and fortified), in conjunction with the limited consumption of cereal-based beverages, was used as a proxy for consumption of cereal-based beverages.

Over time, there may be changes to the ways in which manufacturers and retailers make foods and present them for sale. Since the data were collected for the Australian and New Zealand NNSs, there have been significant changes to the Code to allow more innovation in the food industry. As a consequence, another limitation of the dietary modelling is that some of the foods that are currently available in the food supply were either not available or were not as commonly available in 1995/1997. Since the data were collected for the NNSs, there has been an increase in the range of products that are fortified with nutrients. Consequently, the nutrient databases from the NNSs are not entirely representative of the nutrient levels in some foods that are now on the market.

The information on the use of complimentary medicines (Australia) or dietary supplements (New Zealand) from the NNSs was either not detailed enough or not available in DIAMOND. Consequently, these could not be included in the dietary intake assessments.

While the results of national nutrition surveys can be used to describe the usual intake of groups of people, they cannot be used to describe the usual intake of an individual (Rutishauser, 2000). In particular, they cannot be used to predict how consumers will change their eating patterns as a result of an external influence such as the availability of a new type of food.

FSANZ does not apply statistical population weights to each individual in the NNSs in order to make the data representative of the population. This prevents distortion of actual food consumption amounts that may result in an unrealistic intake estimate. Maori and Pacific Islanders were over-sampled in the 1997 NNS so that statistically valid assessments could be made for these population groups. As a result, there may be bias towards these population groups in the dietary exposure assessment because population weights were not used.

5. Results

All the dietary modelling results can be found in the Nutrition Assessment Report at Attachment 2.

Detailed estimated dietary intakes from 'model 3', 'model 5' and 'model 6' can be found in Appendix 1 (A1.1 and A1.2) of this report.

6. Risk Characterisation

In order to determine if the level of intake of vitamins and minerals is likely to be a public health and safety concern, the estimated dietary intakes were compared against an EAR for each vitamin and mineral. An EAR is "the median usual intake estimated to meet the requirement of half the healthy individuals in a life stage/gender group" (NHMRC, 2004). Since EARs have not been formally established for the Australian and New Zealand populations, overseas EARs set by the US (United States Institute of Medicine, 1998; United States Institute of Medicine, 2000; United States Institute of Medicine, 2001) and the UK (United Kingdom Department of Health, 1993) were used. Vitamin D was not compared against an EAR as no overseas EAR has been set.

6.1 Comparison of the Estimated Dietary Intakes with the Reference Health Standard

The estimated dietary intakes for vitamins and minerals, as compared to EAR, are shown in Tables A1.3 and A1.4 of Appendix 1 for the Australian and New Zealand population groups assessed.

When estimated mean dietary intakes are compared against the EAR, there are some consumers with estimated dietary intakes below the EAR for each vitamin and mineral assessed. Due to such small consumer numbers for some population sub groups and the fact that second day adjustments were not done, care needs to be taken in the interpretation of these results, as they may not accurately reflect longer-term nutrient intakes. This caution is more relevant where there were only a small percentage of consumers under the EAR. Where there were a large percentage of consumers under the EAR, this is indicative that, in reality, there would be some people with inadequate nutrient intakes.

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Appendix 1

Complete Information on Dietary Intake Assessment Results

Table A1.1: Estimated mean dietary intakes of vitamins and minerals for 'model 3' in the Australian and New Zealand populations

Vitamin/Mineral	Country	Population Group	Mean Intake
Protein (g/day)	Australia	2 years and above	71
		2-4 years	43*
		5-14 years	57
		15 years and above	74
	New Zealand	15 years and above	68
Total fat (g/day)	Australia	2 years and above	64
		2-4 years	44*
		5-14 years	59
		15 years and above	65
	New Zealand	15 years and above	70
Total carbohydrate (g/day)	Australia	2 years and above	223
		2-4 years	231*
		5-14 years	236
		15 years and above	220
	New Zealand	15 years and above	222
Energy (kJ/day)	Australia	2 years and above	7,700
		2-4 years	6,200*
		5-14 years	7,100
		15 years and above	7,820
	New Zealand	15 years and above	7,770
Calcium (mg/day)	Australia	2 years and above	337
		2-4 years	231*
		5-14 years	296
		15 years and above	346
	New Zealand	15 years and above	329
Magnesium (mg/day)	Australia	2 years and above	251
		2-4 years	144*
		5-14 years	186
		15 years and above	264
	New Zealand	15 years and above	245
Phosphorus (mg/day)	Australia	2 years and above	1,045
		2-4 years	643*
		5-14 years	823
		15 years and above	1,088
	New Zealand	15 years and above	1,008

Vitamin/Mineral	Country	Population Group	Mean Intake
Zinc (mg/day)	Australia	2 years and above	9.7
		2-4 years	4.9*
		5-14 years	7.5
		15 years and above	10.1
	New Zealand	15 years and above	10.0
Vitamin A (µg/day)	Australia	2 years and above	1,010
		2-4 years	326*
		5-14 years	553
		15 years and above	1,095
	New Zealand	15 years and above	759
Thiamin (mg/day)	Australia	2 years and above	1.3
		2-4 years	1.0*
		5-14 years	1.2
		15 years and above	1.4
	New Zealand	15 years and above	1.0
Riboflavin (mg/day)	Australia	2 years and above	1.2
		2-4 years	0.8*
		5-14 years	1.0
		15 years and above	1.3
	New Zealand	15 years and above	1.0
Folate (µg/day)	Australia	2 years and above	240
		2-4 years	160*
		5-14 years	181
		15 years and above	251
	New Zealand	15 years and above	187
Vitamin B_6 (mg/day)	Australia	2 years and above	1.2
		2-4 years	0.9*
		5-14 years	0.9
		15 years and above	1.3
	New Zealand	15 years and above	1.1
Vitamin B_{12} (µg/day)	Australia	2 years and above	4.1
		2-4 years	2.2*
		5-14 years	2.4
		15 years and above	4.4
	New Zealand	15 years and above	3.7
Vitamin D (µg/day)	Australia	2 years and above	1.6
		2-4 years	0.7*
		5-14 years	1.3
		15 years and above	1.6
	New Zealand	15 years and above	2.0
Iodine (µg/day)	Australia	2 years and above	50

Vitamin/Mineral	Country	Population Group	Mean Intake
		2-4 years	48*
		5-14 years	46
		15 years and above	50
	New Zealand	15 years and above	44

Total number of respondents for Australia: whole population = 13,858, 2-4 years = 583, 5-14 years = 1,844, 15 years and above = 11,431; New Zealand: whole population = 4,636. Respondents include all members of the survey population whether or not they consumed dairy products.
Total number of consumers for Australia: 2 years and above = 734, 2-4 years = 12, 5-15 years = 99, 15 years and above = 623; New Zealand: 15 years and above = 205. Consumers only – This only includes the people who have not consumed 'dairy products'.
* Note: these figures are to be used as a guide only due to the small consumers in this population group (n=12).

Table A1.2: Estimated mean dietary intakes of vitamins and minerals for 'Model 5' and 'Model 6' for the Australian population aged 2 years and above

			Estimated Mean Intake	
Country	Population Group (n=60)	Vitamin/Mineral	'Model 5' Unfortified	'Model 6' Fortified
Australia	2 years and above	Protein (g/day)	70	70
		Total, fat (g/day)	61	61
		Total, carbohydrate (g/day)	269	269
		Energy (kJ/day)	8,115	8,115
		Calcium (mg/day)	407	690
		Magnesium (mg/day)	347	364
		Phosphorus (mg/day)	1,208	1,426
		Zinc (mg/day)	9.6	10.4
		Vitamin A (µg/day)	1,012	1,170
		Thiamin (mg/day)	1.7	1.7
		Riboflavin (mg/day)	1.3	1.8
		Folate (µg/day)	411	333
		Vitamin B_6 (mg/day)	1.7	1.8
		Vitamin B_{12} (µg/day)	2.1	3.2
		Vitamin D (µg/day)	1.5	3.5
		Iodine (µg/day)	43	46

Table A1.3: Number and percent of 'Model 3' consumers with dietary vitamin or mineral intakes below the EAR for the Australian and New Zealand populations

			Non-Dairy Consumers#	
Vitamin/Mineral	**Country**	**Population Group**	**No. consumers <EAR**	**% of Consumers < EAR**
Calcium	Australia	2 years and above	629	85
		2-4 years	10	85*
		5-14 years	82	85
		15 years and above	537	85
	New Zealand	15 years and above	183	90
Magnesium	Australia	2 years and above	335	45
		2-4 years	2	15*
		5-14 years	49	50
		15 years and above	284	45
	New Zealand	15 years and above	117	55
Phosphorus	Australia	2 years and above	51	7
		2-4 years	1	8*
		5-14 years	10	10
		15 years and above	40	6
	New Zealand	15 years and above	26	15
Zinc	Australia	2 years and above	332	45
		2-4 years	1	8*
		5-14 years	34	35
		15 years and above	297	50
	New Zealand	15 years and above	100	50
Vitamin A	Australia	2 years and above	354	50
		2-4 years	6	50*
		5-14 years	49	50
		15 years and above	299	50
	New Zealand	15 years and above	116	55
Thiamin	Australia	2 years and above	176	25
		2-4 years	1	8*
		5-14 years	13	15
		15 years and above	162	25
	New Zealand	15 years and above	46	20
Riboflavin	Australia	2 years and above	374	50
		2-4 years	3	25*
		5-14 years	52	55
		15 years and above	319	50
	New Zealand	15 years and above	125	60

			Non-Dairy Consumers#	
Vitamin/Mineral	**Country**	**Population Group**	**No. consumers <EAR**	**% of Consumers < EAR**
Folate	Australia	2 years and above	193	25
		2-4 years	2	15*
		5-14 years	31	30
		15 years and above	160	25
	New Zealand	15 years and above	81	40
Vitamin B_6	Australia	2 years and above	386	55
		2-4 years	4	35*
		5-14 years	42	40
		15 years and above	340	55
	New Zealand	15 years and above	116	55
Vitamin B_{12}	Australia	2 years and above	238	30
		2-4 years	3	25*
		5-14 years	26	25
		15 years and above	209	35
	New Zealand	15 years and above	70	35
Iodine	Australia	2 years and above	653	90
		2-4 years	9	75*
		5-14 years	84	85
		15 years and above	560	90
	New Zealand	15 years and above	188	90

Total number of consumers for Australia: 2 years and above = 734, 2-4 years = 12, 5-14 years = 99, 15 years and above = 623; New Zealand: 15 years and above =205.

[#] Consumers only – This only includes respondents who have not consumed any 'dairy products'.

[*] Note: these figures are to be used as a guide only due to the small consumers in this population group (n=12).

Table A1.4: Number and percent of 'Model 5' and 'Model 6' consumers with dietary vitamin or mineral intakes below the EAR for the Australian population aged 2 years and above

			'Model 5' Unfortified		'Model 6' Fortified	
Country	Population Group (n=60)	Vitamin/Mineral	No. of consumers < EAR	% of consumers <EAR	No. of consumers <EAR	% of consumers <EAR
Australia	2 years and above	Calcium	44	75	22	35
		Magnesium	9	15	8	15
		Phosphorus	2	3	1	2
		Zinc	21	35	17	30
		Vitamin A	16	25	11	20
		Thiamin	2	3	1	2
		Riboflavin	22	35	7	10
		Folate	1	2	2	3
		Vitamin B_6	19	30	15	25
		Vitamin B_{12}	27	45	15	25
		Iodine	57	95	56	95

Attachment 4

Summary of Submissions

FSANZ received 13 submissions in response to the Initial Assessment Report on Application A500 – Addition of Calcium to Cereal-based Beverages, during the 6-week public consultation period of 16 June to 28 July 2004. A summary of submitter comments is provided in the table below.

One late submission was received from the Nutrition Department of the Royal Children's Hospital, however, these comments have not been included in the table below.

Two regulatory options were presented in the Initial Assessment Report:

Option 1 – Maintain Status Quo; and

Option 2 – Amend Standard 1.3.2 to permit the voluntary addition of calcium to cereal-based beverages equal to the level permitted for beverages derived from legumes.

	Submitter	Submission Comments
1	**Allergy New Zealand** **Sara-Jane Murison**	**Supports Option 2** ***Substitute Food and Nutritional Equivalence*** • Cereal-based beverages, especially rice milk, are commonly used as a cow's milk substitute for people with cow's milk allergy. ***Labelling*** • An advisory statement regarding the low fat and protein content would be beneficial, to alert those with cow's milk allergy who have not received specific nutritional assessment and advice. • Support including advice on packaging that those eliminating foods from their diet should seek medical advice. ***Responses from Allergy New Zealand members to selected questions raised in the Initial Assessment Report*** Fifteen responses from members on email who have a self-reported allergy or intolerance to cow's milk. *How are cereal-based beverages consumed?* • 14 responses

	Submitter	Submission Comments
		• As a cow's milk and soy milk substitute. • General uses – on breakfast cereal, as a beverage (hot and cold), in fruit smoothies, and in baking and cooking. • One mother uses rice milk as "a top up between breast milk" for her one year old son. • Many report using calcium fortified products. *Who is drinking cereal-based beverages? What is the age profile of these consumers?* • 14 responses • Many parent-child combinations using soy or cereal-based milk alternatives. • 15/23 aged less than 8 years • 8/23 aged between 32-60 years *Should FSANZ permit the voluntary addition of other relevant vitamins and minerals to cereal-based beverages equal to levels based on cow's milk content?* • 14 responses • 11/14 in favour, 2/14 against and 1/14 unsure • Those not in favour had children with multiple food allergies, and have concerns regarding the source of the vitamins and minerals (i.e. do not want vitamins and minerals from legume, shellfish or gluten sources). They generally preferred to use dietary supplements instead. • Some were in favour as long as the additions are safe and beneficial for the consumer. • Two members perceive the cost of cereal-based beverages manufactured in New Zealand and Australia would be less, compared with imported products from the US. *Should fortified cereal-based beverages be required to carry an advisory statement that alerts consumers to the fact the product is low in protein?* • 15 responses • 11/15 in favour and 3/15 felt this was not necessary • Those that felt this was not necessary commented "people who buy these products normally read labels and understand the nutritional content of foods well", and "if they have to use a substitute they are usually doing so under the supervision of a dietitian or health professional". • One in favour felt labelling to the effect of "isn't suitable as a complete food for under 2's" would be beneficial. *Should unfortified cereal-based beverages also be required to carry an advisory statement that alerts consumers to the fact the product is low in protein?* • 14 responses • 11/15 in favour and 3/15 felt this was not necessary

	Submitter	Submission Comments
		• Two that felt it was not necessary commented "if the fortified had to then the unfortified should too" and "all products should meet the same standards regarding advisory statements". *Should the statement also include a recommendation that consumers seek medical advice on the use of this product?* • 13 responses • 6/13 in favour and 7/13 either replied no or not necessary • General comments of "most people who have an allergy are read up on the subject or under a dietitian for advice", "no…they would be well aware of their needs", and "consumers should take responsibility too and seek a dietitian anyway if their children are on a strict diet with allergies". *Could the presence of a 'calcium content' claim on cereal-based beverages mislead consumers into believing these products are nutritionally equivalent to milk?* • 12 responses • 2/12 agreed this could be misleading, 2/12 replied "possibly" and 8/12 said a content claim would not be misleading. • Two felt a content claim was not necessary if the amount of calcium was disclosed as part of the nutrition information panel. *Will consumers make use of this additional/alternative choice of calcium containing products in the food supply?* • 15 responses • 13/15 in favour, 1/15 against and 1/15 replied "possibly". • The member against adding calcium wrote "no please don't put additional calcium in the rice milk or oats as most additives are legume based", as her son has both dairy and soy allergies. *What is the size of the cereal-based beverage market in Australia and New Zealand? Are these products readily available?* • 10 responses • Readily available from New Zealand supermarkets in large centres, though not as readily available in smaller towns. • No data for Australia, as all responses from New Zealanders. *How many people allergic/intolerant to cow's milk use calcium-fortified soy beverages?* • 10 responses • 5/10 use calcium fortified soy milk, 1/10 not at present as her child is still using formula, and 4/10 don't use these products as their children are also allergic to soy.

	Submitter	Submission Comments
2	**Australian Food and Grocery Council** **Tony Downer**	**Supports Option 2 with adaptations** ***Substitute Food and Nutritional Equivalence*** • Agrees that cereal-based beverages meet the definition of a substitute food for cow's milk, but not for nutritional equivalence. ***Labelling*** • Considers labelling statements or information/education campaigns are relevant for all cereal-based beverages, not just those that contain added vitamins or minerals. ***Population Groups at Risk*** • Considers the addition of calcium to cereal-based beverages will have "little or no impact" on consumer subgroups. • Comment regarding evidence of children fed cereal-based beverages without medical or dietetic supervision and becoming severely nutritionally compromised, as per the IAR – "Although not having read the article, the AFGC considers it unlikely that it was the consumption of cereal-based beverages alone that caused the problem". ***Addition of other Vitamins and Minerals*** • Considers it "logical" to consider extending the application to allow voluntary addition of other vitamins and minerals to cereal-based beverages. • Recommend FSANZ also consider "reverse equivalence", i.e. if soy beverages or cereal-based beverages naturally contain any vitamins or minerals at higher levels than that found in milk, then their addition to milk should be permitted. ***Other Comments*** • Considers that "there will be very few soy beverages on the market that contain added thiamine, B_6, folate, magnesium or zinc, as FSANZ does not permit a claim to be made for their presence". • Would like the statement "cereal-based beverages…either for health or philosophical reasons", 4.1 of the Initial Assessment Report, be changed to incorporate those who are allergic/intolerant to dairy but not soy who choose to consume cereal-based beverages as a milk substitute. Thus, "…allergic/intolerant to dairy and/or soy foods…" • Would like FSANZ to comment further on the nature of overseas provisions regarding fortified rice beverages.

	Submitter	Submission Comments
3	**Ceres Natural Foods Pty Limited** **Leigh Carlson**	**Supports Option 2** ***Consumer Characteristics*** • Anecdotally, cereal-based beverages are used as a substitute for cow's milk on cereal, in cooking and as a drink. • Consumers are either lactose intolerant and/or soy intolerant, or are health conscious and looking for a reduced saturated fat product. • Not aware of any empirical evidence that consumers of cereal-based beverages have inadequate protein or micronutrient intakes. ***Market Characteristics*** • Estimates approximately 60% of soy beverages on the market contain added forms of permitted micronutrients. • Estimates the size of the cereal-based beverage market in Australia and New Zealand to be approximately 6 million litres annually. • Believes they are "greatly" disadvantaged by the current discrepancy between Australian and New Zealand regulations, as they "cannot compete against other manufacturers". • Reports that little product coming into Australia is manufactured in or imported from New Zealand. • Expects growth of the calcium fortified product market to be approximately 30%. ***Manufacturer's Perspective*** • Believes commercial decision and consumer acceptance of taste and ingredients will be the decisive factors, as to the likelihood of manufacturers voluntarily adding the permitted micronutrients. • Pureharvest expects that consumers will make use of fortified products, as suggested by their customers via the company's Customer Service communications. ***Labelling*** • Support the use of advisory statements that alert consumers that both fortified and unfortified cereal-based beverages are low in protein. • Consider a medical advice warning is necessary for vulnerable groups, e.g. infants or someone following a very restricted diet. However, does not consider seeking medical advice is necessary when cereal-based beverages are used as part of a mixed diet. • Does not believe a 'calcium content' claim would mislead consumers to believe the product is nutritionally equivalent to milk, unless it was supported with other statements on the packet. • Support that Clause 2 of Standard 1.2.3 be extended to apply to all cereal-based beverages that contain less than 2.5% fat. ***Addition of other Vitamins and Minerals*** • Does not believe permitting the addition of calcium without also permitting other significant micronutrients would mislead or deceive the consumer as to the nutritional merit of cereal-based beverages. • Agree that addition of other vitamins and minerals to cereal-based beverages should also be permitted, equal to levels found in cow's milk. ***Other Comments*** • Reports the bioavailability of calcium salts in their cereal-based beverages is "high".

	Submitter	Submission Comments
4	**Dairy Australia** **Janine Cornel**	**Supports Option 1** ***Substitute Food and Nutritional Equivalence*** • Cereal-based beverages are not a substitute for milk, and should not be allowed to be fortified with calcium to grant them this status. • 'Substitute foods' must first satisfy the definition for 'nutritional equivalence' before being allowed to add specific vitamins or minerals. • Consumers may be mislead by the milk-like nature of cereal-based beverages believing them to be nutritionally equivalent to cow's milk, particularly if the word 'milk' appears in the product title. • If the protein level is set at >0.3% this will set a precedent for future applications, and defeats the purpose of having 'qualifying' nutritional criteria. ***Labelling*** • Stated the definition of 'milk', as per Standard 2.5.1, does not incorporate beverages derived from cereals. • Promote the use of labelling to avoid inappropriate consumption of cereal-based beverages, regardless of whether the product is fortified or not. • Excluding 'milk' from the product title would be a measure to prevent consumption by non-target audiences and/or in adequate amounts. • Suggest Standard 1.2.3 be amended to include all relevant cereal-based beverages, therefore requiring an advisory statement acknowledging the product is not suitable as a complete milk food for infants. • Mandatory warning statements (Standard 1.1A.5) for modified milks should also apply to cereal derived beverages, stating that the product is not suitable for infants except on medical advice. ***Addition of other Vitamins and Minerals*** • Concern regarding the low levels of other micronutrients in cereal-based beverages, and the potential impact on diet quality and overall dietary status. ***Source of Calcium and Bioavailability*** • Dairy Australia would like clarification on the proposed source of calcium, and its bioavailability and efficacy in cereal-based beverages. ***Cited Research*** *Evidence of nutritional deficiency secondary to cow's milk substitutes:* • Carvalho et al (2001) – 13 month old infant developed kwashiorkor after consuming 72% total energy from a rice beverage. The parents had inferred from the label and the use of the word 'milk' that the product was nutritionally equivalent to cow's milk. *Impact of excluding milk from the diet:* • Black et al (2002) – Found milk-avoiders had a lower average calcium intake, were shorter, had smaller bones and a lower bone mineral density, than the milk-drinkers. • Goulding et al (2004) – Found a significant association between the avoidance of cow's milk and fractures.

	Submitter	Submission Comments
		Dairy consumption associated with improved nutritional quality of the diet: • Substitution of dairy foods with calcium fortified foods that are not nutritionally equivalent increases the risk of inadequate intakes of other nutrients (e.g. riboflavin, magnesium and zinc). • Ballew et al (2000) – Milk consumption is positively associated with children achieving the recommended intakes of vitamin A, folate, vitamin B12, calcium and magnesium. • Parsons et al (1997) – Use of a macrobiotic diet in early childhood negatively influences adjusted bone mass at age 9-15 years. ***Other Comments*** • Recommend "FSANZ should first consider the wider addition of vitamins and minerals to foods and review Standard 1.3.2 in total, to correct for major discrepancies between food groups".
5	**Dietitians Association of Australia** **Ruth Kharis**	**Supports Option 1** ***Substitute Food and Nutritional Equivalence*** • Cow's milk is an appropriate reference food for milk substitutes. • Cereal-based beverages are not nutritionally equivalent to cow's milk. • Cereal-based beverages fortified with calcium alone would not be nutritionally equivalent. • Voluntary fortification of foods should only be permitted where the substitute food is 'nutritionally equivalent' to the primary food. ***Labelling*** • If labelled as "milk" this may deceive some customers into believing the products are nutritional substitutes for cow's milk. • Recommends that cereal-based beverages be "forbidden" to use the word "milk". • Recommends that current products available should carry an advisory statement such as "these products are not suitable substitutes for milk". ***Population Groups at Risk*** • Considers weaned infants and small children with a past history of dairy and soy allergies most at risk, where the proposed product would not be a suitable alternative. • Concern that some parents may unnecessarily continue dairy and soy restrictions into childhood, without proper medical supervision, and thus increase the risk of nutritional deficiencies in their children. ***Addition of other Vitamins and Minerals*** • Nutritionally equivalent products should be available, to allow choice for consumers. • If only calcium is added, this ignores other important nutrients such as protein, riboflavin and vitamins A, D and B_{12}. ***Other Comments*** If cereal-based beverages were fortified with macro and micronutrients to the nutritional equivalence of milk, then the DAA would reconsider its position.

	Submitter	Submission Comments
6	**Environmental Health Unit of Queensland Health** **Gary Bielby**	**Supports Option 2** Considers it "appropriate and prudent" that cereal-based beverages be fortified with calcium. ***Substitute Food and Nutritional Equivalence*** • Cereal-based beverages do not meet the criteria for nutritional equivalence, due to their low protein content and lower quality micronutrient profile compared with cow's milk. ***Labelling*** • Supports use of an advisory statement to alert consumers of the low protein and micronutrient content, if the cereal-based beverages do not have to be nutritionally equivalent. • Believes a recommendation that consumers seek medical advice should accompany the advisory statement. ***Population Groups at Risk*** • The addition of calcium to cereal-based beverages has the potential to increase the calcium intake of population subgroups (e.g. vegans), who choose not to or who are unable to consume cow, goat or soy based beverages. • Anticipate the addition of calcium to have very little nutritional impact on the general population. ***Addition of other Vitamins and Minerals*** • Permitting the addition of calcium to cereal-based beverages, without also permitting other significant micronutrients found in cow's milk, is "likely to misled or deceive consumers as to the nutritional merit of cereal-based beverages". Particularly where cereal-based beverages use the word 'milk' in their product title. ***Other Comments*** • Believes the addition of calcium to cereal-based beverages has the potential to reduce the public health costs associated with osteoporosis, fractures and other conditions associated with inadequate calcium intake.

	Submitter	Submission Comments
7	**Fonterra Co-operative Group Limited** **Joan Wright**	**Option Supported Not Specified** Fonterra would like the wider issue of adding vitamins and minerals to foods to be considered. Before processing A500, they would prefer Standard 1.3.2 to be reviewed in total, commenting "there are major differences in current allowances for the addition of vitamins and minerals to different food groups". ***Substitute Food and Nutritional Equivalence*** • Believe "rice liquid" should not be viewed as a milk substitute. • Consumers see milk as a staple in their diet and any substitute food must have nutritional equivalence. • Rice milk does not contain the same amount and quality of protein, and is also lower in calcium, vitamin A and vitamin D compared with cow's milk, and is therefore only akin in appearance. • The quality of the protein from these plant sources is of specific concern. • Support that "substitute foods should satisfy the definition for nutritional equivalence before permitting the addition of relevant added vitamins and minerals". ***Labelling*** • If labelled as 'milk' consumers may assume it has an equivalent protein content to cow's milk, and could lead to risks for the consumer. • Labelling these products as low in protein "may be of some value". However, they state that "not all people will understand the significance of such statements unless the labelling explicitly identifies the risks", where risks are unlikely to be "adequately communicated by labelling". ***Population Groups at Risk*** • Consider children who consume cereal-based beverages at risk of "significant nutritional deficiencies", if their parents believe they are receiving the equivalent protein from a plant based source as from a dairy based product.
8	**Food Technology Association of Victoria Inc.** **David Gill**	**Supports Option 2** ***Support option 2, however raised the following issues:*** • A health and safety issue may exist if these cereal-based beverages are marketed and purported to be acceptable substitutes for cow's milk, but do not contain the same protein or other micronutrient levels as naturally present in milk. • The above comment was raised based on the Applicant's described purpose "to provide a suitably nutritious milk alternative for consumers….". • The source of calcium should be stated and those permitted calcium sources with the highest rates of absorption should be used, to ensure the efficacy of the fortification. • Suggest that the Standard 1.1A.6 be amended to "require fortification with other nutrients as well as calcium for the New Zealand manufactured products".

	Submitter	Submission Comments
9	**Manufactured Food Database, Auckland City Hospital** **Lyn Gillanders/ Alannah Steeper**	**Option Supported Not Specified** ***Population Groups at Risk*** • Potential risk to children using these cereal-based beverages due to their low protein and micronutrient content. • Perceived minimal risk to adults who include cereal-based beverages as part of a varied diet, compared to infants and children. ***Protein and micronutrient intakes of New Zealander's*** *Cited important findings of the 2002 National Children's Nutrition Survey:* • 38% of New Zealand children reported drinking milk daily, 34% weekly and 17% less than monthly or never. • 59% consumed a milk-based food drink weekly. • Milk and milk products were significant sources of phosphorus, zinc, calcium, riboflavin, retinol and protein for New Zealand children. • No data available for children under five years old, where milk and milk products would contribute a higher proportion of these nutrients in this age group. Thus children in this age group that consume rice milk as a substitute for milk may be at risk of "nutritional inadequacy" ***Labelling*** • Supports use of an advisory statement that "cereal-based beverages are not a milk substitute for infants and children". • Supports the recommendation for consumers to seek medical or dietetic advice on the use of these products, if they are to be consumed by infants and children. ***Addition of other Vitamins and Minerals*** • Believes that permitting the addition of calcium to cereal-based beverages without other significant micronutrients and protein has the potential to deceive or mislead the consumer as to the nutritional merit of cereal-based beverages.
10	**New Zealand Dairy Foods** **Hamish Conway**	**Support Option 2** ***Substitute Food and Nutritional Equivalence*** • Cereal-based beverages are not nutritionally equivalent to cows' milk. • These products are used as a milk alternative, and subsequently consumers should be aware that they do not have the same nutritional profile. ***Labelling*** • Support that clause 2 of Standard 1.2.3 be extended to apply to all cereal-based beverages that contain less than 2.5% fat. • Both fortified and unfortified cereal-based beverages should be required to carry an advisory statement that advises consumers that the product is low in protein. • To recommend that consumers seek medical advice is not necessary, if the above advisory statements are made.

	Submitter	Submission Comments
		Addition of other Vitamins and Minerals • If allowing voluntary calcium fortification of cereal-based beverages, then this should be extended to other relevant vitamins and minerals to the levels found in cows' milk.
11	**New Zealand Food Safety Authority** **Carole Inkster**	**Supports Option 2** NZFSA believes that calcium fortified cereal-based beverages should continue to be available to consumers in New Zealand, and supports option 2 to amend Standard 1.3.2. They perceive no anticipated costs associated with this option. ***Use of Cereal-based Beverages*** • Many dairy allergic individuals consume cereal-based beverages, as reported by New Zealand dietitians. • New Zealand dietitians consider cereal-based beverages as the "last resort alternatives" to cow's milk, though there are circumstances where its use is warranted. • Cereal-based beverages can also be consumed in 'family foods'. • Some New Zealand dietitians believe that calcium fortified cereal-based beverages are preferable to using dietary supplements, as compliance with supplements in children is difficult. ***Consumer Characteristics*** • Dairy allergic consumers are already making use of these products in New Zealand. • New Zealand Children's Nutrition Survey (2002) found 15 out of 3275 (0.46%) surveyed had consumed soy milk in the past 24 hours. Mean daily intake was 226 grams. • National Nutrition Survey 1997 found 51 out of 4636 (1.1%) people aged over 15 years had consumed soy milk in the past 24 hours. Mean daily intake was 200 grams. • Above data did not state if the soy milk was fortified with calcium or reason for consumption. • Insufficient data on soy milk intake for children aged less than five years. • No evidence that consumers of cereal-based beverages have inadequate protein intakes. • New Zealand Children's Nutrition Survey showed children were consuming at least double their age specific Recommended Nutrient Intake for protein. Milk provided 11% of total protein intake. • National Nutrition Survey 1997 showed protein intakes of New Zealand adults are almost double the Recommended Nutrient Intake. • Insufficient protein consumption data for children under the age of 5 years. ***Labelling*** • Supports use of an advisory statement on both fortified and unfortified cereal-based beverages, informing the purchaser that the product is not suitable as a complete food for children under the age of two years. • Recommendation to seek medical advice is not considered necessary. • Considers cereal-based beverages to be general purpose foods, not special purpose foods.

	Submitter	Submission Comments
		• Does not believe consumers would be misled by the presence of a 'calcium content' claim. NZFSA supports these claims as it allows consumers to differentiate between fortified and non-fortified varieties. ***Addition of other Vitamins and Minerals*** • Supports the addition of other vitamins and minerals to cereal-based beverages, in amounts equal to cow's milk, as they believe many consumers use these products as substitutes for cow's milk.
12	**Sanitarium Health Food Company** **Paul Ginn**	**Supports Option 2 with adaptations** ***Substitute Food and Nutritional Equivalence*** • Believes providing a range of nutritionally equivalent alternatives to dairy milk is "responsible and beneficial to customers". • Considers that cereal-based beverages should contain a minimum of 3% protein, before being permitted to contain added calcium. • Sanitarium understands it is "technically achievable" to achieve higher levels of protein in cereal-based beverages. They propose using a cereal protein isolate, stating that oat and rice protein isolates are currently available in Australia for use. • Cereal-based beverages that contain less than 3% protein should not be promoted as a milk substitute. • Possible that consumers may assume that calcium-fortified beverages with a similar appearance to milk, have a similar nutritional profile to milk. • Recommends conducting dietary modelling to evaluate the impact on protein intakes if cereal-based beverages replaced cow's milk. ***Population Groups at Risk*** • Risk that children substituting unfortified cereal-based beverages in place of cow's milk may not achieve adequate protein and micronutrient intakes. • If children consumed cereal-based beverages as their main source of calcium, they may miss out on significant amounts of protein. • Believes children consuming cereal-based beverages should consult with a doctor or dietitian. ***Consumer Characteristics*** • Commented that National Nutrition surveys show dairy milk contributes approximately 15-16% of protein intake for children. • Commented that National Nutrition surveys show dairy milk contributes significant amounts of nutrients, such as calcium (42-44%), vitamin A (15-17%) and riboflavin (9%), to children's dietary intakes. ***Market Characteristics*** • Around 1/3 of soy beverages currently on the market contain added vitamins as permitted in Standard 1.3.2. • For the 12 month period ending May 2004 – 2.713 million litres of rice milk and 0.247 million litres of oat milk were purchased. Therefore, approximately 5% and 0.5% respectively of the total soy and cereal-based beverages purchased in Australia. ***Manufacturer's Perspective***

	Submitter	Submission Comments
		• Sanitarium believes it is "technically achievable, nutritionally responsible and cost effective" to voluntary add permitted vitamins and minerals to cereal-based beverages. ***Labelling*** • Recommends that Clause 2 of Standard 1.2.3 be extended to include all legume, cereal, nut and other plant-based beverages that are alternatives to milk. • Maintains that cereal-based beverages should contain at least 3% protein before being permitted to fortify with calcium. Therefore removing the need for an advisory statement. • If unfortified cereal-based beverages are to be promoted as cow's milk substitutes, then they recommend the use of a mandatory advisory statement highlighting the low protein levels. • Supports the recommendation that consumers seek medical advice for unfortified low protein products promoted as milk substitutes. • Potential for consumers to mistake a calcium content claim as meaning nutritional equivalence to milk, as milk is generally known to be a source of calcium. • Commented that packaging of various rice milks currently on the market portray them as milk alternatives, and therefore they assume that people will be using them as cow's milk substitutes. • Commented that one brand claims that rice milk is 'perfect on cereal, or in your cooking, wherever you would usually use dairy milk'. ***Addition of other Vitamins and Minerals*** • Recommends that Standard 1.3.2 be extended to include the permission to add vitamins and minerals to cereal-based beverages with a minimum of 3% protein, similarly to legume-based beverages.
13	**SoNatural Foods Australia Limited** **(The Applicant)** **Howard Hurwitz**	**Supports Option 2** ***Note: the following comments have been provided by the Applicant*** ***Consumer Characteristics*** • High percentage of sales to those who have intolerances to dairy milk and soy milk. • Information suggests cereal-based beverages to some degree replace cow or soy milk in consumer's diets. • Assume young people form the highest percentage of consumers as they are "pre-disposed to allergic responses". • Believes substituting cereal-based beverages for cow's milk is unlikely to result in inadequate protein intakes for consumers who are eating a 'typical Australian diet', citing the 1995 Australian National Nutrition Survey that shows protein intakes above the RDI. • Concluded the above for young children consuming a 'typical Australian diet' too. • Not aware of evidence that consumers of cereal-based beverages have an inadequate micronutrient intake. • Not aware of evidence to suggest that consumers of cereal-based beverages are at risk of excessive intakes of calcium. Considers risk of excess intake to be the same, if not lower, than those consuming cow's milk.

	Submitter	Submission Comments
		Market Characteristics • No information regarding the size of the New Zealand market for cereal-based beverages. • Report that New Zealand imports cereal-based beverages from Australia, as no cereal-based beverages are produced in New Zealand. Australia does not import cereal-based beverages from New Zealand. • Therefore, So Natural Foods does not consider Australian manufacturers to be disadvantaged by the current discrepancy between Australian and New Zealand regulations. • Cereal-based beverages are sold both in supermarkets and health food stores. • Cereal-based beverage market is estimated at 5 million litres per annum, based on total sales in Australia of 3.5 million litres for the year ended July 2004 (Aztec) plus the estimated sales in New Zealand and in health food stores. • Reports the soy beverage market is currently not showing any growth. The cereal beverage market is showing some signs of slowing, with an additional 250,000 litres growth for the year ended June 2004. • Historically cereal based beverages have sold at a premium – ~10-15% higher than soy beverages, and 25-30% higher than cow's milk. • At least 78% of soy beverages sold contained some added vitamins (based on supermarket scan sales information, Aztec July 2004) ***Population Groups at Risk*** • Believes there is a risk that consumers of non-fortified beverages will not meet the RDI for calcium. • Acknowledged that cow's milk is also a significant source of riboflavin and vitamin B12, however note the average intake of riboflavin is above the RDI and that vitamin B12 intake is unknown. • Considers vegans consuming cereal-based beverages will be at a higher risk of low vitamin B12, compared with those including other sources of animal products as part of a varied diet. ***Costs*** • No increased costs are expected associated with option 2. ***Labelling*** • Does not support use of an advisory statement regarding the low protein content of cereal-based beverages, due to survey data that shows average protein intake above the RDI. • Considers a warning statement regarding the use of the product for children under 2 years of age "sufficient" to cover at risk groups. • Does not support a statement recommending consumers seek medical advice on the use of cereal-based beverages. They believe many consumers choose these products for non-medical reasons and therefore seeking medical advice would be "unnecessary and potentially misleading". • Considers there is a "possibility" that a 'calcium content' claim could mislead consumers to believe these products are nutritionally equivalent to milk. ***Addition of other Vitamins and Minerals*** • Supports voluntary fortification of cereal-based beverages with other significant micronutrients.

	Submitter	Submission Comments
		• Considers there is a "possibility" that fortifying cereal-based beverages with calcium alone may mislead or deceive consumers as to the nutritional merit of these products compared with cow's milk. • SoNatural would "be keen" to add other vitamins and minerals if permitted. ***Other Comments*** • SoNatural Foods have not tested the bioavailability of added calcium salts consumed in the form of rice or oat beverages. • Supports the extension of Clause 2 of Standard 1.2.3 to apply to cereal-based beverages, in order to minimise inappropriate feeding of these products to infants and young children.