EXPLANATORY STATEMENT

APPLICATION A500

FORTIFICATION OF CEREAL-BASED BEVERAGES

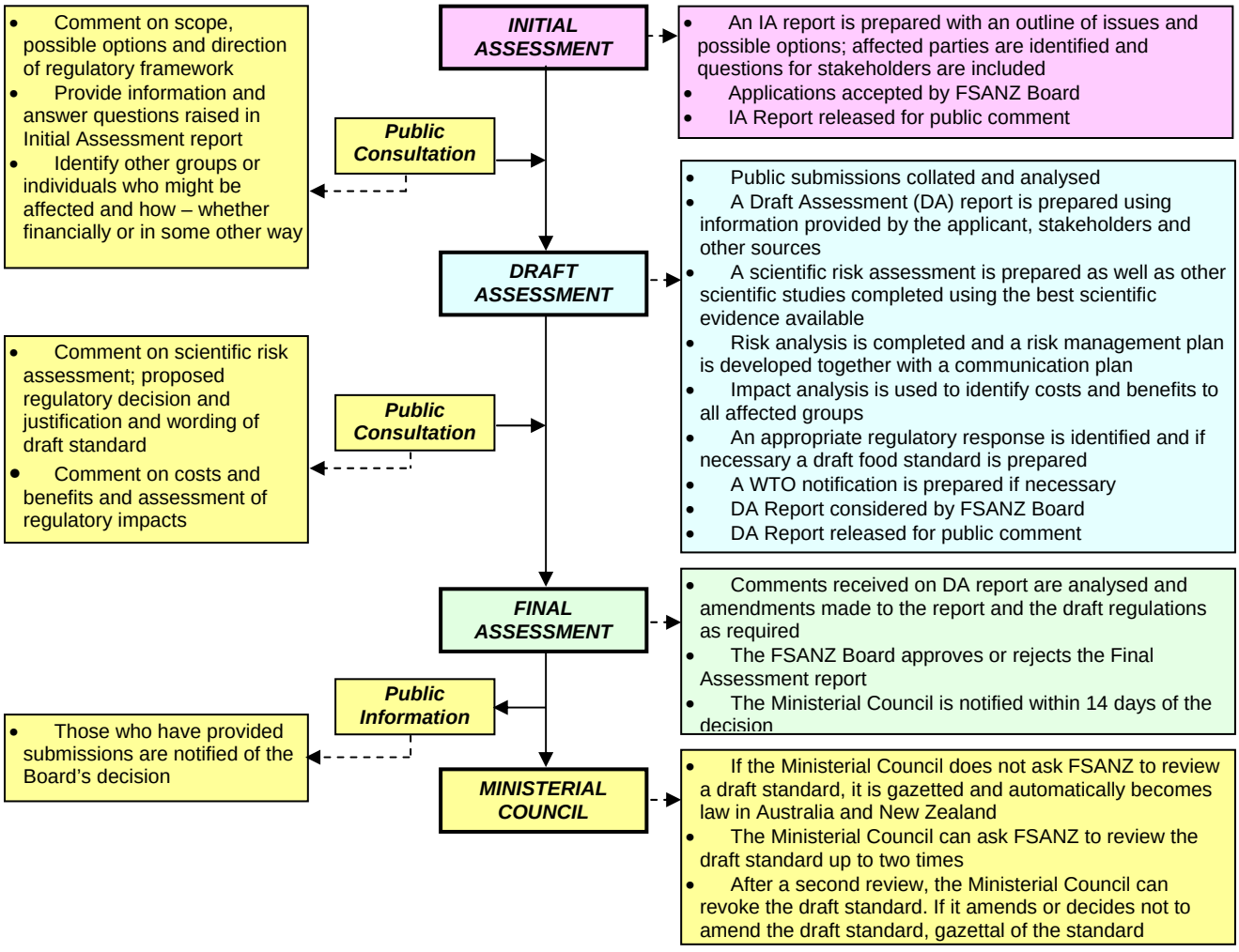
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

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

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

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



Final Assessment Stage

FSANZ has now completed two stages of the assessment process and held two rounds of public consultation as part of its assessment of this Application. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Ministerial Council.

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

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

Further Information

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

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

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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 Final Assessment Report discusses issues involved with this Application, including issues raised in submissions in response to the Draft Assessment, and recommends variations to the Code as at Attachment 1.

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 compounds are currently added to some cereal-based beverages as food additives. Although added for technological function, they contribute towards the calcium content of the beverage, which may result in a content claim. These claims inform consumers of the presence of calcium in cereal-based beverages, which to some consumers, may be important information and affect their purchase decision.

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 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.

Risk Assessment

FSANZ has undertaken a risk assessment involving several components to inform an overall assessment of risk. The risk assessment included a Nutrition Assessment and Dietary Intake Assessment, which are provided in full detail at Attachment 2. The methodology for the Dietary Intake Assessment is described in Attachment 3.

The overall conclusions from the risk assessment suggest that non-dairy consumers are at risk of inadequate intakes of a variety of vitamins and minerals for which dairy milk makes an important contribution to the diets of the general population, and that use of a fortified cereal-based beverage may aid in mitigating this risk. In addition, there is a low prevalence of protein inadequacy among young non-dairy consumers that increases with age. Although the data for young children does not suggest overtly compromised protein intake, low protein intake in young children has more adverse health consequences than low protein intake in adults, as protein is important for normal growth and development.

Risk Management

This Final Assessment Report considers a number of issues relevant to the regulation of both fortified and non-fortified cereal-based beverages including:

- managing the identified public health and safety risks associated with cereal-based beverages, with respect to their lower protein, fat and micronutrient content compared with cows' milk and soy beverages;
- the feasibility of increasing the protein content of cereal-based beverages;
- the efficacy of adding vitamins and minerals to cereal-based beverages; and
- the requirement for mandatory advisory labelling.

Regulatory Options and Impact Analysis

There are three possible regulatory options proposed at Final Assessment for this Application. 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.

Consultation

The Draft Assessment Report for this Application was released for public comment from 3 August to 14 September 2005. A total of twenty submissions were received, with eleven submissions from industry, six from government, two from public health and one from a consumer of cereal-based beverages.

Ten submitters supported Option 3 to amend Standard 1.3.2 to permit the addition of selected vitamins and minerals to cereal-based beverages, as permitted for beverages derived from legumes. Six others supported a modified Option 3, two dairy industry submitters supported maintaining the status quo, one industry submitter did not specify their preferred regulatory option, and the consumer submitter supported fortification of cereal-based beverages. A summary of submitter comments is at Attachment 4.

Targeted consultation on the recommended advisory statement was conducted at Final Assessment. Eight participants were consulted, involving four representatives from the respective Australian and New Zealand national allergy and vegetarian/vegan societies and four health professionals specialising in allergies and intolerances.

All participants agreed that cereal-based beverages should be required to carry an advisory statement on their label. However, there were divergent views on the content of the advisory statement, particularly regarding the level of detail that should be provided to consumers.

Conclusion and Statement of Reasons

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 product development and market innovation. Therefore, FSANZ recommends the draft variations to the Code as detailed in Attachment 1 be approved 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 soy beverages; and
    - a prescribed requirement for mandatory advisory labelling to reduce the risk of inappropriate use of cereal-based beverages, particularly in the diets of children under the age of five years;

- is consistent with FSANZ's 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.

Decision

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;
- Standard 1.2.3 be amended to require cereal-based beverages containing no more than 2.5% fat and less than 3% protein, or less than 3% protein only to carry a mandatory advisory statement to the effect that the product is not suitable as a complete milk replacement for children under the age of five 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 recommended draft variations to the Code are at Attachment 1.

The Table below outlines the recommended 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: Recommended 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%)	

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 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 Final Assessment Report discusses issues involved with this Application, including issues raised in submissions in response to the Draft Assessment, and recommends a variation to the Code as at Attachment 1.

1.1 Nature of Application

1.1.1 Basis of the Application

The Applicant requested an amendment to 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 recommended that the scope of the original Application be extended. Permission for the addition of calcium alone to cereal-based beverages was originally requested. At Draft Assessment a third regulatory option was considered to permit 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, and was supported by the majority of submitters at Draft Assessment. The Applicant supports this proposed third regulatory option.

As this third option was the preferred regulatory option at Draft Assessment, the name of the Application was 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.

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 compounds are currently added to some cereal-based beverages as food additives. Although added for technological function, they contribute towards the calcium content of the beverage, which may result in a content claim. These claims inform consumers of the presence of calcium in cereal-based beverages, which to some consumers, may be important information and affect their purchase decision.

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 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. 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].

[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 1.3.1 – 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*.

- 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 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*[4], an internal working document that details FSANZ's revised decision making in light of the Policy Guideline.

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[5]. 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[6]. In early 2005, Health Canada released a *Proposed Policy and Implementation for the Addition of Vitamins and Minerals to Foods*[7], 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[8].

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[4] Available at: http://www.foodstandards.gov.au/whatsinfood/fortification.cfm

[5] 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.

[6] 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

[7] 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

[8] 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

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'.

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[9]. FSANZ is aware of further consideration by the EC on this Proposal, with the most recent amendment[10] 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 or soy beverage 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 replacement.

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.

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[9] *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

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

Beverages that are blends of cereals and legumes are also being manufactured. One Australian-made rice beverage contains added chickpeas as a means to increase the protein content to 1.6 g/100 mL. An imported beverage found in New Zealand is a blend of soy and rice, which contains 2.9 g/100 mL protein and added kombu seaweed and carrageenan to improve its micronutrient profile.

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.

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).

As these compounds are also permitted forms of calcium (as nutrients) under Standard 1.1.1, they contribute towards the calcium content of rice beverages, which if above 10% of the RDI for calcium per reference quantity may result in a content claim. All three product labels include content claims such as 'calcium enriched', 'calcium equal to milk' and 'high in calcium', which appears inconsistent with the intent of the Code, as the presence of calcium is for a technological purpose rather than nutritive.

One imported rice beverage product contains added 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[11].

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. Small quantities of additional imported products are also available in some health food stores in 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[11].

4.4.4 Sales

Australian supermarket retail sales of cereal-based beverages totalled 3,800,000 litres for the year ending April 2005[12]. 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[13].

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

The concepts of reference food, substitute food and nutritional equivalence are important to this Application, and are discussed in relation to the *Fortification Implementation Framework*.

[11] Based on cost of goods in New Zealand as at 19.05.05
[12] Aztec Information Systems – year ending April 2005.
[13] Retail World Australasian Grocery Guide 2004. 14th edition. Sydney, New South Wales

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 *Fortification Implementation Framework* does not define nutritional equivalence, as compared to the previously used Codex General Principles. Instead it outlines four aspects to consider when assessing nutritional equivalence, these are:

- the nutrients in the substitute food compared to the reference food;
- distinguishing core nutrients14, 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
- 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 a significant source of energy in the Australian and New Zealand diets, contributing 6%[15] and 5%[16] of total energy respectively. In addition, cows' milk contains a number of core nutrients such as 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 *Fortification Implementation Framework*, 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 cows' milk in appearance and viscosity, and are promoted and used as cows' milk substitutes. Therefore, FSANZ considers that cereal-based beverages meet the above definition for a substitute food for cows' milk, 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 than 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, FSANZ considers that while cereal-based beverages are not nutritionally equivalent to cows' milk (the reference food), they are considered a substitute food.

[14] 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.

[15] FSANZ (2004). DIAMOND Modelling – contribution based on plain, non-flavoured dairy milks and not including dairy desserts.

[16] 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.

5. Relevant Issues

5.1 Risk Assessment

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 protein, 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, the fortification of cereal-based beverages with selected vitamins and minerals to levels based on cows' milk was proposed at Draft Assessment. The general dietary risks of low protein and lower fat intake of non-dairy consumers[17] were also investigated. This was due to the low protein content of these beverages and their regular consumption by some children, and since consumers might perceive fortified cereal-based beverages as nutritionally equivalent to dairy milk and thus not take steps to ensure adequate protein intake.

5.1.1 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 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.

Model 6 was a scenario model assessing the effectiveness of fortification for non-dairy consumers who had consumed a soy-based beverage, with the composition of the soy-based beverage being replaced by that of a cereal-based beverage fortified according to the permissions proposed in this Application.

[17] 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 in 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 was found on the nutrient intake of infants and toddlers aged less than 2 years who consume cereal-based beverages.

5.1.2 Nutritional Risks to Consumers of Cereal-Based Beverages

5.1.2.1 Vitamins and Minerals

Milk is an important contributor of vitamins and minerals in the diet, particularly in children. The importance of milk as a provider of vitamins and minerals decreases somewhere between the ages of 5 and 14 years as diets become more varied. 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, that is, at least 50% of one or more subpopulation age groups did not meet their respective EAR. Older consumers appear to be more at risk with respect to compromised vitamin and mineral intakes compared with the 2-4 year age group.

5.1.2.2 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, particularly for children aged 2-4 years. As is the case with the vitamins and minerals, the importance of milk as a contributor of protein decreases somewhere between the ages of 5 and 14 years of age. 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 the literature review do not provide conclusive evidence of low protein and lower fat intakes by consumers of cereal-based beverages. However, these data sources identified a low prevalence of protein inadequacy among young non-dairy consumers that increases with age. Although prevalence of relative protein deficiency is lower in the younger age groups, 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 that could have detrimental effects on growth and development. Consumers' possible perception of fortified cereal-based beverages as nutritionally equivalent to dairy milk may increase this risk of protein inadequacy as they may not appreciate the need to ensure adequate intakes of protein from appropriate dietary sources.

5.1.3 Effect of Fortifying Cereal-Based Beverages

5.1.3.1 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 folic acid 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.

5.1.3.2 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.

5.1.4 Conclusion

From available data, it is not possible to identify 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 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. Although the small numbers of young children (2-4 years) in Models 1-5 do not suggest overtly compromised protein intake, low protein intake in young children has more adverse health consequences than low protein intake in adults. 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 that 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.

5.2 Risk Management

5.2.1 Nutritional Equivalence

As discussed in sections 4.4.2 and 4.5, cereal-based beverages are not nutritionally equivalent to cows' milk (the reference food) due to their lower protein, fat, and vitamin and mineral content. This view is held by many submitters to this Application, who have particular concerns regarding the low protein content of these products. However, although they are not nutritionally equivalent to cows' milk they are used as substitute for cows' milk and soy beverage, and many non-fortified cereal-based beverages are readily available on the market.

5.2.2 Composition

As discussed previously, dairy milk is an important contributor of many core nutrients, such as protein, calcium and riboflavin, which are not naturally present in cereal-based beverages at the same levels. Consequently, non-dairy consumers are at risk of inadequate intakes of a variety of vitamins and minerals compared with dairy consumers. This provides the basis for considering fortification of cereal-based beverages with vitamins and minerals, as a means to make them more nutritionally equivalent to the reference food (i.e. cows' milk).

5.2.2.1 Fortifying Cereal-Based Beverages with Vitamins and Minerals

The Nutrition Assessment Report (Attachment 2) identified that non-dairy consumers are at risk of inadequate intake of seven vitamins and minerals that are naturally present in dairy milk and other dairy products. It was concluded that fortifying cereal-based beverages would, to some extent, address the risk of inadequate intake of these vitamins and minerals for cereal-based beverage consumers who avoid dairy products.

Sixteen of the twenty submitters to the Draft Assessment Report supported the addition of selected vitamins and minerals to cereal-based beverages, in some cases conditionally.

Ministerial policy guidance for fortification includes a 'Specific Order' Policy Principle for voluntary fortification that 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 consumption 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 completely 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 of vitamins and minerals from 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 recommended addition of selected vitamins and minerals to cereal-based beverages rather than calcium alone may reduce the likelihood that consumers are misled as to their nutritional quality, 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 likely exception of protein.

Therefore, FSANZ recommends permitting the voluntary fortification of cereal-based beverages with selected vitamins and minerals, including calcium, as currently permitted for beverages derived from legumes.

5.2.2.2 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. No additional forms of vitamins or minerals have been considered as part of this Application.

5.2.2.3 Macronutrients

5.2.2.3.1 Fat

The estimated dietary intake assessment and literature review suggest that consumers of cereal-based beverages are not at risk of inadequate fat intakes, regardless of age. Therefore, no additional risk management measures are required specific to the fat content of these beverages.

5.2.2.3.2 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 Nutrition Assessment suggests that a small percentage of young children (i.e. aged 2-4 years) who avoid dairy foods and regularly consume cereal-based beverages are at risk of inadequate protein intakes. No dietary intake data is available for infants (i.e. 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 in infants, 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 non-fortified rice beverage was used as the primary source of food.

5.2.2.4 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 from legumes are a possible option, where chickpeas have been used to increase the protein content of rice beverages, however these products may also be unsuitable for those individuals who have an allergy to specific legumes. Proteins derived from cereals such as maize 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.

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

Four submitters to the Draft Assessment Report commented on adding protein to cereal-based beverages to achieve a more nutritionally equivalent product to cows' milk. Of these, two commented that they would support Option 3 should it include the addition of protein and thus enable cereal-based beverages to be used as a replacement for cows' milk. Similarly another stated their second choice would be an amended Option 3 whereby a minimum of 3% protein would be required before vitamin and mineral fortifications are permitted.

As demonstrated above, while it is feasible to increase the protein content of cereal-based beverages, it is both technically difficult and economically onerous to do so. Therefore, requiring cereal-based beverages to have a protein content similar to that of cows' milk and soy beverage before fortification with vitamins and minerals would not be effective regulation. Such a requirement may reduce competitive trade and access to fortified product, and therefore would be unlikely to address the public health and safety risk of inadequate vitamin and mineral intakes by non-dairy consumers.

Therefore, 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 recommending other risk management strategies, such as labelling with an advisory statement for low protein beverages, to manage the small risk of protein inadequacy among younger cereal-based beverage consumers.

5.2.3 Labelling and Advisory Statements

Nutrition labelling standards for foods are outlined in Standard 1.2.8, and include the requirement for food labels to include a nutrition information panel to facilitate informed consumer choice. A nutrition and health claims standard for foods is under development, and these voluntary claims will provide additional information to consumers about the nutritional content of foods. No specific labelling requirements are specified for fortified foods under the Policy Guideline, however advisory statements can be used to help mitigate risk when required.

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. The specific text of advisory statements is not prescribed, and manufacturers may use their own words provided they convey the intended meaning and the statement is prominent and legible.

The Nutrition Assessment Report concluded that young children (i.e. aged 2-4 years) who consume cereal-based beverages are at greatest risk from inadequate protein intake, even though the likelihood of this occurring is lower than for adults, as inadequate protein intake in children can adversely affect their growth and development (i.e. the consequences from inadequate protein intake are greatest in young children). In addition, the case studies presented highlight the risk to children under the age of 2 years if cereal-based beverages are used inappropriately in their diets, and that fortified cereal-based beverages may potentially mislead consumers as to their nutritional quality, and thus heighten the risk.

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

5.2.3.1 Current Advisory Statement for Low Fat Milks and Beverages

Currently, as prescribed in Standard 1.2.3, milk and equivalent 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 versions of these 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. This advisory statement is required as limited fat intake from milk in infants may interfere with optimal energy intake and hence affect growth and development[18]. 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.

[18] As documented in the Final Assessment Report for Proposal P240 – Labelling Statements on Reduced Fat and Condensed Milks.

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 also contain less than 2.5% fat, but unlike rice beverages they are not required to carry this advisory statement. The reason for this is unclear, and may have been an oversight when Proposal P240 was considered.

Rice beverages currently available in Australia and New Zealand all provide an advisory statement on their product labels. As illustrated 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. The low protein content of their product, as a mark of social responsibility, is the reason for Vitasoy specifying five years of age on their rice beverage compared with the currently required two years. 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 Product
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.

In addition, the manufacturer of the US imported rice beverages provides the following statement on their website[19], together with the display of their rice beverage products: *Rice Dream products are not for use as an infant formula. For Children under age 5, consult your child's doctor.*

5.2.3.2 Recommended Advisory Statement for Cereal-Based Beverages

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* was proposed at Draft Assessment. Fourteen of the twenty submitters commented on the proposed advisory statement, including five who agreed with the proposed statement. Issues from submitters predominantly related to including additional information in the advisory statement such as specifying that the product is low in protein and fat, and the need to seek medical advice. Two others questioned the rationale for selecting children under the age of 12 years, and the Applicant requested that *less than two years of age* be used.

[19] www.imaginefoods.com/pages/products/ricedream.php Accessed 07/10/05.

5.2.3.2.1 Specified Age

The intent of the recommended advisory statement is to prevent the inappropriate use of cereal-based beverages, especially in the diets of children, as adequate protein and caloric intake is essential for normal growth and development. At Draft Assessment, *under the age of twelve years* was specified in the proposed advisory statement. This has been revised to *under the age of five years* at Final Assessment, to more accurately reflect the findings of the Nutrition Assessment.

FSANZ acknowledges that a nutritionally compromised cereal-based beverage consumer could be of any age, as noted by one submitter, who recommended that the age be removed. However, FSANZ recognises children as being at greatest risk of nutritional inadequacy from the inappropriate use of these beverages, as adequate protein and energy intake are essential for their normal growth, where fat contributes approximately 30% of total energy intake in a child's diet.

Table 1 of the Nutrition Assessment report illustrates the importance of milk as a source of protein for children aged 2-4 years old, contributing 22% of their protein intake. It appears that the importance of milk as a contributor of protein and other nutrients decreases sometime between the ages of 5-14 years as dietary patterns change and food intake becomes more varied.

Those under two years also need to be protected against the inappropriate use of these cereal-based beverages as a complete milk replacement, as demonstrated in the case studies. The case studies suggest that low protein intake resulting from a disproportionately high consumption of cereal-based beverages places children less than two years of age at great risk to health. It could be assumed 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. However, of particular concern are those infants and children not under medical or dietetic supervision, and thus likely to be consuming cereal-based beverages for reasons other than allergy, where sufficient protein and calories may not be adequately substituted elsewhere in the diet.

5.2.3.2.2 Additional Information for Consumers/Caregivers

The recommended advisory statement should inform consumers/caregivers that these products are not a complete milk replacement. The statement should imply that while it is acceptable for people to use cereal-based beverages, additional food sources are required 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. It should also inform caregivers that cereal-based beverages should not replace breast milk and/or formula in the diets of infants.

As discussed previously, many submitters recommended that the advisory statement provide additional information such as specifying that these beverages are low protein and fat and a recommendation to seek medical advice.

FSANZ acknowledges these comments, however considers that is not appropriate to require a reference to the low protein and low fat content as part of the advisory statement at this time, for the following reasons:

- As discussed previously, an advisory statement should be used when the general public or the sub-population is exposed to a potential risk to health but the risk is not life threatening, or when guidance about use of a food is needed to protect public health and safety. In terms of this Application, the message that is to be conveyed is that cereal-based beverages should not be used as a complete milk replacement for children under five years. A reference to specific nutrients such as protein and fat in the advisory statement may detract from that message and does not take into account other factors in cereal beverages that may contribute to the unsuitability of the product as a milk replacement;

- The protein and fat content are required to be declared in the NIP, therefore consumers can refer to the NIP to obtain further information on the nutrient profile of these products;

- It has been stated by some submitters that including information about the low protein and fat content of the product as part of the advisory statement provides consumers with clearer information about the potential risk. It is arguable whether the inclusion of further information is in fact more meaningful as consumers may not understand the implications of a low fat and low protein content. It is also arguable whether consumers actually use this additional information. Specifically in relation to nutrition and health claims, consumer research has found that consumers prefer shorter health messages than longer, more complex ones[20,21,22,23];

- Mandating a reference to the nutrient content of a food, (i.e. 'low protein' and/or low fat') as part of an advisory statement is inconsistent with the current and proposed regulations for nutrition content claims, where these types of statements are voluntary;

- Including the rationale for requiring specific advisory statements as part of the statement itself is generally inconsistent with the approach taken for other advisory statements listed in Standard 1.2.3 and could be seen as precedent-setting;

- An approach to include rationale in advisory statements that are developed in the future could be problematic, particularly where consumption of a product is unsuitable for a specific target group for a number of reasons. In this regard, advisory statements could become lengthy and contribute to consumer confusion;

- The wording of advisory statements is not prescribed, therefore manufacturers have the option of including additional wording as long as the intent of the statement is consistent with the relevant requirements in Standard 1.2.3; and

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[20] Levy, AS 1995, *Summary on health claims focus groups*, Food and Drug Administration Centre for Food Safety and Applied Nutrition, Division of Market Studies, Washington, DC.
[21] Levy, A, Derby, B & Roe B 1997, *Consumer impacts of health claims: an experimental study*, Food and Drug Administration Centre for Food Safety and Applied Nutrition, Division of Market Studies, Washington, DC.
[22] National Consumer Council 1997, *Messages on food: consumers' use and understanding of health claims on food packs*, National Consumer Council, London.
[23] Paul, GL, Ink, SL & Geiger, CJ 1999, 'The Quaker Oats health claim: a case study', *J. Nutraceuticals, Functional & Med Foods* 1(4): 5–32.

- A future review of Standard 1.2.9 - Legibility Requirements is planned, and therefore advisory statements will be considered more broadly as part of that review.

Similarly, it is not considered appropriate to require a reference to seeking medical advice as part of the advisory statement for the following reasons:

- It is assumed that the majority of children who do not consume dairy and/or soy will be under medical and/or dietetic supervision for reasons of allergy/intolerance to these foods, and thus consuming a hypoallergenic formula in place of dairy and/or soy to meet their nutritional requirements;

- Cereal-based beverages are readily available and considered general-purpose foods rather than a food for special medical purposes; and

- The wording of advisory statements is not prescribed, therefore manufacturers have the option of including additional wording as long as the intent of the statement is consistent with the relevant requirements in Standard 1.2.3.

5.2.3.2.3 Targeted Consultation

Given the nature of the issues surrounding the advisory statements and its importance in informing consumers about the appropriate use of cereal-based beverages, particularly for children, targeted consultation was conducted at Final Assessment. Four representatives from the respective Australian and New Zealand national allergy and vegetarian/vegan societies and four health professionals specialising in allergies and intolerances were consulted on the advisory statement.

The advisory statement consulted on was a statement to the effect that *the product is not suitable as a complete milk replacement for children under the age of five years*.

All participants agreed that cereal-based beverages should be required to carry an advisory statement on their label. However, there were divergent views on the content of the advisory statement, particularly regarding the level of detail that should be provided to consumers.

Several participants considered it preferable for the advisory statement to include additional information to explain why cereal-based beverages are not suitable as a complete milk replacement, namely a statement to the effect that *the product is low in protein and fat and not suitable as a complete milk replacement for children under the age of five years*. Some also considered that the statement should be extended to include a recommendation to seek medical advice. Their reasons for requesting this additional information included that consumers may be unaware of the low protein and fat content of these beverages, consumers may not receive adequate information regarding their use as access to allergy specialists and dietitians can be variable, consumers/caregivers are generally reading labels for allergen content and not necessarily nutritional content information, to clarify the statement, and to protect those young consumers that are not under medical supervision.

As discussed previously in section 5.2.3.2.2, the provision of additional information as part of the advisory statement is not considered appropriate at this time. However, consumers can use other elements of the label, such as the nutrition information panel, to obtain additional nutrition information about a food.

5.2.3.2.4 Criteria for the Advisory Statement

The advisory statement will 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.

The protein content of cereal-based beverages (i.e. less than 3% protein) will act as the trigger for the advisory statement, as inadequate protein intake may result in compromised nutritional status for consumers. 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 equivalent beverages made from soy and rice will continue to apply. However, it is also recommended 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.

5.2.3.2.5 Conclusion

Therefore, at Final Assessment, FSANZ recommends 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 five years*.

5.2.4 Nutrient Content Claims

If cereal-based beverages are permitted to be fortified, 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 nutrients that can be added to beverages derived from legumes. Claims are not permitted for 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 with cows' milk, it is appropriate that manufacturers not be permitted to make content claims when adding these nutrients to beverages derived from legumes.

As FSANZ recommends permitting 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, it is appropriate that the same content claims be permitted for cereal-based beverages as for beverages derived from legumes.

5.2.5 Other Issues Raised in Submissions

5.2.5.1 Use of the term 'Milk'

The use of the term 'milk' in the product title of cereal-based beverages remained an important issue for submitters to the Draft Assessment Report. Several submitters from industry, government and public health did not support the use of the term 'milk' for cereal-based beverages, as this could mislead consumers to consider these products as nutritionally equivalent to cows' milk. Other submitters from government, public health and industry considered this even more important if cereal-based beverages are permitted to contain and promote higher levels of nutrients than are typically found in milk.

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*[24] 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.*

A government submitter considered the retention of the term 'milk' acceptable for cereal-based beverages on the basis that it is a commonly used phrase for other non-dairy products. However, while some dairy industry submitters agree that the use of 'milk' to describe non-dairy products such as coconut milk and soy milk is traditional, they consider the risk to consumers of using these products inappropriately would be lower compared to the risk associated with cereal-based beverages labelled as 'milk'.

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 this Application. 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.

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

5.2.5.2 Classification of Cereal-Based Beverages as General-Purpose Foods

Dairy industry submitters, in support of Option 1, considered that cereal-based beverages could be viewed as special medical foods rather than general-purpose foods under Standard 1.3.2. While cereal-based beverages may be consumed by those with allergy and intolerance to dairy and/or soy, they do not meet the proposed definition of a food for special medical purposes[25], as management of these conditions can be achieved by modifying the normal diet and using other special purpose foods.

5.2.5.3 Mandatory Vitamin and Mineral Permissions

A couple of submitters recommended that the vitamin and mineral additions to cereal-based beverages be made mandatory, even though the protein level is not reached, thereby raising the nutritional quality of these products to be closer to that of cows' milk. However, the 'Specific Order' Policy Principles for mandatory fortification do not address nutritional equivalence, and instead address broader public health needs. Therefore, as nutritional equivalence is the basis of this Application, considering mandatory fortification of these nutrients for cereal-based beverages would not be consistent with the Policy Guideline.

In addition, from an assessment of the uptake of voluntary fortification permissions for soy-based beverages, as investigated by FSANZ in 2004[26], it could be assumed that there would be a reasonable uptake by industry of voluntary permissions for cereal-based beverages. Findings from the study in 2004 showed that between two and seven vitamins and minerals were added to each fortified soy beverage product, and seven of the twelve permitted vitamins and minerals were utilised.

5.2.5.4 Sugar Limit

A government submitter expressed concern that Option 3 would allow manufacturers to add sugars to cereal-based beverages, and suggested a limit on total sugars equal to the sugar content of cows' milk. This restriction would avoid sugars being added to make these beverages more acceptable to consumers, where they consider the addition of sugars would be inconsistent with the Policy Guideline that states fortification should not promote the increased consumption of foods high in fat, salt and sugar.

FSANZ is not aware of any cereal-based beverages that currently contain added sugars, however sugars are commonly added to soy beverages and flavoured cows' milk. FSANZ considers that applying a sugar restriction to cereal-based beverages would be inconsistent with the requirements for soy and cows' milk beverages, which are able to contain added sugars. In addition, sugar containing cereal-based beverages are unlikely to promote increased consumption of sugar, as cereal-based beverage consumers would be unlikely to consume these in addition to the flavoured cows' milk and soy beverages currently available. Therefore, FSANZ is not recommending limiting the addition of sugars to cereal-based beverages.

[25] As defined in the Preliminary Final Assessment Report for Proposal P242 – Food for Special Medical Purposes.
[26] Voluntary Fortification Issues – a student project (2004). Not published.

5.2.5.5 B-Group Vitamin Permissions

Dairy submitters highlighted that some proposed B-group vitamin permissions, particularly riboflavin and vitamin B_6, are higher than levels that occur naturally in cows' milk. They recommended that the levels be reduced to 'not more than' the levels found in cows' milk.

The vitamin and mineral levels proposed at Draft Assessment were adopted from the current permissions for beverages derived from legumes. These permissions, approved in 1995, were based on cows' milk data from Australian and British food composition tables available in 1993. During development of these permissions, the maximum claim was rounded to the nearest 5% of the RDI per reference quantity if the amount was already 10% of the RDI or more. If the food contained less than 10% of the RDI then no claim was permitted, and the amount found in cows' milk became the maximum amount permitted per reference quantity. Hence, the rounding to the nearest 5% RDI for vitamin B_{12} and riboflavin may have resulted in permissions that were slightly higher than found naturally in cows' milk. In addition, data on the composition of cows' milk in Australia and New Zealand has been updated, and thus slight variations now exist when compared to the 1993 data that was used.

Considering the above reasons for the variation in B-group vitamin levels and the future revision of the Code to accommodate the new Nutrient Reference Values (NRVs)[27], FSANZ has not recommended that the levels of B-group vitamin permissions be amended as part of this Application.

5.2.5.6 Vitamin D

The New Zealand importer of Rice Dream Enriched stated that their product contains 25% of the US RDI for vitamin D per 240 mL serve, or 2.08 µg per 200 mL. They requested that FSANZ consider increasing the proposed vitamin D permissions for cereal-based beverages based on the US Recommended Daily Allowance of 10 µg/day.

Standard 1.1.1 of the Code provides a schedule of vitamin and mineral RDIs for use in labelling. Currently the RDI for vitamin D is 10 µg/day. Standard 1.3.2 permits addition of vitamin D to legume-based beverages based on a maximum claim of 10% of the RDI per reference quantity, i.e. 1 µg /200 mL, with a maximum permitted quantity of 1.6 µg/200 mL. New NRVs for Australia and New Zealand have been drafted and are expected to be officially endorsed late in 2005. No RDI has been set for vitamin D but an Adequate Intake of 5 µg/day for most age/sex groups and an Upper Limit of 80 µg/day are proposed. FSANZ will review the reference RDIs in the Code on the basis of the new NRVs in due course.

In addition, during the consideration of Proposal P166 - Vitamins and Minerals in Foods, the decision was made to increase the permission for fortification of legume-based beverages with vitamin D sufficient to permit a content claim. This increased permission was based on the public health case made to retain mandatory vitamin D fortification in edible oil spreads in Australia on the basis of some evidence of increasing prevalence of vitamin D insufficiency. FSANZ plans to review the case for mandatory fortification of Vitamin D in due course. This approach would enable a systematic response to consideration of fortification issues and provides for an equitable approach to all dairy foods and dairy substitutes permitted to fortify with vitamin D.

[27] NHRMC and MoH 2004

These issues considered, FSANZ is not recommending the extension of permissions for vitamin D fortification of cereal-based beverages at this time.

5.2.5.7 Bioavailability

Comments regarding bioavailability of the added vitamins and minerals were made by some submitters from industry and government. Government submitters considered that the form of the vitamins and minerals should be mandated[28], and be present in the most readily bioavailable form to benefit consumers.

A couple of dairy industry submitters disagreed with FSANZ's conclusion that tricalcium phosphate in rice beverages is relatively bioavailable, and one commented that there is no scientific evidence to demonstrate that plant sourced nutrient fortification in cereal-based beverages will have the same bioavailability as the nutrients naturally present in cows' milk. They also considered that consumers may be misled as to the nutritional quality of their diet, as they may assume that they are absorbing the same amount of nutrients from fortified cereal-based beverages as they would from cows' milk.

One submitter had strong views regarding the bioavailability, stability and efficacy of vitamins and minerals added to cereal-based beverages. They did not support the conclusion that the bioavailability of the vitamins and minerals is likely to be comparable to other food sources, and comment that the report does not address the stability of the supplemental ingredients over the shelf-life of the product. They too considered that consumers may be misled to believe that their nutritional needs are being catered for by eating certain foods.

An assessment of bioavailability of added vitamins and minerals in cereal-based beverages is detailed in section 4.1.2 of Attachment 2. This assessment concluded that as the actual bioavailability of any one vitamin or mineral is dependent on a wide range of factors, it is not possible to draw definitive conclusions on the bioavailability as it applies to any individual food product, including cereal-based beverages. It is however, expected that the vitamins and minerals in cereal-based beverages are bioavailable to varying extents.

5.2.5.8 Allergenicity of Cereal-Based Beverages

A dairy industry submitter quoted the Draft Assessment Report (page 23) that fortification of cereal-based beverages 'poses no greater risk than cows' milk' and 'is therefore considered to be safe', and questions this in relation to the low allergenicity of cereal-based beverages. They suggested that FSANZ had not provided any evidence of low allergenicity and that permission to fortify cereal-based beverages may increase consumption and possibly provide a risk similar to that observed for soy beverages, where a study by Lack et al prompted the UK Food Standards Agency to discourage parents from giving soy-based formulas to infants because of concerns of increased risks of peanut allergy.

The most likely users of cereal-based beverages are people allergic to both cows' milk and soy. Traditionally rice has been used as the basis of elimination diets in western countries because of its low allergenicity. In Japan and other Asian countries where rice is consumed in large amounts, atopic rice allergy is not uncommon.

[28] Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions of the Code specifies the permitted forms of vitamins and minerals that can be added to foods.

The literature suggests that rice allergy is increasing in the western world but the prevalence is much lower and more common in adults than in children[29,30]. Although some consumers may be allergic to rice and/or oats, the base of most cereal-based beverages, they can choose to avoid these products as they would another food with these ingredients.

FSANZ reiterates its initial conclusion that fortification of cereal-based beverages with vitamins and minerals as recommended in this Application does not pose any greater risk, in respect of vitamin and mineral intake, than does cows' milk itself.

5.2.5.9 Beyond Scope of this Application

5.2.5.9.1 Legibility of the Advisory Statement

A couple of government submitters commented on the legibility of the advisory statement. One recommended that the location on the label and font size for the advisory statement should be specified. Similarly, the other submitter recommended that the legibility of the advisory statement be addressed, as previously considered for Applications A433, A434 and A508, which relate to phytosterols in foods.

The issue of specific legibility criteria for mandatory advisory statements[31] was examined and discussed with the jurisdictions during the review of the Code and the *New Zealand Food Regulations,* culminating in the development of Standard 1.2.9 of the Code. At that time it was agreed that as advisory statements were of lesser importance in relation to protection of public health and safety (compared to mandatory warning statements), it was not necessary to prescribe additional specific legibility criteria or a minimum print size.

Instead, general provisions regarding legibility and prominence are supported by the *User Guide to Standard 1.2.9* to assist manufacturers with adherence to the principles on which the standard operates. In addition, FSANZ proposes to undertake a broader review of Standard 1.2.9 in relation to the legibility of all mandatory warning statements, advisory statements and declarations in due course.

5.2.5.9.2 Literacy

A government submitter expressed concern that the proposed advisory statement may not be adequate for vulnerable groups, especially those with low literacy. They stated that evidence suggests 25% of Australians have low literacy skills. They recommended that readability criteria, in addition to legibility requirements, be applied to the proposed advisory statement for cereal-based beverages.

The issue of readability extends beyond this Application to broader labelling requirements in the Code, and therefore is likely to be considered as part of the proposed review of Standard 1.2.9.

[29] UK FSA www.eatwell.gov.uk/healthissues/foodintollerance/foodintolleranetypes/riceallergy/ as at 30 September 2005.
[30] Internet symposium on food allergens 1(4) 147-60 (1999) http://www.food-allergens.de/symposium-vol1(43)/data/rice/rice-abstract.htm as at 29 September 2005
[31] Under Proposal P 142-Print Size and Quality of Prescribed Information Appearing on a Food Label

5.2.5.9.3 Equivalent advisory statement for low protein soy beverages

A submitter noted that there are soy beverages available in New Zealand that have less than 3% protein and less than 2.5% fat, and consider that these products should be required to carry the same advisory statement as proposed for cereal-based beverages. Currently these products are required to carry an advisory statement to the effect that 'the product is not suitable as a compete milk food for children under the age of two years', as they contain no more than 2.5% fat. Of note is that soy beverages with less than 3% protein are not permitted to be fortified with vitamins and minerals.

The changes to advisory statements and their criteria as proposed at Draft Assessment did not affect the advisory statement requirements for soy beverages. Extending the proposed advisory statement criteria for cereal-based beverages to include soy beverages with low protein and/or fat content is beyond the scope of this Application, and would need to be raised as part of a specific proposal.

5.2.5.9.4 Use of folic acid vs. folate

A submitter commented on the use of the terms folic acid and folate within the Code and referred to the term dietary folate equivalents (DFEs) to be utilised in the new NRVs for Australia and New Zealand. Currently the Code treats folic acid and folate as having equivalent bioavailability; this applies to reference amounts for nutrition labelling and the derivative criteria for health and nutrition claims as well as indirectly controlling voluntary fortification. When the draft proposed NRVs are officially adopted, expected at the end of 2005, FSANZ plans to raise in due course, a proposal to review all vitamin and mineral reference amounts in the Code. This will include consideration of the new term 'dietary folate equivalents', which recognises a differential bioavailability between folate and folic acid.

5.2.5.9.5 Review of Standard 1.3.2 – Vitamins and Minerals

One dairy industry submitter considers Standard 1.3.2 needs to be reviewed to allow greater fortification of milk, to create a 'level playing field' and correct major discrepancies across food groups. This also includes the ability for milk to make a greater number of nutrient content claims.

A review of Standard 1.3.2 is beyond the scope of this Application. The dairy industry can lodge an application with FSANZ to permit the addition of vitamin and minerals to milk under Standard 1.3.2.

6. Regulatory Options

There are three possible regulatory options to progress this Application, these are:

6.1 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.

6.2 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.

6.3 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.

7. Impact Analysis

7.1 Affected Parties

The parties affected by this Application are: **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; **industry** being Australian and New Zealand manufacturers and importers of cereal-based beverages, the dairy industry, and the dairy substitute (e.g. soy beverage) industry; and the **Governments** of Australia and New Zealand.

7.2 Cost Benefit Analysis

This analysis assesses the immediate and potential impacts of each regulatory option on the affected parties.

7.2.1 Option 1 – Maintain status quo

7.2.1.1 Consumers

7.2.1.1.1 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.

7.2.1.1.2 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. However, the inclusion of a mandatory advisory statement indicating that these products are not a complete milk replacement would lessen this risk.

7.2.1.2 Industry

7.2.1.2.1 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.

7.2.1.2.2 Costs

- Australian industry faces a risk that government enforcement agencies will enforce the intent of the Code with respect to content claims made for calcium compounds present in cereal-based beverages as food additives. This may involve re-labelling costs.

- If Standard 1.1A.6 were repealed 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.

7.2.1.3 Government

7.2.1.3.1 Benefits

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

7.2.1.3.2 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 the Code which could increase enforcement costs.

7.2.2 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 cows' milk.

7.2.2.1 Consumers

7.2.2.1.1 Benefits

- Amending Standard 1.3.2 to permit the voluntary fortification of calcium to cereal-based beverages would provide a means 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 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.

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

7.2.2.1.1 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 a mandatory advisory statement indicating that these products are not a complete milk replacement would lessen this risk.

7.2.2.2 Industry

7.2.2.2.1 Benefits

- Australian manufacturers would be permitted to voluntarily fortify cereal-based beverages with calcium and gain regulatory clarity with respect to making claims. This may potentially encourage product development and market innovation both domestically and internationally.

- 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.

7.2.2.2.2 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.

7.2.2.3 Government

7.2.2.3.1 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 reduce any regulatory uncertainty concerning the claiming of the presence of calcium.

7.2.2.3.2 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.

7.2.3 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 cows' milk.

7.2.3.1 Consumers

7.2.3.1.1 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.

7.2.3.1.2 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.

7.2.3.2 Industry

7.2.3.2.1 Benefits

- Australian manufacturers would be permitted to voluntarily add selected vitamins and minerals to the proposed products, and this may potentially encourage product development and market innovation 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.

7.2.3.2.2 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.

7.2.3.3 Government

7.2.3.3.1 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.

7.2.3.3.2 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.

8. Consultation

8.1 Public Consultation

The Draft Assessment Report for this Application was released for public comment from 3 August to 14 September 2005. A total of twenty submissions were received, with eleven submissions from industry, six from government, two from public health and one from a consumer of cereal-based beverages.

Ten submitters supported Option 3 to amend Standard 1.3.2 to permit the addition of selected vitamins and minerals to cereal-based beverages, as permitted for beverages derived from legumes. Six others supported a modified Option 3, with modifications relating to the advisory statement (3), the addition of protein (2), applying a limit on total sugars (1) and the permitted levels of vitamins and minerals (1).

Two dairy industry submitters supported maintaining the status quo. One industry submitter did not specify their preferred regulatory option, and the remaining consumer supported fortification of cereal-based beverages.

In addition, targeted consultation on the recommended advisory statement was conducted at Final Assessment. Details on this consultation have been provided previously (see section 5.2.3.3).

8.3 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.

Amending the Code to permit the fortification of cereal-based beverages with selected vitamins and minerals is not expected to 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 comply with this Standard. 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, it has not been considered necessary to notify WTO member nations of the recommended amendment to allow the addition of selected vitamins and minerals to cereal-based beverages.

9. Conclusion and Recommendations

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 providing regulatory clarity with respect to making content claims.

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.

Therefore, FSANZ recommends the draft variations to the Code as detailed in Attachment 1 be approved 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 soy beverages; and
    - use of an advisory statement to reduce the risk of inappropriate use of cereal-based beverages, particularly in the diets of children under the age of five years;
- 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.

10. Implementation and Review

FSANZ believes the public health and safety underpinning the decision to permit the addition of vitamins and minerals to cereal-based beverages is robust and based on a sound science. We are however aware that some stakeholders have expressed concerns about the possible future impact of such fortification permissions. In an effort to provide a greater level of assurance for stakeholders, a package of measures will be introduced to review the impact of this and future voluntary fortification permissions.

The key elements of this package will include a:

- a review to examine the impact of this and future voluntary fortification permissions over the next five years;
- a new proposal to examine vitamin and mineral content claims with a view to aligning them with the new health claims standard; and

- a workshop with FSANZ staff and jurisdictions to consider a range of issues relevant to voluntary fortification.

Following consideration and approval of the Final Assessment Report by the FSANZ Board, a notification will be made to the Ministerial Council. Subject to any request from the Ministerial Council for a review, the amendments to the Code with respect to Standard 1.2.3 and Standard 1.3.2, would come into effect shortly thereafter upon gazettal.

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 five 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 five 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 protein, 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, the fortification of cereal-based beverages with selected vitamins and minerals to levels based on cows' milk was proposed at Draft Assessment. The general dietary risks of low protein and lower fat intake of non-dairy consumers[32] were also investigated. This was due to the low protein content of these beverages and their regular consumption by some children, and 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 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. Model 6 was a scenario model assessing the effectiveness of fortification for non-dairy consumers who had consumed a soy-based beverage, with the composition of the soy-based beverage being replaced by that of a cereal-based beverage fortified according to the permissions proposed in this Application.

[32] 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 in 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 was 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

Milk is an important contributor of vitamins and minerals in the diet, particularly in children. The importance of milk as a provider of vitamins and minerals decreases somewhere between the ages of 5 and 14 years as diets become more varied. 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, that is, at least 50% of one or more subpopulation age groups did not meet their respective EAR. Older consumers appear to be more at risk with respect to compromised 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, particularly for children aged 2-4 years. As is the case with the vitamins and minerals, the importance of milk as a contributor of protein decreases somewhere between the ages of 5 and 14 years of age. 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 the literature review do not provide conclusive evidence of low protein and lower fat intakes by consumers of cereal-based beverages. However, these data sources identified a low prevalence of protein inadequacy among young non-dairy consumers that increases with age. Although prevalence of relative protein deficiency is lower in the younger age groups, 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 that could have detrimental effects on growth and development. Consumers' possible perception of fortified cereal-based beverages as nutritionally equivalent to dairy milk may increase this risk of protein inadequacy as they may not appreciate the need to ensure adequate intakes of protein 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 folic acid 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 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

From available data, it is not possible to identify 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 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. Although the small numbers of young children (2-4 years) in Models 1-5 do not suggest overtly compromised protein intake, low protein intake in young children has more adverse health consequences than low protein intake in adults. 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 that 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[33]. 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[34]. The cost of rice- and oat-based beverages is 10-15% higher than soy beverages and 28-128% higher than cows' milk[35].

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[36]. 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. Contribution 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 Final Assessment Report.

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

According to the Australian 1995 NNS, despite a decrease in the amount consumed with increasing age, cows' 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.

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[37], 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.

Table 1 also describes the contribution of protein from cow's milk and dairy foods. The results suggest that these foods are an important contributor of protein particularly for children aged 2-4 years. It appears that the importance of milk as a contributor of both protein and other nutrients decreases sometime between the ages of 5-14 years as dietary patterns change and food intake becomes more varied. It is important to note that although dairy milk contributes a significant amount of protein to the diet, this Table does not take into consideration total intake of these nutrients. Mean protein intakes in both Australia and New Zealand exceed the respective population Recommended Dietary Intakes (RDI). These are described in more detail in section 3.3.1.2.

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

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 this 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-based 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.

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 Name	Model Description	Population Groups Assessed
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 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. The numbers of subjects in each age group is lower for non-dairy consumers than for the whole population; this has particular impact in Models 2 and 3 where the numbers of children 2-4 years and 5-14 years is 12 and 99 respectively. Given these smaller sample numbers, the age specific results for Models 2 and 3 should be interpreted as a guide. FSANZ decided previously[38] 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 Estimated Average Requirement(s) (EAR). 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, 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.

[38] FSANZ Fortification Implementation Framework 2005

The EARs used in this report for riboflavin, thiamin, folate, vitamin B_{12}, vitamin C, calcium magnesium and zinc were based on the UK EARs (UK Department of Health, 1993), the US EARs (US Institute of Medicine, 1997) were used for vitamin A, vitamin B_6, zinc and iodine. The EARs and RDIs for protein 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 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 percentage of consumers below the 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.

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

Vitamin/Mineral	Country	Population Group^	Mean intake	% of Consumers < EAR
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 µg	50
		2-4 years	326 µg*	50*
		5-14 years	553 µg	50
		15 years and above	1095 µg	50
	New Zealand	15 years and above	759 µg	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
Folate	Australia	2 years and above	240 µg	25
		2-4 years	160 µg*	15*
		5-14 years	181 µg	30
		15 years and above	251 µg	25
	New Zealand	15 years and above	187 µg	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/Mineral	Country	Population Group^	Mean intake	% of Consumers < EAR
Vitamin B_{12}	Australia	2 years and above	4.1 µg	30
		2-4 years	2.2 µg*	25*
		5-14 years	2.4 µg	25
		15 years and above	4.4 µg	35
	New Zealand	15 years and above	3.7 µg	35
Vitamin D	Australia	2 years and above	1.6 µg	-
		2-4 years	0.7 µg *	-
		5-14 years	1.3 µg	-
		15 years and above	1.6 µg	-
	New Zealand	15 years and above	2.0 µg	-
Iodine	Australia	2 years and above	50 µg	90
		2-4 years	48 µg*	75*
		5-14 years	46 µg	85
		15 years and above	50 µg	90
	New Zealand	15 years and above	44 µg	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 severely compromised[39] 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. Further information pertaining to the estimated dietary intake assessments can be found in Attachment 3.

3.3.1.2 Protein

Table 4 shows the estimated mean protein intakes (g/day) and percent of consumers below the EAR for protein in the Australian and New Zealand populations for models 1-5 assessed for this Application. Table 5 describes the EARs and RDIs for protein according to age.

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

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
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.

Table 5: Recommended Dietary Intakes (RDI) and Estimated Average Requirements (EAR) of protein (g/day)

Age	Sex	RDI	EAR
1-3 years	all	14 g/day	12 g/day
4-8 years	all	20 g/day	16 g/day
9-13 years	boys	40 g/day	31 g/day
	girls	35 g/day	24 g/day
14-18 years	boys	60 g/day	49 g/day
	girls	45 g/day	35 g/day
19-70 years	men	64 g/day	52 g/day
	women	46 g/day	37 g/day
>70 years	men	81 g/day	65 g/day
	women[1]	57 g/day	46 g/day

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

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, taking account of the low sample numbers for some of the Models, the extent of inadequacy appears to increase with age from low to moderate levels, regardless of beverage preference. 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 Models 4 and 5 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.

Although the Models show a greater proportion of non-dairy consumers aged 2 years and older whose protein intake appears to be below the EAR compared to that of dairy consumers, mean protein intakes well exceed the respective RDIs.

3.3.1.3 Fat

Table 6 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 6: 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 7 illustrates the 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 7: 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[40] 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 recommends permitting fortification of cereal-based beverages to levels permitted for legume-based beverages, which are based on cows' 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.

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.

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

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 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, cows' 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 in the diets of Australians and New Zealanders are meats, poultry and fish (about 30%), cereals and cereal-based foods (about 25%), and dairy foods (about 15%) (NHMRC and MoH, 2004).

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. Whilst it is expected that that risk for the majority of young children who suffer from allergies will be mitigated by medical supervision, there is as described in the case studies, some children who consume these products will not be under medical supervision and will be at risk.

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 National Children's Survey showed that dairy milk contributed 11% to the mean protein intakes of children aged 5-14 years.

The set of draft NHMRC EARs and RDIs for protein is provided in Table 5. 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, 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 (NHMRC and MoH, 2004).

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 (NHMRC and MoH, 2004). 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 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.

3.5.2 Young Children Aged 2-4 Years

3.5.2.1 General Population

Dairy milk contributes a significant amount of vitamins and minerals to the diets of Australian children 2-4 years (Table 1). FSANZ referred to data from national nutrition surveys to assess the level of vitamin and mineral inadequacy in the general population (Annex 1). These baseline dietary estimates suggest that this age group exceeds the age specific EARs[41] for all the listed vitamins and minerals. No nutrient intake data has been collected for this age group in New Zealand.

Dairy milk contributes approximately 22% of protein to the diets of Australian children 2-4 years (Table 1) with the contribution dropping to 13% somewhere between 5-14 years. The results of the estimated dietary intake assessment in Model 1 in Table 4 suggest that less than 1% of children in this age group have intakes below the EAR for protein. Mean protein intake for Australian children 2-4 years was 54 g/day, well in excess of the RDI of 14 g/day. Protein is important for the 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.

3.5.2.2 Non-dairy Consumers

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 (Table 3) suggest that this age group has a more nutritionally adequate diet than older age groups (i.e. more likely to exceed the EAR for a variety of nutrients), the results could perhaps be due to carers receiving appropriate dietary advice or they may be an uncertain result due to small number of consumers in the model (n=12). The results of the literature review are mixed and inconclusive. There is a small risk that non dairy consumers aged 2-4 years would have inadequate intakes of some vitamins and minerals.

Given the uncertainties in the data for the 2-4 year old age group, there appears to be very little difference in level of protein adequacy between this group and the older children aged 5-14 years. The dietary intake assessment suggests that both age groups are likely to be more adequately nourished with respect to protein compared to those aged 15 year and older (Table 4, Model 3). This is shown by the smaller percentage of unadjusted protein intakes below the EAR for the younger age groups compared to the oldest group (7-8% versus 25%).

[41] UK EARs were used for thiamin, riboflavin, folate, vitamin B_{12}, vitamin C, calcium, magnesium and phosphorus. The US EARS were used for vitamin A, vitamin B_6 and zinc. Vitamin D and iodine were not assessed.

However, the relative impact of avoiding dairy and soy foods is greatest for children aged 2-4 years as shown by the difference in percentage of non-dairy and dairy consumers with unadjusted protein intakes below the EAR. The fact that the mean protein intake of 2-4 year old non-dairy consumers considerably exceeds their age-specific RDI indicates a wide distribution of protein intakes. These data therefore indicate that although most 2-4 year old non dairy consumers would *not* be at risk of inadequate protein intakes, there is likely to be a small proportion that would be so affected. Because the consequences of compromised protein intake in this age group are far greater than for any other age, it is concluded that a small percentage of non dairy children would be at risk of protein inadequacy with potential for poor growth and suboptimal development.

3.5.3 Older Children 5-14 Years

3.5.3.1 General Population

The contribution of dairy milk to vitamin and mineral intake decreases in importance between the ages of 5 and 14 years. Estimates based on the Australian national nutrition survey data suggest that all the Australian children surveyed in this age group exceed the EARs for the proposed vitamins and minerals with the exception of folate, calcium, magnesium, zinc and vitamin B_6. Children to the age of about 8 years had adequate vitamin and mineral intakes, however for children aged 11-14 years: 3% had adjusted intakes below the EAR for folate; 25% for calcium; 35% for magnesium; 3% for zinc; and 10% for vitamin B_6.

Results provided in the New Zealand Children's National Nutrition Survey (MoH, 2003) show that for children aged 5-14 years: 8% had intakes below the EAR for Vitamin A; 3% for riboflavin; 5% for folate; 15% for calcium; and 7% for zinc.

Although protein is not generally considered to be inadequate in the diets of Australians and New Zealanders, Table 4 suggests that 2% of Australian children aged 5-14 years had intakes below the EAR for protein. This is likely to be an overestimate due to the dietary intake assessments being based on one-day intakes. The New Zealand Children's Nutrition Survey states that New Zealand children were consuming at least double their age specific Recommended Nutrient Intake[42]. Table 4 indicates similar results for Australian children.

3.5.3.2 Non-dairy Consumers

There is little information in the literature 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 (Table 1) shows that milk is a less important food in this age group compared to the 2-4 year age group, the estimated dietary intake assessment in section 3.3 (Table 3) suggests that the vitamin and mineral intake in this age group is poorer than that of the 2-4 year age group and that consumers aged 5-14 years are less likely to exceed the EAR for the full range of assessed vitamins and minerals. Therefore, compared with young children, there is a greater risk that non-dairy consumers aged 5-14 years would have inadequate intakes of several vitamins and minerals.

[42] RNI for Protein used in the New Zealand Children's Nutrition Survey was based on the UK Dietary reference value, UK department of Health 1991.

Whilst the mean protein intake is above the age-specific RDI, and suggests that this group would have an adequate protein intake, the Models 2 and 3 (Table 4) show that up to 7% of dairy avoiders in this age group may have protein intakes below the EAR. Because this age group are still growing, the requirement for adequate protein to meet growth and development remains important.

Because the consequences of compromised protein intake in this age group are not of the magnitude of the youngest age group, but still of concern because of demands for growth and development, it is concluded that a small percentage of non dairy consumers aged 5-14 years would be at risk of protein inadequacy with potential for poor growth.

3.5.4 Adolescents and Adults 15 Years and Older

3.5.4.1 General Population

Dairy milk becomes a less important contributor of vitamins and minerals to the diet after the age of 15 however it still about 37% of calcium, 26% of riboflavin and 65% of iodine intakes. The baseline estimates of dietary intake in Annex 1 suggests that calcium, magnesium and vitamin B_6 are the nutrients for which the greatest percentage of consumers over the age of 15 have intakes below the EAR.

Model 1 in Table 4 shows that the mean protein intake for this age group exceeds the RDI, but that 10% of Australians and New Zealanders over the age of 15 years have unadjusted protein intakes below the EAR.

3.5.4.2 Non-dairy Consumers

For the majority of proposed vitamins and minerals (Table 3), the percentage of non-dairy consumers with intakes below the EAR is greater than the younger age groups. The clear exceptions are calcium and vitamin A where the percentage of non-dairy consumers below the EAR essentially stays the same irrespective of age. Therefore, compared with children, there is a greater risk that non-dairy consumers aged 15 years and older would have inadequate intakes of several vitamins and minerals.

The estimated dietary intake assessment in Table 4 shows that mean protein intakes for adult non-dairy consumers exceed the RDI. Compared with younger age groups, this age group has the greatest percentage of non-dairy consumers with protein intakes below the EAR and the lowest relative increase in percentage below EAR compared to the normal population (Models 1 and 3).

Whilst the percentage of consumers aged 15 years and over whose protein intakes are below the EAR is highest of all age groups, the consequences of inadequate protein intakes are not as profound as protein inadequacy in the younger age groups, particularly those aged 2-4 years. There is wide variation in dietary protein intake, to which the body is able to adapt over a few days. However, severe disease states or fasting can cause substantial body protein losses mostly in the form of loss of muscle mass as energy needs take priority (NHMRC and MoH, 2004). For the majority of adults, low intakes of protein will not result in the same consequences as low protein intake in young and growing children because of the absence of growth.

Therefore, combining the relatively light consequence of protein inadequacy with its greater prevalence in this age group, the risk to health of consuming cereal-based beverages for this age group is least for all assessed age groups and is small overall. The more likely cause of compromised protein and other nutrient intake in this age group is overall poor dietary habits and not as a result of the consumption of a single product. .

3.5.5 Conclusion

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 prevalence of inadequate nutrient intake appears to be for those over the age of 15 years. However, combining the relatively light consequence of protein inadequacy with its greater prevalence in the over 15 years age group, the risk to health of consuming cereal-based beverages for this age group is least for all assessed age groups and is small overall.

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 or those who are suffering severe ill health. The replacement of unfortified 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 8 shows the impact of fortifying cereal-based beverages with vitamins and minerals at concentrations equivalent to levels found in milk as permitted in Standard 1.3.2 for soy-based beverages (Model 6) and contrasts them with dietary vitamin and mineral intake of consumers of unfortified cereal-based beverage (Model 5).

Table 8: 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 µg	30
Vitamin A	1,012 µg	25	1,170 µg	20
Thiamin	1.7 mg	3	1.7 mg	2
Riboflavin	1.3 mg	35	1.8 mg	10
Folate	411 µg	2	333 µg	3
Vitamin B_6	1.7 mg	30	1.8 mg	25
Vitamin B_{12}	2.1 µg	45	3.2 µg	25
Vitamin D	1.5 µg	-	3.5 µg	-
Iodine	43 µg	95	46 µg	95

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

The results in Table 8 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 percentage of consumers below the 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/100 g) was based on a US product – Rice Dream, canned (USDA 2005). In Model 6, cereal-based beverages were assigned a folate concentration (6 µg/100 g) based on the maximum permitted quantity of folate in Standard 1.3.2 and assuming equivalent bioavailability of natural folates and folic acid. 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 Intestinal Absorption of Specific Vitamins and Minerals

Investigations into the toxicity of vitamins and minerals by the UK Expert Group on Vitamins and Minerals (United Kingdom Department of Health, 1993) have yielded information on absorption rates of those vitamin and minerals (with the exception of vitamin B6 and vitamin D) that are the subject of this Application (see Table 9 below). The absorption rates encompass values for both natural and synthetic sources of the vitamins and minerals.

Table 9: Absorption rates of proposed vitamins and minerals

Vitamin / Mineral	Absorption (%)	Notes
Vitamin A (retinol)	~80	Absorption rate is dependent on concurrent fat intake.
Folic Acid	50-100	The lower absorption values apply to naturally occurring forms of folic acid, while supplemental forms are more highly bioavailable.
Vitamin B_{12}	1.2-50	Vitamin B_{12} is dose dependent; a maximum of 2 µg can only be absorbed from a dose/meal due to saturation of transport mechanisms. Lower doses have higher absorption rates.
Calcium	25-60	Calcium is absorbed approximately the same from food and supplemental sources. The higher absorption rates are found in young children, and decrease down to 25% by adulthood.
Iodine	~97	
Magnesium	~50	This value applies to food sources of magnesium. This value can decrease depending on dietary fibre and protein intake. Supplemental forms of magnesium are not as well absorbed as food sources.
Phosphorus	55-90	This value applies to all forms of phosphorus. Children absorb phosphorus more efficiently than adults.
Zinc	15-60	This value applies to dietary sources of zinc. Values for supplemental zinc have not been identified. Values fluctuate widely depending on dietary factors, including concurrent copper intake.

Table 9 shows that there is no consistent pattern across the various vitamins and minerals; for some of these nutrients the form available in food is more readily absorbed, whereas for others the supplemental sources are more readily absorbed. Table 8 also shows that even under ideal conditions, regardless of its source, a vitamin or mineral is generally not fully absorbed and thus not fully bioavailable. This differs from the perception that might exist in the community that all vitamins and minerals are fully bioavailable.

At a population diet level, the confounding factors that contribute to the variable nature of bioavailability can be taken into account. Population health recommendations on vitamins and minerals such as the draft Nutrient Reference Values for Australia and New Zealand (NHMRC, 2005) already accommodate fluctuations in bioavailability across a national diet.

Such accommodation makes the bioavailability from individual foods less relevant to population health, unless the vitamins and minerals in those foods are providing an important public health function (e.g. mandatory fortification), or act as the sole source of an individual's nutrition (e.g. infant formula products).

4.1.2.4 Studies on Calcium Bioavailability

For calcium, studies have shown that age plays the most significant role in determining how much of the nutrient is absorbed, rather than its source or chemical form (United States Institute of Medicine, 1997).

The impact of confounding factors is significant for calcium, and can lead to inappropriate conclusions on its bioavailability. For example, when the various forms of calcium are compared to each other, short-term biochemical assessments (e.g. changes in serum calcium following calcium intakes) indicate that different forms of calcium (including dairy sources) have different bioavailabilities (Talbot *et al*., 1999; Heller *et al*., 2000; Kenny *et al*., 2004).

However, assessments of the different forms on physiological parameters, such as bone mineral density, show that a wide range of different calcium sources, both supplemental and food types, have approximately the same impact (Reid, 2005). Although high doses of different supplemental calcium forms (such as calcium carbonate, calcium citrate-malate, and calcium lactate-gluconate) have been shown on occasions to differ in their impact on bone mineral density, the overall difference in the impact between these forms is not significant (Dawson-Hughes *et al*., 1990; Chevalley *et al*., 1994; Prince *et al*., 1995; Ruegsegger *et al*., 1995). More importantly, comparisons between similar doses of supplemental and dairy-based sources of calcium indicate that their impact on bone mineral density is approximately the same (Lau *et al*., 2002; Reid, 1993).

The above studies demonstrate that while assessments under isolated, experimental conditions on the different forms of calcium show variations in bioavailability, these variations are not reproduced over the longer-term when the different forms are used in actual human life situations. As a specific example, calcium carbonate is widely cited as having a poor bioavailability *in vitro*, yet the bone mineral density comparisons with dairy-based calcium listed above include this form of supplemental calcium (Reid, 1993). The reasons for these differing results from experimental and actual life studies becomes apparent when consideration is given to the wide variety of confounding factors that can affect bioavailability.

4.1.2.5 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 potential absorption 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 in an *in vitro* experiment. 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.

According to the author, this implies that although the majority of calcium in rice beverages fortified with tricalcium phosphate has the potential to be absorbed, consumers could still be mislead if they believed they would be absorbing the amount of calcium stated on the label. No studies have been undertaken to look at the bioavailability or absorption of any other nutrients in fortified cereal-based beverages.

4.1.3 Conclusion

The data in Models 5 and 6 suggest that permission to fortify cereal-based beverages would address to some extent the risk of inadequate intake of a variety of dairy-supplied vitamins and minerals for consumers of cereal-based beverage who are also 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. Comparison of gastrointestinal absorption rates among vitamins and minerals – irrespective of whether naturally occurring or supplemental – show wide variation with very few vitamins and minerals attaining complete intestinal absorption. Differences in bioavailability have been generally accounted for in setting nutritional reference values based on the national diet.

Therefore, as the actual bioavailability of any one vitamin or mineral is dependent on a wide range of factors, it is not possible to draw definitive conclusions on the bioavailability as it applies to any individual food product, including cereal-based beverages. It is, however, expected that the vitamins and minerals in cereal-based beverages are bioavailable to varying extents.

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.

REFERENCE LIST

Black, R., Williams, S., Jones, I. and Goulding, A. (2002). Children who avoid drinking cows' milk have low dietary calcium intakes and poor bone health. *Am. J. Clin. Nutr*. 76: 675-80.

Carvalho, N., Kenney, R., Carrington, P. and Hall, D. (2001). Severer nutritional deficiencies in toddlers resulting from health food milk alternatives. *Pediatrics*. 107: 46-54.

Chevalley, T., Rizzoli, R., Nydegger, V., Slosman, D., Rapin, C.H., Michel, J.P., Vasey, H. and Bonjour, J.P. (1994) Effects of calcium supplements on femoral bone mineral density and vertebral fracture rate in vitamin-D-replete elderly patients. *Osteoporos.Int* 4(5):245-252.

Christie, L., Hine, J., Parker, J. and Burks, W. (2002). Food allergies in children affect nutrient intake and health. *JADA.* 102: 1648-1651.

Dawson-Hughes, B., Dallal, G.E., Krall, E.A., Sadowski, L., Sahyoun, N. and Tannenbaum, S. (1990) A controlled trial of the effect of calcium supplementation on bone density in postmenopausal women. *N Engl J Med* 323(13):878-883.

Department of Health and Human Services, DHHS. (1988). *The surgeon generals report on nutrition and health.* US. Publication No. 88-52010. United States: US Department of Health and Human Services

Fairweather-Tait, S. and Teucher, B. (2002). Iron and calcium bioavailability of fortified foods and dietary supplements. *Nutr Rev* 60: 360-367.

Fairweather-Tait, S. and Southon, S. (2004). Bioavailability of Nutrients. In: Caballero, B., Trugo, L.C., and Finglas, P.M. eds. *Encyclopaedia of Food Sciences and Nutrition*. 2nd ed, Academic Press, Sydney, pp478-484.

Finglas, P. (2004). Vitamins: Overview. In: Caballero, B., Trugo, L.C., and Finglas, P.M. eds. *Encyclopaedia of Food Sciences and Nutrition*. 2nd ed, Academic Press, Sydney, pp6046-6053.

Heaney, R. (2001). Factors influencing the measurement of bioavailability, taking calcium as a model. *J. Nutr.* 131(4 Suppl):1344S-1348S.

Heaney, R., Rafferty, K. and Bierman, J. (2005). Not all calcium fortified beverages are equal. *Nutrition Today* 40: 39-44.

Heller, H.J., Greer, L.G., Haynes, S.D., Poindexter, J.R. and Pak, C.Y. (2000) Pharmacokinetic and pharmacodynamic comparison of two calcium supplements in postmenopausal women. *J Clin Pharmacol* 40(11):1237-1244.

Henrickson, C., Eggesbo, M., Halvorsen, R. and Botten, G. (2000). Nutrient intake among two-year-old children on cows' milk restricted diets. *Acta. paediatr*. 89:272-8.

Hill, D., Hoskings, C. and Heine, R. (1999). Clinical spectrum of food allergy in children in Australia and South-East Asia: identification and targets for treatment. *Ann. Med*. 31: 272-81.

Jones, G. (1997) 'Minerals', Wahlqvist M. Editor: '*Food and Nutrition*', Chapter 25: p20

Kenny, A.M., Prestwood, K.M., Biskup, B., Robbins, B., Zayas, E., Kleppinger, A., Burleson, J.A. and Raisz, L.G. (2004) Comparison of the effects of calcium loading with calcium citrate or calcium carbonate on bone turnover in postmenopausal women. *Osteoporos.Int* 15(4):290-294.

Lau, E.M., Lynn, H., Chan, Y.H. and Woo, J. (2002) Milk supplementation prevents bone loss in postmenopausal Chinese women over 3 years. *Bone* 31(4):536-540.

McGowan, M. and Gibney, M. (1993). Calcium intakes in individuals on diets for the management of cows' milk allergy: a case control study. *Euro. J. Clin. Nutr.* 47**:** 609-616.

McLennan, W. and Podger, A. (1999). *National Nutrition Survey: Foods Eaten*, Australian Bureau of Statistics and Commonwealth Department of Health and Aged Care, Canberra, Australia (ABS Catalogue No. 4804.0).

New Zealand Ministry Of Health. (2003) *Food and Nutrition Guidelines for Healthy Adults: A Background Paper*. Wellington, New Zealand

National Health and Medical Research Council and New Zealand Ministry of Health (2004) *Nutrient Reference Values for Australia and New Zealand including Recommended Dietary Intakes.* Draft for public comment

Paganus, A., Juntunen-Backman, K. and Savilahti, E. (1992). Follow up of nutritional status and dietary survey in children with cows' milk allergy. *Acta. Paediatr*. 81: 518-21.

Prince, R., Devine, A., Dick, I., Criddle, A., Kerr, D., Kent, N., Price, R. and Randell, A. (1995) The effects of calcium supplementation (milk powder or tablets) and exercise on bone density in postmenopausal women. *J Bone Miner.Res* 10(7):1068-1075.

Russell, D.G., Parnell, W.R. and Wilson, N.C. et al (1999). *NZ Food NZ People. Key Results in the 1997 National Nutrition Survey.* Ministry of Health: Wellington

Recker, R., Bammi, A., Barger-Lux, M. and Heaney, R. (1988). Calcium absorbability from milk products, an imitation milk, and calcium carbonate. *Am. J. Clin. Nutr.* 47: 93-95.

Reid, I.R., Ames, R.W., Evans, M.C., Gamble, G.D. and Sharpe, S.J. (1993) Effect of calcium supplementation on bone loss in postmenopausal women. *N Engl J Med* 328(7):460-464.

Ruegsegger, P., Keller, A. and Dambacher, M.A. (1995) Comparison of the treatment effects of ossein-hydroxyapatite compound and calcium carbonate in osteoporotic females. *Osteoporos.Int* 5(1):30-34.

Talbot, J.R., Guardo, P., Seccia, S., Gear, L., Lubary, D.R., Saad, G., Roberts, M.L., Fradinger, E., Marino, A. and Zanchetta, J.R. (1999) Calcium bioavailability and parathyroid hormone acute changes after oral intake of dairy and nondairy products in healthy volunteers. *Osteoporos.Int* 10(2):137-142.

Turnlund, J. (1991). Bioavailability of dietary minerals to humans: the stable isotope approach. *Crit Rev Food Sci Nutr* 30: 387-396.

United Kingdom Department of Health. (1993) Dietary Reference Values for Food, Energy and Nutrients for the United Kingdom. Crown Publications; London, pp3-10. Report on Health and Social Subjects.

United States Institute of Medicine. (1997) Dietary Reference Intakes: Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride. National Academy Press, Washington DC.

Wylie-Rosset, J. and Swencionis, C. *'Nutritional Approaches to Hypertension'*. Langford, L. (ed.) and Langford, E. (ed) (1990) '*Nutritional Factors in Hypertension'*

ANNEX

Table 1: Estimated Percentage of Respondents for Australian and New Zealand Population Groups With Vitamin and Mineral Intakes Below UK EARs (Results of 3% or more have been highlighted in bold text)

Nutrient	*Modelling*	*Sub-category*	*2-3 yrs*	*4-6 yrs*	*7-10 yrs*	*11-14 yrs*	*15-18 yrs*	*19-50 yrs*	*51+ yrs*	*2+ yrs#*
Thiamin	EAR (mg)	Males	0.4	0.5	0.6	0.7	0.8	0.8	0.8	-
		Females	0.4	0.5	0.5	0.6	0.6	0.6	0.6	-
	% below EAR	Aust	0	0	0	0	<1	<1	1	<1
		NZ	-	-	-	-	<1	<1	4	2
Riboflavin	EAR (mg)	Males	0.5	0.6	0.8	1.0	1.0	1.0	1.0	-
		Females	0.5	0.6	0.8	0.9	0.9	0.9	0.9	-
	% below EAR	Aust	0	0	0	0	**5**	**3**	**5**	**3**
		NZ	-	-	-	-	2	1	**3**	2
Folate	EAR (µg)	Males	50	75	110	150	150	150	150	-
		Females	50	75	110	150	150	150	150	-
	% below EAR	Aust	0	0	<1	**3**	**4**	**3**	2	2
		NZ	-	-	-	-	**4**	**3**	**8**	**5**
Vitamin B_{12}	EAR (µg)	Males	0.4	0.7	0.8	1.0	1.3	1.3	1.3	-
		Females	0.4	0.7	0.8	1.0	1.3	1.3	1.3	-
	% below EAR	Aust*	0	0	0	0	0	0	0	0
		NZ	-	-	-	-	0	0	0	0
Calcium	EAR (mg)	Males	275	350	425	750	750	525	525	-
		Females	275	350	425	625	625	525	525	-
	% below EAR	Aust	0	0	1	**25**	**30**	**15**	**25**	**20**
		NZ	-	-	-	-	**35**	**15**	**25**	**20**
Magnesium	EAR (mg)	Males	65	90	150	230	250	250	250	-
		Females	65	90	150	230	250	200	200	-
	% below EAR	Aust	0	0	**3**	**35**	**30**	**10**	**15**	**15**
		NZ	-	-	-	-	**20**	**5**	**20**	**10**
Phosphorus	EAR (mg)	Males	213	273	327	578	404	404	404	-
		Females	213	273	327	483	404	404	404	-
	% below EAR	Aust	0	0	0	<1	0	0	<1	<1
		NZ	-	-	-	-	0	0	0	0

* Vitamin B_{12} was not assessed in the 1995 Australian NNS. Therefore, vitamin B_{12} concentrations in foods from the 1997 New Zealand NNS were used in the assessment of vitamin B_{12} intakes for the Australian population.

\# 15 years and above for New Zealand.

\- No intake data.

Table 2: Estimated Percentage of Respondents for Australian and New Zealand Population Groups With Vitamin and Mineral Intakes Below US EARs (Results of 3% or more have been highlighted in bold text)

Nutrient	*Modelling*	*Sub-category*	*2-3 yrs*	*4-8 yrs*	*9-13 yrs*	*14-18 yrs***	*19-30 yrs*	*31-50 yrs*	*51-70 yrs*	*71+ yrs*	*2+ yrs#*
Vitamin A	EAR (µg)	Males	210	275	445	630	625	625	625	625	-
		Females	210	275	420	485	500	500	500	500	-
	% below EAR	Aust	0	0	0	**3**	2	0	0	0	<1
		NZ				0	0	0	0	0	0
Vitamin B_6	EAR (mg)	Males	0.4	0.5	0.8	1.1	1.1	1.1	1.4	1.4	-
		Females	0.4	0.5	0.8	1.0	1.1	1.1	1.3	1.3	-
	% below EAR	Aust*	0	0	0	**10**	**15**	**25**	**45**	**60**	**25**
		NZ	-	-	-	0	0	**15**	**55**	**65**	**25**
Zinc	EAR (mg)	Males	2.2	4.0	7.0	8.5	9.4	9.4	9.4	9.4	-
		Females	2.2	4.0	7.0	7.5	6.8	6.8	6.8	6.8	-
	% below EAR	Aust	0	0	**3**	**8**	**8**	**3**	**9**	**17**	**6**
		NZ	-	-	-	**5**	**4**	1	**13**	**18**	**7**

* Vitamin B_6 intake data are available only for New Zealand (1997 NNS); the data for Australia has been adapted from the New Zealand NNS data.

** 15-18 years for New Zealand.

\# 15 years and above for New Zealand.

\- no intake data

Attachment 3

Dietary Modelling Methodology Report

An Application was received from So Natural Foods Australia Limited requesting a new food category be included in the Australia New Zealand Food Standards Code (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 Final Assessment, FSANZ recommends permitting the fortification of cereal-based beverages with selected vitamins and minerals, as permitted under Standard 1.3.2 for beverages derived from legumes. This Application has been considered on the basis of nutritional equivalence, where cereal-based beverages are considered a substitute food for cows' milk.

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 National Nutrition Survey (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 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 were 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.

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 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). The EARs used in this dietary intake assessment came from a range of sources. Since the EARs for the Australian and New Zealand populations are still under development, the most appropriate EAR for each nutrient were assessed and used by FSANZ. Therefore, 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 for most of the vitamins and minerals assessed in this dietary intake assessment. Vitamin D was not compared against an EAR as no overseas EAR has been set. Protein was compared against draft EARs established by NHMRC (NHMRC, 2004).

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.

REFERENCES

Cook, T., Rutishauser, I. and Allsopp, R. (2001) *The Bridging Study: comparing results from the 1983, 1985 and 1995 Australian national nutrition surveys*. Australian Food and Nutrition Monitoring Unit, Commonwealth Department of Health and Aged Care, Commonwealth of Australia, Canberra.

Gunton, J.E., Hams, G., Fiegert, M. and McElduff, A. (1999) Iodine deficiency in ambulatory participants at a Sydney teaching hospital: is Australia truly iodine replete?. *Medical Journal of Australia* (171):467-470.

NHMRC (2004) *Draft nutrient reference values for Australia and New Zealand including Recommended Dietary Intakes*., Canberra.

Rutishauser, I. (2000) Getting it right:- how to use the data from the 1995 National Nutrition Survey. Commonwealth of Australia, Canberra.

United Kingdom Department of Health (1993) *Dietary Reference Values for Food, Energy and Nutrients for the United Kingdom*. Report on Health and Social Subjects Crown Publications, London, 3-10.

United States Institute of Medicine (1998) *Dietary Reference Intakes: Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, Choline*. National Academy Press, Washington DC.

United States Institute of Medicine (2000) *Dietary Reference Intakes: Vitamin C, Vitamin E, Selenium, Carotenoids*. National Academy Press, Washington DC.

United States Institute of Medicine (2001) *Dietary reference intakes: vitamin A, K, arsenic, boron, chromium, copper, iodine, iron, manganese, molybdenum, nickel, silicon, vanadium, and zinc. A Report of the Panel on Micronutrients, Subcommittees on Upper Reference Levels of Nutrients and Interpretation and Use of Dietary Reference Intakes, and the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes*. National Academy Press, Washington DC.

USDA (2005) *USDA National Nutrient Database for Standard Reference*. 2 May 2005.

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

Vitamin/Mineral	Country	Population Group	Mean Intake
Iodine (µg/day)	Australia	2 years and above	50
		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 20 submissions in response to the Draft Assessment Report on Application A500 – Fortification of Cereal-Based Beverages, during the 6-week public consultation period of 3 August to 14 September 2005. A summary of submitter comments is provided in the table below. One late submission was also received.

Three regulatory options were presented in the Draft Assessment Report:

Option 1 – Maintain 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.

No.	Submitter	Submission Comments
1	**Australian Food and Grocery Council** *Kim Leighton*	**Supports Option 3** *Supports Option 3 on the basis that:* • There is a significant potential health-benefit for a specific target population which is at risk of illness through nutritional deficiency; • The addition of proposed vitamins and minerals at the recommended levels are safe; • It promotes fairness and equity in trade with New Zealand; and • It promotes innovation and development. *Use of the term 'milk'* • Notes that cereal-based beverages have significantly lower levels of protein, fat and energy, and that it is not economically feasible to increase the protein content of these products. • Therefore, recommend that use of the descriptor 'milk' should be prohibited, as it is not possible for this product to be nutritionally equivalent to milk. *Advisory Statement* • Supports use of an advisory statement to inform consumers and parents of children under 12 that the product is low in fat and protein. • Recommends that in order to avoid confusion between cereal-based beverages and milk that any advisory statements should avoid comparing the product with milk. • Recommends an advisory statement that, without reference to milk, identifies the product as a low protein and low fat product not intended to be used as a complete meal replacement which should be consumed with foods that are rich in proteins to form a balanced healthy diet.

No.	Submitter	Submission Comments
		Impact Analysis • Notes the increased cost of cereal-based beverages compared to milk, and the higher cost of the imported 'enriched' product. • Notes that there are technical issues that the manufacturer will need to resolve to ensure that the proposed vitamin and mineral additions remain suspended in solution and have suitable bioavailability, which may add to the cost of manufacture and affect the price point for market entry.
2	**Ceres Enterprises Ltd** *Ian Cambourn/ Marina Adams*	**Supports a Modified Option 3** *General Comments* • Ceres Enterprises is the New Zealand importer of Rice Dream Enriched, which is fortified with calcium and vitamins A, B_{12} and D_2. • Rice Dream Enriched is currently imported under Standard 1.1A.6, and they note that once this transitional standard is repealed that Standard 1.3.2 will govern the sales of this product. • Notes that as the levels of vitamin D contained in Rice Dream Enriched are greater than those proposed for Standard 1.3.2, that Rice Dream Enriched may no longer be able to be sold in New Zealand. • In general, supports the proposed application and the spirit thereof. • Considers it important to be able to enrich cereal-based beverages with vitamins and minerals to the level they occur in cows' milk, due to the large number of their customers who rely on Rice Dream Enriched as a substitute for dairy or soy milk. *Vitamin and Mineral Permissions* • Considers that the proposed permitted level of vitamin D could be raised. • Notes that the vitamin D content of Rice Dream Enriched is 0.48µg or a 30.2% increase over the proposed permitted quantity, and is based on 25% of the US RDA of 10µg of vitamin D. • Propose that higher levels of vitamin D be permitted as: ▪ overdosing from food source of vitamin D is not known; ▪ the US RDA for vitamin D has been set since the 1930's; ▪ vitamin D has an important role in protecting against medical conditions such as osteoporosis; ▪ sources of vitamin D are commonly from animal sources, and as such those on restricted or vegan diets benefit from a vitamin D source like Rice Dream Enriched; and ▪ the upper tolerable intake level for vitamin D was set at 25µg for infants and 50µg for children, adults, pregnant and lactating women (US Food and Nutrition Board of the Institute of Medicine, 1999). • Notes that all other vitamins and minerals added to Rice Dream Enriched are within the proposed limits. *Impact Analysis* • Consumers: ▪ if sale of Rice Dream Enriched were prohibited then consumers who rely on this product will be unable to source it; and

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		▪ notes that while other products may emerge in time, Rice Dream Enriched is a market leader and well-known brand which meets a specific set of needs. • Ceres Enterprises: ▪ over 200,000 units of Rice Dream Enriched were sold last year, and the product has experienced a 15% growth in sales per year; ▪ Ceres Enterprises is the sole importer of this brand of product; ▪ over 91% of sales are via large supermarkets; and ▪ this product is Ceres Enterprises' single largest-selling product, and discontinuation would lead to significant impacts. *Advisory Statement* • Supports the proposed advisory statement. • The company recognises that Rice Dream Enriched should not be used in place of infant formula, breast milk or cows' milk, and should not be used as a single source of food.
3	**Ceres Natural Foods Pty Ltd** *Don Lazzaro*	**Supports Option 3** Supports the recommendation of the Draft Assessment Report. No additional comments.
4	**Coles Myer Ltd** *Helen Mair*	**Supports Option 3** *General Comments* • Considers the ability to improve the nutritional content of cereal-based beverages can only be of benefit to consumers. • Considers that protein should also be permitted as a voluntary addition to cereal-based beverages. *Advisory Statement* • Considers it imperative that specific advisory statements be included due to the potential adverse health outcomes for infants and children consuming cereal-based beverages as a substitute for cows' milk.
5	**Complementary Healthcare Council** *Allan Crosthwaite*	**Supports Option 3, in general** *General Comments* • In general, supports Option 3. • Strongly recommends that the development of any new standard ensures that the food industry is responsible for label claim verification (e.g. analysis of multi-micronutrients in a complex matrix), analytical method development and method validation, stability studies to substantiate the allocated shelf life, bioavailability (to substantiate efficacy) and label requirements. • Considers the report does not address the above issues and their impact on bioavailability, safety and misleading consumers. *Vitamin and Mineral Stability* • Understands that some vitamins in aqueous solutions may be highly instable.

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		• Considers it a major omission that the report did not address the issue of stability of the vitamins and minerals over the shelf life of the product, and that this undermines the arguments that these products are meeting consumer nutritional or health requirements. • Considers fortification can only be useful if the food contains effective and bioavailable amounts of the nutrients and is ingested at regular intervals over time. • Without stability information it is difficult to determine that the vitamin or mineral is effectively being delivered to the consumer. • States that the report does not address how FSANZ and the relevant States/Territory governments will implement the required manufacturing standards to ensure label claims over the shelf-life of the product. • Notes there are currently inadequate controls over manufacturing procedures and substantiation of content, stability and bioavailability in foods containing supplementation. Consumers may be misled to believe that their nutritional needs are being catered for by eating certain foods. • Comments that the complementary healthcare industry is currently subject to considerable costs to meet the requirements of the *Therapeutic Goods Act 1989* in order to achieve the above outcomes. It is therefore to be expected that the cost to the food industry should be similar. These costs would inevitably be passed onto consumers. • Considers consumers want to know exactly how much they consume from a food and need to be confident that the product is stable and contains what it says on the label. They consider that at present foods can't provide this. *Efficacy* • Do not support the conclusion that the bioavailability of the vitamins and minerals is likely to be comparable to other food sources. • Comments that the report does not address stability of the supplemental ingredients over the shelf-life of the product. *Impact Analysis* • Agrees there is potential for fortified foods to compete with therapeutic supplements. Considers this may potentially misled consumers regarding the bioavailability of the nutrients over the shelf-life of the product, where manufacturers of supplements must meet these requirements under the *Therapeutic Goods Act 1989*.
6	**Dairy Australia** *Jacinta Orr*	**Supports Option 1** *General Comments* • Believes Standard 1.3.2 needs to be reviewed to allow greater fortification of milk to create a 'level playing field' and correct major discrepancies across food groups. • Considers it inequitable that milk, a highly nutritious vehicle, can only have three vitamins and minerals added, whereas legume-based beverages can have 12 added, and the addition of 12 vitamins and minerals to cereal-based beverages is being proposed.

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		• Considers cereal-based beverages are not nutritionally equivalent to cows' milk, and are not appropriate vehicles for fortification as they have a very low protein level. • Cereal-based beverages could be viewed as a special medical food and perhaps should not be considered under Standard 1.3.2 as a food. *Misleading Consumers* • Believes that consumers may be misled by their milk-like nature, believing them to be nutritionally equivalent to cows' milk, where the Policy Guideline states that 'fortification should not mislead the consumer as to the nutritional quality of the fortified food'. • Considers that fortification of cereal-based beverages may encourage consumers to self diagnose rather than follow up a medical diagnosis and appropriate treatment. *Protein Content* • Believes that children remain at high risk of being adversely affected due to the low protein content of cereal-based beverages, if used as a substitute for cows' milk, despite FSANZ modelling suggesting such outcomes are inconclusive. • Considers there is clear evidence for deleterious effects of drinking cereal-based beverages, as shown by the case studies in the report. *Use of the term 'milk'* • Notes the definition of milk does not incorporate beverages derived from cereals. • Considers the use of the term 'milk' for other non-dairy products such as coconut milk and soy milk is traditional, and the risk that consumers may confuse the nutritional benefits of these with cows' milk may be lower. However, consider that if cereal-based beverages are labelled as 'milk' they may be perceived by the consumer to be of nutritional equivalence, especially with respect to protein. • Considers that allowing 'milk' to be used for cereal-based beverages could lead to misinformation and increased risk to consumer's health and safety. • Considers the inappropriate use of the word 'milk' may be detrimental to the dairy industry, reducing its ability to promote the important role and health benefits of milk and milk products. • Recommends excluding the term 'milk' from the product title and labelling appropriately using the words 'drink' or 'beverage'. *Advisory Statement* • Supports a clear mandatory advisory statement. • Considers there is a probable likelihood that the risks would not be adequately communicated. • Recommends that the advisory statement should alert parents/carers *specifically* to the low protein content and the need to seek medical advice.

No.	Submitter	Submission Comments
		Bioavailability • Disagrees with FSANZ's conclusion that tricalcium phosphate in rice beverages is relatively bioavailable, and instead interprets this as calcium added to rice beverages is less bioavailable than cows' milk and hence is not nutritionally equivalent in terms of calcium. • Comments that if consumers see on the food label that cereal-based beverages contain a similar amount of calcium as milk, they would naturally believe they were absorbing about the same amount of calcium, when in many instances, they would be absorbing significantly less. Thus consumers may be misled into believing their diet provides adequate calcium when due to poor bioavailability this is not the case. *Vitamin and Mineral Permissions* • Highlight that the levels of B-group vitamins proposed are higher than in cows' milk, and believes that the maximum allowable levels need to be reduced to a level not more than cows' milk. *Other Considerations* • Comments that cereal-based beverages are usually considered inert and to have low allergenicity. • Notes that the risk assessment concludes that fortification of cereal-based beverages 'poses no greater risk' than cows' milk and 'is therefore considered safe'. • Caution against this approach, citing recent research that showed an increase in peanut allergy was associated with the intake of soy milk or soy formula. *References (additional to those cited in the Draft Assessment Report)* • Heaney, R et al. (2005). Calcium fortification systems differ in bioavailability. *JADA.* 105:807-10. • Lack, G et al. (2003). Factors associated with the development of peanut alert in childhood. *The New England Journal of Medicine*. 348(11):977-85. • Miller, G et al. (2000). Handbook of Dairy Foods and Nutrition, second edition. National Dairy Council, CRC New York. • UK Food Standards Agency – Eat wee, be well, Children and babies. Available from http://www.eatwell.gov.uk/asksam/agesandstages/childrenandbabies, cited 15/07/05.

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7	**Dairy Farmers Research & Development** *Norm Reynolds*	**Preferred Option Not Specified** *General Comments* • Expressed concerns that cereal-based beverages are not nutritionally equivalent, by virtue of their lower protein level. Therefore considers that proposing the same vitamin and mineral levels as permitted for beverages derived from legumes is not a fair comparison, as these beverages have a requirement for a minimum 3% protein content. • Also concerned that the levels of fortification proposed are not nutritionally equivalent, especially for the B-group vitamins, where Option 3 allows for a higher level of fortification than occurs naturally in cows' milk. *Vitamin and Mineral Permissions* • State that the levels of fortification proposed for the B-group vitamins to cereal-based beverages are 15-50% higher than naturally occur in cows' milk. They consider that this does not appear appropriate, especially for a beverage of such low protein content. • Suggests that if Option 3 is to be accepted, that FSANZ reviews the maximum permitted levels of fortification and sets them at levels no greater than occur naturally in cows' milk.
8	**Department of Health and Human Services Tasmania** *Jennifer Savenake*	**Supports Option 3** Supports Option 3, though recommends some changes to the advisory statement. *Advisory Statement* • Considers the proposed advisory statement is likely to be adequate for people who are under the care of qualified health professionals, however are concerned that it may not be adequate for vulnerable groups, especially those with low literacy. • Notes that evidence suggests that 25% of Australians have low literacy skills (reference provided). • Notes that FSANZ has addressed legibility of advisory statements in previous applications (A433, A434, A508) and recommends that this be applied to the current advisory statement, in addition to consideration of further readability criteria. • Recommends that the advisory statements include reference to the facts that: • the product is not a complete milk replacement; • it is low in protein and energy; and • to consult your health professional if used for children under 12 years of age. *Use of the term 'milk'* • Concerns that the term 'milk' could be misleading as cereal-based beverages are not nutritionally equivalent, especially if they are marketed as a milk alternative. • Considers that the term 'milk' should be restricted given their low protein content and ability to make vitamin and mineral content claims, or an appropriate comment made on the low protein content of these products.

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		References • Highlights from the Second Report of the International Adult Literacy Survey: Literacy Skills for the Knowledge Society. http://www.hrsdc.gc.ca/en/hip/lld/nls/Surveys/ialssrh.shtml, accessed 13 September 2005. • Readability criteria: http://www.gopdg.com/plainlanguage/readability.html, accessed 13 September 2005.
9	**Department of Human Services Victoria** *Victor Di Paola*	**Supports a Modified Option 3** *General Comments* • Considers Option 3 is the best of the options proposed, however suggest the following changes are required before this Option could be supported: ▪ include fortification with protein, to enable their use as a replacement for cows' milk; ▪ mandating the forms of vitamins and minerals to be used, to ensure efficacy; and ▪ limit total sugars. • Their alternative position would be to support Option 1 and reject the Application. • In general, they are not comfortable that cereal-based beverages are a substitute food for milk, as they require substantial fortification with a range of vitamins, minerals and protein. • Concerned that if this Application was to proceed as proposed it would set an undesirable precedent for future Applications, and defeats the purpose of the Codex principles of having qualifying nutritional criteria which state that a product should not be fortified unless it is to be made nutritionally equivalent to the primary food (e.g. cows' milk). *Sugar Content* • Concerned that the current drafting would allow manufacturers to add sugar at any level, which would be inconsistent with the Policy Guideline that states fortification should not promote the increased consumption of foods high in salt, sugar or fat. • Notes that while the sugar content of cereal-based beverages is currently not high and equivalent to cows' milk, in order to ensure that additional sugar is not added to these products to make them more acceptable to consumers, especially children, a sugar restriction should be imposed. • A total sugar limit equal to the sugar content of cows' milk should be applied. *Bioavailability* • Considers that the vitamins and minerals to be added to cereal-based beverages should be in the form that most closely replicates cows' milk, on the basis of bioavailability. • Considers it insufficient to permit fortification of cereal-based beverages to provide and alternative to milk if the efficacy and bioavailability of the vitamins and minerals to be added are not also mandated to ensure that these products are a true alternative to cow and soy milk.

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		Protein Content • If cereal-based beverages are to be equivalent to cow milk it is considered necessary to mandate the addition of rice or cereal protein isolates to achieve a protein level of 3% to achieve equivalence. • Considers a protein level of 0.3% is not a viable proposition for these products if they are claimed to be a milk substitute. *Use of the term 'milk'* • Concern that there is the potential to confuse or mislead consumers if the work 'milk' is used for cereal-based beverage products that have not been fortified to the same nutritional level as cows' milk.
10	**Dietitians Association of Australia** *Sue Cassidy*	**Supports a Modified Option 3** Supports a modified Option 3, whereby the advisory statement be amended to specifically refer to the low protein content of these products. *Advisory Statement* • Suggests that the advisory statement should be clearer and easier to understand, and should highlight the specific reason why these products are not suitable as a complete milk replacement. • Suggests that the advisory statement refer to the low protein content of cereal-based beverages, and where they are also low in fat the advisory statement should also refer to kilojoules. • Suggested advisory statement for a product low in both fat and protein: 'This product is low in protein and kilojoules and unsuitable as a complete milk replacement for children. Seek professional nutritional advice if this product is to be used as a milk substitute by children under the age of twelve years'. *Use of the term 'milk'* • Continues to have serious concerns regarding the use of the term 'milk' in relation to cereal-based beverages. • Consider these beverages are not nutritionally equivalent to cows' milk and the designation of cereal-based beverages as 'milks' may deceive some consumers into believing they are equivalent substitutes for cows' milk. • Consider this consumer perception may become even more probable if cereal-based beverages contain higher amounts of B vitamins and vitamin A, in addition to calcium.

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11	**Environmental Health Unit, Queensland Health** *Brett Esbensen*	**Supports Option 3** *Advisory Statement* • Strongly supports specific advisory labelling. • Recommends that this requirement specifies a suitable location on the label for an advisory statement and a suitable font size. • Considers advisory labelling imperative, especially when considering the impact cereal-based beverages may have on low socio-economic sectors and indigenous communities in relation to nutritional impacts on infants and children. *Vitamin and Mineral Permissions* • Would prefer that the addition of vitamins and minerals be a requirement for cereal-based beverages, thereby raising the nutritional status of these products to be closer to that of cows' milk. • Notes that issues relating to allergenicity stemming from the origins of the vitamins and minerals need to be considered.
12	**Fonterra Co-operative Group Ltd** *Mara Fisher*	**Supports Option 1** *General Comments* • Fonterra's preferred option is Option 1 as they believe that fortification of cereal-based beverages would mislead consumers and have a negative impact on public health and safety. • Their second choice would be an amended Option 3 where the protein content is raised to a *minimum* of 3% before *mandatory* micronutrient fortifications are permitted. • Considers cereal-based beverages could be viewed as a special medical food and perhaps should not be considered under Standard 1.3.2 as a food. *Protein Content* • Considers it is not appropriate to treat cereal-based beverages as cows' milk substitutes, when they only have one tenth of the protein content of cows' milk. • Considers a shift away from dairy milk may hinder the currently sufficient protein status of the population. *Voluntary Fortification* • Notes that voluntary fortification permissions mean that not all cereal-based beverages will have equivalent amounts of nutrients to cows' milk, which will increase consumer confusion and may mislead consumers to believe that all cereal-based beverages are a 'nutrient-equivalent' substitute for cows' milk. • Believes that it is important to raise the protein content of cereal-based beverages to at least 3% and that the vitamin and mineral permissions be mandatory, before a cereal-based beverage can be marketed as fortified. Otherwise, no fortifications should be permitted so as not to mislead consumers.

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		Vitamin and Mineral Permissions • Highlight that the proposed levels for B-group vitamins are higher in cereal-based beverages than in milk, e.g. thiamin is 2.5 fold higher, riboflavin 1.1 fold higher and B_6 is 1.5 fold higher. • Recommends that the proposed maximum allowable levels of B-group vitamins be reduced to a level not more than cows' milk. *Bioavailability* • Considers there is no comprehensive scientific evidence to demonstrate that plant sourced nutrient fortification in cereal-based beverages will have the same bioavailability as the nutrients naturally present in cows' milk. • Notes that the Draft Assessment Report only assessed two scientific studies to conclude that nutrients should be biocompatible. • Comment that the low fat nature of cereal-based beverages will have a negative effect on the bioavailability of fat-soluble vitamins when consumed. • Disagrees with FSANZ's conclusion that tricalcium phosphate in rice beverages is relatively bioavailable, as it is less bioavailable than cows' milk and therefore not nutritionally equivalent in terms of calcium. • Considers that fortified cereal-based beverages will not necessarily provide consumers with good quality nutrients, and will mislead consumers as to their nutritional status. *Nutrient Claims* • Notes that fortified cereal-based beverages will be allowed to make content claims for 7 nutrients, compared with 4 claims for cows' milk. • Consider this would result in a higher probability that consumers are misled to believe that cereal-based beverages are more nutritious than cows' milk, because it appears higher level of nutrients are present than in cows' milk. • Proposes that if fortification is permitted, that any fortification to allow nutrient content claims for cereal-based beverages should be possible for cows' milk. *Use of the term 'milk'* • Notes that the definition of milk does not incorporate beverages derived from cereals or legumes. • Considers the use of the term 'milk' for other non-dairy products such as coconut milk and soy milk is traditional, and the risk that consumers may confuse the nutritional benefits of these with cows' milk may be lower. However, consider that if cereal-based beverages are labelled as 'milk' they may be perceived by the consumer to be of nutritional equivalence, especially with respect to protein. • Considers that allowing 'milk' to be used for cereal-based beverages could lead to misinformation and increased risk to consumer's health and safety. • Recommends excluding the term 'milk' from the product title and labelling appropriately using the words 'drink' or 'beverage'. • At a minimum, consider the term 'milk' should only be used at all times when linked to the major ingredient.

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		Advisory Statement • Considers that the case studies presented at Draft Assessment show that warning statements on packaging cannot mitigate the risk for children consuming these products. • Consider that once fortification of cereal-based beverages is permitted that more adults may choose these products as a substitute to cows' milk and do the same for their children, and thus potentially cause adverse health effects in younger children. *Impact Analysis* • State there is no benefit to the dairy industry in permitting fortification of cereal-based beverages. • State there will be a cost to the dairy industry as consumers may choose to substitute fortified cereal-based beverages for dairy milk due to the possible misleading nutrient fortifications and claims.
13	**Food Technology Association of Victoria Inc** *David Gill*	**Supports Option 3** *General Comment* Contend that if cereal-based beverages are to be considered as substitutes for cows' milk and/or soy beverages, then the vitamin and mineral additions should be mandatory rather than voluntary, even though the protein level is not reached.
14	**Manufactured Food Database** *Lyn Gillanders/ Alannah Steeper*	**Supports Option 3** *General Comments* • Supports the advisory statement, given the key contribution of milk in terms of protein and riboflavin intakes as shown by the 2002 New Zealand National Children's Nutrition Survey. • Supports the comments on increasing the protein content of cereal-based beverages, and comment that lupin flour is increasingly being recognised as a potential food allergen, and therefore should not be considered as a potential protein source.
15	**National Foods** *Janine Waller*	**Supports a Modified Option 3** *Supports Option 3 as it would:* • provide consumers with a more suitable, nutritious beverage alternative; • increased food choice and meet an identified need in the market; • minimise inappropriate consumption by minimising the risk of nutritional inadequacy; and • promote harmonisation of regulations between Australia and New Zealand. *Advisory Statement* • Considers the risk of nutritional inadequacy from inappropriate consumption would be minimised through requirements for specific mandatory advisory statements for all cereal-based beverages. • Advocates the extension of the current advisory statement to include all cereal-based beverages, when fat levels fall below 2.5%.

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		• Supports an advisory statement for protein when levels fall below 3%, but raise concerns with the rationale for selecting children under the age of 12 years. • Recommends a tiered advisory statement whereby the age recommendations are aligned to the percentage of protein in the beverage. Considers this will provide both a safety measure for consumers as well as providing an incentive to manufacturers to increase the protein content of cereal-based beverages. • Seeks clarity on the criteria for the fat and protein advisory statements (pg 41 of the report), and recommends adding protein criteria to each of the statements to ensure they are clearly interpreted and implemented.
16	**NSW Food Authority** *Kelly Boulton*	**Supports a Modified Option 3** *General Comments* • Do not support the Application as it currently is. • Would agree with the Application should it include the addition of such nutrients as protein that are present in milk, so that they are nutritionally equivalent to milk. • Alternatively, consider the label should indicate that the product is not suitable as a replacement for milk especially for children and other vulnerable populations. • Consider the form of the nutrient to be fortified should be specified, and in the most readily bioavailable form. • Consider that should this Application be approved as presented at Draft Assessment, other public health issues may become prevalent (i.e. deficiencies in nutrients available in milk and its products).
17	**New Zealand Food Safety Authority** *Carole Inkster*	**Supports a Modified Option 3** *General Comments* • Supports the proposed changes to Standard 1.3.2. • Notes that consumers will only benefit if manufacturers voluntarily fortify their products. • Requests that FSANZ reconsiders the way the terms folate and folic acid are referred to in the Code. As folic acid is being added to foods, they consider that this term should be used in the Code and on nutrition information panels. • Supports the continued availability of fortified cereal-based beverages for the small proportion of the population who choose to consume these products. *Advisory Statements* • Do not support the proposed advisory statement. • Recommends the proposed advisory statement be revised to remove the reference to 'children under the age of twelve years'. • Questions what appears to be the arbitrary way in which the age of 12 years was reached, and comment that a nutritionally compromised consumer of cereal-based beverages could be of any age. • Notes that there are soy beverages that have less than 3% protein and less than 2.5% fat, and consider these products should also be required to carry the same advisory statement.

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		• Considers that fortified and non-fortified soy and cereal-based beverages containing less than 3% protein and no more than 2.5% fat should be subject to different advisory statements, with the statement for the fortified product being less restrictive. • Recommends a statement to the effect that 'the product is not suitable as a complete milk replacement' for non-fortified products, and a statement to the effect that 'the product is not suitable as a complete milk replacement for children under the age of two years' for fortified products. • Considers the term 'milk replacement' rather than 'milk food' better describes how these products are used. *Dietary Modelling* • Questions the results of the dietary modelling which indicated a percentage of people had protein intakes below the estimated average requirement, which appears to differ from the results of the New Zealand Children's Nutrition Survey and the New Zealand National Nutrition Survey 1997.
18	**Private** Jared Kwong	**Supports Option 2** *General Comments* • Agrees with the proposal to allow calcium to be added to cereal-based beverages. • Consider this would greatly increase the selection of non-lactose beverage alternatives available. • Considers a calcium enriched product to be beneficial to consumers who are lactose intolerant. • Agrees that there should be a warning to discourage complete substitution of milk products and the overuse in children. • Believes consumer knowledge is important to assist them in making appropriate decisions about products.
19	**Sanitarium Health food Company** *Trish Guy*	**Supports a Modified Option 3** Supports Option 3, however recommends a revised advisory statement that clearly refers to the low protein and fat content of these beverages. *Advisory Statement* • Considers it important that consumers are adequately informed and aware of the risk of children consuming inadequate amounts of protein if dairy milk is replaced with a cereal-based beverage. • Notes that the report highlighted that functional and cost-effective ingredients are not currently available to increase the protein content of cereal-based beverages. • Supports the requirement for a mandatory advisory statement similar to that suggested in the report. • Strongly recommends that the proposed advisory statement be modified to focus on the low protein and fat content of these products, so that consumers are provided with clearer information about the potential risk.

No.	Submitter	Submission Comments
		• Suggests the advisory statement: 'Because [this product] is low in protein and fat, it is not suitable as a complete milk replacement for children under the age of 12 years'. *Use of the term 'milk'* • Continues to recommend that cereal-based products with a low protein content (<3%) should not be labelled as 'milk', as they are not nutritionally equivalent to milk. • Considers the above will become even more important if cereal-based beverages are permitted to contain and promote high levels of nutrients that are typically found in milk.
20	**South Australia Health Department** *Joanne Cammans*	**Supports Option 3** *General Comments* • Supports the permissions for selected vitamins and minerals to be added to cereal-based beverages. • Supports specific advisory labelling of all cereal-based beverages that contain less than 3% protein. • Considers there does not appear to be any adverse health implications associated with fortifying these products and that there is an overriding benefit for consumers of these products with respect to nutrient intakes. • Considers the retention of the term 'milk' is considered acceptable, as it is a commonly used phrase for other non-dairy products.