



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

5-04

16 June 2004

INITIAL ASSESSMENT REPORT

APPLICATION A500

ADDITION OF CALCIUM TO CEREAL-BASED BEVERAGES

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:
28 July 2004

(See 'Invitation for Public Submissions' for details)

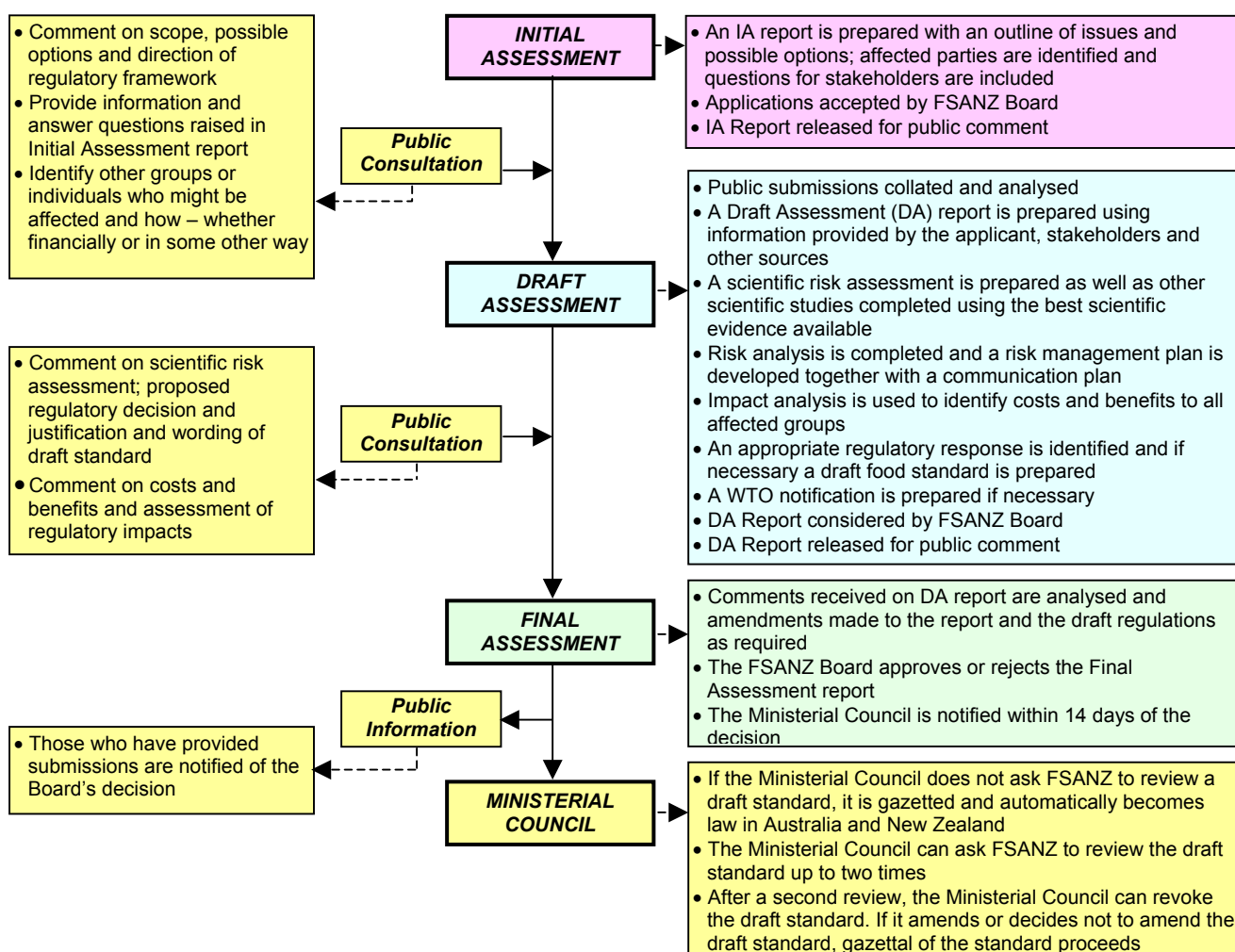
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Commonwealth; 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 Commonwealth, 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 Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

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



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial Assessment Report of Application A500, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

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

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

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

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

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

Submissions should be received by FSANZ **by 28 July 2004**

Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension.

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

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

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Executive Summary

Food Standards Australia New Zealand (FSANZ) has received an Application from SoNatural Foods Australia Limited 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, such as rice or oat ‘milks’.

The Applicant is seeking permission to add calcium to cereal-based beverages in order to ‘provide a suitably nutritious milk alternative for consumers who choose not to drink dairy products or cannot drink dairy products due to food allergy or intolerance’.

Objectives

The specific objectives for the assessment of this Application are to:

- protect the public health and safety of consumers of cereal-based beverages; and
- ensure adequate information is provided to enable consumers to make informed choices should this Application be accepted.

Regulatory Problem

A vitamin or mineral is not permitted to be added to a food unless the addition of that vitamin or mineral is specifically permitted in Standard 1.3.2 – Vitamins and Minerals, or elsewhere in the Code, and the vitamin or mineral is in a permitted form¹. Standard 1.3.2 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. Standard 1.3.2 currently permits the voluntary addition of calcium to certain foods such as breakfast cereals and most dairy products, and soy-based analogues, such as soy drinks and soy yoghurts; however, there is no current permission for the voluntary addition of calcium to cereal-based beverages as requested by the Applicant.

Issues

Several issues have been identified as important in assessing this application, in particular:

- principles for nutritional equivalence of substitute foods;
- the appropriateness of cow’s milk as a reference food;
- the assessment of cereal-based beverages as a substitute food;
- the protein content of cereal-based beverages compared to cow’s milk and beverages derived from legumes, such as ‘soy-milk’;
- an assessment of the risk of nutrient deficits or imbalances;
- the potential public health impact of fortification; and

¹ As specified in the Schedule to Standard 1.1.1 of the Code, unless stated otherwise in the Code.

- consideration of risk management strategies in relation to addressing the inappropriate consumption of calcium-fortified food products.

Regulatory Options and Impact Analysis

There are two options for addressing this Application:

Option 1 – No approval

Maintain the status quo by not amending the Code to allow the addition of calcium to cereal-based beverages.

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.

Amend the Code to permit the voluntary addition of calcium to cereal-based beverages so that the calcium content resulting from fortification is equivalent to that permitted in beverages derived from legumes, and which reflects the natural calcium content of cow's milk.

For each regulatory option, an initial analysis has been undertaken to assess the potential costs and benefits to the affected parties.

Statement of Reasons

This Application has been assessed and is recommended for acceptance at Initial Assessment for the following reasons:

- The Application relates to a matter that warrants a variation to Standard 1.3.2, if further assessment supports such a variation. There is no current permission in Standard 1.3.2 for the voluntary addition of calcium to cereal-based beverages. If the information provided by the Applicant and the assessment of all relevant material supports the addition of calcium to cereal-based beverages then a variation to the standard will be warranted.
- This Application is not so similar to a previous application that it ought not be accepted.
- The potential costs and benefits are dealt with at Section 7 of this report. In short, there is no basis for considering at this stage of assessment that the costs that would arise from a variation to Standard 1.3.2 to permit calcium fortification of cereal-based beverages would outweigh the direct and indirect benefits to the community, Government or Industry.
- There are no other measures available to permit the Applicant's request.

Consultation

For both the Issues and Impact Analysis sections in this Initial Assessment Report, a number of questions have been posed to facilitate consideration of this Application. Public comment is invited on these questions, the proposed regulatory options, and the Report as a whole.

1. Introduction

Food Standards Australia New Zealand (FSANZ) has received an Application from SoNatural Foods Australia 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 or oat ‘milk’) to be listed in the Standard, with an accompanying reference quantity of 200 mL and a maximum claim per reference quantity of 240 mg (30% RDI) for calcium.

This Initial Assessment Report discusses the issues involved in the proposed amendment and seeks comment from stakeholders, including the expected regulatory impact(s), to assist FSANZ in making an assessment of this Application.

2. Regulatory Problem

A vitamin or mineral is not permitted to be added to a food unless the addition of that vitamin or mineral is specifically permitted in Standard 1.3.2 – Vitamins and Minerals or elsewhere in the Code and the vitamin or mineral is in a permitted form². Standard 1.3.2 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. Standard 1.3.2 currently permits the voluntary addition of calcium to certain foods such as breakfast cereals and most dairy products, and soy-based analogues, such as soy ‘milk’ and soy yoghurts; however, there is no current permission for the voluntary addition of calcium to cereal-based beverages.

Calcium is an important nutrient for good health, protecting bones and teeth and playing a key role in the regulation of muscle contraction, blood pressure, nerve transmission and enzyme action. The addition of calcium to cereal-based beverages has the potential to increase the calcium intake of those subgroups of the population who choose not to or who are unable to consume cow’s milk or fortified soy beverages.

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

² As specified in the Schedule to Standard 1.1.1 of the Code, unless stated otherwise in the Code.

- 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 consumers of cereal-based beverages; and
- ensure adequate information is provided to enable consumers to make informed choices, should this Application be accepted.

Further, section 13 of the FSANZ Act provides:

- (1) The Authority must make an initial assessment of the application.
- (2) In making an initial assessment of the application, the Authority must have regard to the following matters:
 - (a) whether the application relates to a matter that may be developed as a food regulatory measure, or that warrants a variation of a food regulatory measure, as the case requires;
 - (b) whether the application is so similar to a previous application for the development or variation of a food regulatory measure that it ought not to be accepted;
 - (c) whether costs that would arise from a food regulatory measure developed or varied as a result of the application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the measure or variation;
 - (d) whether other measures (available to the Authority or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the application;
 - (e) any other relevant matters.

4. Background

4.1 Current Market

Cereal-based beverages, such as rice and oat ‘milks’, can be used as a milk substitute either by individuals who:

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

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

4.1.1 *Domestic market*

Monthly sales figures up to April 2004, as supplied by the Applicant, suggest that approximately 0.25 million litres of rice beverage and 0.02 million litres of oat beverage are consumed in Australia per month. This compares with 80 million litres of dairy milk and 4 million litres of soy beverage.

Because of its relatively small market, the addition of calcium to cereal-based beverages is anticipated to have very little nutritional impact on the general population as a whole, but could significantly affect those individuals with allergies/intolerances to cow's milk and soy products.

Calcium-fortified cereal-based beverages are permitted to be manufactured and/or sold in New Zealand under Standard 1.1A.6 - Transitional Standard for Special-Purpose Foods (including amino acid modified foods). Although these products cannot legally be manufactured in Australia, they can be imported from New Zealand by virtue of the Trans-Tasman Mutual Recognition Arrangement (TTMRA).

4.1.2 *International market*

The Applicant states that fortified rice beverages are currently available in the USA, UK, Europe and Canada, although there are no provisions permitting specific fortification of these products in the respective food legislation. The Applicant also states that Health Canada has received a request to permit the optional addition of vitamins and minerals to plant based beverages.

4.2 **Ministerial Council Guideline on Fortification of Foods with Vitamins and Minerals**

The Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) has recently agreed to a policy guideline for the fortification of foods with vitamins and minerals³. The excerpts relevant to this Application are from the 'Specific order policy principles – Voluntary fortification':

- The voluntary addition of vitamins and minerals to food should be permitted only:
 - to enable the nutritional profile of a specific substitute foods to be aligned with the primary food (through nutritional equivalence).
- The permitted fortification has 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.
- Permissions to fortify should ensure that the added vitamins and minerals are present in the food at levels which 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.

³ <http://www.foodsecretariat.health.gov.au>

- The fortification of a food, and the amounts of fortificant in the food, should not mislead the consumer as to the nutritional quality of the fortified food.

4.3 FSANZ’s Regulatory Principles for the Addition of Vitamins and Minerals to Foods

Prior to the release of these Ministerial Guidelines, FSANZ’s *Regulatory Principles for the Addition of Vitamins and Minerals to Foods* (Regulatory Principles) were used as a basis for decision making in relation to assessing the addition of vitamins and minerals to food.

The Regulatory Principles are presented in detail on the FSANZ website⁴. As FSANZ is required to have regard to any written policy guidelines formulated by the Ministerial Council (see section 3), the FSANZ Regulatory Principles will now be revised in light of the above-mentioned Ministerial Guidelines.

The Ministerial Policy Guideline does not explicitly define ‘substitute food’ and ‘nutritional equivalence’, and so FSANZ proposes to adopt into its revised Regulatory Principles the definitions from the *Codex General Principles for the Addition of Essential Nutrients to Foods*, with minor adjustment to account for Australian and New Zealand conditions.

4.4 Codex General Principles for Nutritional Equivalence of Substitute Foods

The *Codex General Principles for the Addition of Essential Nutrients to Foods*⁵ defines:

A substitute food as:

a food which is designed to resemble a common food in appearance, texture, flavour and odour, and is intended to be used as a complete or partial replacement for the food it resembles.

Nutritional equivalence as:

being of similar nutritive value in terms of quality and quantity of protein and in terms of kinds, quantity and bioavailability of essential nutrients. For this purpose, nutritional equivalence means that essential nutrients provided by the food being substituted, that are present in a serving or portion or 100 kcal of the food at a level of 5% or more of the recommended intake of the nutrient(s), are present in the substitute or partially substituted food (extender) in comparable amounts.

Section 5 of the Codex General Principles lists three general principles in relation to nutritional equivalence that are reproduced below:

⁴ Regulatory Principles for the Addition of Vitamins and Minerals to Foods
<http://www.foodstandards.gov.au/standardsdevelopment/Applications/Applicationa424calciuminjuices/a424darcalciuminjuic1838.cfm>

⁵ General Principles for the Addition of Essential Nutrients to Foods, CAC/GL 09-1987

Codex General Principles for Nutritional Equivalence

5.1 Where a substitute food is intended to replace a food that has been identified as a significant source of energy and/or essential nutrients in the food supply, and particularly where there is demonstrated evidence of public health need, nutritional equivalence in terms of the essential nutrients of concern should be strongly recommended.

5.2 A food being substituted or partially substituted should be considered a significant source of an essential nutrient if a serving or portion or 100 kcal of the food contains the essential nutrient in amounts equal to or greater than 5% of the recommended nutrient intake.

5.3 Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be equivalent.

4.5 FSANZ Principles for Nutritional Equivalence of Substitute Foods

Based on the Codex definition, FSANZ proposes the following definition of a ‘substitute food’:

‘A substitute food is one that 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. This definition refers to both the physical properties of the food and its intended use.’⁶

In contrast to the Codex definition, FSANZ is proposing to delete the reference to flavour and odour as it is often difficult to accurately and objectively assess these characteristics. FSANZ considers that the appearance and texture of the food, as well as the intended use, are sufficient to characterise a food as a ‘substitute food’

Similarly, based on the Codex definition, FSANZ proposes the following definition for ‘nutritional equivalence’:

‘Being of similar nutritive value in terms of quality and quantity of protein and in terms of kinds, quantity and bioavailability of essential nutrients. For this purpose, nutritional equivalence means that essential nutrients provided by the food being substituted, that are present in a serving or portion or 419 kJ (100 kcal) of the food at a level of 5% or more of the recommended intake of the nutrient(s), are present in the substitute or partially substituted food (extender) in comparable amounts’.

FSANZ is proposing, in the first instance, that substitute foods should satisfy the definition for nutritional equivalence before permitting the addition of relevant added vitamins and minerals. However if substitute foods are unable to meet the nutritional equivalence definition, a further assessment can be undertaken to determine the potential impact and possible risks. If considered appropriate, additional risk management strategies may be employed to minimise any identified risks, thereby allowing substitute foods that fail to meet the definition of nutritional equivalence to be fortified.

5. Risk Assessment

The Applicant has sought permission for the voluntary addition of calcium to cereal-based beverages in recognition of these foods being used as substitutes for cow's milk. At this stage in the assessment process, FSANZ intends to consider this Application according to the Ministerial Guidelines and the revised FSANZ Regulatory Principles which allow for the addition of vitamins and minerals for the purpose of nutritional equivalence to specified foods that substitute for certain basic foods.

This approach is consistent with FSANZ's previous decision to permit the addition of the relevant vitamins and minerals to beverages derived from legumes (i.e. soy 'milks')⁷. The FSANZ Regulatory Principle for this previous decision was based on the following excerpt:

'Vitamins and minerals may be added, for the purpose of nutritional equivalence, to specified foods that substitute for certain basic foods'.

This Application (A500) differs from a previous Application FSANZ received requesting the voluntary addition of calcium to various foods (Application A424 – Fortification of Foods with Calcium). The focus of Application A424 is to provide **additional** food sources of calcium for the whole population. In contrast, in A500 the Applicant has stated that calcium-fortified cereal-based beverages are intended to **replace** cow's milk by those who are unable to or choose not to consume cow's milk.

In order to assess the possibility of permitting the addition of calcium to cereal-based beverages under these principles, FSANZ must first recognise cow's milk as an appropriate reference food.

5.1 Is Cow's Milk an Appropriate Reference Food?

5.1.1 Is cow's milk a significant source of energy? (Principle 5.1)

According to the 1997 New Zealand National Nutrition Survey (NZ NNS97), on average, all cow's milk contributes to 5% of the energy intake for New Zealanders⁸. The only food categories making a higher contribution are bread 11%, potatoes and kumara 7%, and butter and margarine 6%. In Australia all unflavoured dairy or cow's milk contributes on average 6% of total energy intake⁹. Therefore, cow's milk is considered to be a significant source of energy in the Australian and New Zealand diet.

5.1.2 Is cow's milk a significant source of essential nutrients? (Principle 5.1 & 5.2)

According to Principle 5.2, a substitute food should be considered a significant source of an essential nutrient if a serving or portion or 100 kcal (419 kJ) of the food contains the essential nutrient in amounts equal to or greater than 5% of the recommended dietary intake (RDI).

⁷ National Food Authority Proposal 24 - Draft Revised Standard A9, Vitamins and Minerals

⁸ 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

⁹ DIAMOND modelling, (contribution based on plain, non flavoured dairy milks and not including dairy desserts)

The data in Table 2 illustrates that cow’s milk is a significant source of protein, vitamin A, riboflavin, vitamin D, vitamin B12 and calcium. Cow’s milk meets the criteria stipulated in Principle 5.2 since essential nutrients are present in amounts equal to or greater than 5% of the RDI per 100 kcal as well as in a serving.

Table 1: Per cent contribution from cow’s milk to the mean population intakes of various nutrients

		Contribution from cow’s milk (%)		>5% RDI/ 100 kcal*
		Australia	New Zealand	
Macronutrient	Protein	9.1#	9.6	Yes
Micronutrient	Vitamin A	6.7	6.3	Yes
	Riboflavin	22.7	26.9	Yes
	Vitamin D	N/A	2.0	Yes
	Vitamin B12	N/A	15.1	Yes
	Calcium	37	30	Yes

N/A = Not available

*100 kcal = 150 mL of milk , which is a small serving

= DIAMOND modelling (contribution based on plain, non flavoured dairy milks and not including dairy desserts)

5.1.3 Demonstrated evidence of public health need (Principle 5.1)

Calcium is one micronutrient in cow’s milk for which there is demonstrated evidence of public health need. In Australia, the percentage of the population whose intakes are below the Estimated Average Requirement (EAR)¹⁰ has been established in the following population subgroups: young males aged 11-15 years and for females aged 11-65+ years and in New Zealand for males aged 15-18 years and 45-65+ years and for all female age groups. This is explained in length in the FSANZ Draft Assessment Report for A424 – Fortification of Foods with Calcium. A copy of this report can be found on the FSANZ website¹¹.

5.1.4 Conclusion

FSANZ considers cow’s milk qualifies as an appropriate reference food. This is consistent with the previous decision to use cow’s milk as an appropriate reference in order to permit vitamin and mineral addition to beverages derived from legumes which contain no less than 3% protein¹².

5.2 Do Cereal-based Beverages Qualify as a Milk Substitute?

5.2.1 Assessment of cereal-based beverages as a substitute food

Rice and oat beverages are designed to resemble cow’s milk in appearance and viscosity, as implied by the use of the word ‘milk’ in the names of most brands of cereal beverage products. These products are an off-white colour and have a similar viscosity to cow’s milk.

¹⁰ EAR is a value that represents the medium requirement for the dietary intake of a particular nutrient in a given population group.

¹¹ http://www.foodstandards.gov.au/_srcfiles/A424%20DAR%20-%20Calcium%20Fortification.pdf.

¹² National Food Authority Proposal 24 - Draft Revised Standard A9, Vitamins and Minerals

Rice and oat beverages are promoted as a dairy substitute: as an ingredient in baking, cooking and in hot beverages. These beverages perform in a sufficiently similar manner to cow’s milk to enable total replacement of cow’s milk in the diet.

5.2.2 Conclusion

FSANZ considers that cereal-based beverages meet the definition of ‘substitute food’ for cow’s milk on the basis of their physical properties. However to support this assumption, FSANZ is keen to obtain further information to clarify whether consumers use cereal-based beverages as a substitute for cow’s milk or alternatively, as part of a mixed diet that includes cow’s milk.

Question:

1. How are cereal-based beverages consumed e.g. as beverages, on breakfast cereal etc? What evidence is there that cereal-based beverages replace cow’s milk in the diet?

5.3 Do Cereal-based Beverages meet the Definition of Nutritional Equivalence?

Below, Table 2 illustrates the nutrient composition of cow’s milk, unfortified rice ‘milk’ and unfortified oat ‘milk’ as supplied by the Applicant and augmented by FSANZ. Energy content is similar among all beverage types, however rice ‘milk’ is naturally lower in fat and protein, and higher in carbohydrate content when compared to cow’s milk. Oat ‘milk’ has a lower energy and higher carbohydrate content than cow’s milk and its fat and protein content, although lower than cow’s milk, is higher than rice ‘milk’.

Table 2: Key nutrients in cow’s milk, oat and rice beverages (per 100 mL)

Nutrition Content		Cow’s Milk Whole	Pureharvest Oat Milk	So Natural Rice Milk
Energy (kJ)		280	179	272
Protein (g)		3.4	1.4	0.6
Fat (g)				
-	total	3.9	2	1.0*
-	saturated	2.6	0.35	0.1
-	polyunsaturated	0.1	0.73	0.3
-	monounsaturated	1.0	0.62	0.5
Cholesterol (mg)		13.4	0	0
Carbohydrate (g)				
-	total	4.9	5.9	13.4
-	sugars	4.9	0.4	4.2
Calcium (mg)		117	0	0
Riboflavin (mg)		0.21	0	0
Vitamin A (ug)		49.5	0	0
Vitamin B12		0.35	0	0

* Fat content and profile will vary depending on the amount and source of fat used in the manufacturing process

5.3.1 Protein discrepancy for cereal-based beverages

The definition of nutritional equivalence makes particular reference to the protein content of the substitute food as 'being of similar nutritive value in terms of quality and quantity of protein' to the reference food. Data in Table 2 indicate that cereal-based beverages have low protein contents with rice 'milk' having a protein content of 0.6% and oat 'milk' a protein content of 1.4%.

5.3.2 Micronutrient discrepancy for cereal-based beverages

As indicated previously in section 5.1.2, cow's milk is a significant source of vitamin A, riboflavin, vitamin D, vitamin B12 and calcium. However, cereal-based beverages are not significant sources of these micronutrients.

5.3.3 Conclusion

Cereal-based beverages have a lower protein content and lower quality micronutrient profile compared with cow's milk. While cereal-based beverages meet the definition of a substitute food for cow's milk, they do **not** meet the criteria for nutritional equivalence.

Previously, beverages derived from legumes have been considered an appropriate substitute for cow's milk. However, only beverages derived from legumes which have a protein content of not less than 3% can meet FSANZ's previously adopted criteria for nutritional equivalence. Beverages derived from legumes have a similar macronutrient profile, and through the addition of relevant vitamins and minerals, they can have a similar micronutrient profile to cow's milk. Due to their low protein content, cereal-based beverages cannot be considered to be 'nutritionally equivalent' according to the Codex definition.

5.4 Risk Characterisation of Cereal-based Beverage Consumption

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 health or philosophical reasons.

Cow's milk allergy (CMA) is one of the most common food allergies in children and nearly half of all children with CMA also have adverse reactions to soy¹³. Although most children out-grow CMA by the age of four years, but some retain the allergy for life. Most food allergy is acquired in the first two years of life, with the prevalence peaking at 5% - 8% at one year of age and then progressively falling until late childhood, after which the prevalence remains stable at 1 - 2%.

The number of vegetarians/vegans in both Australia and New Zealand is not well defined. FSANZ is keen to obtain any additional information that will help determine the nutritional impact of consuming cereal-based beverages.

¹³ Bishop JM, Hill DJ et al. (1990) Natural history of cow's milk allergy: Clinical outcome. *J Paediatrics*. 116:862-867
<http://www.allergy.org.au/aer/infobulletins>

Question:

2. Who is drinking cereal-based beverages? What is the age profile of these consumers?

5.4.1 Risk of inadequate protein intake

The Applicant has requested that cereal-based beverages be permitted to contain added calcium if the protein content is higher than 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^{14,15}. 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 milk or soy beverages.

The Applicant considers that children who consume rice ‘milk’ as a substitute for milk or soy beverage, and thus may be at risk of nutritional inadequacy, usually do so under dietetic or medical supervision for food allergy or intolerance. However, there is evidence to suggest that some children are being fed cereal-based beverages without medical or dietetic supervision and as a result have been severely nutritionally compromised¹⁶. FSANZ will consider these issues further at Draft Assessment.

Question:

3. Is there any evidence that consumers of cereal-based beverages (with a protein content of 0.3%) have an inadequate protein intake?

5.4.2 Risk of inadequate micronutrient intake

Cow’s milk has a higher micronutrient content than cereal-based beverages. By not consuming cow’s milk, drinkers of cereal-based beverages may also be at risk of low intakes of riboflavin, vitamin B12 and to a lesser extent vitamin A and D.

Question:

4. Is there any evidence that consumers of cereal-based beverages have an inadequate micronutrient intake?

The FSANZ principle, based on Codex General Principle 5.1, states, ‘nutritional equivalence of substitute food in terms of the essential nutrients of concern should be strongly recommended’. The Applicant however, has requested permission **only** for the addition of calcium to cereal-based beverages.

¹⁴ McLennan, W. & 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).

¹⁵ 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

¹⁶ Allergy Today, Rice milk – a case study highlights the risks associated with restricted diets. Summer 2002, issue 103 p16.

FSANZ could consider including the permissions for the voluntary addition of other vitamins and minerals in addition to calcium to cereal-based beverages.

Standard 1.3.2 permits ‘beverages containing no less than 3% protein derived from legumes’ to be fortified with a variety of vitamins and minerals, including vitamin A, riboflavin, thiamin, vitamins B6 and B12, vitamin D, folate, calcium, magnesium, phosphorus, zinc and iodine. All of these nutrients are permitted in amounts that are comparable to the average content of cow’s milk.

Questions:

- 5. Could permitting the addition of calcium to cereal-based beverages, without also permitting other significant micronutrients found in milk, mislead or deceive the consumer as to the nutritional merit of cereal-based beverages?**
- 6. Should FSANZ permit the voluntary addition of other relevant vitamins and minerals to cereal-based beverages equal to levels based on cow’s milk content?**
- 7. What is the likelihood that manufacturers of cereal-based beverages would voluntarily add the permitted vitamins listed in Standard 1.3.2 to ensure cereal-based beverages are ‘micro-nutritionally’ equivalent to cows milk?**
- 8. What proportion of soy beverages, currently on the market, contain added forms of the permitted vitamins listed in Standard 1.3.2?**

5.4.3 Risk of excess calcium intake from fortification of beverages derived from cereal grains

Based on the sales data supplied by the Applicant, it appears that cereal-based beverages are used by a small segment of the population, usually as an alternative to dairy and/or soy beverage. This Application requests permission to fortify cereal-based beverages with calcium to a level found naturally in whole cow’s milk (i.e. about 240 mg/200 mL). Consumers would be required to have an intake of more than two litres of fortified cereal-based beverages per day to reach the upper tolerable limit for calcium assuming no other dairy source in the diet.

Question:

- 9. What evidence is there of excessive calcium intakes in consumers of cereal-based beverages?**

5.4.4 Absorption of calcium sources

The permitted forms of calcium that can be added to food are specified in Standard 1.1.1 Preliminary Provisions – Application, Interpretation and General Prohibitions. Literature sources report variations in calcium absorption from the permitted forms ranging from 25 to 35%. Under the same conditions, calcium absorption from milk is approximately 29%. Intestinal absorption of calcium is influenced by many nutritional and physiological factors. Children absorb up to 75% of ingested calcium compared to 20 to 40% observed in young adults, and absorption decreases with age.

A higher percentage of ingested calcium is absorbed at low intakes and decreases at higher intakes. It is uncertain if there are biologically important differences in the absorption of calcium from different food sources¹⁷.

Question:

10. What is the bioavailability of added calcium salts consumed in the form of rice or oat beverages?

5.5 Supporting Documentation

The Applicant has supplied two letters of endorsement for the Application. One letter was from a paediatric dietitian in reference to children with dairy and/or soy allergies. She stated that although these beverages have low protein contents, due to the physical similarity between these products and milk, they are used by parents of children with allergies as a substitute in baking and on cereals; and would be more acceptable to children as a source of calcium than taking supplements.

The second letter from an allergy clinic suggested that rice beverages would be a good vehicle for calcium as many people with allergies already use them as an alternative to dairy and soy beverage. The letter commented that people with allergies can overlook calcium supplements in tablet form, often due to the added expense.

6. Risk Management

While cereal-based beverages meet the definition of a substitute food for cow's milk, they fail to meet the criteria for nutritional equivalence, due to their lower micronutrient and protein content when compared with cow's milk. If this Application were to be approved, this would provide those individuals who are unable to or choose not to drink milk with an additional source of dietary calcium. However these individuals may be at risk of having an inadequate intake of protein and/or micronutrient intake that would normally be provided by cow's milk.

To help address this risk, FSANZ could consider including an advisory statement on the label and/or the implementation of information/education strategies.

6.1 Advisory Statements

When the general population or a subgroup of the population is exposed to a public health and safety risk, labelling requirements, such as the inclusion of an advisory statement, can be applied to help mitigate the risk.

For advisory statements, the specific wording is not prescribed and manufacturers may use their own words provided they convey the intended meaning and the statement is prominent and legible. Advisory statements are provided when the general population or subgroup of the population is largely unaware of a potential, but not life threatening risk to public health and safety and they need advice about the risk.

¹⁷ NHMRC. (2003). Food for Health. Dietary Guidelines for Children and Adolescents in Australia. Commonwealth of Australia

6.1.1 *Advisory statements in relation to the fat content of cereal-based beverages*

Currently rice ‘milks’ are required to include an advisory statement on the label. Under Clause 2 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations, ‘Milk and beverages made from soy or rice, where these foods contain no more than 2.5% m/m fat’ are required to be labelled with, or otherwise make a statement to the effect that these products are not suitable as a complete milk food for children under the age of two years. Because rice ‘milk’ has a fat content of 1%, an advisory statement to this effect is required. However, oat ‘milk’ and other ‘milk’ beverages based from cereals are not required to make this statement.

Question:

11. Should Clause 2 of Standard 1.2.3 be extended to apply to all cereal-based beverages that contain less than 2.5% fat?

6.1.2 *Advisory statements in relation to the low protein content of cereal-based beverages*

The Applicant states that they currently place a statement on their products ‘low fat diets are not suitable for children under 5 years’. The labelling statement, in accordance with Standard 1.2.3, alerts consumers to the low fat content of the food. However, it does not address the low protein content of these cereal-based beverages, or the importance of protein for the growth of children.

Questions:

12. Should fortified cereal-based beverages be required to carry an advisory statement that alerts consumers to the fact the product is low in protein?

13. Should unfortified cereal-based beverages also be required to carry an advisory statement that alerts consumers to the fact the product is low in protein?

14. Should the statement also include a recommendation that consumers seek medical advice on the use of this product?

6.2 Nutrient Content Claims and Implications for Education

If this Application were to be approved, claims to the effect that the product is a ‘source’ or ‘good source’ of calcium would be permitted if the product provides at least 10% or 25% RDI/ 200 mL respectively.

Food labels are a valuable source of nutrition information at the point of purchase. However, there is some evidence to suggest that the presence of a nutrient content claim can cause consumers to perceive a product as healthier than when no claim is made.¹⁸

Question:

15. Could the presence of a ‘calcium content’ claim on cereal-based beverages mislead consumers into believing these products are nutritionally equivalent to milk?

¹⁸ Levy, A.S., Derby, B.M., Roe, B.E. (1997). Consumer impacts of health claims: An experimental study. Washington DC: Food and Drug Administration, Center for Food Safety and Applied Nutrition, Division of Market Studies.

6.3 Regulatory Options

FSANZ is currently considering two options for addressing this Application:

6.3.1 Option 1 – No approval

Maintain the status quo by not amending the Code to allow the addition of calcium to cereal-based beverages.

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

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, and which reflects the natural calcium content of cow's milk.

7. Impact Analysis

7.1 Affected Parties

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

7.1.1 Consumers

- specifically consumers who do not achieve adequate calcium intakes because of dietary choices, health or cultural reasons.

7.1.2 The following sectors of the food industry

- those who will benefit from permission for the voluntary addition of calcium to the proposed products, such as manufacturers of rice and oat 'milks';
- the dairy industry, which currently has a large market share of food sources of calcium; and
- the dairy substitute (e.g. soy based beverages) industry which currently provides food sources of calcium and other vitamins and minerals for those individuals who, for whatever reason, do not consume dairy products.

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

7.2 Impact Analysis

The costs and benefits arising as a result of this Application for the affected parties are considered below for each of the options identified.

7.2.1 Option 1 - Status Quo

7.2.1.1 Consumers

Benefits

- There is no direct benefit to consumers of maintaining the status quo. Australian consumers of Calcium-fortified cereal-based beverages can access these products that are imported from New Zealand. New Zealand consumers can access these products as they are legally permitted to be manufactured and imported into New Zealand.

Costs

- FSANZ has identified some subgroups of the community who are at risk of inadequate calcium intakes, such as, vegetarians, vegans and those who suffer from milk allergy or lactose intolerance and soy intolerance. It is not known if Calcium-fortified cereal-based beverages that are imported from New Zealand are readily available to all consumers in the Australian market. In these circumstances the subgroups would incur the costs of a likely continuing calcium deficit.
- Calcium-fortified cereal-based beverages, imported from New Zealand, may be more expensive than similar products manufactured in Australia.
- Consumers may be misled by the milk-like nature of these cereal-based beverages to believe they are nutritionally equivalent to cow's milk and this could result in these consumers, especially young children, being nutritionally compromised.

Questions:

- 16. What is the size of the cereal-based beverage market in Australia and in New Zealand? Are these products readily available throughout all of Australia and New Zealand?**
- 17. How many people allergic/intolerant to cow's milk use Calcium-fortified soy beverages?**

7.2.1.2 Industry

Benefits

- There is no particular benefit to the Australian industry under the current arrangements, although New Zealand manufacturers may benefit.

Costs

- There are some costs associated with lack of opportunity for Australian manufacturers who may wish to fortify the proposed products with vitamins and minerals. This situation is exacerbated by the potential manufacture of fortified products under the Transitional standards for New Zealand thereby giving New Zealand manufacturers an advantage over their Australian counterparts.

Questions:

- 18. To what extent are Australian manufacturers of cereal-based beverages disadvantaged by the current discrepancy between Australian and New Zealand regulations?**
- 19. To what extent are cereal-based beverages manufactured or imported into New Zealand imported into Australia?**

7.2.1.3 Government

Benefits

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

Costs

- Calcium-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 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 cow's milk.

7.2.2.1 Consumers

Benefits

- Fortification of the proposed products with calcium would provide all consumers with additional and/or alternative food sources of calcium.
- For individuals who have a cow's milk allergy or are lactose intolerant, the availability of calcium-fortified products provides an alternative food source of calcium to the currently fortified dairy substitutes (e.g. soy beverages). Currently dietary sources of calcium for this population are limited.
- For individuals with allergies/intolerances to both cow's milk and soy, amending the Code to permit the voluntary addition of calcium to cereal-based beverages may increase the availability of these products because they could be manufactured in Australia and directly imported to Australia, rather than via New Zealand.
- Permission for Australian manufacturers and importers to produce and sell Calcium-fortified cereal-based beverages may increase the availability of these products.
- There may be potential to reduce the direct health costs to consumers that are associated with inadequate calcium intake.

Question:

20. Will consumers make use of this additional/alternative choice of calcium containing products in the food supply?

Costs

- If Calcium-fortified products are used as an alternative to cow's milk in young children, this could result in these individuals being nutritionally compromised, affecting their growth and development.
- Consumers may be further confused about what products they should choose as their sources of calcium.
- It is unknown what costs would be added by the manufacturer of these products and so it is difficult to determine the potential increase in retail price of fortified cereal-based beverages.

7.2.2.2 Industry

Benefits

- Industry would be permitted to voluntarily add calcium to the proposed products that may potentially open up new markets or increase market share both domestically and internationally.

Questions:

21. What is the overall size and makeup of the markets for these products?

22. What is the expected growth in markets or shift of existing markets to Calcium-fortified products?

23. To what extent will these products be premium products, i.e. are they likely to cost more?

Costs

- There is a potential for those consumers currently taking calcium supplements to choose Calcium-fortified food sources over calcium supplements and so the calcium supplement industry may be adversely affected.

7.2.2.3 Government

Benefits

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

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.

Question:

24. Are there any anticipated costs associated with this option such as increased enforcement?

8. Consultation

This Initial Assessment Report is intended to seek early input on a range of specific issues known to be of interest to various stakeholders on the likely regulatory impact of this Application. At this stage FSANZ is seeking public comment to assist it in assessing this Application and is particularly interested in receiving further information on the:

- consumption data detailing who is drinking these cereal-based beverages;
- potential risks to consumers of using cereal-based beverages as a cow's milk substitute when the protein and micronutrient content remains low;
- parties that might be affected by having this Application approved or rejected;
- arguments in support or opposition to permitting the voluntary addition of calcium and other relevant vitamins and minerals to cereal-based beverages; and
- potential costs and benefits to consumers, industry and government.

8.1 World Trade Organization (WTO)

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

This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

9. Conclusion

This Application has been assessed and is recommended for acceptance at Initial Assessment for the following reasons:

- The Application relates to a matter that warrants a variation to Standard 1.3.2, if further assessment supports such a variation. There is no current permission in Standard 1.3.2 for the voluntary addition of calcium to cereal-based beverages. If the information provided by the Applicant and the assessment of all relevant material supports the addition of calcium to cereal-based beverages a variation to the standard will be warranted.
- This Application is not so similar to a previous application that it ought not be accepted.

- The potential costs and benefits are dealt with at Section 7 of this report. In short, there is no basis for considering at this stage of assessment that the cost that would arise from a variation to Standard 1.3.2 to permit calcium fortification of cereal-based beverages would outweigh the direct and indirect benefits to the community, Government or Industry.
- There are no other measures available to permit that which the applicant is requesting.