So Natural Foods Australia Ltd
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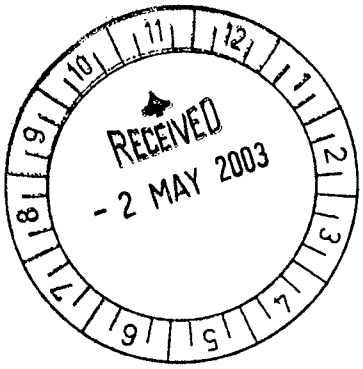

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APPLICATION TO FOOD STANDARDS AUSTRALIA NEW ZEALAND TO ADD CALCIUM TO BEVERAGES DERIVED FROM CEREALS

Applicant: *So Natural Foods Australia*

Contact person: *Howard Hurwitz*

Marketing Manager

1 May 2003

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PART 1 GENERAL INFORMATION

1.1 Applicant

So Natural Foods Australia
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Contact person: Mr Howard Hurwitz, Telephone 02 9526 2555, Facsimile 02 9525 5406, email hhurwitz@sonatural.com.au
So Natural Foods is a manufacturer of soy milks, soy yoghurts and rice milk.

1.2 Nature of application

This application is to vary an existing standard - Standard 1.3.2 Vitamins and Minerals of the Australia New Zealand Food Standards Code. It is being made on behalf of So Natural Foods Australia (SNFA).

PART 2 SPECIFIC INFORMATION

2.1 Details of the application

SNFA proposes that a new food category be included in the Australia New Zealand Food Standards Code under Standard 1.3.2 (Vitamins & Minerals) in the Table to Clause 3 to enable the addition of calcium to beverages derived from cereals. SNFA acknowledges that some products currently available on the market that would be regulated under this new category already contain added calcium. This application seeks to address this situation by legally allowing the addition of calcium to beverages derived from cereals. The products that would be regulated under this new food category include rice milk (a product manufactured by the applicant) and oat milk (a product not manufactured by the applicant).

(a) Description of the proposed variation to the Standard.

It is proposed the new food category for beverages derived from cereals appear in Standard 1.3.2 Vitamins and Minerals in the Table to Clause 3 as follows:

Food	Reference quantity	Vitamins and minerals that may be added	Maximum claim per reference quantity	Maximum permitted quantity of vitamin or mineral per reference quantity
Analogues derived from cereal grains Beverages containing no less than 0.5% protein derived from grains	200ml	Calcium	240 mg (30%)	-

The addition of this new food category allows the same amount of calcium to be added to beverages derived from cereals as is currently permitted for beverages derived from legumes.

(b) The specific type of foods to which the application relates.

This application relates to rice milk and oat milk and any other beverages derived from cereal grains.

2.2 Purpose and efficacy of the proposed variation

The purpose of this application is to provide a suitably nutritious milk alternative for consumers who choose not to drink other milk products for personal reasons, or who cannot drink other milk products due to food allergy or intolerance. The addition of calcium to beverages derived from cereals would ensure these products provide a nutritionally suitable milk alternative.

2.3 Justification of the application

The same objectives cannot be obtained by good manufacturing practice as calcium is not naturally present in sufficient quantities in cereal grains such as rice or oats, from which these milk products are derived. The applicant notes that rice milk is not covered in any other food definition within Standard 1.3.2 nor are any other beverages derived from cereal grains.

2.4 Need for the application

Beverages derived from cereals, such as rice milk, are used as dairy milk alternatives for children and adults with milk and/or soy allergy or intolerance, as well as consumers wishing to avoid dairy and soy milks for personal reasons. Children with special dietary considerations (such as a milk-free or soy free diet), have difficulty obtaining their requirements for calcium without using calcium-fortified analogues.

Adults who choose to avoid dairy milk and soy milk also have difficulty meeting the recommended 800mg of calcium daily, without the use of fortified analogues.

2.5 Nutritional implications

Rice milk is not a commonly consumed beverage in Australia. The size of the current market is small, and consumers of rice milk are usually those who avoid dairy milk and soy milk due to food allergy/intolerance or personal reasons.

Calcium-fortified rice milk compliments the range of dairy milk substitutes presently available on the market. Enabling the addition of 120 mg calcium per 100 ml rice milk provides consumers with similar calcium levels as found in dairy milk and calcium fortified soy beverages. Legally allowing the addition of calcium to beverages derived from cereals is not expected to encourage consumers to cease drinking dairy or soy milks if they are satisfied with their current choice[1].

The nutrient profiles of dairy milk, rice milk and soy milk are shown in Table 1. Energy content is similar, however rice milk is naturally lower in fat and higher in carbohydrate. The lower protein levels in rice milk are unlikely to impact on the nutritional status of adult consumers of rice milk considering Australian mean protein intakes are greater than physiological requirements[2]. Australian adult's total fat intakes and intake of saturated fat are also above recommended levels[2], therefore the lower fat content (predominantly unsaturated) of rice milk may be a nutritionally positive attribute of the product in the diets of adult consumers.

For children who consume rice milk in place of dairy or soy milk, the reduced protein and fat content may pose a risk for nutrient inadequacy, however these children are often under medical or dietetic supervision for food allergy or intolerance. *So Natural* rice milk contains a warning statement that "a low fat diet is not recommended for children less than 5 years of age".

Table 1: Key Nutrients in dairy, soy and rice milk.

Nutrition Information (per 100ml)	Dairy Milk Whole*	Soy Milk Full Fat, fortified*	Rice Milk, fortified #
Energy (kJ)	280	260	272
Protein (g)	3.4	3.5	0.6
Fat (g)			
- total	3.9	3.5	1.0
- saturated	2.6	0.4	0.1
- polyunsaturated	0.1	2.1	0.3
- monounsaturated	1.0	0.9	0.5
Cholesterol (mg)	13.4	0	0
Carbohydrate (g)			
- total	4.9	4.9	13.4
- sugars	4.9	1.5	4.2
Calcium (mg)	117	116	** (120)
Riboflavin (mg)	0.21	0.19	N/a
Vitamin A (ug)	49.5	39.0	N/a

**Figures from Foodworks Professional Edition, Version 3, Xyris Software.*
 # Figures for So Natural rice milk.
*** Calcium is currently added to So Natural Rice milk, however natural calcium content is negligible*

2.6 Dietary implications

The size of the rice milk market is small. National sales data show *So Natural* rice milk sales are approximately 165 000 litres per month. This volume is considerably lower than dairy or soy milk sales which account for 80 million litres per month (dairy) and 5 million litres per month (soy). As such, population-based nutrition survey data has limited relevance for this application. Rice milk is generally consumed by a small proportion of the population who have sensitivities to dairy and/or soy milk. *So Natural* estimates its share of the rice milk market is 68%.

Strong evidence exists to conclude that people whose diets involve total or partial withdrawal from milk products for a prolonged period of time are at potential risk of calcium deficiency resulting in defective bone mineralisation[3,4].

The fortification of rice milk with calcium will assist this group in meeting the recommended dietary intake for calcium. In addition to addressing possible deficiencies of this sub-population, the addition of calcium to rice milk facilitates greater choice for consumers.

2.7 Advantage to the consumer

Enabling the addition of calcium to beverages derived from cereals provides consumers with a more nutritionally similar alternative to dairy or soy milk. The availability of calcium fortified cereal based beverages may reduce the need for nutritional supplementation in this group of consumers. For children with dairy and/or soy allergy/intolerance, the availability of a calcium fortified milk alternative provides reassurance for parents and health professionals that children are able to meet daily calcium requirements.

Beverages derived from cereals, such as rice milk, are low in total fat and saturated fat, and provide an additional option for adults with high cholesterol.

Please see attached letters of support for the addition of calcium to rice milk.

PART 3 REGULATORY/LEGISLATIVE IMPLICATIONS

3.1 International standards

This application is consistent with the *General Principles for the Addition of Essential Nutrients to Food* published in the Codex Alimentarius, under the Joint Food and Agriculture Organization of the United Nations/World Health Organization Food Standards Programme. The General Principles state:

"**5.1** Where a substitute food is intended to replace a food which 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."

The Codex Alimentarius *General Principles for the Addition of Essential Nutrients to Foods* describe several terms relevant to this application.

Codex defines an essential nutrient as "any substance normally consumed as a constituent of food which is needed for growth and development and maintenance of healthy life and which cannot be synthesized in adequate amounts by the body". Of relevance to this application is that calcium is an *essential* nutrient and has population-based recommended dietary intakes (RDI).

According to Codex, a *substitute food* is a food 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. In this application, beverages derived from cereals, such as rice milk, can be seen as *substitutes* for dairy and soy milks.

3.2 International legislation

3.2.1 At present, the USA Food and Drug Administration has no provision for the fortification of cereal based products with calcium. However, a general fortification policy exists, stipulating:

> 3.2.1.1 "a nutrient may appropriately be added to a food to correct a dietary insufficiency recognized by the scientific community to exist and known to result in nutritional deficiency disease if sufficient information is available to identify the nutritional problem and the affected population groups, and the food is suitable to act as a vehicle for the added nutrients"; and
>
> 3.1.2.2 "a nutrient may appropriately be added to a food that replaces traditional food in the diet to avoid nutritional inferiority".

3.2.2 The UK Food Standards Agency is consulting with the European Commission to regulate the addition of vitamins and minerals to foods. The draft report has been published and includes a risk assessment for the fortification of foods with calcium. This document reports there is insufficient data from studies in animals or humans to establish a safe upper level for calcium. The document does not contain guidelines on the fortification of foods with calcium.

3.2.3 There is presently no provision in the Canadian Food and Drug Regulations to permit the addition of vitamins or mineral nutrients to beverages made from plant bases such as soy, rice, almond, etc. Health Canada has received a request to permit the optional addition of vitamins and mineral nutrients to plant-based beverages. The rationale for the application is to enable these products to be used as nutritionally adequate alternatives for milk by those individuals who are allergic to milk protein or are lactose intolerant.

3.3 Regulatory Impact Statement

The applicant can only comment on the regulatory impact of this application as it applies to rice milk due to lack of consumption data on other beverages derived from cereals. However, it can reasonably be assumed that other products such as oat milk, along with rice milk, constitute a very small market in Australia and New Zealand. This, along with the fact some products are already fortified with calcium means the regulatory impact of this application is expected to be negligible.

PART 4 ANALYTICAL PROCEDURES

The addition of calcium already occurs in some beverages derived from cereals, such as So Natural Rice Milk. The calcium salt used in this product is the same as that already added to soy beverages, therefore discussion of analytical methods is not relevant to this application.

PART 5 DETAILS OF REASONING

This application is for the addition of calcium to beverages derived from cereals to make them nutritionally appropriate dairy and soy milk alternatives. This application is not expected to have any other effect apart from increasing calcium intakes in consumers of these products and this is considered a health benefit.

PART 6 MANUFACTURING AND PUBLIC HEALTH

6.1 Manufacturing process

The applicant can only comment on the production of rice milk as an existing product in Australia and New Zealand. Commercial in confidence production techniques for other beverages derived from cereals prevent the applicant from including details on other relevant products. However, this application relates to the addition of calcium only, and does not require changed, or novel production methods for products that would fit under the category being proposed.

Rice milk is made from filtered water, rice flour, oil, sea salt and may have added calcium. Production of rice milk involves cooking rice flour in water, ultra heat treating the liquid and aseptically packaging the product. During the cooking process, some of the rice starch is converted to soluble starch, giving the product its distinctive rice flavour.

Please see below for a flow chart indicating manufacturing process, analytical controls and quality assurance procedures. So Natural Foods Australia has a HACCP type food safety plan in place. **Please treat this information as commercial in-confidence.**

Product Description and Intended use (rice milk)

PRODUCT DESCRIPTION	Rice Milk
COMPOSITION	Filtered water, Brown rice, Canola oil, Sea salt, Calcium phosphate Optional ingredients: Cocoa powder & flavour
METHOD OF PRESERVATION	Ultra Heat treatment at 140 ^{0}C for 4 scc.
PACKAGING- PRIMARY	One litre Tetra Brik
PACKAGING - SECONDARY	Cardboard trays & shrink wrapped
STORAGE CONDITIONS	Room temperature
DISTRIBUTION METHODS	Non-refrigerated transport
SHELF LIFE	10 months
CUSTOMER REQUIREMENTS	Ready to use
SENSITIVE CONSUMER	None, intended for general consumption not recommended for children less than 5 years of age.
FINAL CUSTOMER PREPARATION	None

6.2 Public health and safety

The addition of calcium to beverages derived from cereals is expected to achieve improvement in nutritional status for consumers of these products, but due to the small market for rice milk in Australia the public health implications are expected to be negligible.

PART 7 STATUTORY DECLARATION - AUSTRALIA

I, HOWARD HURWITZ declare that the information provided in this application fully sets out the matters required and that the same are true to the best of my knowledge and belief and that no information has been withheld which might prejudice this application.

Signature

Declared before me* (ERIC BELZER J.P. N° 790721)
this 30th day of APRIL 2003

* A Chief, Police, Resident or Special Magistrate; Stipendiary Magistrate or any Magistrate in respect of whose office an annual salary is payable; a Justice of the Peace; a person authorised under any law in force in Australia or its Territories to take affidavits; a person appointed under the *Statutory Declarations Act 1959* to be a Commissioner for Declarations; a person appointed as a Commissioner for Declarations under the *Statutory Declarations Act 1911* and holding office immediately before the commencement of the *Statutory Declarations Act 1959*; a Notary Public; a person before whom a statutory declaration may be made under the law of the State in which a declaration is made; or a person appointed to hold, or act in, the office in a country or place outside Australia of Australian Consul-General, Consul, Vice-Consul, Trade Commissioner, Consular Agent, Ambassador, High Commissioner, Minister, Head of Mission, Commissioner, Charge d' Affaires, or Consellor, Secretary of Attache at an Embassy, High Commissioner' s office, Legation or other post.

References

[1] Moro, GE, Warm, A, Arslanoglu, S, Miniello, V. Management of bovine protein allergy: new perspectives and nutritional aspects. *Ann Allergy Asthma Immunol* 2002 Dec;89(6 Suppl 1):91-6
[2] Australian Bureau of Statistics. National Nutrition Survey. Nutrient Intakes and Physical Measurements. Australia 1995. Commonwealth of Australia 1998.
[3] Infante, D, Tormo, R. Risk of inadequate bone mineralization in diseases involving long term suppression of dairy products. *J Pediatr Gastroenterol Nutr* 2000 Mar; 30(3):310-3
[4] Hidvegi, E, Arato, A, Cserhati, E, et al. Slight decrease in bone mineralization in cow milk-sensitive children. *J Pediatr Gastroenterol Nutr* 2003 Jan;36(1):44-9

Dept Nutrition & Dietetics
10 March 2003

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The Food Standards Liason Officer
FSANZ
PO Box 7186
Canberra BC ACT 2610

Dear Colleague,

Re: Calcium in rice milk

I am writing to support the addition of calcium to rice milks.

Children with a cow or soymilk allergy are at risk of an insufficient intake of calcium and consequent osteoporosis. Finding a suitable substitute can be difficult.

Calcium supplementation is one solution. Many children dislike taking these supplements however or they may be taken infrequently.

Another option is to use rice milk fortified with calcium to a level comparable with the calcium content of standard cow's milk. While this is not the ideal milk replacement, as it is low in protein, it is a useful way of getting calcium into the diet of these children. Parents find they can use it on cereals, in desserts and as a drink and children find it more acceptable than calcium supplements.

I'd like to endorse the fortification of rice milks with calcium and support the necessary food standard changes to make this happen.

Many thanks.

Yours sincerely

Barbara Dennison
Paediatric Dietitian

cc. Nicole Senior, Dietitian Food & Nutrition Australia Pty Ltd, GPO Box 222, Sydney NSW 2001

Allergy Unit
Royal Prince Alfred Hospital
Suite 210 RPAH Medical Centre, 100 Carillon Ave, Newtown 2042

The Food Standards Liaison Officer
FSANZ,
PO Box 7186,
Canberra BC ACT 2610

Dear Sir,

Re: Calcium in Rice Milk

At the Allergy clinic at RPAH we see many children and adults who experience adverse effects from food and beverages. These can be due to food allergies and/or food intolerances. For some individuals the dietary restrictions can wide ranging and so alternative food choices are important in order to maintain adequate nutrition..

Milk and Soy products in the normal diet provide a rich source of calcium. In those with an intolerance to milk and/or soy, other sources of calcium are required in order that an adequate intake of calcium is achieved.

Calcium can be taken in the tablet form but is an added cost and can be overlooked.

Rice drink, when fortified with calcium, is another useful way to supplement the diet with calcium. Rice drink has the added advantage that it can be used like milk or soy as a drink or in cooking because it has similar physical properties to milk and soy without the problems of adverse reactions. This allows individuals who are intolerant or allergic to milk or soy to have a relatively more normal diet and still achieve an adequate intake of calcium on a regular basis.

I look forward to the continuance of this valuable product on the market.

Yours truly,

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Allergy Unit, RPAH

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