Application for the Fortification of Almond and other Nut and Seed-based Beverages

For submission to Food Standards Australia New Zealand,
P O Box 7186, Canberra BC ACT 2610, Australia

Australia New Zealand Food Standards Code – Table to Clause 3 permitted addition of vitamins and minerals to food by varying an existing standard, Standard 1.3.2 Vitamins and Minerals

Submitted by Australasian Health & Nutrition Association Limited, trading as Sanitarium Health & Wellbeing, 1 Sanitarium Drive, Berkeley Vale NSW 2261, Australia

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3.1.1 Executive Summary

Sanitarium Health and Wellbeing is seeking permission to vary an existing standard, Standard 1.3.2 Vitamins and Minerals of the Australian New Zealand Food Standards Code. The variation would enable the voluntary addition of a range of vitamins and minerals to nut and seed-based beverages promoted as milk alternatives (such as almond 'milk') similarly to those permitted for addition to legume-based and cereal-based beverages (in Standard 1.3.2 these are known as Analogues derived from legumes and Analogues derived from cereals). If permitted, this will provide suitably nutritious milk alternatives for consumers who are allergic/intolerant to dairy, soy foods and/or cereal-based beverages or those who choose not to consume dairy products (or the above-named products) for health or philosophical reasons. These nut and seed-based beverages could be described as 'Analogues derived from nuts and seeds' forming a logical category of foods in table to clause 3 of ANZFSC 1.3.2.

Permission is sought to add:

Vitamin A, Thiamin, Riboflavin, Vitamin B_6, Vitamin B_{12}, Vitamin D, Folate, Calcium, Magnesium, Phosphorus, Zinc, Iodine.

The forms of these nutrients proposed to be added are the same as those currently listed in ANZFSC 1.1.1 SCHEDULE Permitted Forms of Recommended Dietary Intakes (RDIs) and Estimated Safe and Adequate Daily Dietary Intakes (ESADDIs) for Vitamins and Minerals. The permitted levels for addition and the permitted claim levels for these nutrients would be the same as that for "Beverages containing no less than 3% m/m protein derived from legumes" and also "Beverages containing no less than 0.3% m/m protein derived from cereals" in ANZFSC Standard 1.3.2. As part of the safeguards to ensure responsible use, it is proposed that an advisory statement be included on fortified nut and seed-based beverages to the effect that the product is not suitable as a complete milk replacement for children under the age of five years. This approach would be similar to that in Standard 1.2.3 for Beverage Analogues derived from cereals. It is therefore requested that an amendment be made to Table to Clause 2 of Standard 1.2.3 to include the requirement for the statement to be present on labels of fortified nut and seed-based beverages.

The proposed fortification approach for nut and seed-based beverages aligns with the Australia New Zealand policy guideline 'Fortification of food with vitamins and minerals' (ANZ Food Regulation Ministerial Council, 2009) and also with international fortification policies. The proposed fortification fits well with the 'Specific order policy principles – voluntary fortification: To enable the nutritional profile of specific substitute foods to be aligned with the primary food (through nutritional equivalence)."

To align with the requirements for the addition of vitamins and minerals to beverage Analogues derived from cereals, as regulated in Standard 1.3.2 (3); Table to Clause 3, this application seeks to allow the addition of vitamins and minerals to "Analogues derived from

nuts and seeds" using the subcategory "Beverages containing no less than 0.2% m/m protein derived from nuts and/or seeds". The 0.2% protein level is a result of both practical and technical issues and also captures most products available on the market.

The lower protein content of nut and seed-based beverages is comparable to cereal beverages and is unlikely to adversely affect the protein adequacy of adult consumers diets as the most recent Australian national nutrition survey found average protein intakes across all age groups exceeded requirements by some margin (ABS, 2014. First Nutrition Results. Table 1.1 Mean Daily Energy and Nutrient Intake.) Modelling and risk assessment of the likely situation in children has been previously undertaken by FSANZ (as part of the assessment of A500). Although this was completed before the 2011-13 Australian Health Survey data was obtained, it was found that young children (2 to 4 years) were most at risk of inadequate protein intake if consuming non-dairy milk alternatives, and an advisory statement was required. This analysis also concluded that non-dairy consumers were at risk of inadequate intakes of a number of vitamins and minerals ordinarily supplied by dairy foods, in particular calcium, magnesium, zinc, vitamin A, riboflavin, B_6 and iodine, with older consumers more at risk than the two to four year age group (FSANZ 2005a). The permitted fortification of cereal- based beverages may assist with addressing these potential inadequacies in cereal milk consumers; this application seeks to extend this principle to nut and seed-based beverages.

3.1.2 Applicant details

Applicant name	[redacted]
Company name	Sanitarium Health and Wellbeing
Address	1 Sanitarium Drive, Berkeley Vale, NSW 2261 Locked Bag 7, Central Coast Mail Centre, NSW 2252
Telephone number	[redacted]
Email address	[redacted]
Nature of applicant's business	Food manufacturing
Other individuals, companies or organisations associated with the application	

3.1.3 Purpose

The purpose of this application is to vary an existing standard, Standard 1.3.2 Vitamins and Minerals of the Australian New Zealand Food Standards Code. The applicant is Sanitarium Health and Wellbeing.

The application pertains to Standards Related to Substances Added to Food (section 3.3 of the FSANZ Application Handbook) and specifically deals with the addition of a range of vitamins and minerals to nut and seed-based beverages such as almond-based beverages. These plant-based milk alternatives are commonly called 'milks' in the marketplace but will be referred to as 'beverages' throughout the remainder of this application. When referring to nut- and seed-based beverages throughout this application, we refer to beverages made from either single or combinations of nuts and seeds, including coconut.

3.1.4 Justification

Sanitarium Health and Wellbeing is seeking permission for the voluntary addition of a range of vitamins and minerals to nut and seed-based beverages (such as almond 'milk') similarly to those permitted for addition to legume- and cereal-based beverages. If permitted, this will provide a suitably nutritious milk alternative for consumers who are allergic/intolerant to dairy, soy foods and/or cereal-based beverages or those who choose not to consume dairy products (or the above-named 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, soy-based analogues of dairy products, such as soy-based beverages and soy yoghurts as well as cereal-based beverages; however, there is no permission for the voluntary addition (i.e. fortification) of vitamins and minerals to nut and seed-based beverages.

Calcium compounds are currently added to the almond-based beverages manufactured by Sanitarium Health & Wellbeing as a food additive. Although added for technological functions, the calcium additive contributes towards the calcium content of the beverage, resulting in enough to enable a content claim. A claim informs consumers of the presence of calcium in almond-based beverages, which to some consumers, may be important information and affect their purchase decision.

Dairy milk and fortified soy-based beverages also contribute significant amounts of other vitamins and minerals to the diet. These include vitamin B_{12}, vitamin A, vitamin B_2 and magnesium. There is an increasing demand, due to health and/or philosophical reasons, for nutritious beverages other than dairy milk or soy-based versions. However, it is important to ensure that consumers can obtain similar levels of key nutrients when replacing core foods in their diet.

Sanitarium Health and Wellbeing have not made a similar application in any other country.

3.1.4 Justification for the application

A. Regulatory Impact Information

1 Costs and Benefits

If the application is successful, the benefit to consumers will be the provision of suitably nutritious nut and seed-based beverages, such as almond-based milk alternatives, for consumers who are allergic/intolerant to dairy, soy foods and/or cereal-based beverages or those who choose not to consume dairy products (or the above-named products) for health or philosophical reasons. The nutritional impact is addressed specifically in section 3.3.3 C and E.

There may be some cost to consumers if manufacturers decide to fortify their nut or seed-based beverage which was previously available on shelf unfortified. However, it is likely that there will remain a proportion of the nut and seed-based beverage market that is unfortified or minimally fortified (eg with calcium only) based on data for the current soy- and cereal-based beverages market. (See Section 3.3.3 C4 for further information). Therefore, consumers should always have a choice between fortified and unfortified nut- and seed-based beverages, should they prefer one over the other for reasons such as cost.

Industry will benefit from acceptance of the application via the capacity for other manufacturers to add vitamins and minerals to nut and seed-based beverages similarly to legume- and cereal-based beverages thereby providing additional market opportunities. The cost to industry is anticipated to be negligible since the decision to fortify nut and seed-based beverages with the vitamins and minerals within this application would be voluntary.

The current and anticipated total size of the nut and seed-based beverages market is small relative to alternatives such as dairy and as such, any additional cost to Government will be negligible.

2. Impact on International Trade

The application, if successful, does not seek to mandate the addition of vitamins and minerals to currently available almond-based beverages which may be either locally produced and subsequently exported or imported for sale. As such, no impact on international trade is anticipated.

3.1.5 Information to support the application

The application refers to Section 18 of the FSANZ Act which sets out FSANZ's objectives (in descending priority order) in developing food regulatory measures and variations of food regulatory measures as:

(a) The protection of public health and safety; and
(b) The provision of adequate information relating to food to enable consumers to make informed choices; and
(c) The prevention of misleading or deceptive conduct.

(a) The protection of public health and safety

The addition of calcium, vitamin B_{12} and other vitamins and minerals to nut and seed-based beverages, like almond-based beverages, is expected to be beneficial in terms of improving nutritional status (more details are provided in section 3.3.3 C and E). However, given the small market size for nut and seed-based beverages in Australia, any public health implications are expected to be negligible. The safety of individual consumers would also be protected by mirroring the maximum permitted quantities per reference quantity as per column 5 of ANZFSC 1.3.2 table to clause 3; provision of nutritional information as required by ANZFSC 1.2.8 and directions for safe use via extension of the mandatory advisory statements in ANZFSC 1.2.3 table to clause 2.

(b) The provision of adequate information relating to food to enable consumers to make informed choices

At present the Food Standards Code does not include a provision to allow the fortification of nut and seed-based beverages with any vitamins and minerals. However, previous successful applications created two other fortified beverage categories namely, "Beverages containing no less than 3% m/m protein derived from legumes" and "Beverages containing no less than 0.3% m/m protein derived from cereals".

Importantly, Standard 1.3.2 dictates which vitamins and minerals can be added to these two (and other) categories and PART 1.2 Labelling and other Information Requirements in the Food Code dictates how such products must be labelled. A successful application will see the creation of "Analogues derived from nuts and seeds", with a subcategory "Beverages containing no less than 0.2% m/m protein derived from nuts and/or seeds". This would similarly be controlled in terms of which vitamins and minerals can be added, the level to which they can be added and the way in which these products will be labelled to "ensure adequate information" to allow for informed decisions to be made.

(c) The prevention of misleading or deceptive conduct.

A successful application would result in the category "Analogues derived from nuts and seeds" that may be fortified – however the type and extent of the fortification will be controlled (Standard 1.3.2), as will the labelling of such products to reduce the risk of misleading or deceptive conduct.

3.1.5 (a)

Any public health and safety issues related to the proposed change including details of target groups and population groups that may be adversely affected.

It is not anticipated that any particular groups in the population will be adversely affected by the application to fortify nut and seed-based beverages being successful. The issue of low protein content in these types of products is addressed in section 3.3.3 E1. Briefly, the lower protein content of nut and seed-based beverages is comparable to cereal-based beverages and is unlikely to adversely affect the protein adequacy of adult consumers diets as the most recent Australian national nutrition survey found average protein intakes across all age groups exceeded requirements by some margin (ABS, 2014a.) Modelling and risk assessment of the likely situation in children has been previously undertaken by FSANZ as part of the assessment of A500 (FSANZ, 2005a). Although this was completed before the 2011-13 Australian Health Survey data was obtained, it was found that young children (2 to 4 years) were most at risk of inadequate protein intake if consuming non-dairy milk alternatives, and an advisory statement was required in ANZFSC 1.2.3.

For those consumers that may have adverse reactions to nuts or seeds, adhering to the allergen labelling requirements of Standard 1.2.3 will ensure those consumers are adequately informed.

3.1.5 (b)

Any consumer choice issues related to the proposed change.

If the application is successful, a nutritionally similar option will be available for those consumers who are allergic/intolerant to dairy, soy foods and/or cereal-based beverages or those who choose not to consume dairy products (or the above-named products) for health or philosophical reasons. As such, consumer choice will be enhanced.

Section 3.3.3 C4 discusses the proportion of the nut and seed-based beverages market expected to become fortified, should this application be successful. It is expected that a significant proportion of the market would remain unfortified, or only contain added calcium, thereby giving consumers a choice between nut and seed-based beverages with and without added vitamins and minerals.

3.1.5 (c)

Any evidence that the food industry generally or other specific companies have an interest in, or support, the proposed change to the Code.

Due to the need for confidentiality prior to the application being submitted, it is difficult to state with certainty that other companies will have an interest in or support the application. Once the Initial Assessment Report for this application is commented upon, other companies' interest can be gauged.

3.1.6 Recommended assessment procedure.

In recommending the type of assessment procedure required, both the nature of the proposed change and successful applications involving similar changes should be considered. In the case of the type of change, the application does not require the assessment of any new substances. A successful application (A500) also exists as a logical template to model the type of regulatory response that should address potential concerns with respect to nutrient intake over the spectrum of population ages and dietary patterns.

Specifically:

- Appropriate permitted forms of the vitamins and minerals in question are already defined in the schedule "Permitted Forms of Recommended Dietary Intakes (RDIs) and Estimated Safe and Adequate Daily Dietary Intakes (ESADDIs) for Vitamins and Minerals" of Standard 1.1.1
- Appropriate maximum claimable levels and permitted quantities are already specified for similar foods such as "Beverages containing no less than 0.3% m/m protein derived from cereals" in the table to clause 3 of Standard 1.3.2.
- Advisory statements exist in the table to clause 2 of Standard 1.2.3 that could be adapted to appropriately advise that these products are not suitable as complete milk replacements for young consumers.

On this basis, as the application simply involves extending the permitted use of a substance to another food, general procedure should be sufficient to develop a proposed regulatory response, collect community feedback and adjust the response if required.

3.1.7 Confidential Commercial Information

The parts of this application that are considered by Sanitarium to be confidential commercial information are:

1. the table 3.3.3 A 2 Nutrition Quality Assurance Data for So Good. This data provides details regarding the amount of overage needed to ensure adequate vitamin levels at end of shelf life, according to the manufacturing process that So Good undergoes. The table is found in the separate Confidential Commercial Information (CCI) document, Appendix CCI I;

2. the table 3.3.3 A 3 Shelf Life Data for Fortified Almond Milk. Again this data provides details regarding the amount of vitamins and minerals added ensure adequate levels at the end of shelf life, according to the So Good manufacturing process. This table is found in the CCI document, Appendix CCI I also;

3. supermarket sales data found in the CCI document, Appendix CCI II; and

4. an excerpt from a consumer research report commissioned by Sanitarium (Forethought Research, 2012) which is in the CCI document, Appendix CCI III.

The request and justification for maintaining confidentiality of this information is found within the Confidential Commercial Information document.

3.1.8 Exclusive Capturable Commercial Benefit

If this application is successful, the amendments to the Food Standards Code would create an opportunity for all food manufacturers to produce fortified nut and seed-based beverages. Therefore, Sanitarium does not expect that this application would result in it gaining an exclusive capturable commercial benefit.

3.1.9 International and other national standards

A. International Standards

Codex Alimentarius

There are no specific requirements in Codex for nut and seed-based beverages, although guidelines exist for the addition of vitamins and minerals to foods (Codex Alimentarius, 1994). These guidelines discuss the permitted purposes for adding nutrients, including “nutritional equivalence of substitute foods”. A “substitute food” is defined 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". This application seeks to enable addition of vitamins and minerals to a milk substitute (in this case, Analogues derived from nuts and seeds) in order to help achieve nutritional equivalence.

B. Other national standards or regulations.

Canada

Fortification of foods is governed by the *Food and Drug Regulations* in Canada and currently they do not cover the addition of vitamins or minerals to plant-based milk alternatives such as soy-, rice- and almond-based beverages. An Interim Marketing Authorisation (IMA) was issued in November 1997 to allow the fortification of soy and other plant-based beverages as an alternative to milk (Health Canada, 1997). In early 2005, Health Canada released a proposed new fortification policy which would enable fortification to most foods at levels deemed safe by the authority, including fortification of plant-based beverages (Health Canada, 2005). The vitamin and mineral permissions proposed for plant-based beverages were those permitted in the IMA. The proposed regulatory change was placed on hold pending completion of the scientific evaluation required for this process. In 2013, IMAs were replaced with ability to provide Marketing Authorizations. IMAs in effect prior to the introduction of Marketing Authorizations continue until either: the IMA is cancelled; the IMA becomes part of an MA; or two years after the day on which the IMA came into effect elapses. Health Canada is still working on the implementation of food safety and nutrition decisions previously authorized via IMAs. Therefore, it is unknown whether the previous IMA on fortification of plant-based beverages will be made into a recognised regulatory permission by being incorporated into a new MA. In the meantime, there continue to be a number of brands of nut-based beverages that are fortified with a range of nutrients.

The IMA considered the fortification of plant-based beverages to 'enable them to be used as nutritionally adequate alternatives for milk'. This purpose is consistent with Codex General Principles as mentioned previously. 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. This is similar to the approach to cereal-based beverages in Standard 1.3.2 which has protein requirements before fortification is possible and a mandatory advisory statement in Standard 1.2.3 when protein and fat are under similar amounts as that in the IMA.

United States of America

US Code of Federal Regulations: *Title 21 - Food and Drugs, Chapter 1, Subchapter B, Part 104, Subpart B – Fortification Policy* (FDA, 1993) sets out the policy and circumstances under which vitamins and mineral may be added to foods in the US. Fortification of nut and seed-based beverages is permitted under Section *§104.2(e),* which states: "*(e) A nutrient(s) may appropriately be added to a food that replaces traditional food in the diet to avoid nutritional inferiority in accordance with § 101.3(e)(2) of this chapter*. [§ 101.3(e)(2) deals with the circumstances in which a food could be deemed to be an 'imitation' food and therefore misbranded.]"

Section *§104.2(g),*sets out the criteria under which the nutrients in question can be added, including defining maximum levels as those that give "reasonable assurance that the consumption of the food containing the added nutrient will not result in an excessive intake..." added nutrients must also be stable, physiologically available and compliant with applicable safety requirements. Minimum levels are not specifically defined. However, additions made under *§104.2(e),* to avoid nutritional inferiority, can reasonably be presumed to require minimum levels similar to those of the traditional food being replaced.

European Countries

Regulation within the EU, including the UK, stems from *Regulation (EC) No. 1925/2006 – On the addition of vitamins and minerals and certain other substances to foods* (European Commission, 2006). The effect of this regulation is to permit the addition of the vitamins and minerals, in the amounts listed in table C5A, below. This regulation not only defines the vitamins and minerals which can be added, and the maximum and minimum amounts, but also the forms which can be used.

Nut and seed-based beverages do not meet the criteria for restriction of addition set out in *Regulation (EC) No. 1925/2006, Article 4* (which does not permit additions to unprocessed foodstuffs and some alcoholic beverages). Therefore nut and seed-based beverages may be fortified according to the other requirements of this regulation.

Regulation (EC) No. 1925/2006 must be read in conjunction with *Council Directive 90/496/EEC on nutrition labelling rules of foodstuffs, Annex* (Council of European Communities, 1990). From December 14 2014, this directive will be replaced by *Regulation (EU)No. 1169/2011 – On the provision of information to consumers (food labelling), Annex 13* (European Commission, 2011). These annexes define the term 'significant amounts', which is used in *Regulation (EC) No. 1925/2006* to calculate minimum amounts of vitamins and minerals to be added. The new annex changes the requirements for minimum amounts, as shown in Table

C5A, below. This is because the new regulation introduces an additional category of foods – liquid foods. The older regulation treats solids and liquids together per 100g or 100mL; while the newer regulation keeps this level for foods other than beverages, and introduces a beverages requirement which halves the minimum amount required for beverages. The newer regulation also makes changes to the RDAs used.

The EU was due to provide guidance on maximum permitted levels in January 2009. Although there has been consultation on this matter it does not yet appear to be resolved. Therefore EU regulations do not currently include guidance on maximum levels for the vitamins and minerals permitted to be added to foods.

Table C5A: EU legislation

Permitted nutrients	Minimum amount		Maximum amount	rRDAs which apply	
	Current (276/44)	New (1169/2011)		Current (276/44)	New (1169/2011)
Vitamin A (mcg)	120	60	NOT DETERMINED: UNDER CONSIDERATION	800	800
Vitamin D (mcg)	0.8	0.375		5	5
Vitamin E (mg)	1.5	0.9		10	12
Vitamin K (mcg)	na	5.625		na	75
Vitamin C (mg)	9	6		60	80
Thiamin (mg)	0.2	0.0825		1.4	1.1
Riboflavin (mg)	0.2	0.105		1.6	1.4
Niacin (mg)	2.7	1.2		18	16
Vitamin B6 (mg)	0.3	0.105		2	1.4
Folacin (mcg) [Folic acid in 1169/2011]	30	15		200	200
Vitamin B12 (mcg)	0.2	0.1875		1	2.5
Biotin (mcg)	23	3.75		150	50
Pantothenic acid (mg)	0.9	0.45		6	6
Potassium (mg)	na	150		na	2000
Chloride (mg)	na	60		na	800
Calcium (mg)	120	60		800	800
Phosphorus (mg)	120	52.5		800	700
Iron (mg)	2.1	1.05		14	14
Magnesium(mg)	45	28.125		300	375
Zinc (mg)	2.3	0.75		15	10
Iodine (mcg)	22.5	11.25		150	150
Copper (mg)	na	0.075		na	1
Manganese (mg)	na	0.15		na	2
Fluoride (mg)	na	0.2625		na	3.5
Selenium (mcg)	na	4.125		na	55
Chromium (mcg)	na	3		na	40
Molybdenum (mcg)	na	3.75		na	50

na: A value is not allocated in this directive.
Nutrients highlighted in green are those proposed in this application.

3.1.10 Statutory Declaration

See Appendix I for a statutory declaration regarding the information provided for this application.

3.1.11 Checklist

See Appendix II for a completed checklist for application format and information requirements.

3.3.3 Nutritive Substances

A. Technical information on the nutritive substance

1. Information to enable identification of the nutritive substance.

The following table lists the permitted forms, structural formula, common names, CAS number and ANZFSC specification reference for each of the vitamins and minerals requested for permission to add to nut and seed-based beverages.

Table 3.3.3 A 1 Chemical identification for permitted forms (IUPAC)

Chemical Name	Structural Formula	Common Name / Synonyms	CAS registry number	Spec Source ANZFSC
Vitamin A				
Retinol	$C_{20}H_{30}O$	Vitamin A (+ 75 synonyms)	68-26-8	1.3.4 **2**(c)
Retinyl Acetate	$C_{22}H_{32}O_2$	Vitamin A Acetate, Retinol Acetate	127-47-9	1.3.4 **2**(c)
Retinyl Palmitate	$C_{36}H_{60}O_2$	Retinol, hexadecanoate	79-81-2	1.3.4 **2**(c)
Retinyl Proprionate	$C_{23}H_{34}O_2$		7069-42-3	1.3.4 **2**(c)
Beta-apo-8'-carotenal	$C_{30}H_{40}O$	CI Food Orange 6; CI (1975) No. 40820	1107-26-2	1.3.4 **2**(b)
Beta-carotene-synthetic carotenes – natural	$C_{40}H_{56}$	CI Food Orange 5; INS No. 160a(i); CI (1975) No. 40800	7235-40-7	1.3.4 **2**(b)
Beta-apo-8'-carotenoic acid ethyl ester	$C_{32}H_{44}O_2$	CI Food Orange 7; CI (1975) No. 40825	1109-11-1	1.3.4 **2**(b)
Thiamin (Vitamin B1)				
Thiamin hydrochloride	$C_{12}H_{17}N_4OS.ClH.Cl$	Thiamin Monohydrochloride	67-03-8	1.3.4 **2**(c)
Thiamin mononitrate	$C_{12}H_{17}N_5O_4S$		532-43-4	1.3.4 **2**(c)
Thiamin monophosphate	$C_{12}H_{18}N_4O_4PS+$	Thiamin phosphate	532-40-1	1.3.4 **3**(d)
Riboflavin (Vitamin B2)				

Chemical Name	Structural Formula	Common Name / Synonyms	CAS registry number	Spec Source ANZFSC
Riboflavin	$C_{17}H_{20}N_4O_6$	C.I. Food Yellow 15, E 101	83-88-5	1.3.4 **2**(b)
Riboflavin 5'-phosphate	$C_{17}H_{21}N_4O_9P$	E 101a, Riboflavin monophosphate	146-17-8	1.3.4 **2**(b)
Vitamin B6				
Pyridoxine hydrochloride	$C_8H_{11}NO_3.CH$	Benadon, Hexabetalin	58-56-0	1.3.4 **2**(c)
Folate				
Folic acid	$C_{19}H_{19}N_7O_6$	Folacin, Pteroylglutamic acid	59-30-3	1.3.4 **2**(c)
L-methyltetrahydrofolate, Calcium	$C_{20}H_{23}CaN_7O_6$	L-methylfolate, calcium	151533-22-1	1.3.4 **2**(b)
Vitamin B12				
Cyanocobalamin	$C_{63}H_{88}CoN_{14}O_{14}P$		68-19-9	1.3.4 **2**(c)
Hydroxocobalamin	$C_{62}H_{89}CoN_{13}O_{15}P$		13422-51-0	1.3.4 **2**(c)
Vitamin D				
Vitamin D2 (ergocalciferol)	$C_{28}H_{44}O$	Calciferol	50-14-6	1.3.4 **2**(c)
Vitamin D3 (cholecalciferol)	$C_{27}H_{44}O$		67-97-0	1.3.4 **2**(c)
Calcium				
Calcium carbonate	$CaCO_3$	Limestone	471-34-1	1.3.4 **2**(b)
Calcium chloride	$CaCl_2$	Calcium chloride anhydrous, E509	10043-52-4	1.3.4 **2**(b)
Calcium chloride, anhydrous	See above			1.3.4 **2**(b)
Calcium chloride solution				1.3.4 **2**(b)
Calcium citrate	$Ca_3(C_6H_5O_7)_2$	E333	813-94-5	1.3.4 **2**(b)
Calcium gluconate	$C_{12}H_{22}CaO_{14}$		299-28-5	1.3.4 **2**(b)
Calcium glycerophosphate	$C_3H_7CaO_6P$		27214-00-2	1.3.4 **2**(c)
Calcium lactate	$C_6H_{10}CaO_6$	E327	814-80-2	1.3.4 **2**(b)
Calcium oxide	CaO	Burnt lime, quicklime	1305-78-8	1.3.4 **2**(b)
Calcium phosphate, dibasic	$CaHPO_4$	Dicalcium phosphate, E341(ii)	7757-93-9	1.3.4 **2**(b)
Calcium phosphate, monobasic	$Ca(H_2PO_4)_2$	Monocalcium phosphate, E341(i)	7758-23-8	1.3.4 **2**(b)
Calcium phosphate, tribasic	$Ca_3(PO_4)_2$	Tricalcium phosphate, E341(iii)	7758-87-4	1.3.4 **2**(c)
Calcium sodium lactate	$C_9H_{15}CaNaO_9$		71060-51-0	1.3.4 **3**(d)
Calcium sulphate	$CaSO_4$	Gypsum	7778-18-9	1.3.4 **2**(b)
Iodine				
Potassium iodate	KIO_3		7758-05-6	1.3.4 **2**(b)
Potassium iodide	KI		7681-11-0	1.3.4 **2**(c)

Chemical Name	Structural Formula	Common Name / Synonyms	CAS registry number	Spec Source ANZFSC
Sodium iodate	$NaIO_3$	Iodic Acid, Sodium Salt	7681-55-2	1.3.4 **3**(g)
Sodium iodide	NaI		7681-82-5	1.3.4 **3**(b)
Magnesium				
Magnesium carbonate	$MgCO_3$	Magnesite	546-93-0	1.3.4 **2**(b)
Magnesium chloride	$Mg\ Cl_2$		7786-30-3	1.3.4 **2**(b)
Magnesium gluconate	$MgC_{12}H_{22}O_{14}$	E580	3632-91-5	1.3.4 **2**(b)
Magnesium oxide	MgO	Magnesia	1309-48-4	1.3.4 **2**(b)
Magnesium phosphate, dibasic	$MgHPO_4$	E343	7757-86-0	1.3.4 **2**(b)
Magnesium phosphate, tribasic	$Mg_3(PO_4)_2$		10233-87-1	1.3.4 **2**(c)
Magnesium sulphate	$MgSO_4$	Epsom salt	7487-88-9	1.3.4 **2**(b)
Phosphorus				
Calcium phosphate, dibasic	$CaHPO_4$	Dicalcium phosphate, E341(ii)	7757-93-9	1.3.4 **2**(b)
Calcium phosphate, monobasic	$Ca(H_2PO_4)_2$	Monocalcium phosphate, E341(i)	7758-23-8	1.3.4 **2**(b)
Calcium phosphate, tribasic	$Ca_3(PO_4)_2$	Tricalcium phosphate, E341(iii)	7758-87-4	1.3.4 **2**(c)
Bone phosphate	$3Ca_3(PO_4)_2$	INS No. 542		1.3.4 **2**(b)
Magnesium phosphate, dibasic	$MgHPO_4$	E343	7757-86-0	1.3.4 **2**(b)
Magnesium phosphate, tribasic	$Mg_3(PO_4)_2$		10233-87-1	1.3.4 **2**(c)
Calcium glycerophosphate	$C_3H_7CaO_6P$		27214-00-2	1.3.4 **2**(c)
Potassium glycerophosphate	$(C_3H_7O_6P)_2K$		1319-69-3	1.3.4 **2**(c)
Phosphoric acid	H_3PO_4	Orthophosphoric acid	7664-38-2	1.3.4 **2**(b)
Potassium phosphate, dibasic	K_2HPO_4	Dipotassium phosphate	7758-11-4	1.3.4 **2**(c)
Potassium phosphate, monobasic	KH_2PO_4	Monopotassium phosphate	7778-77-0	1.3.4 **2**(b)
Sodium phosphate, dibasic	Na_2HPO_4	Sodium hydrogen phosphate	7558-79-4	1.3.4 **2**(c)
Zinc				
Zinc acetate	$Zn(O_2CCH_3)_2$		557-34-6	1.3.4 **3**(b)
Zinc chloride	$ZnCl_2$	Butter of zinc	7646-85-7	1.3.4 **3**(b)
Zinc gluconate	$C_{12}H_{22}O_{14}Zn$	Zinc Verla	4468-02-4	1.3.4 **2**(c)
Zinc lactate	$ZnC_6H_{10}O_6$		16039-53-5	1.3.4 **3**(g)
Zinc oxide	ZnO		1314-13-2	1.3.4 **2**(c)
Zinc sulphate	$ZnSO_4$	Sulphuric acid, zinc salt	7733-02-0	1.3.4 **2**(c)

2. Information on the chemical and physical properties of the nutritive substance.

This application seeks permission to add vitamins and minerals to nut and seed-based beverages, at the same levels that are permitted for soy-based and cereal-based beverages in Standard 1.3.2. Permission is sought to add:

Vitamin A, Thiamin, Riboflavin, Vitamin B_6, Vitamin B_{12}, Vitamin D, Folate, Calcium, Magnesium, Phosphorus, Zinc, Iodine.

The success of food fortification depends on a number of factors, including the stability of micronutrients added to the food. Food processing has the potential to alter the stability of added vitamins and minerals in food. The use of stabilised forms of vitamins and minerals has greatly improved the resistance of vitamins and minerals to severe processing and storage conditions. For example, complexing retinoid with cyclodextrin inhibits photoisomerisation and photodegradation. In addition, gum arabic provides an additional complex which acts as a suitable vehicle for vitamin A encapsulation. Processing and manufacturing technologies of commercial fortification ingredients considers bioavailability, sensory acceptability, and storage stability. Therefore, these commercial nutrient forms are all designed for efficacy in processed foods.

Evidence that the vitamins and minerals added to plant-based milk alternatives are stable throughout the production process can be provided by data from Sanitarium's nutritional quality assurance programme. This programme tests all Sanitarium products annually to ensure their nutritional content reflects the information provided on the products' nutrition information panels. Confidential Table 3.3.3 A2 (found in CCI document, Appendix CCI I) shows the average analytical results for all nutrients displayed on the nutrition panels for So Good Lite and Essential Soy Milks and also So Good Rice Milk. The results show that the vitamins and minerals added to So Good soy beverages are present in sufficient quantities after the production process to provide the amounts claimed in the product's nutrition tables. Data used is from samples at the beginning and towards the end of shelf life and provides information on vitamin A, riboflavin, vitamin B_{12}, calcium, phosphorus, thiamin, vitamin B_6 and folate. This data demonstrates the adequate stability of these nutrients throughout the production process as well as post production. Data is not available for the remaining nutrients requested for permission to add in this application (magnesium, iodine and zinc), since they are currently not added to and or claimed on So Good products. Vitamin D is now added to So Good soy beverages, however no analytical data is available at this time as methods are not sensitive enough to detect the low levels added.

Confidential Table 3.3.3 A3 (in CCI document, Appendix CCI I) contains the quality assurance data gathered to date for So Good Almond Milk Regular and Unsweetened as part of our quality assurance monitoring programme. Although there has only been one sample of each variant tested so far, calcium content has been found to at least meet the NIP level claimed. As mentioned in Section 3.1.4, calcium is present from the addition of tricalcium phosphate which is added for technical purposes.

Evidence of the stability of other vitamins and minerals in fortified nut and seed-based milk alternatives is provided in Confidential Table 3.3.3 A4 (found in CCI document, Appendix CCI I). This table shows analytical data on levels over shelf life of all the vitamins and minerals that can be claimed (except for vitamin D which cannot be detected using current analytical methods). The data demonstrates that the levels of these nutrients are both present in amounts corresponding to levels requested for addition in this application, as well as stable over time.

3. Information on the impurity profile.

Since the chemical form of the nutrients being added (fortificants) has the potential to influence the bioavailability, chemical stability, appearance, and homogeneity of fortified nut and seed-based beverages, Sanitarium proposes only to use permitted forms of vitamins and minerals. For example, the form of vitamin A currently used by Sanitarium is retinyl acetate which is delivered in a matrix of the following ingredients: Corn Maltodextrin, Gum Arabic, Corn Starch and DL-alpha-Tocopherol. The impurity profile of each permitted form is covered in the monograph referred to in Table 3.3.3 A 1 and further discussed in 3.3.3 A 5.

4. Manufacturing process

All of the vitamins and minerals proposed in this application to be used will be sourced in commercially available forms from specialist nutrient suppliers. As such the methods of manufacture are well established, but beyond the scope of this application. However suitable food grade nutritive substances can be assured through supplier assessment and specification management.

Suppliers will be assessed to ensure that they are manufacturing according to a Hazard Analysis and Critical Control Point (HACCP) system, as adopted by WHO/FAO Codex (e.g. GENERAL PRINCIPLES OF FOOD HYGIENE CAC/RCP 1-1969). Evidence that these suppliers are meeting the manufacturing process outcomes sought by part 3 of the Australia New Zealand Food Standards code) (ANZFSC) may be via review of their suppler specification, completion of a Product Information Form (PIF)[a] or any external quality accreditation they may have.

Once the nutrients are received on site along with other ingredients they are handled in accordance with ANZFSC 3.2.2 on equipment compliant with ANZFSC 3.2.3. Dosages would be set during the design phase to meet the new requirements of ANZFSC 1.3.2 table to clause 3. A quality assurance compliance program would check the fortification levels to ensure

[a] A standardised product information form facilitated by the Australian Food and Grocery Council (AFGC) and the allergen bureau. http://www.allergenbureau.net/vital/food-industry-product-information-form-pif

addition rates were meeting the requirements of ANZFSC 1.3.2 and claims in accordance with ANZFSC 1.2.8.

5. Specification for identity and purity

All nutrients covered in this application are approved vitamins and minerals as laid out in ANZFSC 1.1.1 SCHEDULE Permitted Forms of Recommended Dietary Intakes (RDIs) and Estimated Safe and Adequate Daily Dietary Intakes (ESADDIs) for Vitamins and Minerals. The identity & purity of these substances are set out in ANZFSC 1.3.4 which, in the case of nutritive substances, generally refers to reputable international specification sources. The location of the specification monographs is summarised in the table "Chemical identification for permitted forms" located in section 3.3.3 A 1 of this application.

Commercial supplies of these nutrients may include additives as stipulated in ANZFSC 1.3.1 Schedule 1 0.1 preparations of food additives, and generally permitted additives specified in schedule 2. Commercially available nutrients may also use carriers and stabilising agents, which assist in the stability of the nutrient prior to being added to the food, but which have no technological function in the final food, these processing aids are specified in ANZFSC 1.3.3 especially in clauses 3, 10 and 18.

6. Analytical method for detection.

The AOAC analytical methods used for detection of the vitamins and minerals proposed for addition are detailed in the table below.

Table 3.3.3 A.6 Analytical Methods for Detection.

Nutrient	**AOAC Method**
Vitamin A	2001.13
Thiamin	953.17
Riboflavin	970.65
Vitamin B6	961.15
Vitamin B12	2011.08
Vitamin D	2011.12
Folate	2004.05
Calcium	991.25
Magnesium	991.25
Phosphorus	991.25
Zinc	999.10
Iodine	992.22

7. **Information on the proposed food label.**

The addition of the proposed vitamins and minerals to nut and seed-based beverages would require inclusion of many of these nutrients on the nutrition information panel, as well as declaration in the ingredients list (eg vitamins (A,...)). The claimed levels of these nutrients is proposed to be the same as that for "Beverages containing no less than 3% m/m protein derived from legumes" and also "Beverages containing no less than 0.3% m/m protein derived from cereals" in ANZFSC Standard 1.3.2. In addition to the vitamin and mineral claims, it is proposed that an advisory statement be included on fortified nut and seed-based beverages to the effect that the product is not suitable as a complete milk replacement for children under the age of five years. This is similar to that in Standard 1.2.3 for cereal-based beverages. It is therefore requested that an amendment be made to Table to Clause 2 of Standard 1.2.3 to include the requirement for the statement to be present on labels of fortified nut and seed-based beverages. An example of how the amended Table might be worded is below:

Column 1	Column 2
Food	Advisory Statement
Bee pollen presented as a food, or a food containing bee pollen as an ingredient as defined in Standard 1.2.4	Statement to the effect that the product contains bee pollen which can cause severe allergic reactions
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.
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.
Food containing aspartame or aspartameacesulphame salt	Statement to the effect that the product contains phenylalanine
Food containing quinine	Statement to the effect that the product contains quinine
Food containing guarana or extracts of guarana	Statement to the effect that the product contains caffeine
Foods containing added phytosterols, phytostanols or their esters	Statements to the effect that – 1. when consuming this product, it should be consumed as part of a healthy diet; 2. this product may not be suitable for children under the age of five years and pregnant or lactating women; and 3. plant sterols do not provide additional benefits when consumed in excess of three grams per day.
Kola beverages containing added caffeine, or food	Statement to the effect that the product contains

containing a kola beverage containing added caffeine as an ingredient as defined in Standard 1.2.4.	caffeine
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.
Nut and seed-based beverages, where these foods contain 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.
Propolis presented as a food, or food containing propolis as an ingredient as defined in Standard 1.2.4	Statement to the effect that the product contains propolis which can cause severe allergic reactions
Unpasteurised egg products	Statement to the effect that the product is unpasteurised
Unpasteurised milk and unpasteurised liquid milk products	Statement to the effect that the product has not been pasteurised

Following is the Nutrition Information Panel for a fortified version of So Good Almond Milk, assuming the maximum permitted claim per 200mL reference quantity.

NUTRITION INFORMATION (Average)		
Serving Size: 200ml		
Servings Per Package: 5		
	Per Serve	Per 100ml
Energy (kJ)	252	126
(Cal)	60	30
Protein (g)	1.0	0.6
- Gluten (g)	0.0	0.0
Fat, Total (g)	2.8	1.4
- Saturated fat (g)	0.2	0.1
- Trans fat (g)	0.0	0.0
- Polyunsaturated fat (g)	0.8	0.4
- Monounsaturated fat (g)	1.8	0.9
Cholesterol (mg)	0.0	0.0
Carbohydrate, Total (g)	7.2	3.6
- Sugars (g)	6.8	3.4
- Lactose (g)	0.0	0.0
- Galactose (g)	0.0	0.0
Dietary Fibre (g)	0.6	0.3
Sodium (mg)	60	30
Potassium (mg)	38	19

Vitamin A (µg)	110 (15%)*	55
Riboflavin (mg)	0.43 (25%)*	0.21
Vitamin B12 (µg)	0.8 (40%)*	0.4
Vitamin D (µg)	1.0 (10%)*	0.5
Calcium (mg)	240 (30%)*	120
Phosphorus (mg)	200 (20%)*	100
Iodine (µg)	15 (10%)*	7.5

* Percentage of Recommended Dietary Intake (RDI)

Note that So Good Almond milk contains 10% of the RDI for vitamin E per 250mL serving, and is currently included on the nutrition information panel. The vitamin E is contributed solely by the almonds in the formulation. This application does not seek permission to fortify nut and seed-based beverages with vitamin E.

B. Information related to the safety of the nutritive substance.

A number of evaluations of the safety of different doses of vitamins and minerals have been conducted by both national and international bodies such as those conducted by the US Food and Nutrition Board to develop dietary reference intake values for calcium, phosphorus, magnesium and vitamin D (Food and Nutrition Board, 1997), the European Food Safety Authority (European Food Safety Authority, 2006), and the United Kingdom (Expert Group on Vitamins and Minerals, 2003). In addition, the safety of vitamins and minerals has been considered by the French Ministries (AFSSA, 2001a and 2001b) and also by associations of the manufacturers and producers of vitamins and vitamin supplements, such as the Council for Responsible Nutrition (Council for Responsible Nutrition, 2004). Recent reviews (Verkaik-Kloosterman et al., 2012, Rasmussen et al., 2006) on the safe strategy for addition of vitamins and minerals to foods have highlighted the importance of how policy makers and enforcing agencies need to decide how to manage the role of food fortification and/or dietary supplements between the "free space" of trying to ensure adequate population intakes, while protecting populations from adverse health effects which may come from excessive intakes. In the case of the vitamins and minerals requested for addition to nut and seed-based beverages, out of the 'claimable' vitamins and minerals, only vitamins A and D have maximum permitted quantities listed in Standard 1.3.2 for legume- and cereal-based milk analogues (which Sanitarium is proposing to base permissions for nut and seed-based milk analogues on). All of the remaining 'claimable' vitamins and minerals for legume and cereal-based milk analogues are permitted at GMP levels. For those 'non-claimable' vitamins and minerals, the permitted addition levels are kept at controlled levels similar to those found naturally in dairy milk. In this way, the ANZFSC balances maintaining nutritional adequacy with protecting against excess intakes. By mirroring the same controls for the proposed fortification of nut

and seed-based beverages, the safety of these nutritive substances will be kept to the same level as existing permitted products.

3.3.3.B.1. Information on the toxicokinetics and metabolism of the nutritive substance and, if necessary, it's degradation products and major metabolites.

The nutritive substances proposed are already permitted fortificants in the current food supply, so the safety of these nutritive substances is already established. However a brief summary on metabolism is set out below.

Brief pharmacokinetics/toxicokinetics of major vitamins and minerals

Vitamin A

The physiologically active form of vitamin A is retinol esters. In the intestine, the ester of the vitamin is converted to retinal and absorbed. This is stored in the liver as retinol palmitate. It is carried to the target sites by retinol binding protein and by oxidation of retinol, retinal is obtained. Normal hepatic stores will last for 2 years. Vitamin A absorption is reduced in the presence of neomycin, cholestyramine and liquid paraffin

Vitamin B1

It is well absorbed orally, not stored in body and excess is excreted in the urine.

Vitamin B2

It is well absorbed from the upper gastro – intestinal tract. This vitamin is not stored in the body and excess amounts are excreted in the urine.

Vitamin B6

It is well absorbed from the gastro-intestinal tract. Excess excreted in the urine as pyridoxic acid .

Vitamin B12

There are a number of proteins (such as intrinsic factor) and enzymes in the body involved in the absorption of vitamin B12 as well as organs, namely the stomach, pancreas and small intestine. Impairments to any of these organs or enzyme secretions can cause reduced bioavailability of the vitamin. Excretion occurs slowly via faeces, urine and skin.

Folate

It is well absorbed in the small intestine and excreted from the body via urine in the metabolically active form or as it's broken down products.

Vitamin D

Cholecalciferol is formed through the action of UV rays on 7-deydrocholesterol in the skin. Ergocalciferol is formed by the UV radiation of the plant sterol ergosterol. Both forms are transported to the liver and metabolised to 25-OHD (the major circulating form). There is significant storage of vitamin D in the adipose tissue, with excretion occurring mainly in the bile and then urine.

Minerals

Most of the minerals consumed in the diet are stable in structure and unlikely to undergo structural modification during metabolism. The body has two ways to regulate body stores of minerals: by absorption and excretion. Minerals can be lost in the urine and can be excreted in the gastrointestinal tract, in breast milk for lactating women, and in minor amounts in sweat, sloughing of tissue, and semen. Many minerals are absorbed in a particular way. In the stomach, they are mixed with proteins or amino acids, which serve as carrier substances to assist their absorption. This process requires an acidic stomach and the presence of enough protein in the diet. The process is called chelating the minerals. In their chelated form, they are far more absorbable. Bioavailability is also dependant on the structural form of minerals.

3.3.3.B.2. Information from studies in animals or humans that is relevant to the toxicity of the nutritive substance and, if necessary, its degradation products and major metabolites.

A safety evaluation was performed on vitamins and minerals in the course of assessing Application 470: Formulated Beverages (A470). Since this evaluation was completed, Nutrient Reference Values have been developed for use in Australia and New Zealand with an established Upper Limit, similarly to that used in the safety evaluation. The safety evaluation for A470 found that there were potential safety concerns for children up to the age of 3 years, and maybe up to 6 years, "with the addition of retinol to formulated beverages at a level of 187.5 µg in a 600ml serve" (FSANZ, 2005b). For all other age groups and life-stages, it was concluded that there was no appreciable risk posed by excess intake of retinol.

A nutrition assessment was performed as part of the overall assessment of A500 (FSANZ, 2005a) and concluded that "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."

Some recent studies demonstrating the safety and efficacy of vitamins & minerals (including vitamin A) fortification on human health are summarized in Table 3.3.3 B 2

Table 3.3.3 B2 Safety studies on fortification.

Study	Objective	Result
Flynn A et al. (2003). Vitamins and minerals: a model for safe addition to foods. Eur J Nutr. 42(2):118-30.	To develop a model to estimate the level of each micronutrient that can be added safely to foods.	A wide range of vitamins and minerals can be added safely to foods at nutritionally important levels in the current diets of Europeans.
Klemm RD et al. (2010). Vitamin A fortification of wheat flour: considerations and current recommendations. Food Nutr Bull. 31(1 Suppl): S47-61.	To provide guidance on fortifying wheat and maize flour milled in industrial rollers for national fortification programs in countries where vitamin A deficiency is considered a public health problem.	Vitamin A should be fortified in flour for providing nearly 25% of the Recommended Dietary Allowance to vulnerable groups consuming varying ranges of flour products.
Touvier, M. (2005). Efficacy and safety of regular vitamin and mineral supplement use in France: Results from the ECCA study. Int J Vit Nutr Res. 75: 201-209.	This study investigated the prevalence of inadequate micronutrient intake and the proportion of subjects who exceed Tolerable Upper Intake Levels	Supplement use brought a nutritional benefit for some targeted nutrients, but not associated with excessive intake.
Walter P. (2001). Towards ensuring the safety of vitamins and minerals. Toxicology Letters 120, 83–87	Multi-step risk assessment procedure on the basis of mainly human data.	Discussed the relationship of RDA, higher RDA and upper limit of supplementation

The impact of fortifying nut and seed-based beverages on dietary intakes is unlikely to be different to that assessed for A500 because nut and seed-based beverages are aimed at providing an alternative to dairy milk, which contains similar levels to that requested in this application (see Table C2A for proposed levels). Therefore, dietary modelling would be substituting dairy milk with a beverage containing similar levels of vitamins and minerals thus intakes should remain about the same.

3.3.3.B.3. Safety assessment reports prepared by international agencies or other national government agencies, if available

As vitamins and minerals are nutrients, consumption of appropriate amounts across the population is necessary to avoid deficiencies and maintain health and wellbeing. The exact amounts required are dependent on the individual, but estimated adequate intakes (AI's) for

various jurisdictions have been developed to estimate population nutritional needs. However, some individuals consume more nutrients than others, potentially to excess. For this reason upper limits (UL) of safe consumption are set to benchmark against the range of population intakes. One of the best ways to monitor whether there are any emerging concerns with the safety of an individual vitamin or mineral is to monitor whether the recommended AI's and UL's are being changed significantly. Significant reductions in UL's in credible jurisdictions may be indicative of emerging reseach showing that the amount of the nutrient that can be safely consumed may be less than previously thought. Hence a review of the fortification recommendations in key jurisdictions is a good way to establish this. There is particular attention given to vitamin A as there is a relatively small difference between the maximum claimable level in Standard 1.3.2 for legume and cereal analogues, relative to the maximum permitted level.

Voluntary fortification, the addition of vitamins and minerals to foods at the discretion of manufacturers, has long been permitted in the United States (FDA, 1993) and in parts of Europe (Flynn et al., 2009; Hannon et al., 2007), and in 2007, harmonized regulations came into effect in the European Union (European Commission, 2006). A review of the Codex Alimentarius' general principles for the addition of vitamins and minerals to foods has also been initiated, in part to discuss the introduction of international standards for the practice of voluntary fortification and to examine how to protect against excesses, deficits or imbalances (Codex Committee on Nutrition and Foods for Special Dietary Uses, 2007).

It is anticipated that nut and seed-based beverages will be marketed as general purpose foods as the likely target group do not have particular dietary requirements. Therefore it is appropriate to adopt the same approach to regulating the addition of vitamins and minerals to nut and seed-based beverages as other fortified general purpose foods and beverages.

USA

U.S. Food & Drug Administration (FDA) also recognized the need for fortification of various foods in CFR Code of Federal Regulation Title 21, subpart B-Fortification policy (FDA, 1993) which states in part:

Sec. 104.20 Statement of purpose.

> (a)"The fundamental objective of this subpart is to establish a uniform set of principles that will serve as a model for the rational addition of nutrients to foods. ...The addition of nutrients to specific foods can be an effective way of maintaining and improving the overall nutritional quality of the food supply. However, random fortification of foods could result in over- or under fortification in consumer diets and create nutrient imbalances in the food supply. It could also result in deceptive or misleading claims for certain foods". And

(e) “A nutrient(s) may appropriately be added to a food that replaces traditional food in the diet to avoid nutritional inferiority in accordance with 101.3(e)(2) of this chapter.” To appropriately cover the wide range of food that could be fortified under this option, the amount of vitamin or mineral that can be added is on a per 100 calorie basis.

The US approach allows for maintenance of the nutritional quality of the food supply to be maintained as dietary patterns change, ensuring that substitute foods need not be nutritionally lacking relative to the food they may be replacing.

The Dietary Reference Intakes (DRI’s) in the US and Canada were developed to be used for a number of different settings, including to help shape nutrition labelling and food fortification requirements (Institute of Medicine, 2003). The Tolerable Upper Intake Levels (as part of the DRI’s) are recommended to be used, in particular, for assessing the safety of discretionary fortification. Where discretionary fortification is used in “substitute foods”, such as soy-based beverages, it is recommended that “the intended use of the targeted food should determine the amount of the proposed nutrient addition”.

Europe

The European Commission evaluated the safety risks of consuming excessive amounts of different micronutrients and established Tolerable Upper Intake Levels for different population groups (European Food Safety Authority, 2006). This risk assessment was prepared to support harmonized EU legislation regarding food supplements and food fortification. These UL’s remain in place today, however, in 2005, the European Food Safety Authority (EFSA) received a mandate from the European Commission to review the Dietary Reference Values (DRVs) published in 1993. While the setting of DRVs for macronutrients and energy has almost been finalized by the EFSA NDA Panel, the work on micronutrients was launched at the end of 2010. Ten micronutrients were selected by the NDA Panel as priority for further review of existing data. These were vitamins A, C, E, K (Heinonen et al, 2010), chromium, manganese, molybdenum (Mullee et al, 2012), and magnesium, potassium, fluoride (Brown et al, 2012). Scientific opinions on dietary reference values for all the micronutrients are still to be completed, therefore, currently recommended UL’s for most vitamins and minerals remain unchanged.

The daily UL of 3000 µg RE from preformed vitamin A was originally set taking into account the available data. This is the same as the Upper Level of Intake set for vitamin A in Australian and New Zealand. Quantitative correlations between retinol intake and bone health risk justifying the establishment of a lower UL for a specific population subgroup (elderly people) could not be established, however postmenopausal women were advised to keep to a maximum intake of 1 500 µg RE day^{-1} until new data indicates the necessity of a re-evaluation(European Food Safety Authority, 2006). .

In Europe, fortification is controlled by the 'EC Regulation on the Addition of Vitamins, Minerals and Certain Other Substances to Foods (1925/2006/EC)' (European Commission, 2006) . This Regulation came into force in January 2007 and aims to regulate and harmonise voluntary fortification across the EU. It sets out which nutrients are allowed to be added to food and drink, and in what forms. It also specifies the minimum amount of the nutrient that should be added, and sets out provisions for developing maximum amounts. There has been no change of minimum and maximum allowable limits of vitamins and minerals in supplemented foods. The reviews (Heinonen et al, 2010; Mullee et al, 2012; Brown et al, 2012) of different nutrients for EFSA in preparation for developing the Dietary Reference Values identified several health outcomes that can be assisted by vitamin and mineral supplementation such as; anemia, bone health (fractures), cancer (by cancer type), child health, eye diseases, lung diseases, mortality. It is well established that food fortification has a positive impact on population health and well-being and outweighs by far any potential risk. Food fortification efforts should be integrated within the context of a country's public health and nutrition situation and a clearly defined component of an overall micronutrient strategy that uses a combination of interventions to address key deficiencies.

Australia and New Zealand

Since the A500 and A470 safety assessments, there are no changes in recommended fortification levels of vitamin and minerals globally. It is also important to note that the proposed fortification approach for nut and seed-based beverages aligns with the Australia New Zealand policy guideline 'Fortification of food with vitamins and minerals' (ANZ Food Regulation Ministerial Council, 2009). The "High Order Policy Principles state the following:

"The objectives (in descending priority order) of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures are:

(a) the protection of public health and safety
(b) the provision of adequate information relating to food to enable consumers to make informed choices; and
(c) the prevention of misleading or deceptive conduct.
2. In developing or reviewing food regulatory measures and variations of food regulatory measures the Authority must also have regard to the following:
(a) the need for standards to be based on risk analysis using the best available scientific evidence;
(b) the promotion of consistency between domestic and international food standards;
(c) the desirability of an efficient and internationally competitive food industry;
(d) the promotion of fair trading in food; and
(e) any written policy guidelines formulated by the Council for the purposes of this paragraph and notified to the Authority."

By aligning with the fortification levels and controls that are already in place for 'Analogues derived from cereals', the 'higher order' policy principles 1 (a) and (b) would be well covered along with promoting trade on an internationally competitive footing in line with the 'higher order' policy principles 2 (b) & (c). In addition, the proposed fortification fits well with the 'Specific order policy principles – voluntary fortification: To enable the nutritional profile of specific substitute foods to be aligned with the primary food (through nutritional equivalence)."

On this basis the fortification permission sought in this application would appear to be congruent with international approaches and national policies with regard to voluntary fortification.

C. Information on dietary intake of the nutritive substance

C.1 A detailed list of the food groups or foods proposed to contain the nutritive substance, or changes to currently permitted foods.

This application seeks to amend Standard 1.3.2 to permit the addition of a range of vitamins and minerals (as detailed in C2, below) to nut and seed-based beverages (or mixtures of these), to bring these products into line with other similar beverages, such as cereal-based and soy-based beverages.

A wide range of beverages derived from various nuts and seeds can be made, and almond-based beverages are now commonly available in Australia and New Zealand. However other varieties manufactured in Australia and overseas include coconut-, sesame- and sunflower-based beverages, and also beverages made from other nuts such as hazelnuts. The following table C1 details examples of a range of available nut and seed-based beverages and their characterising nutrients. So Good Almond Milk and So Good Coconut Milk products are manufactured by the applicant; three other almond-based beverages brands available in Australia are also shown; the sesame, sunflower, coconut and hazelnut variants are sold other than in Australia and New Zealand, and are not manufactured by the applicant.

Table C1: per 100mL	**So Good Almond Milk**	**Blue Diamond Almond Breeze Original Almond Milk**	**Australia's Own Almond Milk**	**Pure Harvest Almond Milk**	**So Good Coconut Milk**	**EcoMil Sesame Milk***	**SoL Sunflower Beverage**	**Alpro Hazelnut Drink**	**Silk Original Coconut Milk**
Energy (kJ)	126	105	150	175	183	214	122	119	140
(Cal)	30	25	36	42	44	51	29	29	33
Protein (g)	0.6	0.4	0.6	0.3	0.2	0.6	0.4	0.3	0.0
Fat, total (g)	1.4	1.1	2.7	0.4	3.4	2.4	1.7	1.6	2.1
- Saturated fat (g)	0.1	<0.1	0.2	<0.1	2.2	0.5	0.2	0.2	2.1

- Polyunsaturated (g)	0.4	0.3	0.7	0.1	0.7	0.5	u/s	0.1	0.0
- Monounsaturated (g)	0.9	0.7	1.8	0.3	0.5	1.4	u/s	1.3	0.0
Cholesterol (mg)	0	0	0	0	0	0	0	0	0
Carbohydrate, total (g)	3.6	3.2	2.4	9.1	3.1	6.7	3.8	3.0	2.9
- Sugars (g)	3.4	2.8	1.9	6.3	2.9	3.4	2.9	3.0	2.5
- Lactose (g)	0	0	0	0	0	0	0	0	0
Dietary Fibre (g)	0.3	0.2	ns	ns	0.1	0.2	0.4	2.3	0
Sodium (mg)	30	52	60.0	56.0	25	10	50	50	20
Calcium (mg)	75	75	Unfortified	Unfortified	75	Unfortified	Fortified	Fortified	Fortified

**Figures for Ecomil Sesame are only available per 100g as shown.*

Accordingly, to align with the requirements for the addition of vitamins and minerals to cereal-based beverages, as regulated in Standard 1.3.2 (3); Table to Clause 3, this application seeks to allow the addition of vitamins and minerals to nuts and seed-based beverages with no less than 0.2% m/m protein derived from nuts and/or seeds. This level captures the varied protein content of these products, as shown in Table C1.

With regard to the protein content of nut and seed-based beverages, it should be noted that although nuts and seeds typically have higher protein levels than cereal grains there are both practical and technical issues that impact upon the protein levels in the final product:

- The higher protein levels in nut and seed-based beverages are associated with higher fat levels compared to dairy and/or soy beverages of comparable protein content. For example, both almond and sesame have a fat to protein ratio of around 5:2. This means an increase in protein level to the levels achievable in soy of 3% would result in a fat content of over 8%. Although this fat is largely unsaturated, it would be undesirably high for many consumers.
- The large quantity of nuts and seed required to reach a 3% protein beverage would result in a high solids content, which presents both technical and consumer acceptance issues such as product stability, development of rancidity and negative mouthfeel.
- In practical terms, a protein level of 3% would require a nut or seed content in the order of 15%, which would make the product prohibitively expensive.

The suggested protein level of 0.2% m/m is similar to the current Australian standard for cereal-based beverages, but also captures most nut and seed-based beverages currently available (see Table C1 above). Even though the level of 0.2% protein is low and would mean that the contribution to protein intakes from these foods could be minimal to most consumers, requiring this minimum helps to define this product category. It would help avoid the situation where beverages made using only refined portions of nuts and seeds, such as extracted oils, could make use of the fortification provisions requested in this application.

C.2 The maximum proposed level of the nutritive substance for each food group or food, or the proposed changes to the currently permitted levels

This application seeks permission to add vitamins and minerals to nut and seed-based beverages, at the same level as is permitted for cereal-based beverages. Permission is sought to add:

Vitamin A
Riboflavin
Vitamin B_{12}
Vitamin D
Calcium
Magnesium
Phosphorus
Iodine
Thiamin
Vitamin B_6
Folate
Zinc

Table C2 A: Nutrients permitted in current standard 1.3.2	**Maximum claim per reference quantity (%RDI)**	**Maximum permitted quantity per reference quantity**
Vitamin A	110 mcg (15%)	125 mcg
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 mcg (40%)	
Vitamin D	1.0 mcg (10%)	1.6 mcg
Folate	no claim permitted	12 mcg
Calcium	240 mg (30%)	
Magnesium	no claim permitted	22 mg
Phosphorus	200 mg (20%)	
Zinc	no claim permitted	0.8 mg
Iodine	15 mcg (10%)	

The following table shows the comparison levels in a 200mL reference quantity of So Good Almond Milk in its current form, and if fortified with all nutrients put forward in this proposal.

Table C2B: effect of proposed level of fortification	**So Good Almond Milk**	**So Good Almond Milk - with proposed additions**

per 200mL		
Energy (kJ)	252	252
(Cal)	60	60
Protein (g)	1.2	1.2
Fat, total (g)	2.8	2.8
- Saturated fat (g)	0.2	0.2
- Polyunsaturated (g)	0.8	0.8
- Monounsaturated (g)	1.8	1.8
Cholesterol (mg)	0	0
Carbohydrate, total (g)	7.2	7.2
- Sugars (g)	6.8	6.8
- Lactose (g)	0	0
Dietary Fibre (g)	0.6	0.6
Sodium (mg)	60	60
Calcium† (mg)	150	240
Vitamin A* (mcg)	0	110
Thiamin* (mg)	0	0.1‡
Riboflavin* (mg)	0	0.43
Vitamin B_6* (mg)	0	0.1‡
Vitamin B_{12}* (mcg)	0	0.8
Vitamin D* (mcg)	0	1.0
Folate* (mcg)	2	12‡
Magnesium* (mg)	11	22‡
Phosphorus* (mg)	20	200
Zinc* (mg)	0.1	0.8‡
Iodine◊ (mcg)	0	7.5

† The value for calcium in current So Good Almond milk is as a result of the use of the mineral salt tricalcium phosphate as an additive.
‡ Levels shown for these nutrients where no claim is permitted are at the proposed maximum levels permitted.
* The values for these nutrients in unfortified Almond Milk is calculated from USDA data for blanched almond. The almond ingredient is the only significant source of these nutrients in the product, and is made from US blanched almonds. The beverage contains 2% by weight almond, and has a density of 1.019g/mL.
◊ The value for iodine in unfortified Almond Milk is calculated from NUTTAB 2010, using the same calculations as for * - no iodine data exists in USDA database for almonds.

C.3 For foods or food groups not currently listed in the most recent Australian or New Zealand National Nutrition Surveys (NNSs), information on the likely level of consumption.

Although there is some limited information on nut-based milk substitute consumption in the Australian Health Survey 2011-2012, the growth of the nut and seed-based beverages has grown quickly enough since the survey was carried out to warrant further discussion on likely level of consumption. In addition, New Zealand national nutrition surveys are out of date, such that nut and seed-based beverages were not available at the time they were carried out.

Nut and seed-based beverages do not represent a large part of the plant-based milk alternatives market in Australia or New Zealand at this time. The market is small and relatively new, so they are not commonly consumed. However, the market is growing quickly, and in the US, where the market is more mature, significant growth has been achieved over the past five years.

The Australian market for almond-based beverages, which is the main nut or seed-based beverage available at this time, is currently 9% of the non-dairy milk alternatives market (which also includes soy-based and cereal-based beverages) compared to 0.3% at the end of the 2011 financial year (AZTEC Supermarket Scan Data, 2011-13. See CCI document Appendix CCI II). Non-dairy milk alternatives currently represent only around 6% of the total milk market.

Confidential Table C3A (found in CCI document Appendix CCI II) shows the growth in the supermarket volumes of UHT and chilled non-dairy milk alternatives over the three years to the end of financial year 2013 in Australia. There has been a steady growth in the almond-based beverages category, which over this time period represented the vast majority of supermarket-available nut and seed-based beverages, with volumes tripling from 2012 to 2013. Confidential Table C3B (found in CCI document Appendix CCI II) shows the same information for the New Zealand UHT non-dairy milk alternatives market, with a similar pattern of growth in a smaller market off a lower base. In both countries, volume for nut-based beverages appears to be contributed to from the decline in soy beverages volume.

National Nutrition Survey Data

The 2011-12 Australian Health Survey found that only 0.6% and 0.8% of males and females respectively consumed “cereal- or nut-based milk substitutes”, however a total of 2.4% and 4.1% of males and females consumed from the “dairy milk substitutes, unflavoured” category (ABS, 2014b). Given the fast growth of the nut-based beverages category over the past 3 years, it is likely that the proportion of consumption of these products as part of the overall milk substitutes category has increased. The survey found that amongst people who consumed “cereal- or nut-based milk substitutes”, the median intake for males and females was 203g and 131g respectively on the day surveyed (ABS, 2014d), which is around a half to one serving. Median intakes for nut and cereal-based milk substitutes were not provided across different age groups, however median intakes for total “dairy milk substitutes, unflavoured” were. Median intakes for 2-3 year old males was highest at 466g (one to two cups), while other data provided for males up to the 31-50 years age group was noted as having a large relevant standard error and so should be used with caution. Median intakes for males aged 31-50 years was 250g (1 cup). Data on median intakes for girls also either had a high relative standard error or was deemed not publishable. Median intakes for females

aged 19-30 years was 203g (ABS, 2014c). In summary, the survey data showed that adult users typically consumed around 1 cup (or one serve) of a milk substitute on the day surveyed.

The 2008-2009 New Zealand Adult Nutrition Survey (University of Otago et al, 2011a), collected data for consumption of both "soy milk" and "other milk". Both these categories had very small intakes on a population basis, with 1.4% of males and 3.4% of females drinking "soy milk" "most of the time" and around 1% of people drinking "other milks" "most of the time". This compares to over 90% of adults who reported they consumed dairy milk "most of the time"; around 5% of New Zealand adults reported not drinking milk at all.

The New Zealand National Children's Nutrition Survey 2002 found that 4% of schoolchildren drank "other milk", compared to well over 90% drinking dairy milks (Ministry of Health, 2003). The 2007 Australian National Children's Nutrition and Physical Activity Survey (CSIRO, 2008) found variations in intake of 'dairy substitutes' with age; boys aged 4-8 years consuming around 7g/day, and girls around 11g/day. The highest levels of intake were in children aged 2 to 3 years, with around 20g/day for boys and 13g/day for girls. This can be compared to the same dataset for 'milk products and dishes' where depending on age, boys consumed a mean of 362.5 to 445.9g/day, and girls 287.3 to 416.3g/day. Due to the comparatively small volumes compared to dairy milks and even other non-dairy milks, this type of population-based nutrition survey data, where average intakes is spread across users and non-users, is of limited relevance.

Nut and seed-based beverages are typically consumed by people who are allergic or intolerant to dairy milks and who either cannot tolerate, or do not enjoy, soy-based or cereal-based beverages. Nut and seed-based beverages are promoted as a general milk alternative for mainstream use by people over 5 years of age, and in these groups might be expected to replace all serves of dairy milk normally consumed. The data provided above suggests these products are not currently excessively consumed by most users.

C.4 The percentage of the food group in which the nutritive substance is proposed to be used or the percentage of the market likely to use the nutritive substance

Confidential Table C4 (found in CCI document Appendix CCI II), shows the proportion of the Australian non-dairy milk alternatives market held by the various types of non-dairy beverages. The data was adapted from AZTEC Supermarket Scan data by product (SKU) volume (AZTEC Supermarket Scan Data, 2011-13. Found in CCI document Appendix CCI II), together with on-pack and online information relating to the degree of fortification for each.

Soy-based beverages is a more mature market than either cereal-based beverages or almond beverages in Australia, and soy beverages fortified with a range of permitted nutrients hold the bulk of the soy beverage market (69%), with a further 27% of soy beverages being fortified

with calcium alone. Unfortified soy beverages make up only a very small part of the market, around 4%.

In the case of the less mature cereal beverages market, the largest segment is fortified with calcium (88.5%), with only a small percentage including other nutrients (1%). A relatively small percentage of the cereal beverages market (compared to the calcium fortified cereal beverages) is sold unfortified, around 11%.

It is anticipated that the almond beverages and nut & seed beverages market would follow a similar pattern over time, with more products becoming available with added vitamins and minerals to provide better nutritional equivalence to dairy milks. Indeed, from Table C4, it can be seen that around 79% of almond milks in Australia already contain added calcium. Based on the same AZTEC sales data for the same period, the applicant holds nearly half the almond beverages market by volume. If this application is successful, the applicant may fortify its product not only with calcium, but also with a wider range of permitted nutrients. This alone would result in around 41% of the market being fortified.

C.5 Information relating to the use of the nutritive substance in other countries

See Section 3.1.9 B for information on regulations regarding addition of vitamins and minerals to foods in other countries

Consumption levels in other countries

Minimal data is available on levels of individual's consumption of nut and seed-based beverages in other countries. In the US, this data may be captured in the NHANES data, however, it does not appear to be of sufficient nutritional significance to have been the subject of NHANES analysis, nor is it considered in the *What we eat in America, DHHS-USDA Dietary Survey Integration* analyses, where nut and seed-based beverages do not feature as food categories assessed. While there has been no data obtained on intake levels, a reported 9% of adults in the US consumed almond beverages in 2011, with sales reportedly increasing by 79% in 2011 (Scott-Thomas, 2012).

Some data is available in the UK, where The National Diet and Nutrition Survey (data from 2008/9 to 2011/12) (Public Health England, 2014) includes a consumption category "Other Milk". This covers "soya milk, goats, sheeps, evaporated, condensed, lactose-free, dried milk, milkshake, milk with added fibre, coffee whitener, buttermilk, flavoured milk drinks, purchased hot chocolate, breast milk, rice milk".

For adult consumers aged 19-64 years in the UK, 20% consumed other milks, the mean intake was 49g per day and the median 19g per day. This compares to the most popular type of liquid milk, semi-skimmed milk, with 72% of 19-64 year olds consuming it, with a median consumption of 100g and a mean of 128g.

For children aged 4 to 10 years, other milks were consumed by 22% of children, with a mean consumption of 74g and median of 50g; compared to semi-skimmed milks (also the most popular choice in this group) of which were consumed by 60% of children, mean 176g, median 150g.

Milk and other liquid dairy milk products contributed 6% of kilojoules in boys, 4% in men, 6% in girls and 4% of women, compared to only 1% contributed by 'other milks' in all these groups (Table 5.5 Percentage contribution of food groups to average daily total energy intake (MJ), by age and sex).

These data demonstrate that due to the relatively small market volumes compared to population numbers, population-based dietary survey data has limited relevance to consideration of this category of products. High consumers with a food allergy or intolerance are likely to replace all of their liquid dairy intake with alternate milks, while most consumers are unlikely to have even inadvertent consumption of these products. In the case of high consumers, fortification of nut and seed-based beverages to the same levels as for legume- and cereal-based beverages, means those consumers choosing these products are not missing out on key nutrients generally delivered by this food group.

C.6 For foods where consumption has changed in recent years, information on likely current food consumption

Section C3 of this application outlines market trends and current volumes as well as discussion on the limited consumption data from Australia and New Zealand national nutrition surveys.

From the historical data on UHT dairy and non-dairy milk alternatives (AZTEC Supermarket Scan Data, 1999-2013, found in CCI document Appendix CCI II), shown in Confidential Table C6A, (found in CCI document Appendix CCI II), it can be seen that while the UHT market for non-dairy beverages has remained relatively stable over time, as cereal- , nut and seed-based beverages have grown in popularity, soy beverages have declined. This suggests that many nut and seed-based beverage consumers are now drinking these beverages where they would have previously consumed soy beverages.

Internal Sanitarium survey data (Symphony Analytics, 2011.) on the purchasing habits of 350 households either already purchasing non-dairy milk alternatives, or considering doing so in the near future, showed that 20% reported that their household consumed soy or other non-dairy milk alternatives every day. A total of 35% reported consuming them more than 3-4 times per week.

Current dietary guidelines (NHMRC, 2005) for inclusion of the food group dairy milk, yoghurts, cheeses and alternatives recommend a minimum of two serves per day (250mL milk equivalent) for most ages and genders with the exception of 12 to 18 year old boys who are

recommended to consume 3 serves. However, a recent analysis (Doige et al, 2012) of the 1995 National Nutrition Survey, which set out to assess the consumption levels of dairy in line with these recommendations found that for the people studied (males and females over the age of 12 years), 24% of men and 32% of women consumed less than 1 serve per day, 55% and 71% respectively having less than the recommended two serves. The results of this analysis also show that the vast majority of consumers have 3 or fewer serves of dairy per day, with only a very small number of people consuming four to six serves (although this proportion is somewhat higher in the 12-18 year age group, particularly for boys). Liquid dairy milk consumption is currently estimated by Dairy Australia (Dairy Australia Consumption Summary, 2012/3 data) to be 107L per person per year, or around 280mL (a little over 1 serve) per day. The most recent Australian national nutrition survey, as part of the Australian Health Survey 2011-12, found that amongst dairy milk consumers, the median intake for males and females was 200g and 130g for the day surveyed. (ABS, 2014c). In New Zealand, a survey of over 1400 Auckland residents, published in 2003, found that one third consumed less than 1 serve of milk per day (Wham et al, 2003).

Nut and seed-based beverages are typically consumed by people who are allergic or intolerant to dairy milks and who either cannot tolerate, or do not enjoy, soy or cereal-based beverages. Nut and seed-based beverages are promoted as a general milk alternative for mainstream use by people over 5 years of age, and in these groups might be expected to replace all serves of dairy milk normally consumed.

E. NUTRITIONAL IMPACT

E.1 Need for nutritive substance

Nut and seed-based beverages are a new category of beverage giving additional options to consumers who choose not to drink dairy milks. The table E1 below shows how the almond-based beverages currently available in the Australian/New Zealand market and a range of seed-based beverages available overseas compare nutritionally to dairy cows' milk, soy and cereal beverages.

Currently, if consumers prefer a cereal beverage, they have the option of selecting a fortified or unfortified beverage depending on their needs. However, if they choose a nut-based beverage (seed varieties are not available here at this time), they can only purchase unfortified varieties. This application seeks to address this situation by allowing fortified nut and seed-based beverages to be sold.

Table E1 indicates that nut and seed-based beverages are similar in composition to cereal-based beverages; the non-dairy milk alternatives have variable, but relatively comparable levels of nutrients, with key attributes which differentiate them from dairy milks, such as low saturated fat (>0.5%) content and absence of lactose.

Table E1: **per 100mL**	Cow's milk, regular†	Oat Milk‡	Rice Milk‡	So Good Almond Milk	Australia's Own Almond Milk	Pure Harvest Almond Milk	EcoMil Sesame Milk*	SoL Sunflower Beverage	Alpro Hazelnut Drink
Energy (kJ)	293	119	216	130	150	175	214	122	119
(Cal)	70	28	51	31	36	42	51	29	29
Protein (g)	3.5	0.6	0.6	0.5	0.6	0.3	0.6	0.4	0.3
Fat, total (g)	3.5	1.4	1.2	1.2	2.7	0.4	2.4	1.7	1.6
- Saturated fat (g)	2.4	0.2	0.1	0.1	0.2	<0.1	0.5	0.2	0.2
- Polyunsat'd (g)	0.1	0.8	0.7	0.3	0.7	0.1	0.5	u/s	0.1
- Monounsat'd (g)	1	0.4	0.3	0.8	1.8	0.3	1.4	u/s	1.3
Cholesterol (mg)	11	0	0	0	0	0	0	0	0
Carbohydrate, total (g)	6.3	3.1	9.5	4.6	2.4	9.1	6.7	3.8	3
- Sugars (g)	6.3	0	4.3	4.4	1.9	6.3	3.4	2.9	3
- Lactose (g)	6.3	[0]	[0]	0	0	0	0	0	0
Dietary Fibre (g)	0	0.5	0.4	0.3	ns	ns	0.2	0.4	2.3
Sodium (mg)	37	0	75	35	60	56	10	50	50
Calcium (mg)	107	3**	123	75	ns	ns	Not fortified, unknown	Fortified	Fortified

†Data from NUTTAB 2010; Milk, cow, fluid, regular fat (~3.5%).
‡ Data from AUSNUT: Milk, oat, fluid, AUSNUT 2007; Milk, rice, fluid not further specified AUSNUT 2010
**Figures for Ecomil Sesame are only available per 100g as shown.*
***Oat milk unfortified.*

The energy content of non-dairy milk alternatives are similar to each other, though lower than regular cow's milk; the protein content is likewise relatively constant, and less than cow's milk. Total fat does vary, though is significantly lower than regular cow's milk in most cases; more importantly the saturated fat content is much lower than in cow's milk.

The lower protein content of nut and seed-based beverages is comparable to cereal-based beverages and is unlikely to adversely affect the protein adequacy of adult consumers diets as the most recent Australian national nutrition survey, as part of the Australian Health Survey found average intakes across all age groups exceeded requirements by some margin (ABS, 2014a). However, the low saturated fat status in these beverages has the potential to positively impact on saturated fat intakes.

Calcium is an important nutrient for bone health, with 18-26% of calcium typically being consumed via dairy milk in adults aged 19 years and over and around 21-28% from dairy milk for children aged 4-18 years (ABS, 2014f). However, average intakes from all female age groups from 14 years onwards did not meet Estimated Average Requirements (EARs) for calcium, while this also occurred in males aged 14-18 and from 51 years onwards (ABS, 2014a) according to the the latest Australian national nutrition survey. In New Zealand, a similar picture emerges, with even higher levels of inadequate intake (University of Otago et al, 2011b) (45% of men and 73% of women failing to meet calcium requirements). In this situation, the fortification of non-dairy milk alternatives, such as nut and seed-based beverages, in line with cereal-based beverages, may assist in maintaining or improving calcium status in some groups.

Modelling and risk assessment of the likely situation in children has been previously undertaken by FSANZ for the Final Assessment Report for A500: Fortification of Cereal Based Beverages (FSANZ, 2005a) and it was found that young children (2 to 4 years) were most at risk of inadequate protein intake if consuming non-dairy milk alternatives, and an advisory statement required. The latest Australian national nutrition survey found that the proportion of protein in the diet coming from dairy milk was highest amongst 2-3 year old children at almost 18%, with the next age group (4-8 years) dropping their proportion of protein from dairy milk down to around 10%. The proportion continues to drop as age increases (ABS, 2014e). These findings support the FAR A500 risk assessment finding regarding young children being most at risk of inadequate protein intakes should low-protein non-dairy milk alternatives totally replace dairy milk in their diets.

The FSANZ FAR A500 risk analysis also concluded that non-dairy consumers were at risk of inadequate intakes of a number of vitamins and minerals ordinarily supplied by dairy foods, in particular calcium, magnesium, zinc, vitamin A, riboflavin, B6 and iodine, with older consumers more at risk than the two to four year age group (FSANZ, 2005a). The permitted fortification of cereal-based beverages may assist with addressing these potential inadequacies in cereal milk consumers; this application seeks to extend this to nut and seed-based beverages.

E.2. Information to demonstrate the permitted addition of the vitamin or mineral has the potential to address the deficit or deliver a health benefit to the population or a population subgroup

Theoretical efficacy:

Modelling previously undertaken by FSANZ as part of the assessment of A500: Fortification of Cereal Based Beverages (FSANZ, 2005a), considered the effectiveness of fortifying cereal-based beverages in line with the now-approved fortification permissions (which mirror those sought by this application in nut and seed-based beverages). The FSANZ modelling showed,

and the Final Assessment Report concluded, that fortification would address to some extent the risk of inadequate intakes of a variety of vitamins and minerals in dairy avoiders who instead chose a non-dairy beverage (in the case of A500, a cereal-based beverage).

Table 8, page 69, of the Final Assessment Report A500 is reproduced below. This table compares the nutrient intakes of unfortified cereal-based beverage consumers (model 5) with the effect of fortifying these beverages (model 6). This table and its associated modelling forms the basis of FSANZ's conclusion that fortification is likely to be efficacious.

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

This current application has outlined the likely usage patterns of nut and seed-based beverages as alternatives to cereal- and legume-based beverages in dairy avoiders. It contends that the modelling undertaken by FSANZ for A500, is equally relevant to the potential of fortified nut and seed-based beverages to address dietary inadequacies and likewise deliver health benefits to those consumers who choose to consume them instead of dairy milks. The A500 Final Assessment Report further concludes that *"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."* This conclusion can clearly be understood to be equally relevant to

other fortified non-dairy-based beverages such as the fortified nut and seed-based beverages proposed in this application.

Bioavailability:

The data on the bioavailability of various vitamins and minerals in a range of foodstuffs, but particularly in non-dairy beverages derived from legume, cereal, nut and seed sources, is limited. FSANZ undertook a review of the bioavailability of added vitamins and minerals in this type of non-dairy beverage for its assessment of A500 (FSANZ, 2005a) which is detailed in section 4.1.2 of Attachment 2 to that report. This assessment concluded that bioavailability of any one vitamin or mineral is dependent on a wide range of factors, making definitive conclusions on the bioavailability, as it applies to any individual food product, impossible. This report goes on to conclude, however, that it is expected that the vitamins and minerals in cereal-based beverages are bioavailable to varying extents. The same could be concluded in the case of the similar nut and seed-based beverages.

There is however, some additional research data specifically looking at the bioavailability of calcium in soy-based beverages compared to dairy milk (Tang et al, 2010) and also a doctoral thesis (Hokin, 2003) considering the in vivo absorption of B_{12} from a variety of sources including fortified soy-based beverages, which further informs the discussion of fortified non-dairy milks.

The calcium study used a randomised, single-blind, crossover design to assess the relative bioavailability of the calcium added to fortified soy-based beverages, compared to that naturally present in dairy milk, in 12 osteopenic post-menopausal women. It concluded that the hourly fractional calcium absorption was comparable in both foods (Tang et al, 2010). This supports the likely bioavailability of calcium in a fortified non-dairy beverage. As pointed out by the FSANZ A500 Final Assessment Report (FSANZ, 2005a), calcium is a critical nutrient in this class of foods, as it isn't widely distributed across the food supply, so non-dairy consumers are more likely to be at risk of poor calcium intakes than those who do consume dairy products.

Vitamin B_{12} is of considerable importance in vegetarians who choose not to consume any animal products and who are likely consumers of non-dairy milk alternatives such as nut and seed-based beverages. An unpublished Australian study conducted as part of a PhD thesis (Hokin, 2003), found that fortified soy-based beverages were more effective at increasing serum B_{12} levels than other treatments, such as intramuscular injection and oral supplements. It is postulated that the beverage vehicle for the B_{12} was most effective as a result of B_{12} being consumed at intervals over the day rather than in one treatment bolus, the later method having the potential to overwhelm absorption capacity at the time of administration.

3.3.3 F. Information related to potential impact on consumer understanding and behaviour

It is presumed that nut and seed-based beverages are predominantly used as a dairy milk or soy-based beverage substitute either by individuals who are allergic or intolerant to dairy and/or soy foods; or choose not to consume dairy products, either for health or philosophical reasons.

1. Information to demonstrate the level of consumer awareness and understanding of the nutritive substances in the food(s)

Consumers have become increasingly aware of, and concerned about, the relationship between diet, food intake and health. A 2011 report (Kapsak et al, 2011) on changes to consumer attitudes and perceptions of functional foods in the United States, stated that awareness of a number of specific food and health associations has increased since 2007. The top two food component and health associations that consumers were aware of were calcium from dairy foods or fortified foods and bone health, and vitamin D from fortified foods and bone health.

A recent report by FSANZ on consumer awareness of food fortification in Australia and New Zealand (FSANZ, 2013) found that 54% of Australians and 62% of New Zealanders surveyed (n=800 Australians and n=802 New Zealanders) purchase some foods based on their added vitamins or minerals. The food type reported to be most commonly purchased based on whether it was fortified was “Dairy products such as yoghurt or milk” which was cited by 22% of Australians and 30% of New Zealanders. In addition, 6.4% of Australians and 9.8% of New Zealanders reported purchasing “Milk substitutes, such as soy or rice milk” because they contained added vitamins or minerals. This demonstrates the interest and awareness of vitamin and mineral addition to the milk and milk substitutes food group.

As part of the consumer research commissioned by Sanitarium (Forethought Research, 2012. See CCI document, Appendix CCI III) on plant-based beverage consumers, it was found that 52% of current plant-based beverage consumers made their purchasing decision based on whether the product provided bone health benefits. This likely demonstrates that many consumers are actively seeking plant-based beverages with added calcium. Whether they correctly identify that a beverage is fortified or not is unclear.

In the last approximately three years, since the introduction of almond beverages in the Australian market, there have been a number of reviews and commentaries about nut and seed-based beverages published in the consumer media. A table summarising these is attached at Appendix III. From a review of the messages contained in these articles, it could reasonably be assumed that these articles could have built an impression for consumers that nut and seed-based beverages currently available do already provide at least calcium, or potentially a range of vitamins and minerals, and secondly, that the consumer could seek out a brand that does contain calcium and other nutrients. There is a consistent message that there are fortified nut and seed-based beverages available, and that there is calcium and a

range of vitamins added in some, if not all nut and seed-based beverages. In support of this, it was found that 16% of consumers surveyed, as part of the consumer research conducted by Sanitarium (Forethought Research, 2012), were consuming non-dairy milks in order to increase either their own or their family's calcium intake. This is a strong indication that at least some of the market believe that calcium and potentially other vitamins and minerals, are present in non-dairy milks such as almond milk.

Since fortified nut and seed-based beverages would be marketed as 'dairy milk alternatives' and promoted to be used in a similar way, it is not expected that the introduction of these products into the market would result in consumers' diets becoming unbalanced by switching from consuming other foods.

Section C3 of this application provides information on the growth of the almond-based beverage market and consumption levels of these types of plant-based milk alternatives as well as others. The nut and seed-based beverages section of the market is small but growing in Australia and New Zealand with almond-based beverages currently representing 9% of the non-dairy milk alternatives market in Australia and non-dairy milk alternatives as a group making up around 6% of the total Australian milk supermarket sales volume. Therefore there is increasing demand for nut and seed-based beverages domestically and this is a trend that reflects the situation in overseas markets, such as the US (See section C5 for further discussion). Sales volume data on fortified soy-based beverages vs unfortified soy-based beverages indicates that consumers are mostly purchasing soy-based beverages that are fortified with calcium and a range of other nutrients (see table C4). In addition, similar data (see table C4) on cereal-based beverages indicates that consumers mostly purchase these beverages that contain added calcium rather than unfortified varieties. Given that the nut and seed-based beverages market is growing and consumers are more likely to purchase plant-based milk alternatives with added vitamins and minerals, it is important to enable new offerings in this category, such as nut and seed-based beverages, the opportunity to be fortified with similar vitamins and minerals to dairy milk. It is possible that consumers trying these new alternatives may not realise that they do not contain the added nutrients such as calcium as they are a feature of the majority of soy-based and cereal-based beverages on the market. This point is further discussed in the next section (2) below.

2. Information on the actual and/or potential behaviour of consumers in response to proposed food(s)

The purpose of this application is to enable nut and seed-based beverages to be fortified with a range of nutrients similar to those in dairy milk and other plant-based beverages, such as those based on soy and rice. Nut and seed-based beverages would then have the opportunity to more adequately act as a substitute for dairy milk and also as an alternative to fortified soy-

and cereal-based beverages. It is expected therefore that there may be some switching by consumers to nut and seed-based beverages from dairy milk or other soy-based beverages.

Sanitarium has conducted some consumer research on plant-based beverages (milk alternatives) consumers (n = 385) and those that would consider purchasing these beverages in the following twelve months (Forethought Research, 2012. See CCI document, Appendix CCI III). The survey found that, of those currently buying plant-based beverages, 47% were actively looking to substitute all of the dairy milk in their diet completely or gradually with plant-based beverages. In addition, amongst current plant-based beverage purchasers, 39% would consider buying almond milk in the next 12 months and even amongst current non-purchasers, 46% would consider purchasing over the next 12 months. This demonstrates the need for enabling manufacturers to provide plant-based beverages with a similar nutritional profile to dairy milk as well as fortified soy and cereal-based beverages.

The consumer research also found that a further 24% of current plant-based beverage purchasers were looking to consume these beverages in addition to dairy milk. This group would theoretically be most at risk of overconsuming the vitamins and minerals requested for addition to nut and seed-based beverages in this application. In practice, the research seemed to indicate that current non-dairy beverage consuming households do purchase less dairy milk as a result of their non-dairy purchases. For example, the median consumption of dairy milk by non-dairy considerers was 6L or more per week, whereas households that also purchase non-dairy milks had a median consumption of about 4.5L per week. The non-dairy consuming households had a median consumption of around 2L per week of soy and around 1L per week of almond beverages, indicating at least partial substitution of non-dairy for dairy milk.

It is difficult to quantitatively establish the levels of additional vitamins and minerals that may be consumed by those who consumer non-dairy beverages in addition to dairy milk . However, given that the amounts of vitamins and minerals requested for addition are similar to the levels found naturally in dairy milk, it could be said that the risk of excessive consumption of these nutrients from including nut and seed-based beverages in addition to dairy milk in the diet is the same as consuming excessive amounts of dairy milk. In addition, it would the same risk if purchasers of fortified soy-based beverages would be looking to consume these in addition to dairy milk. As stated above, the consumer research data shows that across the population, the uptake of nut and seed-based beverages is largely the result of substitution for dairy milk, rather than additional consumption. Therefore, the risk of excessive nutrient intake will be minimal. It also shows that the more plant-based milk alternatives that get substituted into the diet, particularly as they move from soy to almond, the less dairy milk people are consuming. This means that the consumers moving to these plant-based beverages, particularly nut and seed based varieties, will need to replace the nutrition normally provided by dairy milks.

3. Information to demonstrate that the consumption of food(s) containing the nutritive substance will not adversely affect any population groups (e.g. particular age or cultural groups).

Nut and seed-based beverages are an emerging market, so no quantitative information is available on the age group breakdowns of nut and seed-based beverage users; however individuals of all ages may use these products. It is possible that a greater number of children (over 5 years old) compared to adults will consume nut and seed -based beverages for allergy/intolerance reasons, as dairy milk allergy and/or soy allergy is most common in young children. The majority of very young children with allergy/intolerance to dairy and/or soy foods are likely to be 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, and their dietary needs would be monitored by a dietitian. Even so, due to the low protein content typically in these products, it is requested in this application that an advisory statement recommending that these products are not suitable for children under 5 years of age is included as a requirement in the Food Standards Code. This issue is discussed further in Section 3.3.3 E1.

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

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Appendix I

Statutory Declaration – Australia

The information provided in Parts 1 to 3 must be attested to by a statutory declaration in some suitable form along the following lines:

STATUTORY DECLARATION

Statutory Declarations Act 1959 [1]

I, [redacted] 295 Wattagan Road, Martinsville NSW 2265, Corporate Food Environment & Science Manager, Sanitarium Health & Wellbeing

make the following declaration under the *Statutory Declarations Act 1959*:

1. the information provided in this application fully sets out the matters required
2. the information provided in this application is true to the best of my knowledge and belief
3. no information has been withheld that might prejudice this application, to the best of my knowledge and belief

I understand that a person who intentionally makes a false statement in a statutory declaration is guilty of an offence under section 11 of the *Statutory Declarations Act 1959*, and I believe that the statements in this declaration are true in every particular.

[redacted]

Declared at 1 Sanitarium Drive Berkeley Vale NSW 2261 on 4th of September 2014

Before me,

[redacted]

[*Signature of person before whom the declaration is made*][2]
David John Drew, Justice of the Peace #104626, 1 Sanitarium Drive, Berkeley Vale NSW 2261

[1] http://www.comlaw.gov.au/Series/C1959A00052

[2] A statutory declaration must be made before a prescribed person under the *Statutory Declarations Act 1959*. The list of prescribed persons is available in the Statutory Declarations Regulations 1993 at http://www.comlaw.gov.au/Series/F1996B00198

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Appendix II: Checklists

Checklist for General requirements

This Checklist will assist you in determining if you have met the information requirements as detailed in Section 3.1 – General Requirements. All applications must include this Checklist.

General requirements (3.1)	
✓ 3.1.1 Form of application ✓*Application, abstracts and other key documents in English* ✓*Executive Summary (separated from main application electronically and in hard copy)* ✓*Relevant sections of Part 3 clearly identified* ✓*Pages sequentially numbered* ✓*Electronic copy (searchable)* ✓*1 hard copy* ✓*Electronic and hard copy identical* ✓*Hard copy capable of being laid flat* ✓*All references provided (in electronic and hard copy)*	✓ 3.1.6 Assessment procedure ✓*General* ☐ *Major* ☐ *Minor* ☐ *High level health claim variation* ✓ 3.1.7 Confidential Commercial Information ✓*Confidential material separated in both electronic and hard copy* ✓*Formal request including reasons* ✓*Non-confidential summary provided* ***(within the body of the application)***
✓ 3.1.2 Applicant details	✓ 3.1.8 Exclusive Capturable Commercial Benefit *N/A Justification provided*
✓ 3.1.3 Purpose of the application	✓ 3.1.9 International and other national standards ✓*International standards* ✓*Other national standards*
✓ 3.1.4 Justification for the application ✓*Regulatory impact information* ✓*Impact on international trade*	✓ 3.1.10 Statutory Declaration
✓ 3.1.5 Information to support the application *N/A Data requirements*	✓ 3.1.11 Checklist/s provided with application ✓*3.1 Checklist* ✓*Any other relevant checklists for Parts 3.2-3.7*

Nutritive Substances (3.3.3)			
✓	A.1 Identification information	✓	C.2 Proposed maximum levels in food groups or foods
✓	A.2 Chemical and physical properties	✓	C.3 Likely level of consumption
✓	A.3 Impurity profile information	✓	C.4 Percentage of food group to use nutritive substance
✓	A.4 Manufacturing process	✓	C.5 Use in other countries (if available)
✓	A.5 Specification information	✓	C.6 Where consumption has changed, information on likely consumption
✓	A.6 Analytical detection method	N/A	D.1 Nutritional purpose
✓	A.7 Proposed food label	✓	E.1 Need for nutritive substance
✓	B.1 Toxicokinetics and metabolism information	✓	E.2 Demonstrated potential deficit or health benefit
✓	B.2 Animal or human toxicity studies	✓	F.1 Consumer awareness and understanding
✓	B.3 Safety assessments from international agencies	✓	F.2 Actual or potential behaviour of consumers
✓	C.1 List of food groups or foods likely to contain the nutritive substance	✓	F.3 Demonstration of no adverse effects on any population groups

Appendix III: Nut Milk Review Articles

Article Title	**Date**	**Source**	**Circulation**	**Author** **Name and qualification**	**Key Messages**
Milk choices explained	16/2/13	Shepparton News	8,143	Sophie Atkin Naturopath	Nut milks are nutritionally comparable to dairy calcium and minerals so will meet nutritional requirements for calcium, children and bone density
The pros and cons of almond milk	9/1/2011	The Advertiser		Christina Larmer Freelance Journalist	Same as Body & Soul article Highlights lower protein & calcium in almond milk verse diary Choose fortified variant with calcium and vitamins
Milk alternative reviews	26/4/12	CHOICE		Rachel Clemons Investigative Journalist & Content Producer (Food) CHOICE	If vegan choose fortified soy for protein and calcium And generally calcium fortified soy is best alternative to dairy Highlight lack of calcium fortification of most almond milks, only 1 brand has calcium
The Nutritional Benefits of almond milk	27/5/13	Body & Soul		Christine Larmer Freelance Journalist	Ideal for taste as an alternative to diary or soy for vegans and vegetarians Does not have as much protein or calcium as dairy Choose brands with added calcium and vitamins
The Good Life - Food and Wine	4/5/2013	The Saturday Age, Melbourne	241,1029	Simone Egger Editor and Author	Nutritious alternative to dairy Look for calcium and other fortifications in a nut milk
Te Wash	1/3/2013	Women's Fitness and Health, National	57,000 (monthly)	Jessica ColacinoStrategic Communications and Media Advisor	Suitable for vegans and those with lactose intolerances Vitamins and minerals added to some Has a good calcium content which is good when choosing a dairy alternative Not suitable as a milk replacement in terms of protein equivalence
Is almond milk all it's really cracked up to be?	18/7/14	www.news.com.au		Rebecca Sullivan Journalist for news.com.au	Almond milk does not have as much protein or calcium as dairy milk or fortified soy milk.