

### 4 September 2015 [21–15]

# **Call for submissions – Application A1104**

Voluntary Addition of Vitamins & Minerals to Nut- and Seedbased Beverages

FSANZ has assessed an Application made by Sanitarium Health and Wellbeing Australia to permit the voluntary addition of vitamins and minerals to nut- and seed-based beverages at levels equivalent to those permitted for cereal and legume-based beverages that are dairy analogues, and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at information for submitters.

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at <u>information for submitters</u>.

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on <u>documents for public comment</u>. You can also email your submission directly to <u>submissions@foodstandards.gov.au</u>.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

#### DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 16 October 2015

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to <u>standards.management@foodstandards.gov.au</u>.

Hard copy submissions may be sent to one of the following addresses:

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#### Supporting documents

The following documents which informed the assessment of this Application are available on the FSANZ website at <a href="http://www.foodstandards.gov.au/code/applications/Pages/A1104-VitsMinsNutSeedBevs.aspx">http://www.foodstandards.gov.au/code/applications/Pages/A1104-VitsMinsNutSeedBevs.aspx</a>

- SD1 Technical and Nutrition Assessment Voluntary addition of vitamins and minerals to nut- and seed- based beverages
- SD2 Assessment against the Policy Guideline Fortification of food with vitamins and minerals

# **Executive summary**

FSANZ has assessed an Application from Sanitarium Health and Wellbeing Australia to amend Standard 1.3.2 of the current *Australia New Zealand Food Standards Code* (the Code) to extend the voluntary fortification permissions for cereal- and legume-based beverages to nut- and seed-based beverages according to the principle of nutritional equivalence of a substitute food with a primary counterpart food. The Application applied the requested fortification to nut- and seed-based beverages (e.g. almond, sesame) containing at least 0.2% m/m protein and acknowledged that the risk management strategy applied to legume-based (e.g. soy) and cereal-based (e.g. rice, oat, spelt) beverages i.e. to be labelled with appropriate advisory statements contained in Standard 1.2.3 of the current Code, should also extend to *fortified* nut- and seed-based beverages.

The Code permits voluntary fortification of cereal-based beverages containing no less than 0.3% m/m protein derived from cereals with 12 vitamins and minerals (on the basis of nutritional equivalence with full cream cow's milk). Mandatory labelling statements are required on certain cereal-based beverages on the basis of the suitability of their protein or fat content for young children.

Nut- and seed-based beverages are relatively new to the milk substitute market and are produced in a similar way to beverages derived from cereals or legumes. FSANZ considers that several features of the labelling and marketing of nut- and seed-based beverages affirm the identity of these beverages as cow's milk substitutes, as for legume- and cereal-based beverages. The concentration of vitamins, minerals and protein in nut- and seed-based beverages beverages is mostly lower than found naturally in full cream cow's milk.

Recent national nutrition survey information for Australia and New Zealand indicates that cereal- and nut-based beverages are consumed by less than 1% of the population although these beverages are consumed in similar ways and amounts to milk. Cereal-, legume- and nut-based beverages may be consumed as part of a dairy free diet and from survey information, non-dairy consumers are likely to be at risk of much lower intakes of a range of vitamins and minerals in comparison to the general population. Therefore FSANZ proposes to permit voluntary fortification of nut- and seed-based beverages according to nutritional equivalence with full cream cow's milk.

FSANZ gazetted an amended version of Chapter 1 and 2 of the Code which is to take effect from 1 March 2016. Because the draft variations arising from this assessment are likely to take effect around that date, draft amendments are proposed for the revised Code only. The draft variation extends the existing fortification permissions for cereal-based beverages to nut- and seed-based beverages containing at least 0.3% m/m protein derived from cereal, nuts, seeds, or a combination of these. The risk of inadequate protein and energy intakes resulting from consumption of these beverages, particularly for young children, will be managed by applying the mandatory advisory statements that exist for legume- and cerealbased beverages to *all* nut- and seed-based beverages.

The draft variation differs from that sought in the Application for the following reasons: the minimum protein is set at no less than 0.3% protein, consistent with cereal-based beverages; the protein source can be derived from cereals, nuts, seeds, or any combination of these; and application of the advisory statement is to be applied to *all* nut- and seed-based beverages that are milk substitutes and contain no more than 3% m/m protein or no more than 2.5% m/m fat. FSANZ considers that the draft variations satisfy the statutory objectives, including the Ministerial Policy Guideline on *Fortification of Food with Vitamins and Minerals*.

# 1 Introduction

# 1.1 The Applicant

The Applicant is Sanitarium Health and Wellbeing Australia<sup>1</sup>.

# 1.2 The Application

The Application is seeking to amend Standard 1.3.2 of the current *Australia New Zealand Food Standards Code* (the Code) to extend the current permission for voluntary addition of vitamins and minerals to cereal- and legume-based beverages to nut- and seed-based beverages containing at least 0.2% m/m protein according to the principle of nutritional equivalence of a substitute food with a primary counterpart food.

The Application acknowledges that risk management strategies applied to legume- and cereal-based beverages, in this case, the requirement to carry appropriate advisory statements contained in Standard 1.2.3 of the current Code, should also extend to fortified<sup>2</sup> nut- and seed-based beverages.

## 1.3 The current Standard

FSANZ completed a review of the Code in 2015 and the revised Code will commence on 1 March 2016. Because the draft variations arising from this Application are likely to take effect around that date, draft amendments are proposed for the revised Code only. All references to Standards or Schedules in this assessment summary refer to the revised Code requirements only.

#### 1.3.1 Australia and New Zealand

Standard 1.3.2 – Vitamins and Minerals regulates the addition of vitamins and minerals to foods other than to special purpose food. Unless stated otherwise in the Code, a vitamin or mineral may be added to a (general purpose) food only if: a) the addition of that vitamin or mineral is permitted by the Code in section S17—4; and b) the vitamin or mineral is in a permitted form specified in sections S17—2 and S17—3 of Schedule 17 – Vitamins and Minerals.

The addition of vitamins and minerals to food listed in section S17—4 is regulated by establishing specific maximum levels as appropriate. These maximum levels comprise per reference quantity: i) maximum claim and ii) maximum permitted quantity. A maximum claim is prescribed for most nutrient-food combinations whereas a maximum permitted quantity is prescribed only when needed to manage the risk of excess intake of a vitamin or mineral or when a maximum claim is not established.

Maximum claims are established at 10% or more of the regulatory Recommended Dietary Intake (rRDI)<sup>3</sup> per reference quantity. Where the amount falls below 10% rRDI, a maximum claim is not established and the permitted addition is controlled instead by a maximum permitted quantity. These prescribed levels relate to the total content of vitamin or mineral in the fortified food from both the added and natural content of the nutrient concerned.

<sup>&</sup>lt;sup>1</sup> http://www.sanitarium.com.au/about-us

<sup>&</sup>lt;sup>2</sup> The term 'fortified' means a food to which vitamins or minerals are added

<sup>&</sup>lt;sup>3</sup> as per Schedule 1 S1—2

In the case of substitute foods, otherwise known as 'analogues' in section S17—4, permissions are derived from the vitamin and mineral content of the primary counterpart food. Section S17—4 permits many vitamins and minerals found in full cream cow's milk to be voluntarily added to beverages derived from legumes or cereals in a reference quantity of 200 mL as shown in Table 1. No equivalent permissions exist for beverages derived from nuts, seeds or both in section S17—4 or elsewhere in the Code.

Table 1:Permitted fortification of legume<sup>Δ</sup>- and cereal<sup>♦</sup>-based beverages (section S17—4)

Vitamin/ Mineral	Maximum claim per reference quantity (proportion rRDI <sup>+</sup> )	Maximum permitted quantity of vitamin or mineral per reference quantity
Calcium	240 mg (30%)	Not specified
Folate	no claim permitted	12 µg
lodine	15 μg (10%)	Not specified
Magnesium	no claim permitted	22 mg
Phosphorus	200 mg (20%)	Not specified
Riboflavin	0.43 mg (25%)	Not specified
Thiamin	no claim permitted	0.10 mg
Vitamin A	110 µg (15%)	125 µg
Vitamin B <sub>12</sub>	0.8 µg (40%)	Not specified
Vitamin B <sub>6</sub>	no claim permitted	0.12 mg
Vitamin D	1.0 µg (10%)	1.6 µg
Zinc	no claim permitted	0.8 mg

+ regulatory Recommended Dietary Intake as per Schedule 1

Δ Analogues derived from legumes – beverages containing no less than 3% m/m protein derived from legumes

Analogues derived from cereals – beverages containing no less than 0.3% m/m protein derived from cereals

Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations sets out the mandatory advisory statements which must be carried on the labels of certain foods. The table to section S9—2 in Schedule 9 – Mandatory Advisory Statements sets out certain conditions that require advisory statements to be applied to certain milks, soy- and cereal-based beverages. Current and relevant mandatory advisory statements are outlined in Table 2 below.

#### Table 2: Mandatory advisory statements in the table to section S9-2

2	(a) A cereal-based beverage that contains less than 3% m/m protein.	the product is not
	(b) An evaporated or dried product made from cereals that, when	suitable as a complete
	reconstituted as a beverage according to directions for direct	milk replacement for
	consumption, contains less than 3% m/m protein.	children under 5 years.
3	(a) A cereal-based beverage that contains:	the product is not
	(i) no less than 3% m/m protein; and	suitable as a complete
	(ii) no more than 2.5% m/m fat.	milk food for children
	(b) An evaporated or dried product made from cereals that, when	under 2 years.
	reconstituted as a beverage according to directions for direct	
	consumption, contains:	
	(i) no less than 3% m/m protein; and	
	(ii) no more than 2.5% m/m fat.	
	(c) Milk, or an analogue beverage made from soy, that contains no	
	more than 2.5% m/m fat.	
	(d) Evaporated milk, dried milk, or an equivalent product made from	
	soy, that, when reconstituted as a beverage according to	
	directions for direct consumption, contains no more than 2.5%	
	m/m fat.	

#### 1.3.2 Overseas and International Standards

#### 1.3.2.1 Codex Alimentarius

Codex Alimentarius (Codex) has established General Principles for the Addition of Essential Nutrients to Foods<sup>4</sup> which provide guidance to governments on the addition of vitamins and minerals to food (CAC/GL 9-1987). This guidance includes definitions and principles for nutritional equivalence of substitute foods. The General Principles were recently updated and approved by the Codex Alimentarius Commission in July 2015. FSANZ has assessed nutritional equivalence and substitute food in accordance with Codex terminology and principles (see Section 2.2.1).

#### 1.3.2.2 Europe

Regulation (EC) No. 1925/2006 outlines the requirements for the addition of vitamins and minerals (and other substances) to foods. This regulation permits the addition of vitamins and minerals, the maximum and minimum amounts that can be added and the forms that can be used. Article 4 outlines that vitamins and minerals may not be added to the following:

- unprocessed foodstuffs, including fruit, vegetables, meat, poultry and fish
- without exception, beverages containing more than 1.2 % by volume of alcohol and provided that no nutrition or health claim is made [European Commission (2006a)].

Nut- and seed-based beverages do not meet the criteria for restriction of addition set out in Article 4.

Regulation EC 1925/2006 must be read in conjunction with Regulation (EU) No.1169/2011 – *On the provision of information to consumers* (food labelling) Annex 13 EC, 2011). This annex defines the term 'significant amounts' which is used in Regulation 1925/2006 to calculate minimum amounts of vitamins and minerals to be added.

#### 1.3.2.3 United States of America

The US Code of Federal regulations: Title 21 – Food and Drugs Chapter 1, subpart B part 104 outlines the fortification policy and circumstances under which vitamins and minerals can be added. Section §104.2 (e) states that a nutrient(s) may appropriately be added to a food that replaces traditional foods 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 is deemed to be an imitation food and therefore misbranded. FSANZ is aware of fortified almond-based beverages for sale in the United States that are promoted as alternatives to dairy milk.

Section 104.2 (g) sets out the criteria under which nutrients 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 excess intake. Minimum levels are not specifically defined.

## 1.4 Reasons for accepting Application

The Application was accepted for assessment because:

<sup>&</sup>lt;sup>4</sup> <u>http://www.codexalimentarius.org/input/download/report/907/REP15\_NFSDUe.pdf</u>

- it complied with the procedural requirements under subsection 22(2)
- it related to a matter that warranted consideration of a variation of a food regulatory measure.

### **1.5 Procedure for assessment**

The Application is being assessed under the General Procedure.

## 1.6 Terminology

Milk is defined in section 1.1.2—3 (Standard 1.1.2) as *the mammary secretion of milking animals, obtained from one or more milkings for consumption as liquid milk or for further processing, but excludes colostrum.* Standard 1.3.2 permits the voluntary addition of some vitamins and minerals to 'modified milks'; this term is not specifically defined in the Code.

However, several terms referring to replacement products for milk are in general use. In this assessment, 'milk substitute' is FSANZ's preferred term, but other terms such as 'milk alternative' have been used in accordance with the source of the information. For example, when referring to consumers' perceptions of the milk alternative market, milk from mammals other than cows (goat and sheep) are included as well as plant-based milk substitutes. Table 3 shows the different terminology that has been used.

A number of products are presented in the market as 'milks'. Column 3 of the table below provides examples of products sold in the market that meet different descriptions of milk or beverages.

Column 1 Column 2		Column 3	
Term	Description	Examples	
Milk	Defined in Standard 1.1.2 as the mammary secretion of milking animals, obtained from one or more milkings for consumption as liquid milk or for further processing but excludes colostrum.	Cow's milk, sheep milk, goat's milk	
Full cream cow's milk	As for milk but from cows only. Contains approximately 3.5% fat.		
Skim milk	Defined in Standard 1.1.2 as milk from which milkfat has been removed	Skim cow's milk, skim goat's milk.	
Milk substitute	A beverage designed to resemble milk in appearance and texture, and intended to be used as a complete or partial replacement for milk.		
Cow's milk alternative	Milk substitute derived from animals other than cows, and plant-based milk substitutes	Goat's milk, sheep milk, soy 'milk', rice 'milk'.	
Plant-based milk substitute	Milk substitute derived from nuts, seeds, cereals or legumes, or any combination of these.	Soy 'milk', rice 'milk', almond 'milk'	
Nut-based beverage	Milk substitute derived from nuts.	Almond 'milk', coconut 'milk' hazelnut 'milk', macadamia 'milk'	

#### Table 3: Different terms used in this Assessment

Column 1	Column 2	Column 3
Term	Description	Examples
Seed-based beverage	Milk substitute derived from seeds.	Sesame 'milk'
Cereal-based beverage	Milk substitute derived from cereals including fortified versions containing at least 0.3% protein derived from cereals.	Rice 'milk', oat 'milk'.
Legume-based beverage	Milk substitute derived from legumes including fortified versions containing at least 3% protein derived from legumes.	Soy 'milk'
Coconut-based milk substitute	Milk substitute derived from coconut. Specifically excludes coconut milk and coconut cream (i.e. those products used in dishes such as curries), coconut water and coconut water-based beverages.	Coconut 'milk'
Non-dairy consumer	Respondent who did not report consuming products containing dairy ingredients in a national nutrition survey. For example, in FSANZ assessment of the A500 Assessment for the 1995 Australian National Nutrition Survey or 1997 New Zealand National Nutrition Survey non-dairy consumers did not report consuming milk, milk yoghurt, cream, milk cheese, frozen and unfrozen milk desserts, dairy spreads, butter, oil/cream base sauces or pizza. Additionally, for Australian survey respondents, a 'non- dairy consumer' did not eat milk-based meal replacements, infant custards or yoghurts or relevant dairy-based sauces. Non-dairy consumers may or may not have consumed a plant-based milk substitute. Where a plant-based milk substitute was consumed, it was assumed to be unfortified unless otherwise stated.	

# 2 Summary of the assessment

# 2.1 Nutritional equivalence of a substitute food

FSANZ has had regard to the Ministerial Policy Guideline<sup>5</sup> Fortification of Food with Vitamins and Minerals. The Policy Guideline sets out the relevant purpose of addition for this Application, to enable the nutritional profile of specific substitute foods to be aligned with the primary food. The terms substitute food, primary food and nutritional equivalence are not defined in the Code or in the Policy Guideline however the following Codex definitions for nutritional equivalence and substitute food are useful. FSANZ regards the descriptors primary and counterpart as interchangeable.

<sup>&</sup>lt;sup>5</sup><u>http://www.foodstandards.gov.au/code/fofr/fofrpolicy/documents/Fortification%20of%20vitamins%20and%20mine</u> rals%20-%20amended%20Oct%202009.pdf accessed 7/5/2015

Nutritional equivalence means that a substitute food is of similar nutritional value to its counterpart. A substitute food means a food:

- designed to resemble a common food in appearance and texture
- intended to be used as a complete or partial replacement for the counterpart food it resembles.

Codex principle 4.3.1 also outlines that, where nutritional equivalence is to serve as a justification for the improvement of the nutritional quality of a substitute food, especially in relation to public health need, the counterpart food should be a significant contributor to the intake of essential nutrients in the population.

FSANZ has therefore considered that a substitute food is determined according to its market presentation and consumer use as a substitute for the primary/counterpart food it resembles, in this case, milk (as defined in section 1.1.2—3 (Standard 1.1.2)). Milk is an important contributor ( $\geq$ 20%) to the intakes of many vitamins and minerals, particularly calcium, phosphorus, vitamin A, riboflavin, vitamins B<sub>6</sub> and B<sub>12</sub> and iodine; and particularly so for young children. Milk is also an important source of energy (13–14%) and protein (18–19%) for young children.

Nutritional equivalence of a milk substitute was previously determined by reference to the vitamin and mineral composition of full cream cow's milk when FSANZ permitted soy beverage marketed as a milk substitute to be voluntarily fortified. As the market diversified to include cereal-based beverages, permission for their nutritional equivalence with milk was extended through Application A500 – Fortification of Cereal-based Beverages in 2005.

Unfortified nut- and seed-based beverages are relatively new to the Australian and New Zealand markets but sales have grown steadily over the past few years. Sales of almond-based beverages in the United States are now outselling soy beverages<sup>6</sup>. Almond-based beverages are now commonly available in Australia and New Zealand. Other beverages such as coconut-based milk substitutes and sesame-, sunflower-, macadamia- and hazelnut-based beverages, are manufactured in Australia and overseas, and are also sold in Australia and New Zealand.

#### 2.1.1 Nut- and seed-based beverages as milk substitutes

Several features of the market presentation of most nut- and seed-based beverages affirm their identity as milk substitutes. These beverages:

- are named as 'milk' on the label
- resemble milk in appearance and texture
- represent on the label the same uses as for milk, that is, as a white drink, poured on breakfast cereal, added to tea and coffee
- are generally co-located in market outlets with UHT milk which reinforces consumer understanding of the substitutionary role of these products
- are presented in similar packaging to milk and other milk substitutes based on soy, rice or oats
- mostly carry the advisory statement as not suitable for consumption by young children.

<sup>&</sup>lt;sup>6</sup> Ibisworld, 2015 Soy and Almond Milk Production in the United States.

As outlined in SD1, recent national nutrition survey information shows that nut- and cerealbased beverages (no seed-based beverages were reported as consumed in this survey) were consumed by less than 1% of the population. However, consumers of these products were recorded as using them in similar ways and in similar quantities as milk. For around 83% of eating occasions, people referred to using nut- and cereal-based beverages mostly as added to breakfast cereal or in a beverage such as tea or coffee, and as a beverage in its own right.

Coconut 'milk' or 'cream' has been available on the market for many years and is often sold in cans, labelled with recommendations for use as an ingredient in mixed foods such as curries and other dishes. From FSANZ's informal review of coconut 'milk' or 'cream' products available for sale, the labels do not guide either direct or reconstituted consumption as a beverage. Because the intended use and market presentation of these products differ from milk, they are not considered as milk substitutes by this assessment. The draft variation at Attachment A relies on the ordinary meaning of the term 'beverage' (that is, a drink other than water) to exclude these products from the milk substitute category. Coconut-based milk substitutes presented as a beverage (but not coconut waters) are included in this assessment.

### 2.2 Risk assessment

The concentrations of vitamins, minerals and protein in currently available nut- and seedbased beverages are generally lower than those present naturally in full cream cow's milk. Apart from coconut-based milk substitutes, most nut- and seed-based beverages have lower energy and fat contents than full cream cow's milk. Nut- and seed-based beverages contain similar concentrations of magnesium and thiamin as full cream cow's milk.

The protein content of nut- and seed-based beverages is lower than cow's milk but comparable to cereal-based beverages. The Application does not seek to address the energy, fat or protein differences between nut- and seed-based beverages and full cream cow's milk.

Nut- and seed-based beverages are manufactured in a similar way to beverages derived from cereals or legumes including the proposed process of vitamin and mineral addition. The losses of vitamins and minerals during processing and over the product's shelf life are known and accounted for in production processes. Up to 95% of anti-nutritional factors (e.g. phytates and oxalate) present in nuts and seeds are likely to be removed during manufacture of the nut- and seed-based beverages. Therefore, it is unlikely that any residual constituents would impact appreciably on the absorption of added vitamins and minerals from nut- and seed-based beverages.

A comparative analysis from recent nutrition surveys conducted in Australia (2011-12) and New Zealand (2008-9) of estimated mean intakes of calcium, magnesium, phosphorus, zinc, vitamin A, riboflavin, thiamin, vitamins B<sub>6</sub>, B<sub>12</sub> and D indicated intakes were in the same range as those reported in A500 – Fortification of Cereal-Based Beverages, which used nutrition survey data from the 1990s. In all the available national nutrition surveys, milk is reported to be an important contributor ( $\geq$ 20%) to the intakes of many vitamins and minerals, particularly calcium, phosphorus, retinol equivalents, riboflavin, vitamins B<sub>6</sub> and B<sub>12</sub> and iodine; particularly for young children. Milk is also an important source of energy (13–14%) and protein (18–19%) for young children aged 2–3 years. In the A500 assessment, nutrient intakes were reported as being lower for non-dairy consumers than the general population. Of all the vitamins and minerals requested by this Application, the greatest magnitude of difference between nutrient intakes for the general population and non-dairy consumers was for calcium (mean calcium intakes approximately 59–66% lower). Estimated mean protein intakes were 17–22% lower in non-dairy consumers compared to the general population, with estimated mean fat intakes 21–25% lower. It is considered that non-dairy consumers using unfortified nut- and seed-based beverages as a complete milk substitute may be at similar risk of reduced nutrient intakes as the non-dairy consumers previously assessed (i.e. non-dairy consumers who eat unfortified cereal-based beverages).

Little research is available on how consumers perceive nut- and seed-based beverages. However, such beverages were reported in recent national nutrition surveys<sup>7</sup> to be consumed in similar quantities and ways to milk. Therefore, it is reasonable to assume that consumers perceive nut- and seed-based beverages as a milk substitute similar to soy-based beverages, which are another milk substitute. Consumer research from two 2002 studies (Bus & Worsley 2003a; Bus & Worsley 2003b) on the perceptions of unfortified soy-based beverage indicates that it may be viewed as healthier than milk, which may also be the case for unfortified nut- and seed-based beverages.

### 2.3 Risk management

#### 2.3.1 Permitted fortification

Fortification of nut- and seed-based beverages to the levels generally found in full cream cow's milk would provide an opportunity for these foods to contain the same vitamins and minerals as other fortified plant-based milk substitutes and also for consumers to select from a wider range of fortified plant-based milk substitutes. Consumption of the fortified product poses no greater risk of excess intake of vitamins and minerals than the consumption of milk itself. On this basis, FSANZ concludes that nut- and seed-based beverages should be permitted to contain added vitamins and minerals according to the vitamin and mineral profile of milk, as is the case for legume- and cereal-based beverages. This means that the maximum claim amount and maximum permitted quantity per reference quantity for nut- and seed-based beverages in the draft variation to section S17—4 are the same as those for legume- and cereal-based beverages.

Although the Applicant included a request for nut- and seed-based beverages to contain no less than 0.2% m/m protein derived from nuts or seeds, the draft variation applies the voluntary fortification permissions to beverages with no less than 0.3% m/m protein, to be consistent with the minimum protein levels of cereal-based beverages. However, it also broadens the range of protein sources to include those singly from cereals, nuts, seeds, or a combination of these. This supports innovation in the market and provides clarity in the regulation for 'milk substitute blends' derived from a variety of plant-based sources. Specific labelling requirements for allergenic substances are outlined in section 2.3.4 below.

#### 2.3.2 Permitted forms

The Applicant seeks the same permitted forms of vitamins and minerals added to nut- and seed-based beverages as those permitted to be added to other plant-based milk substitutes. SD1 has not identified any factors that would result in the currently permitted forms of vitamins and minerals being absorbed to a lesser extent from a nut- and seed-based beverage matrix than from a cereal- or legume-based beverage matrix.

<sup>&</sup>lt;sup>7</sup> Australian 2011-12 National Nutrition and Physical Activity Survey (NNPAS) and 2008-09 New Zealand Adult Nutrition Survey (2008 NZANS)

The draft variation therefore permits the use of existing permitted forms of the requested vitamins and minerals in nut- and seed-based beverages. FSANZ notes that some requested permitted forms of calcium are also permitted food additives that are added to nut- and seed-based beverages to achieve a technological function. The draft variation allows higher amounts of calcium to be added for the purpose of fortification so that the total amount of calcium claimed, and contributed by natural, food additive, and fortification amounts, is consistent with the calcium content of milk.

#### 2.3.3 Advisory statements

Although fortification of nut- and seed-based beverages allows for alignment of their micronutrient profile with cow's milk, these beverages remain substantially lower in protein, fat and energy than full cream milk.

SD1 shows that fluid mammalian milk contributes around 13% and 7% of energy intake, 18% and 9% of fat, and 18% and 10% of protein intake of Australian children aged 2–3 years and 4–8 years respectively. The risk to health of children consuming nut- and seed-based beverages (identified in SD1) is similar to that identified in A500 for cereal-based beverages, where the mitigation strategy to manage that risk was to apply relevant label advisory statements as given in Table 2 above. Therefore, the draft variation extends the existing mandatory advisory statement requirements in the table to section S9–2 to all nut- and seed-based beverages.

FSANZ is unaware of any currently available nut- and seed-based beverages that contain 3% m/m protein or more. For nut- and seed-based beverages that contain less than 3% m/m protein, an advisory statement to the effect that these products are not suitable as a complete milk replacement for children under five years of age would be required on the label. However, if nut- and seed-based beverages were introduced onto the market with more than 3% m/m protein, but contained less than 2.5% m/m fat, then an advisory statement to the effect that the beverage is not suitable as a complete milk food for children under the age of two years would still be required.

FSANZ is proposing the mandatory advisory statements that currently apply to cereal-based beverages would also apply to nut- and seed-based beverages.

#### 2.3.3.1 Transition period

Although many unfortified nut- and seed-based beverages already carry these advisory statements on a voluntary basis, a transition period of 6 months is proposed to allow time for those beverages currently not carrying the advisory statement to change their labelling. After the transition period expires, the 12-month stock in trade provisions outlined in section 9 of Standard 1.1.1 would apply, at which time the relevant mandatory advisory statements must be carried on all nut- and seed-based beverages that are not already stock in trade.

#### 2.3.4 Other labelling matters

The Ministerial Policy Guideline *Fortification of Food with Vitamins and Minerals* states that *there should be no specific labelling requirements for fortified food, with the same principles applying as to non-fortified foods.* As such, the existing labelling requirements of the Code will apply to fortified nut- and seed-based beverages. FSANZ is not proposing to alter these requirements as part of this Application.

Specifically, there are a number of labelling provisions in the Code that will provide information to enable informed consumer choice regarding the proposed additions, and also mitigate the potential for consumers to be misled. These include:

- The mandatory requirement to declare ingredients, including added vitamins or minerals, in the statement of ingredients in accordance with Standard 1.2.4 Labelling of Ingredients.
- The conditions for making voluntary nutrition content claims or health claims relating to vitamins and minerals as set out in Standard 1.2.7 Nutrition, Health and Related Claims.
- Mandatory nutrition information requirements for declaring the average quantity of claimed vitamins and minerals in the nutrition information panel, as set out in Standard 1.2.8 Nutrition Information Requirements.
- The mandatory requirement in Standard 1.2.3 to declare allergenic substances (e.g. nut and seed ingredients) on the label would also be relevant for nut- and seed-based beverages.

#### 2.3.5 Comparative Claims

Standard 1.2.7 permits claims about legume- and cereal-based beverages that compare the amount of certain properties of the food (excluding vitamins and minerals) with other foods that are dietary substitutes. The dietary substitutes with which legume- and cereal-based beverages can be compared are specified in the definition of 'food group' in Standard 1.1.2 at subsection 1.1.2—2(3) as follows:

(c) milk, skim milk, cream, fermented milk, yoghurt, cheese, processed cheese, butter, ice cream, condensed milk, dried milk, evaporated milk, and dairy analogues derived from legumes and cereals listed in section S17—4

To remain consistent with the permissions for legume- and cereal-based beverages, the draft variation modifies (c) in the definition of 'food group' to include nut- and seed-based beverages as follows (changes in bold text):

(c) milk, skim milk, cream, fermented milk, yoghurt, cheese, processed cheese, butter, ice cream, condensed milk, dried milk, evaporated milk, and dairy analogues derived from **legumes, cereals, nuts, seeds or a combination of these ingredients** listed in section S17—4

The impact of this change is that nut- and seed-based beverages or blended beverages would be able to make comparative claims about properties of food (other than vitamins and minerals), if they meet the conditions specified in Standard 1.2.7, similar to their market competitors' legume- and cereal-based beverages.

#### 2.3.6 Risk Management Summary

FSANZ considers that nut- and seed-based beverages may be used as a substitute for cow's milk in the same way as legume- and cereal-based beverages. The proposed vitamin and mineral fortification of nut- and seed-based beverages would provide consumers of these beverages the opportunity to increase their vitamin and mineral intakes.

Nut- and seed-based beverages are sold in the same market as other plant-based milk substitutes. To allow for regulatory clarity and market innovation, FSANZ proposes that the fortification of these beverages be permitted providing that they contain at least 0.3% m/m protein derived from cereal, nuts, seeds, or a combination of these.

Therefore the draft variation extends the existing fortification permissions of cereal-based beverages to include nut- and seed-based beverages, and applies the same labelling requirements, claim conditions and comparative food group to nut- and seed-based beverages.

## 2.4 Risk communication

#### 2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. Every submission on an application or proposal is considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

FSANZ developed and applied a basic communication strategy to this Application. All calls for submissions are notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News. Subscribers and interested parties are also notified about the availability of reports for public comment.

The draft variation will be considered for approval by the FSANZ Board taking into account public comments received on this call for submissions.

The Applicant and individuals and organisations that make submissions on this Application will be notified at each stage of the assessment.

If the draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council). If the Board's decision is not subject to a request for a review, the Applicant and stakeholders, including the public, will be notified of the gazettal of the variation to the Code in the national press and on the website.

#### 2.4.2 World Trade Organization (WTO)

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

Although there are international principles for the addition of vitamins and minerals, there are no international standards on label statements that advise avoidance based on age. Amending the Code to permit voluntary addition of vitamins and minerals to nut- and seed-based beverages, and requiring the mandatory advisory statement to the effect that these products are not suitable as a complete milk replacement for children under 5 years (or as a complete milk food for children under 2 years, depending on composition), is unlikely to have a significant effect on international trade. FSANZ's review of the market found only domestic manufactured products that were mostly labelled with the proposed requirements. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

#### 2.5 FSANZ Act assessment requirements

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

#### 2.5.1 Section 29

#### 2.5.1.1 Cost benefit analysis

The Office of Best Practice Regulation (OBPR) exempted FSANZ from the need to undertake a formal Regulation Impact Statement (RIS) in relation to the regulatory change proposed in response to this Application (OBPR ID: 18649). This was due to OPBR being satisfied that the sought variation was only minor and machinery in nature for the reasons explained below. FSANZ also has a standing exemption from OBPR from undertaking a RIS for applications that permit voluntary addition of nutritive substances to foods (Reference No. 14943).

FSANZ, however, did undertake a cost benefit analysis for the purposes of section 29. As explained below, that analysis indicates that the direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the Application are likely to outweigh the costs to the community, government or industry.

#### Voluntary fortification

Nut- and seed-based beverages are currently marketed in the same way as legume- and cereal-based beverages in the milk substitute market. The draft variation amends section S17—4 to align the voluntary fortification permissions of nut- and seed-based beverages with those of other products in the milk substitute market. This will allow all plant-based milk substitutes to be fortified with the range and amounts of vitamins and minerals as those present in full cream cow's milk.

The draft variation extends the product choice to those consumers who are not able, or choose not to consume milk. In particular, it will provide an alternative to fortified legume- or cereal-based beverages.

The nut- and seed-based beverages market is expected to operate in a similar way to the more established legume- and cereal-based beverages in the milk substitute market. Legume- and cereal-based beverages have been permitted voluntary fortification for nearly a decade and a range of fortified and unfortified products are available in this category. Hence consumers are expected to have a choice between fortified and unfortified products.

Because the variation to section S17—4 permits manufacturers to choose whether they fortify nut- and seed-based beverages, there is no additional regulatory burden placed on industry resulting from the draft variation. Industry will be able to choose to manufacture these products to meet the expected demand from consumers.

#### Mandatory advisory statements

Because nut- and seed-based beverages are relatively new in the market place, they were not captured in previous variations to Code which introduced mandatory advisory statements on other plant-based milk-substitutes. The draft variation expands the scope of section S9—2, which requires mandatory advisory statements to be carried on some products in the milk substitute market, to include both fortified and unfortified nut- and seed-based beverages.

Consumers who are familiar with cereal- and legume-based beverages and their associated advisory statements may be exposed to a health risk by the omission of advisory statements on the full range of nut- and seed-based beverages. Such an omission may imply that the risk to children from consuming nut- and seed-based beverages does not exist, which is incorrect.

Having the advisory statements mandated for only a subsection of a market, such as fortified product only, may create a competitive bias. This may also lead to industry confusion about when to apply the advisory statements on beverages that are made from a combination of nuts, seeds, and/or cereals.

The draft variation to section S9—2 will align the regulatory treatment of products now in the milk substitute market thus maintaining a fair market. The variations will also mitigate the public health and safety risks to consumers from information being omitted, and help consumers make an informed decision. As noted above, OBPR exempted FSANZ from undertaking a RIS for this regulatory change due to the minor and machinery nature of the change. This is based on:

- The small number of products in this category, thus making the cost of compliance checks minimal.
- Most of the existing products already display the advisory statements listed in Table 2. Data from Retail World report Vitasoy and Sanitarium as having approximately 60% of the milk substitute market and both brands carry the advisory statement across all of their milk substitute products. A small number of products that do not carry the advisory statement have been identified by FSANZ in an informal review of products available for sale. The cost of compliance with the mandatory advisory statement can be minimised with the proposed 6-month transition period and 12-month stock in trade provisions in the draft variation.
- Products that are fortified would require new labelling to update their ingredient list, at a minimum, and the marginal cost of including an advisory statement would be minor.

#### 2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more costeffective than a food regulatory measure developed or varied as a result of the Application.

#### 2.5.1.3 Any relevant New Zealand standards

The affected Standards apply in both Australia and New Zealand.

#### 2.5.1.4 Any other relevant matters

There are no other relevant matters.

#### 2.5.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

#### 2.5.2.1 Protection of public health and safety

Public health and safety is protected by ensuring consumers of nut- and seed-based beverages are able to access products that are fortified to an equivalent level as other products in the milk substitute market (legume- and cereal-based beverages).

The requirement for an advisory statement that nut- and seed-based beverages are not suitable as a complete milk replacement for children under 5 years, or as a complete milk food for children under 2 years (depending on composition), is intended to mitigate the risk to small children from consuming these beverages due to the lower protein, energy and/or fat content of these milk substitutes.

# 2.5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

Section 2.3.4 of this assessment summary outlines the labelling requirements that ensure consumers have adequate information to make informed choices relating to nut- and seed-based beverages. Beverages fortified with vitamins and minerals must declare the added vitamins and minerals as ingredients in the statement of ingredients. Furthermore, a beverage carrying a voluntary nutrition content claim or health claim about vitamins or minerals would have to declare the amount of that micronutrient in the nutrition information panel.

#### 2.5.2.3 The prevention of misleading or deceptive conduct

Application of the existing labelling requirements to nut- and seed-based beverages fortified with vitamins and minerals will help mitigate the potential for consumers to be misled. As the permission to fortify nut- and seed-based beverages is based on nutritional equivalence, some amounts of added vitamin do not meet the claim conditions of 10% of rRDI or ESADDI and so no claim is permitted by section S17—4 of the revised Code.

#### 2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

• the need for standards to be based on risk analysis using the best available scientific evidence

FSANZ has assessed this application on the best available scientific evidence.

# • the promotion of consistency between domestic and international food standards

Because fortification of nut- and seed-based beverages on the basis of nutritional equivalence is permitted internationally, the draft variation promotes consistency between domestic and international food standards.

#### • the desirability of an efficient and internationally competitive food industry

The draft variation permits fortification of nut- and seed- based beverages to the same extent as competing products in the milk substitute market. FSANZ therefore considers that the draft variation supports the desirability for an efficient and competitive food industry.

#### • the promotion of fair trading in food

Nut- and seed-based beverages operate in the same market, are used by consumers in a similar way, and have a similar composition to cereal-based beverages. FSANZ considers that permitting fortification of nut- and seed-based beverages supports the promotion of fair trading in food.

#### • any written policy guidelines formulated by the Ministerial Council<sup>8</sup>

The Policy Guideline *Fortification of Food with Vitamins and Minerals* applies to this Application. The specific order principle about enabling the nutritional profile of specific substitute foods to be aligned with the primary food (through nutritional equivalence) is particularly relevant to this Application. A full assessment of this Application against the Policy Guideline can be found at SD 2.

# 3 Draft variation

The draft variation at Attachment A is intended to take effect on 1 March 2016.

The draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments.

### 3.1 Transitional arrangements

The fortification permissions should take effect on 1 March 2016. However, the draft variation provides a 6-month transition period to apply the mandatory advisory statement, after which time the usual 12-month stock in trade provisions in the Code will apply.

# 4 References

Bus, A.E.M. & Worsley, A., 2003a. Consumers' sensory and nutritional perceptions of three types of milk. *Public Health Nutrition*, 6(2), pp.201–208. Available at: http://search.ebscohost.com/login.aspx?direct=true&db=edb&AN=10395581&site=eds-live.

Bus, A.E.M. & Worsley, A., 2003b. Research Report: Consumers' health perceptions of three types of milk: a survey in Australia. *Appetite*, 40, pp.93–100. Available at: 10.1016/S0195-6663(03)00004-7.

## Attachments

- A. Draft variation to the revised Australia New Zealand Food Standards Code (commencing 1 March 2016)
- B. Draft Explanatory Statement

<sup>&</sup>lt;sup>8</sup> Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

# Attachment A – Draft variation to the revised Australia New Zealand Food Standards Code (commencing 1 March 2016)



# Food Standards (Application A1104 – Voluntary Addition of Vitamins & Minerals to Nut- & Seed-based Beverages) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 2 of the variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX.

#### 1 Name of instrument

This instrument is the Food Standards (Application A1104 – Voluntary Addition of Vitamins & Minerals to Nut- & Seed-based Beverages) Variation.

#### 2 Commencement

(1) Items 1 and 3 of the Schedule commence on 1 March 2016 immediately after the commencement of Standard 5.1.1 – Revocation and transitional provisions — 2014 Revision.

(2) Item 2 of the Schedule commences on 1 September 2016.

#### 3 Variation of Standards and Schedules

The Schedule varies a Standard and Schedules in the Australia New Zealand Food Standards Code.

#### Schedule

- [1] Standard 1.1.2 is varied by omitting from the definition of food group in subsection 1.1.2—2(3)
  - "(c) milk, skim milk, cream, fermented milk, yoghurt, cheese, processed cheese, butter, ice cream, condensed milk, dried milk, evaporated milk, and dairy analogues derived from legumes and cereals listed in section S17—4;"

#### and inserting

- "(c) milk, skim milk, cream, fermented milk, yoghurt, cheese, processed cheese, butter, ice cream, condensed milk, dried milk, evaporated milk, and dairy analogues derived from legumes, cereals, nuts, seeds, or a combination of these ingredients listed in section S17—4;"
- [2] Schedule 9 is varied by omitting from the table to section S9–2

#### "

- 2 (a) A cereal-based beverage that contains less than 3% m/m protein.
  - (b) An evaporated or dried product made from cereals that, when reconstituted as a beverage according to directions for direct consumption, contains less than 3% m/m protein.
- 3 (a) A cereal-based beverage that contains:
  - (i) no less than 3% m/m protein; and
  - (ii) no more than 2.5% m/m fat.
  - (b) An evaporated or dried product made from cereals that, when reconstituted as a beverage according to directions for direct consumption, contains:
    - (i) no less than 3% m/m protein; and
    - (ii) no more than 2.5% m/m fat.
  - (c) Milk, or an analogue beverage made from soy, that contains no more than 2.5% m/m fat.
  - (d) Evaporated milk, dried milk, or an equivalent product made from soy, that, when reconstituted as a beverage according to directions for direct consumption, contains no more than 2.5% m/m fat.

#### substituting

19

the product is not suitable as a complete milk replacement for children under 5 years.

the product is not suitable as a complete milk food for children under 2 years.

...

- " 2
- (a) A beverage made from cereals, nuts, seeds, or a combination of those ingredients, and that contains less than 3% m/m protein.
- (b) An evaporated or dried product made from cereals, nuts, or seeds, or a combination of those ingredients, and that when reconstituted as a beverage according to directions for direct consumption, contains less than 3% m/m protein.
- 3 (a) A beverage made from cereals, nuts, seeds, or a combination of those ingredients, and that contains:
  - (i) no less than 3% m/m protein; and
  - (ii) no more than 2.5% m/m fat.
  - (b) An evaporated or dried product made from cereals, nuts, seeds, or a combination of those ingredients, and that when reconstituted as a beverage according to directions for direct consumption, contains:
    - (i) no less than 3% m/m protein; and
    - (ii) no more than 2.5% m/m fat
  - (c) Milk, or an analogue beverage made from soy, that contains no more than 2.5% m/m fat.
  - (d) Evaporated milk, dried milk, or an equivalent product made from soy, that, when reconstituted as a beverage according to directions for direct consumption, contains no more than 2.5% m/m fat.

the product is not suitable as a complete milk replacement for children under 5 years.

the product is not suitable as a complete milk replacement for children under 2 years.

,,

#### [3] Schedule 17 is varied by omitting from the table to section S17-4

#### "

Analogues derived from cereals Beverages containing no less than 0.3% m/m protein derived from cereals Reference quantity-200 mL Vitamin A 110 µg (15%) 125 µg Thiamin no claim permitted 0.10 mg Riboflavin 0.43 mg (25%) Vitamin B<sub>6</sub> no claim permitted 0.12 mg Vitamin B<sub>12</sub> 0.8 µg (40%) Vitamin D 1.0 µg (10%) 1.6 µg Folate no claim permitted 12 µg Calcium 240 mg (30%) Magnesium no claim permitted 22 mg Phosphorus 200 mg (20%) Zinc no claim permitted 0.8 mg lodine 15 µg (10%)

#### substituting

"

#### Analogues derived from cereals, nuts, seeds, or a combination of those ingredients

Beverages containing no less than 0.3% m/m protein	derived from	cereals, r	nuts, seed	s, or a c	ombination of
those ingredients					
Reference quantity—200 mL					

"

Vitamin A	110 μg (15%)	125 µg
Thiamin	no claim permitted	0.10 mg
Riboflavin	0.43 mg (25%)	
Vitamin B <sub>6</sub>	no claim permitted	0.12 mg
Vitamin B <sub>12</sub>	0.8 µg (40%)	
Vitamin D	1.0 μg (10%)	1.6 µg
Folate	no claim permitted	12 µg
Calcium	240 mg (30%)	
Magnesium	no claim permitted	22 mg
Phosphorus	200 mg (20%)	
Zinc	no claim permitted	0.8 mg
lodine	15 μg (10%)	

# Attachment B – Draft Explanatory Statement

#### 1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1104 which seeks to permit the voluntary addition of vitamins and minerals to nut- and seed-based beverages. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft Variation.

#### 2. Purpose

The purpose of the approved draft variation is to permit the voluntary fortification with vitamins and minerals of nut- and seed-based analogues of milk with prescribed properties. The prescribed properties are, the analogues of milk contain no less than 0.3% m/m of protein derived from cereals, nuts, seeds, or any combination of these ingredients. An additional purpose of the draft variation is to extend the mandatory advisory statement that applies to cereal-based analogues to beverages derived from cereals, nuts, seeds, or any combination of these ingredients.

#### 3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

#### 4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1104 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated report.

A Regulation Impact Statement was not required because the proposed variations to Standard 1.1.2, Schedules 9 and 17 are likely to have a minor impact on business and individuals.

#### 5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

#### 6. Variation

*Item [1]* varies the definition *of* 'food group', in Standard 1.1.2 –Related Claims, to include dairy analogues derived from nuts and seeds.

Item [2] varies section S9—2 in Schedule 9 by extending the advisory statement requirements for beverages derived from cereals to apply to beverages derived from cereals, nuts, seeds, or any combination of those ingredients.

Item [3] varies the table to section S17—4 in Schedule 17 to permit the addition of specified vitamins and minerals to beverages derived from nuts or seeds or a combination of nuts, seeds or cereals, and containing no less than 0.3% m/m protein derived from these ingredients. For each vitamin or mineral, a maximum claim amount is specified in column 2 and a maximum permitted amount is specified in column 3.