

17 December 2015
[32–15]

Approval Report – Application A1104

Voluntary Addition of Vitamins & Minerals to Nut- & Seed-based 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.

On 4 September 2015, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 16 submissions.

FSANZ approved the draft variation on 3 December 2015. The Australia and New Zealand Ministerial Forum on Food Regulation¹ (Forum) was notified of FSANZ's decision on 16 December 2015.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

¹ convening as the Australia and New Zealand Food Regulation Ministerial Council

Table of Contents

EXECUTIVE SUMMARY	2
1 INTRODUCTION	4
1.1 THE APPLICANT	4
1.2 THE APPLICATION	4
1.3 THE CURRENT STANDARD	4
1.3.1 <i>Australia and New Zealand</i>	4
1.3.2 <i>Overseas and International Standards</i>	6
1.4 REASONS FOR ACCEPTING APPLICATION	6
1.5 PROCEDURE FOR ASSESSMENT	7
1.6 TERMINOLOGY USED IN THIS APPROVAL REPORT AND SUPPORTING DOCUMENTS	7
1.7 DECISION	8
2 SUMMARY OF THE FINDINGS	8
2.1 NUTRITIONAL EQUIVALENCE OF A SUBSTITUTE FOOD	8
2.1.1 <i>Nut- and seed-based beverages as milk substitutes</i>	9
2.2 SUMMARY OF ISSUES RAISED IN SUBMISSIONS	10
2.3 RISK ASSESSMENT	15
2.4 RISK MANAGEMENT	17
2.4.1 <i>Permitted fortification</i>	17
2.4.2 <i>Permitted forms</i>	17
2.4.3 <i>Advisory statements</i>	18
2.4.4 <i>Other labelling matters</i>	18
2.4.5 <i>Comparative claims</i>	19
2.4.6 <i>Risk management summary</i>	19
2.5 RISK COMMUNICATION.....	20
2.5.1 <i>Consultation</i>	20
2.6 FSANZ ACT ASSESSMENT REQUIREMENTS	20
2.6.1 <i>Section 29</i>	20
2.6.2 <i>Subsection 18(1)</i>	22
3 TRANSITIONAL ARRANGEMENTS	23
4 REFERENCES	24
ATTACHMENT A – APPROVED DRAFT VARIATION TO THE REVISED <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i> (COMMENCING 1 MARCH 2016)	25
ATTACHMENT B – EXPLANATORY STATEMENT	29

Supporting documents

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

SD1	Technical and nutrition assessment
SD2	Assessment against Policy Guideline on Fortification of food with vitamins and minerals (at Approval)

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 current 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 counterpart primary food. The Application requested fortification for nut- and seed-based beverages (e.g. almond, sesame) containing at least 0.2% m/m protein. The Application also acknowledged that the risk management strategy applied to legume-based (e.g. soy) and cereal-based (e.g. rice, oat, spelt) beverages should also extend to *fortified* nut- and seed-based beverages. That is, that these be labelled with appropriate advisory statements contained in Standard 1.2.3 of the current Code.

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 when their protein or fat content is too low 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 considered that several features of the labelling, marketing and consumer use 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 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 has approved the voluntary fortification of nut- and seed-based beverages according to nutritional equivalence with full cream cow's milk.

FSANZ has gazetted an amended version of Chapters 1 and 2 of the Code to take effect from 1 March 2016. Because the approved draft variation arising from this assessment is also likely to take effect around that date if no review of FSANZ's decision is requested by Ministers, draft amendments are proposed for the revised Code only.

FSANZ called for submissions on the draft variation and received 16 submissions. Thirteen submissions supported the draft variation, two did not provide a position, and one individual did not support the draft variation. However, many jurisdictions raised concerns that fortification on the basis of nutritional equivalence would not ensure complete nutritional equivalence with milk as the counterpart primary food. Permission to fortify foods with vitamins and minerals on the basis of nutritional equivalence does not assume that both products are nutritionally identical; rather it permits the substitute food to have a comparable **micronutrient** composition to the counterpart food.

The approved 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 cereal-based beverages to *all* nut- and seed-based beverages.

The approved 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 rather than just nuts and seeds
- the relevant 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.

The Applicant was notified of this difference prior to FSANZ's approval of the draft variation and raised no objection.

FSANZ considers that the approval of the draft variation is consistent with the statutory requirements for standards development as well as the Australia and New Zealand Ministerial Forum on Food Regulation Policy Guideline on *Fortification of Food with Vitamins and Minerals* and the clarification statement to this Policy Guideline.

1 Introduction

1.1 The Applicant

The Applicant is Sanitarium Health and Wellbeing Australia².

1.2 The Application

The Application sought to amend Standard 1.3.2 of the current *Australia New Zealand Food Standards Code* (the current 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 counterpart primary food.

The Applicant acknowledged 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 fortified³ 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 approved draft variations arising from this Application are likely to take effect around that date if no review of FSANZ's decision is requested by Ministers, 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 the addition of that vitamin or mineral is permitted in the table to section S17—4, which is in Schedule 17 – Vitamins and Minerals; and the vitamin or mineral is in a permitted form specified in the tables to sections S17—2 and S17—3.

The addition of vitamins and minerals to food listed in the table to 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)⁴ 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.

² <http://www.sanitarium.com.au/about-us>

³ The term 'fortified' means a food to which vitamins or minerals are added

⁴ as per section S1—2

In the case of substitute foods, otherwise known as ‘analogues’ in the table to section S17—4, permissions are derived from the vitamin and mineral content of the counterpart primary food. The table to 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 the table to section S17—4 or elsewhere in the Code.

Table 1: Permitted fortification of legume^Δ- and cereal[◆]-based beverages (table to section S17—4)

Vitamin/ Mineral	Maximum claim per reference quantity (proportion rRDI ⁺)	Maximum permitted quantity of vitamin or mineral per reference quantity
Calcium	240 mg (30%)	Not specified
Folate	no claim permitted	12 µg
Iodine	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 ₁₂	0.8 µg (40%)	Not specified
Vitamin B ₆	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. (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.	the product is not suitable as a complete milk replacement for children under 5 years.
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.	the product is not suitable as a complete milk food for children under 2 years.

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 Foods⁵ 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 USA 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:

- it complied with the procedural requirements under subsection 22(2)

⁵ http://www.codexalimentarius.org/input/download/report/907/REP15_NFSDUe.pdf

- it related to a matter that warranted consideration of a variation of a food regulatory measure.

1.5 Procedure for assessment

The Application was assessed under the General Procedure.

1.6 Terminology used in this approval report and supporting documents

There are a number of terms used to describe milk and its substitutes that are in general use within industry and elsewhere. For the purposes of this approval report, 'milk substitute' refers to replacement products for milk. However, such products are also described in this report as a 'milk alternative' when required by the context. Examples include: when responding to a submitter who has used a term other than 'milk substitute'; or 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 in this approval report.

Table 3: Different terms used in this approval report and supporting documents

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'
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'.

Column 1	Column 2	Column 3
Term	Description	Examples
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	<p>Respondent who did not report consuming products containing dairy ingredients in a national nutrition survey.</p> <p>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.</p> <p>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.</p>	

1.7 Decision

The draft variation as proposed following assessment was approved without change. The variation takes effect on 1 March 2016 if no review of FSANZ's decision is requested by Ministers. The approved draft variation is at Attachment A.

The related 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.

2 Summary of the findings

2.1 Nutritional equivalence of a substitute food

FSANZ has had regard to the Ministerial Policy Guideline⁶ *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 applicable and appropriate.

⁶<http://www.foodstandards.gov.au/code/fofr/fofrpolicy/documents/Fortification%20of%20vitamins%20and%20minerals%20-%20amended%20Oct%202009.pdf> accessed 7/5/2015

Codex defines nutritional equivalence to mean that a substitute food is of similar nutritional value to its regular 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 therefore considered that a substitute food is determined according to its market presentation and consumer use as a substitute for the counterpart primary food it resembles, in this case, milk (as defined in section 1.1.2—3). Milk is an important contributor ($\geq 20\%$) to the intakes of many vitamins and minerals, particularly calcium, phosphorus, vitamin A, riboflavin, vitamins B₆ and B₁₂ 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's predecessor revised the 1987 fortification permissions for milk substitutes of vegetable origin to be limited to soy beverages marketed as a milk substitute, in keeping with the market at the time. 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 beverages⁷. 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.

⁷ Ibisworld, 2015 Soy and Almond Milk Production in the United States.

As outlined in the technical and nutrition assessment in SD1, recent national nutrition survey information shows that nut- and cereal-based 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 approved 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 Summary of issues raised in submissions

FSANZ called for submissions on the draft variation and received 16 submissions. Thirteen submissions supported the draft variation, two did not provide a position and one individual did not support the draft variation.

Table 4: Summary of issues

Issue	Raised by	FSANZ response
Supports the draft variation either in full or in principle.	Industry, some jurisdictions, professional associations	Noted.
Does not support Vitamin and mineral intake cannot be regulated if people are consuming them as additives in products.	Private	Noted. The Code regulates the labelling of food additives and added vitamins and minerals. Where a food additive is added to a food, specific labelling requirements apply that may permit the nutrient contribution of food additives to be declared in the nutrition information panel.
Support minimum protein for fortification of 0.3%	Nut industry	Noted.
Supports requirement for advisory statement	Industry, some jurisdictions	Noted.
Milk is defined in Standard 1.1.2, a beverage should not be sold as milk unless it meets this definition. Products deemed not to be nutritionally similar to milk should not be allowed to use the term milk or milk substitute. More preferable terminology would be beverages or drinks.	Some jurisdictions, FTAA	This issue relates to the broader issue of whether and how milk analogues in general should be permitted. Existing provisions of the Code, such as section 1.1.1-13(4) permit the sale of milk substitutes such as ‘soy milk’. The application seeks an extension of existing permissions for dairy analogues to nut- and seed based beverages. Imposing restrictions of the use of terms such as ‘milk’ are matters more appropriately raised and assessed via a separate Application.

Issue	Raised by	FSANZ response
<p>There is no definition of nutritional equivalence in the Code. The Codex definition of nutritional equivalence refers to partial or full replacement, and thereby does not provide a definitive acceptable range of nutrient profile for the substitute food in reference to its counterpart.</p>	<p>Some jurisdictions</p>	<p>This issue relates to substitute foods generally.</p> <p>No definitions for the terms <i>substitute food</i>, <i>primary food</i> and <i>nutritional equivalence</i> are given in the Code. FSANZ has therefore relied upon the Codex definition of nutritional equivalence for the purposes of this assessment. See section 2.1 of the approval report. This is the accepted international understanding of nutritional equivalence.</p> <p>FSANZ remains satisfied that this approach is appropriate, having regard to the statutory requirements for standards development.</p> <p>The principle of addition of vitamins and minerals on the basis of nutritional equivalence describes the framework for regulators to consider permitting fortification of a food towards improving the nutritional quality of products used and marketed as a substitute for the regular counterpart foods.</p> <p>Permission to fortify foods with vitamins and minerals on the basis of nutritional equivalence does not assume that products on the market are nutritionally identical; rather it permits the food to have a comparable micronutrient composition to the regular counterpart food.</p>
<p>The permission to fortify these products is based on their use as a substitute to dairy; it is not necessary to describe them as an analogue or a substitute in the Code. Recommend referring to these products in the Code simply as nut- and seed-based beverages and legume-based beverages for the existing analogues.</p>	<p>Victorian Govt</p>	<p>The use of the term <i>analogue</i> is a term used only in relevant headings in the table to Schedule 17—4. The specific foods included in this section are described as beverages.</p>
<p>The term <i>analogue</i> is not defined in the Code. Recommend not using the term <i>analogue</i>, as an analogue is something which is seen as comparable to another.</p>	<p>Some jurisdictions</p>	<p>As mentioned above, the Application seeks an extension of existing Code provisions and permissions for dairy analogues to nut- and seed based beverages. The Code relies on the ordinary meaning of analogue which relates to comparability rather than identicalness.</p>
<p>The draft variation needs to be clear as to which coconut-based milk substitutes may be fortified.</p>	<p>Some jurisdictions</p>	<p>The approved variation relies on the ordinary meaning of the term <i>beverage</i> to describe the products that can be fortified. This is consistent with the approach taken by the Code to date.</p>
<p>Plant-based milk alternatives are only considered in the milk, cheese and yoghurt group of the Australian Dietary Guidelines (ADGs) if they are fortified with 100 mg calcium per 100 mL. The ADG considers unfortified plant-based milk substitutes to be discretionary foods.</p>	<p>Dairy Australia, some jurisdictions.</p>	<p>Approval of this Application will permit a broader range of plant-based milk alternatives as described in the ADG to not rely on food additive use to meet the calcium criteria for inclusion in this food group.</p>

Issue	Raised by	FSANZ response
<p>A better definition for these products may be formulated legume, cereal, nut- and seed-beverages with associated regulated labelling requirements to support consumer understanding.</p>	<p>Dairy Australia</p>	<p>The definition of these products is for regulatory purposes only (i.e. to provide a permission). No specific additional definition or terminology for labelling has been proposed in the draft variation. FSANZ is satisfied that the current provisions for labelling that will apply to the product will support consumer understanding. See section 2.4.5 below</p>
<p>Suggest a limit be set for nut- and seed-based beverages regarding the ingredient quantity for nuts and seeds. Having a minimum limit for the nut/ seed ingredient in these enriched beverages, such as 4% would help consumers choose enriched products with greater nutritional value.</p>	<p>Ceres Natural Foods</p>	<p>Standard 1.2.10 outlines requirements for declaring characterising ingredients and components. Nut- and seed-based beverages declare in the ingredient list the percent of characterising ingredient present in the product.</p> <p>The fortification permissions associated with this Application require a minimum amount of protein derived from cereals, nuts, or seeds or a combination of these ingredients to be present in the food. However, there is no limitation for higher protein products being sold if developed.</p>
<p>There is substantial variability in the composition of plant based beverages.</p> <p>Fortification permissions are voluntary and do not result in all products being fortified. Some products are choosing to add some but not all of the permitted vitamins and minerals; some are only adding calcium which does not make these products nutritionally equivalent. Cereal, nut- and seed-beverages have less than 3% protein are not nutritionally equivalent to mammalian milk.</p> <p>Consideration could be given to setting minimum or maximum values for selected nutrition parameters such as calcium or protein to ensure that plant based dairy analogues are approaching nutritional equivalence with dairy products.</p>	<p>Dairy Australia, some jurisdictions</p>	<p>Analogues from cereals or legumes, are permitted to be sold with or without fortification. In all cases, the plant-based milk substitutes are currently used by consumers as a substitute for milk. The fortification of these products is permitted on the basis of their use as a substitute food and the specific micronutrient permissions are based on the micronutrient profile of the regular counterpart food.</p> <p>Very few substitute products on the market have an identical composition to their market competitors e.g. butter and edible oil spreads. Established mechanisms in the Code such as ingredient labelling, nutrition information panel and characterising ingredients provide consumers with information on the nutritional composition of their product choice.</p> <p>Voluntary fortification permissions provide industry with flexibility to meet varying consumer demands. Some consumers may wish to choose an unfortified product, e.g. labelled as organic, whereas others may choose a fortified product. Labelling requirements provide consumers with information to enable informed choices.</p> <p>Permission to fortify foods with vitamins and minerals on the basis of nutritional equivalence does not assume that products on the market are nutritionally identical; rather it permits the food to have a comparable micronutrient composition to the regular counterpart food.</p> <p>The minimum amount of protein for fortified products is set, and the amount of vitamins and minerals contained in the product is set at a maximum amount or maximum claim amount. See Section 2.4.1.</p>

Issue	Raised by	FSANZ response
		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. The small potential for risk associated with this difference in macronutrient profile is managed with the mandatory advisory statement, that these products are not suitable as a complete milk replacement in the diet for children under five years. (See Section 2.3 and 2.4.3)
Beverages that are not nutritionally equivalent to milk, particularly those that have low protein levels and limited other nutritional benefit such as coconut milk should not be permitted to be fortified with vitamins and minerals.	Dairy Australia, some jurisdictions	Section 2.1.1 outlines FSANZ's rationale for considering these products as a substitute food for milk. The substitute food should be nutritionally inferior in micronutrients to the regular counterpart food to enable it to be considered suitable for fortification.
The definition of nut- and seed-based beverages captures coconut-based milk substitutes, however coconut-based milk substitutes would not usually contain the 0.3% protein necessary to qualify for fortification. Consider allowing a lower protein level of 0.2% for this category of products or excluding coconut-based milk substitutes from this Application.	Industry	The draft variation extends existing fortification permissions for cereal-based beverages to add vitamins and minerals on a voluntary basis to beverages derived from nuts and seeds with no less than 0.3% m/m protein derived from cereal, nuts and seeds or any combination of the above. There are a number of products on the market that contain less than 0.3% m/m protein. The draft variation allows for blended products and innovation in this market. Should manufacturers of coconut milk beverages wish for a specific fortification permission or exclusion from this regulation, this could be assessed via a separate Application.
The coconut based milk substitutes contain 2% saturated fat, which is substantially higher than other plant-based milk substitutes.	NSW Govt	FSANZ agrees that 2% saturated fat does not qualify the product to carry a low saturated fat claim.
Consumers		
The variability in composition of plant-based milk substitutes raises the issue of whether consumers are likely to be confused or misled about the suitability of some plant-based beverages as alternatives to milk.	Some jurisdictions	The variation to the Code extends the permissions that exist for legume- and cereal-based beverages to nut- and seed-based beverages. No additional evidence has been presented by submitters to show that consumers are confused with the current situation for legume and cereal based beverages. There are a number of provisions in the Code that when applied to food labels are intended to prevent consumers being misled or confused. These include: the statement of ingredients including the requirements for characterising ingredients, the nutrition information panel.
Consumer perceptions are largely driven by the marketing of manufacturer. It would be useful to obtain more up to date information on consumer perceptions and understanding of plant-based demographic consumption.	Qld Health	FSANZ has used the best available scientific evidence. FSANZ is unaware of any more up to date evidence on consumer perceptions that can be used. Consumer food consumption patterns were taken into account by using information from national nutrition surveys, including the most recent 2011-12 National Nutrition and Physical Activity Survey for the Australian population by age group for those aged 2 years and over (comparative tables provided in SD1).

Issue	Raised by	FSANZ response
Comments on the Drafting		
<p>The variation to the food group definition allows inappropriate comparisons between milk and milk substitutes. These comparisons are not appropriate from a nutrition perspective given their dissimilar nutrient profile.</p> <p>Analogues derived from nuts and seeds or a combination of these ingredients should be listed separately to the existing food group list of dairy foods and dairy analogues in 1.1.2-2(3)(c)</p> <p>It would also be appropriate to separate out analogues derived from cereals from the existing food group list of dairy foods and dairy analogues so that it is clear that comparisons between dairy foods and analogues derived from cereals, nuts and seeds are not made due to the significant difference in protein content.</p>	SA Health	<p>FSANZ remains satisfied that the drafting and its approach is appropriate.</p> <p>FSANZ considered how foods were allocated into food groups for comparison claim purposes as part of Proposal P293 – Nutrition, Health and Related Claims. Submitters to P293 specifically raised issues relating to comparisons between milk and milk alternatives during this proposal.</p> <p>P293, determined that comparative claims would be permitted under two different situations:</p> <ul style="list-style-type: none"> • the food can be compared to another food of the same type that has not been modified in terms of the nutrient or energy that is the subject of the claim • between foods that may substitute for one another in the diet. <p>It was recognised at the time that analogue products are used by consumers as a substitute for meat and dairy, and that these analogues should be placed into meat and milk food groups so that accurate comparison claims would be made. To prevent the possibility of misleading claims, FSANZ also added the condition to Standard 1.2.7 that the comparative claim must identify the reference food, as well as indicate the difference in quantity of the energy or claimed nutrient.</p> <p>Revision of the criteria used to establish comparative claims is outside of scope of this Application. The inclusion of nut- and seed-based beverages in the milk food group for comparative claim purposes is consistent with the inclusion of other milk analogue beverages in this group, such as those based on legumes or cereals.</p> <p>FSANZ therefore reaffirms the proposed inclusion of nut and seed based beverages in the list of dairy foods in the definition of 'food group' at clause 1.1.2-2(3)(c).</p>

Issues raised that are outside of scope of the Application	Raised by	FSANZ response
<p>The terminology used by manufacturers currently to describe 'coconut' based nut-based beverages as 'coconut milk' would not be in line with the definitions used in the Code. It is noted that in Standard 1.3.1 coconut milk, coconut cream and coconut syrup are a subset of 14.1.2.1 fruit and vegetable juices. 'Coconut milk' consumed as a beverage would not fit under 14.1.2.1 but 14.1.2.2 fruit and vegetable products.</p>	MPI	<p>The issue of whether coconut milk or cream used as ingredients in cooking should more accurately be considered as a subcategory of category 4 (Fruits and vegetables (including fungi, nuts, seeds, herbs and spices) is outside the scope of the current application. Any amendment would need to be considered as part of a separate standards development process.</p> <p>FSANZ notes two different types of products can be described as 'coconut milk' (see discussion in section 2.1.1 of Approval Report). Currently the products called coconut milk, coconut cream or coconut syrup are listed as a subcategory of non-alcoholic beverages (subcategory 14.1.2.1.1 within the category of fruit and vegetable juices in the Table of S15—5 (Table of permissions for food additives) in the revised Code. The food additive permissions for these products are consistent with their being used as ingredients in cooking and not as beverages.</p> <p>FSANZ agrees that nut- and seed-based beverages should be considered in the same way as cereal- and legume-based beverages (such as soybean-based beverages) which are listed under the food additive category 14.1.2.2 (Fruit and vegetable juice products) within the Table of S15—5.</p>
<p>Advisory statements for soy beverages have criteria for low fat only, not low protein like other analogues.</p> <p>The terminology for the advisory statements in schedule 9 should be modified to align with the terminology used in schedule 17-4 for fortification permissions and refer the term legume based beverages rather than soy based beverages.</p>	Some jurisdictions	<p>This is the existing situation in the Code. The assessment of this Application pertains to nut- and seed-based beverages only. Soy-based beverages are outside of scope of the Application, therefore no change is proposed for mandatory advisory statements relating to Soy based beverages in Schedule 9.</p>
<p>A more general review of the adequacy of voluntary fortification framework for dairy alternatives could be considered by FSANZ in the future.</p>	Some jurisdictions	<p>A full review of dairy alternatives is outside of scope of this Application.</p>
<p>Seek consideration to extending the mandatory advisory statements to include the elderly over 70 years of age consistent with cautions outlined in the NHMRC.</p>	Dairy Australia	<p>This Application sought an extension of existing permissions. The advisory statement for children relates to the protein and energy requirements for growth and development. This does not apply to adults. Therefore consideration of additional advisory statements to include the elderly over 70 years of age is outside of scope of this Application.</p>

2.3 Risk assessment

The concentrations of vitamins, minerals and protein in currently available nut- and seed-based 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 B₆, B₁₂ 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 (≥20%) to the intakes of many vitamins and minerals, particularly calcium, phosphorus, retinol equivalents, riboflavin, vitamins B₆ and B₁₂ 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 surveys⁸ 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.

⁸ Australian 2011-12 National Nutrition and Physical Activity Survey (NNPAS) and 2008-09 New Zealand Adult Nutrition Survey (2008 NZANS)

2.4 Risk management

2.4.1 Permitted fortification

Many submitters raised concerns that permission to fortify nut- and seed-based beverages would not ensure complete nutritional equivalence with the regular counterpart food of cow's milk. The principle of addition of vitamins and minerals on the basis of nutritional equivalence describes the framework for regulators to consider permitting fortification of a food towards improving the nutritional quality of products used and marketed as a substitute for the regular counterpart foods. Permission to fortify foods with vitamins and minerals on the basis of nutritional equivalence does not assume that products on the market are nutritionally identical; rather it permits the food to have a comparable micronutrient composition to the regular counterpart food.

Voluntary fortification permissions provide industry with flexibility to meet varying consumer demands. Some consumers may wish to choose an unfortified product, e.g. labelled as organic, whereas others may choose a fortified product. Labelling requirements provide consumers with information to enable informed choices.

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 concluded 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 approved draft variation to the table 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 approved 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.

2.4.2 Permitted forms

The Applicant sought 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.

The approved draft variation therefore permits the use of existing permitted forms of the requested vitamins and minerals in nut- and seed-based beverages. FSANZ noted 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 approved 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.

2.4.3 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 approved 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 proposed the mandatory advisory statements that currently apply to cereal-based beverages would also apply to nut- and seed-based beverages.

2.4.3.1 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 1.1.1—9 of Standard 1.1.1 – Structure of the Code and general provisions 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.

2.4.4 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*. That is, that existing labelling requirements of the Code should apply to fortified nut- and seed-based beverages. FSANZ has not proposed to alter these requirements as part of this Application.

FSANZ also considered that there are a number of labelling provisions in the Code that provide information to consumers 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 – Information requirements – statement 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.

2.4.5 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 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 approved 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.

2.4.6 Risk management summary

FSANZ considered 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 proposed 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 approved 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.

2.5 Risk communication

2.5.1 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. The call for submissions was notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News. Subscribers and interested parties were also notified about the availability of reports for public comment.

The draft variation was considered for approval by the FSANZ Board taking into account public comments received on the proposed draft variation.

The FSANZ Board's decision to approve the draft variation has been 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.

2.6 FSANZ Act assessment requirements

2.6.1 Section 29

2.6.1.1 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). The OPBR was satisfied that the sought variation was only minor and machinery in nature for the following reasons.

- 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.

FSANZ also has a standing exemption from the 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 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 allows 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.

Because the draft variation to the table 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 the Code which introduced mandatory advisory statements on other plant-based milk substitutes. The draft variation expands the scope of the table to 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 variation to the table to section S9—2 will align the regulatory treatment of products now in the milk substitute market thus maintaining a fair market. The approved draft variations will also mitigate the public health and safety risks to consumers from information being omitted, and help consumers make an informed decision.

2.6.1.2 Other measures

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

2.6.1.3 Any relevant New Zealand standards

There are no relevant New Zealand standards.

2.6.1.4 Any other relevant matters

Other relevant matters are considered below.

2.6.2 Subsection 18(1)

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

2.6.2.1 Protection of public health and safety

FSANZ's risk assessment is that approval of the draft variations will not pose a risk to public health and safety.

FSANZ is satisfied that the requirement for an advisory statement that nut- and seed-based beverages are not suitable as a complete milk replacement for children under five years, or as a complete milk food for children under two years (depending on composition), will address the potential for risk to small children from consuming these beverages due to the lower protein, energy and/or fat content of these milk substitutes

Public health and safety is also 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).

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

Section 2.4.4 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.

2.6.2.3 The prevention of misleading or deceptive conduct

The Code's existing labelling requirements will apply to nut- and seed-based beverages fortified with vitamins and minerals.

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 the table to section S17—4.

2.6.3 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 using 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 approved draft variation promotes consistency between domestic and international food standards.

- **the desirability of an efficient and internationally competitive food industry**

The approved draft variation permits fortification of nut- and seed- based beverages to the same extent as competing products in the milk substitute market. FSANZ therefore considered that the approved 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 considered 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 Council⁹**

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 counterpart 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 SD2.

The Forum notified FSANZ on 2 December 2015 of a clarification statement to the Policy Guideline for the Fortification of Food with Vitamins and Minerals, to not permit fortification in food of little or no nutritional value. Nut- and seed-based beverages are considered appropriate food vehicles for voluntary fortification of substitute foods as they are nutritionally inferior to milk and when fortified according to the principle of nutritional equivalence, would provide a nutritional benefit to those who choose not to consume or need to avoid milk.

3 Transitional arrangements

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.

⁹ Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

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. Approved variations to the revised *Australia New Zealand Food Standards Code* (commencing 1 March 2016)
- B. Explanatory Statement

Attachment A – Approved 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 dates 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. | the product is not suitable as a complete milk replacement for children under 5 years. |
| | (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. | the product is not suitable as a complete milk food for children under 2 years. |
| | (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

“

- 2 (a) A beverage made from cereals, nuts, seeds, or a combination of those ingredients, and that contains less than 3% m/m protein. the product is not suitable as a complete milk replacement for children under 5 years.
- (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.

”

[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 ₆	no claim permitted	0.12 mg
Vitamin B ₁₂	0.8 µg (40%)	
Vitamin D	1.0 µg (10%)	1.6 µg
Folate	no claim permitted	12 µg
Calcium	240 mg (30%)	
Magnesium	no claim permitted	22 mg
Phosphorus	200 mg (20%)	
Zinc	no claim permitted	0.8 mg
Iodine	15 µg (10%)	

”

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, nuts, seeds, or a combination 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 ₆	no claim permitted	0.12 mg
Vitamin B ₁₂	0.8 µg (40%)	
Vitamin D	1.0 µg (10%)	1.6 µg
Folate	no claim permitted	12 µg
Calcium	240 mg (30%)	
Magnesium	no claim permitted	22 mg
Phosphorus	200 mg (20%)	
Zinc	no claim permitted	0.8 mg
Iodine	15 µg (10%)	

”

Attachment B – 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 sought 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.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation¹⁰, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislative Instruments Act 2003*.

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 that 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 those 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.

¹⁰ convening as the Australia and New Zealand Food Regulation Ministerial Council

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 subsection 1.1.2—2(3) to include dairy analogues derived from nuts and seeds.

Item [2] varies the table to 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 those ingredients. For each vitamin or mineral, a maximum claim amount is specified in column 2 and where listed, a maximum permitted amount is specified in column 3.