

A submission of comments relating to
INITIAL ASSESSMENT REPORT FOR
P235
REVIEW OF FOOD-TYPE DIETARY SUPPLEMENTS

Submitted on behalf of
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SUMMARY

- Sanitarium is in support of the harmonisation of requirements between Australia and New Zealand in regards to foods currently produced in New Zealand and marketed under the New Zealand Dietary Supplements Regulations.
- It is considered that the most appropriate approach is full regulation, and that Option 2b is the preferred option of those presented in the Initial Assessment Report for P235.
- Sanitarium currently markets a range of vitamin and mineral fortified beverages which are produced in New Zealand under the New Zealand Dietary Supplement Regulations. As such, we have particular interest to ensure that a standard is developed to encompass this category of products under the new unified code. Such a standard has been drafted, and is included as APPENDIX 1 of this submission.
- Sanitarium supports permissions for Herbal extracts / supplements to be included in Food Type Dietary Supplements. However, any such permissions must be considered within the existing assessment framework for Novel Foods.
- Sanitarium suggests the inclusion of qualifying nutritional criteria for Food Type Dietary Supplements to prevent the marketing of food of otherwise poor nutritional quality as dietary supplements. It is recommended that maximum levels be specified for sugar, fat and sodium, and that these criteria are based on a category by category approach

BACKGROUND

As a producer of health foods in Australia and New Zealand for over 100 years, the Sanitarium Health Food Company is committed to providing healthy and nutritious food products to the community. Sanitarium has a long history of enhancing the nutritional profile of certain foods such as breakfast cereals and soy beverages through fortification with a range of essential vitamins and minerals.

Sanitarium has previously marketed vitamin and mineral fortified water-based beverages in Australia under standard 2.9.4 - Formulated Supplementary Sports Food.

Sanitarium currently markets vitamin and mineral fortified water-based beverages in Australia and New Zealand under the provisions of the New Zealand Dietary Supplements Regulations (1985) and the Trans Tasman Mutual Recognition Agreement.

These products would be considered to fall within the scope of Food Type Dietary Supplements.

SPECIFIC COMMENTS

1 **Sanitarium Supports Option 2 - Full Regulation.**

The Initial Assessment Report for P235 presented a range of options for regulating Food Type Dietary Supplements.

Option 1	<u>Status Quo</u>	No specific provision within the Food Standards Code. Retain current NZ Dietary Supplements Regulations
Option 2	<u>Full Regulation</u>	
	<i>2a - Horizontal Approach</i>	Amend and expand provisions within current Food Standards under Chapter 1 of the Food Standards Code. (eg 1.3.2 Vitamins and Minerals, 1.4.4 Prohibited and Restricted Plants and Fungi)
	<i>2b - Vertical Approach</i>	Develop new standards for discrete products that would be subject to targeted risk assessment, resulting in specific compositional permissions and labelling requirements <ul style="list-style-type: none"> • Option 2b.i - New standards developed under Chapter 2 of the Food Standards Code • Option 2b.ii - New standards moved into a new 'Chapter X' of the Food Standards Code
Option 3	<u>Co-Regulation</u>	Partial provisions in the Food Standards Code and development of industry Codes of Practice, and cessation of the provision for production or importation of Food Type Dietary Supplements under the NZ Dietary Supplements Regulations.

It is Sanitarium's view that the current regulatory arrangements are not satisfactory. Products may currently be produced in New Zealand and be considered legal under the New Zealand Dietary Supplements Regulations, but may not be manufactured legally in Australia. It is clear that the current situation is not sustainable long term, and that option 1 is not appropriate.

In line with Sanitarium's previous submissions in relation to Health Claims and Nutrient Claims, the application of industry self regulation by means of Codes of Practice has been shown to be less than effective. This is due to lack of awareness of many businesses of the existence of such codes, and their perceived (and real) lack of ability to be effectively enforced.

Sanitarium is in favour of clear, well defined, and enforceable legislation in relation to Food Type Dietary Supplements, and as such, supports Option 2 for Full Regulation.

Sanitarium's preference would be to proceed with Option 2b , and develop new standards for specific product categories. It is considered that this would be the most effective means to apply a risk assessment approach to product regulation, regulate compositional requirements and, where appropriate, warning statements.

Sanitarium has no preference in regards to whether such standards should sit within the existing Chapter 2 of the Food Standards Code (option 2b.i) or whether they should form part of a new 'Chapter X' of the Food Standards Code (option 2b.ii)

2 Sanitarium proposes development of a standard for Formulated Water-based Beverages

As part of the development of new product standards under option 2b, Sanitarium would like to take this opportunity to request that consideration be given to the development of a standard for Formulated Water-Based Beverages.

Sanitarium currently manufactures and markets a range of **WaterPlus™** fitness drinks. These are manufactured in New Zealand under the NZ Dietary Supplements Regulations (1985). They consist of a high quality mineral spring water, with a light fruit flavour tint and the addition of a range of vitamins and minerals at a moderate level (10-25% RDI per 710ml serve). The products are intended to encourage rehydration during light sporting and regular daily activity for consumers in all age groups. It contains no sugar, contributes minimally to energy intake (10kJ/710mL serve), but does provide a moderate nutritional contribution (from added vitamins and minerals. A full nutrition and ingredients profile is included in Appendix 2).

WaterPlus™ differs from products typically marketed under the Formulated Supplementary Sports Food standard in that it is not targeted at people participating in highly strenuous levels of sport. It does not contain high levels of sodium, and does not contain added amino acids or biologically active components permitted to be added to Formulated Supplementary Sports Foods.

Nor does it contain caffeine or other biologically active components permitted to be added to Formulated Caffeinated Beverages.

The levels of micronutrients added are such that the product is suitable for consumption by children, as well as adults (for example, the levels are similar to those permitted in breakfast cereals). Hence it is inappropriate for the product to be produced under either the Formulated Supplementary Sports Food or the Formulated

Caffeinated Beverages standards, with their requirement for an advisory statement recommending against consumption by children, pregnant and lactating women.

As stated previously, **WaterPlus™** is manufactured in New Zealand in compliance with the NZ Dietary Supplements regulations, however at this time, there is no equivalent regulation in Australia under which the product may be produced.

Sanitarium proposes the development of a standard for Formulated Water-Based Beverages. Under the review of P235, it is considered that such a standard would fit alongside either Standard 2.6.4 - Formulated Caffeinated Beverages, or 2.9.4 - Formulated Supplementary Sports Foods.

It is anticipated that such a standard would provide for:

- Permission to fortify with vitamins and minerals. Range of permitted fortificants in line with those for Formulated Supplementary Sports Food.
- No permission for addition of amino acids
- No permission for addition of biologically active substances
- No permission for addition of caffeine
- No requirement for the inclusion of a warning statement against consumption by any specific community groups, such as children or pregnant / lactating women.
- Nutritional qualifying and disqualifying criteria

Sanitarium has prepared a rough preliminary draft of such a standard. Please refer to APPENDIX 1 of this submission.

3 Sanitarium supports permissions for Herbal extracts / supplements, subject to full safety assessment

The Food Standards Code already has provision for the consideration of herbal extracts and herbal supplements under standard 1.5.2 - Novel Foods. Sanitarium supports the permission for such herbal extracts to be included in Food Type Dietary Supplements.

However, it is NOT considered appropriate that, as has been suggested, permission may be granted for some substances considered novel on the basis that they are currently included in a variety of products (outside the domestic market)

It is considered that such herbal extracts must be subjected to the existing requirement that novel foods undergo a full safety assessment prior to approval for use.

4 Sanitarium suggests application of Qualifying Nutritional Criteria for FTDS

The concept of qualifying nutritional criteria has been recognised during the reviews on Health Claims and Nutrient Content Claims.

Food Type Dietary Supplements, by their nature, imply certain functional physiological consequences from their consumption, even if such claims are not explicitly stated.

It would not be considered appropriate for products with a non-desirable nutritional profile, such as foods high in sugar, salt or fat to be marketed as Dietary Supplements.

Sanitarium considers that foods marketed as Dietary Supplements should comply with maximum level criteria for fat/saturated fat, added sugar and salt. In addition, Sanitarium recommends that these criteria are based on a category by category approach, due to the inherent variation in nutrient composition of different food groups. The National Heart Foundation and Glycaemic Index Ltd have developed nutrient criteria for their food product endorsement programs, and Sanitarium suggests that nutrient criteria for Food Type Dietary Supplements similarly take this approach.

APPENDIX 1

Proposed New Standard 2.X.X
Formulated Water-Based Beverages

Purpose

The purpose of this Standard is to regulate non-alcoholic water-based flavoured formulated beverages that are manufactured for the purpose of re-hydration and nutritional supplementation

Table of Provisions

1 Interpretation

2 Composition

3 Labelling

1 Interpretation

In this Standard –

formulated water-based beverage means a non-alcoholic water-based flavoured beverage which may contain carbohydrates, vitamins, minerals and other substances, including other foods, for the purpose of re-hydration and nutritional supplementation

one day quantity in relation to formulated water-based beverage, means the maximum amount of that food that should be consumed in one day in accordance with the directions specified in the label.

2 Composition

(1) A Formulated Water-Based Beverage shall meet the requirements of a Low Joule Food in accordance with subclause 14 of Standard 1.2.8

(2) A formulated water-based beverage may contain the substances listed in column 1 of the Table to this subclause, provided the amount of that substance present in the food is no more than the amount specified in relation to that substance in column 2 of the Table.

Table to paragraph 2 (1)

Column 1	Column 2	Column 3
Micronutrient	Maximum claimed amount per one-day quantity	Maximum amount per one-day quantity
Vitamin A	375 µg	375 µg
Thiamin	2.2 mg	
Riboflavin	3.4 mg	
Niacin	20 mg	
Folate	400 µg	
Vitamin B ₆	3.2 mg	

APPENDIX 1**Table to paragraph 2 (1) (continued)**

Vitamin B ₁₂		4.0 µg	
Vitamin C		80 mg	
Vitamin D		2.5 µg	2.5 µg
Vitamin E		20 mg	
Biotin		50 µg	
Pantothenic Acid		3.5 mg	
Calcium		1600 mg	
Chromium:	Inorganic forms	100 µg	100 µg
	Organic forms	50 µg	50 µg
Copper:	Inorganic forms	1.5 mg	1.5 mg
	Organic forms	750 µg	750 µg
Iodine		75 µg	
Iron		12 mg	
Magnesium		640 mg	
Manganese:	Inorganic forms	2.5 mg	
	Organic forms	1.25 mg	
Molybdenum:	Inorganic forms	125 µg	
	Organic forms	62.5 µg	
Phosphorus		1000 mg	
Selenium:	Inorganic forms	52 µg	52 µg
	Organic forms	26 µg	26 µg
Zinc		12 mg	

(3) A formulated water-based beverage must not be mixed with a non-alcoholic beverage as standardised under Standard 2.6.2.

Editorial note:

Other foods such as herbal substances may not be added to formulated water-based beverages unless permitted elsewhere in the *Food Standards Code*.

Standard 1.4.4 regulates prohibited and restricted plants and fungi, and Standard 1.3.1 regulates food additives.

3 Labelling

(1) The label on a package of formulated water-based beverage must include declarations of the average quantities, per serving size and per 100 mL of – the substances listed in column 1 of the Table to subclause 2(1) expressed in the units included in column 2 of the Table.

(2) The declarations under subclause 3(1) may be adjacent to or follow a nutrition information panel on the label of a package of formulated water-based beverage, provided that the declarations are clearly distinguished from the nutrition information required by Standard 1.2.8.

(3) The label on a package of formulated water-based beverage that contains one or more of the substances in the Table to subclause 2(1) must include an advisory statement to the effect that -

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‘Consume no more than [amount of one-day quantity (as cans, bottles or mL)] per day’

4 Vitamin and mineral claims

- (1) The label on a package of formulated water-based beverage must not claim the presence of a vitamin or mineral unless -
- (a) the reference is required elsewhere in this Code; or
 - (b) the reference is specifically permitted by this clause.
- (2) The label on a package of formulated water-based beverage may only claim the presence of a vitamin or mineral in the food if -
- (a) the food contains -
 - (i) at least 10% of the recommended dietary intake for that vitamin or mineral in a serving of that food or, in relation to a food which requires dilution or preparation according to directions, the quantity of the food which when diluted or prepared produces a normal serving; or
 - (ii) at least 10% of the amount specified in column 3 of the Schedule to this Standard for that vitamin or mineral in a normal serving of that food, or in relation to a food which requires dilution or preparation according to directions, the quantity of the food which when diluted or prepared produces a normal serving; and
 - (b) the amount claimed does not exceed the amount specified in column 2 of the Table to paragraph 2(1); and
 - (c) the label on the package of the food includes a statement in accordance with clause 9 of Standard 1.3.2.

SCHEDULE

Additional permitted forms and intake amounts for vitamins and minerals in Formulated Water-Based Beverages

Column 1 Vitamin or Mineral	Column 2 Permitted forms	Column 3 Amount ¹
Biotin	d-biotin	100 µg
Pantothenic acid	d-calcium pantothenate Dexpanthenol d-sodium pantothenate	7 mg
Calcium	Calcium hydroxide Calcium oxide Calcium sulphate	800 mg

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Chromium	<i>Inorganic forms:</i> Chromic chloride <i>Organic forms:</i> High chromium yeast Chromium picolinate Chromium nicotinate Chromium aspartate	200 µg
Copper	<i>Inorganic forms:</i> Cupric carbonate Cupric sulphate <i>Organic forms:</i> Copper gluconate Copper-lysine complex Cupric citrate	3.0 mg
Magnesium	Magnesium citrate Magnesium hydroxide	320 mg
Manganese	<i>Inorganic forms:</i> Manganese carbonate Manganese chloride Manganese sulphate <i>Organic forms:</i> Manganese citrate	5.0 mg
Molybdenum	<i>Inorganic forms:</i> Sodium molybdate <i>Organic forms:</i> High molybdenum yeast	250 µg
Phosphorus	Magnesium phosphate, monobasic Phosphoric acid Potassium phosphate, dibasic Potassium phosphate, tribasic Sodium phosphate, dibasic Sodium phosphate, monobasic Sodium phosphate, tribasic	1000 mg
Selenium	<i>Inorganic forms:</i> Sodium selenate Sodium selenite <i>Organic forms:</i> Selenomethionine	70 µg

¹ The amount represents the recommended dietary intake for the permitted forms of calcium, magnesium, phosphorus and selenium and the estimated safe and adequate daily dietary intake for the remaining minerals listed in column 1 of the Schedule.

APPENDIX 2

Nutrition and Ingredients information for Sanitarium WaterPlus™.

WaterPlus™ is currently manufactured in New Zealand in accordance with the New Zealand Dietary Supplements Regulations (1985)

NUTRITION INFORMATION (AVERAGE)		
Serving Size: 710mL Servings per package:1		
	Per Serve	Per 100mL
Energy (kJ)	10	2
(Cal)	2	<1
Protein (g)	0.0	0.0
Fat, total (g)	0.0	0.0
- Saturated fat (g)	0.0	0.0
Carbohydrate, total (g)	0.1	<0.1
- Sugars (g)	0.0	0.0
Sodium (mg)	41	6
Potassium (mg)	41	6
Calcium (mg)	80 (10%)*	14
Magnesium (mg)	32 (10%)*	5
Zinc (mg)	1.2 (10%)*	0.2
Thiamin (mg)	0.29 (25%)*	0.05
Niacin (mg)	2.6 (25%)*	0.4
Pantothenic acid (mg) (Vitamin B5)	1.2	0.2
Vitamin B6 (mg)	0.45 (25%)*	0.06
Vitamin B12 (ug)	0.5 (25%)*	0.07
Vitamin C (mg)	11 (25%)*	2
Vitamin E (mg)	0.8 (10%)*	0.1

* = Percentage of Recommended Dietary Intake.

Ingredients:

Water [99%], Minerals (Magnesium Gluconate, Calcium Lactate, Potassium Bicarbonate, Sodium Chloride, Zinc Gluconate), Vitamins (C, B3, E acetate, B5, B6, B1, B12), Food Acids (Citric acid, Malic acid), Natural Flavourings, Sweetener (Sucralose).