

4-05 25 May 2005

DRAFT ASSESSMENT REPORT

APPLICATION A470

FORMULATED BEVERAGES

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 6 July 2005 SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

(See 'Invitation for Public Submissions' for details)

FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Australian Government; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Australian Government, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Australian Government, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared a Draft Assessment Report for Application A470; and prepared a draft variation to the *Australia New Zealand Food Standards Code* (the Code).

FSANZ invites public comment on this Draft Assessment Report based on regulation impact principles and the draft variation to the Code for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Final Assessment for this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat inconfidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand PO Box 7186 Canberra BC ACT 2610 AUSTRALIA Tel (02) 6271 2222 www.foodstandards.gov.au Food Standards Australia New Zealand PO Box 10559 The Terrace WELLINGTON 6036 NEW ZEALAND Tel (04) 473 9942 www.foodstandards.govt.nz

Submissions need to be received by FSANZ by 6pm (Canberra time) 6 July 2005.

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ Website and will apply to all submitters.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the <u>Standards Development</u> tab and then through <u>Documents for Public Comment</u>. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing <u>slo@foodstandards.gov.au</u>.

Assessment reports are available for viewing and downloading from the FSANZ website <u>www.foodstandards.gov.au</u> or alternatively paper copies of reports can be requested from FSANZ's Information Officer at <u>info@foodstandards.gov.au</u> including other general enquiries and requests for information.

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Executive Summary and Statement of Reasons

Food Standards Australia New Zealand (FSANZ) received an Application from the Australian Beverages Council Limited (formerly the Australasian Soft Drink Association) on 26 June 2002 seeking the development of a new standard in the *Australia New Zealand Food Standards Code* (the Code) for formulated beverages (FB).

FB are described as non-alcoholic, water-based, flavoured beverages containing claimable amounts of a range of vitamins and minerals. Currently only three vitamins (vitamin C, folate and beta-carotene) are permitted to be added to general purpose beverages including juices and fruit drinks containing at least 25% fruit juice. Application A470 is seeking permissions for the addition of 23 vitamins¹ and minerals, a range of food additives excluding caffeine and carbon dioxide, and the use of some fruit-based ingredients and sugar².

This Draft Assessment discusses issues on the regulation of FB and proposes a preferred regulatory option. FSANZ seeks comment on this Draft Assessment, particularly in relation to the expected impact(s) of the proposed regulatory options from all interested parties. Comments received will assist in the preparation of a Final Assessment, including a recommended regulatory approach for FB.

Regulatory Problem

Currently there are no specific provisions in the Code for the addition of vitamins and minerals to FB. Consequently, any possible public health benefits and/or safety risks have not yet been assessed so that consumer confidence can be assured. There are potential hazards to consumers of FB from over-exposure to some vitamins and minerals and from excess energy (kilojoules) consumption. Most consumers would be unaware of any potential risks associated with the consumption of FB. Hence an assessment of FB is essential to protect public health and safety.

In addition, Australian beverage manufacturers are currently unable to manufacture FB, unless they utilise the existing Formulated Supplementary Sports Foods (FSSF) Standard. This is incongruous with the intent of the FSSF Standard, which is designed to regulate special-purpose food. These products, however, can be lawfully manufactured in New Zealand under the *New Zealand Dietary Supplements Regulations 1985* (NZDSR). New Zealand manufacturers are able to produce FB and sell them in Australia in accordance with the Trans Tasman Mutual Recognition Arrangement.

This situation results in a serious inequity between the New Zealand and Australian beverage industries. Furthermore, the Australian beverage industry is prevented from innovating and developing new products in response to emerging consumer demands. This system of regulations also is inconsistent with the intent of the Code to create a single set of food regulations in Australia and New Zealand.

¹ Note both retinol and carotene forms of vitamin A are considered separately increasing the total number of vitamins and minerals assessed to 24.

² For the purpose of this report, the term 'sugar' as it relates to FB refers to total sugars i.e. monosaccharides and disaccharides.

Objectives

In the context of FSANZ's statutory objectives, which includes having regard to Ministerial policy guidance, the specific objectives of Application A470 are to:

- protect the public health and safety of consumers of FB; and
- ensure a regulatory system which promotes efficiency and competitiveness for all sections of the FB industry.

Risk Assessment

A risk assessment has been conducted in relation to the addition of vitamins and minerals to FB. Both potential benefits and risks have been considered. A Nutrition Assessment (at Attachment 5) has been undertaken to assess the potential nutrition and health need of the addition of vitamins and minerals to FB.

The potential for FB to result in a health risk associated from the over-consumption of the requested vitamins and minerals has also been examined (at Attachment 6).

The methodology used for dietary modelling of the vitamins and minerals is described in Attachment 7. The requested food additives for addition to FB have also been examined. A detailed report outlining the nature of any potential hazard and a characterisation of the risk is provided in Attachment 8.

Risk Management

This Draft Assessment Report considers a number of issues relevant to the regulation of FB including the purpose and definition of FB, the appropriateness of FB as a vehicle for voluntary fortification and the labelling of FB.

Regulatory Options and Impact Analysis

There are three proposed regulatory options for addressing this Application:

- Option 1 Maintain Status Quo i.e. no explicit permissions for FB in the Code.
- Option 2 Amend the Code to permit the addition of a defined set of vitamins and minerals to FB (as detailed in the table on Page 9) excluding cordials, in addition to a restriction on the total sugar content of FB.
- Option 3 Amend the Code to permit the addition of vitamins and minerals to FB and cordials as requested by the Applicant without any other specific compositional requirements.

For each regulatory option, an impact analysis has been undertaken to assess potential costs and benefits to the identified affected parties.

Consultation

The Initial Assessment Report for this Application was released for public comment from 15 January to 26 February 2003 (six weeks). A total of 19 submissions were received and are summarised at Attachment 10. Issues raised in submissions are discussed in this report. FSANZ now seeks public comment on this Draft Assessment Report in order to proceed to Final Assessment.

Conclusion

Option 2 delivers net-benefits in comparison with Option 1.

Option 2 fulfils the specific objectives of this Application. The health and safety of consumers is protected through limits on the level of fortification to ensure safe levels of consumption, and by excluding specific nutrients that could be potentially hazardous, or where their safety cannot be verified. The main benefit offered under Option 2 is the elimination of the opportunity cost incurred by a large part of Australian industry, which cannot supply the domestic market under the current regulatory arrangements. This situation is resolved in Option 2 by allowing the manufacture of FB in Australia.

Option 3 provides greater net-benefits to industry compared with Option 1. These benefits to industry also exceed the benefits from Option 2, because under Option 3 manufacturers may draw from a broader range of vitamins and minerals for future development of FB, eliminating the time and cost of obtaining regulatory approval and facilitating faster innovation. However, Option 3 could potentially impose large costs on consumers, in comparison with Option 1, by allowing specific nutrients that may have adverse health impacts. In addition, by not limiting the levels of vitamins and minerals in FB, this could possibly cause overexposure to these nutrients, and potential harm to consumers. Option 3 does not achieve the objective of protecting public health and safety, and is thus rejected.

Overall, Option 2 is the preferred regulatory option.

Proposed Regulatory Approach

On the basis of public health and safety, and having regard to Ministerial policy guidance, the promotion of fair trading and the desirability for an efficient and competitive food industry, FSANZ is proposing the following regulatory approach for FB:

- classification of FB as a general-purpose food;
- inclusion of a definition for FB in the Code, in association with a maximum limit of 24% fruit ingredients;
- exclusion of cordials as FB;
- restriction of total sugar content of FB to 7.5 g/100 ml;
- application of generic labelling requirements to FB;
- permissions for the range of food additives requested by the Applicant (as detailed in Attachment 9); and

• permissions for the addition of vitamins and minerals in amounts to allow 'source' (10% Recommended Dietary Intake (RDI)) and/or 'good source' (25% RDI) claims with the exception of vitamin C (100% RDI) per 600 ml reference quantity as outlined in the table below:

Vitamin / Mineral	Maximum Claimable Amount Per 600 ml Reference Quantity	No Public Health and Safety Concerns	Consistent with FSANZ's s.10 (2)(c), s.10(2)(d) and s.10(2)(e) Objectives*
Beta-carotene	200 µg	\checkmark	\checkmark
Thiamin	0.28 mg	\checkmark	\checkmark
Riboflavin	0.43 mg	\checkmark	\checkmark
Niacin	2.5 mg	\checkmark	\checkmark
Folate	50 μg folic acid	\checkmark	\checkmark
Vitamin B ₆	0.4 mg pyridoxine	\checkmark	\checkmark
Vitamin B ₁₂	0.5 μg	\checkmark	\checkmark
Vitamin C	40 mg in total of L-ascorbic acid and dehydroascorbic acid	✓	\checkmark
Vitamin D	2.5 μg	\checkmark	\checkmark
Vitamin E	2.5 mg alpha-tocopherol equivalents	\checkmark	\checkmark
Pantothenic Acid	1.3 mg	\checkmark	\checkmark
Calcium	200 mg	\checkmark	\checkmark
Iodine	38 µg	\checkmark	\checkmark
Iron	3 mg	\checkmark	\checkmark
Magnesium	80 mg	✓	✓
Selenium	17.5 µg (inorganic and organic forms)	\checkmark	\checkmark

* FSANZ Act section 10(2)(c) the desirability of an efficient and internationally competitive food industry. FSANZ Act section 10(2)(d) the promotion of fair trading in food. FSANZ Act section 10(2)(e) any written policy guidelines formulated by the Ministerial Council.

Statement of Reasons

FSANZ recommends that the proposed draft variations to the Code (Attachment 1), incorporating defined vitamin and mineral permissions, specific compositional requirements, and a definition for FB, be approved for the following reasons:

- the regulation of FB provides assurance for consumers regarding the protection of public health and safety by:
 - permitting the safe addition of vitamins and minerals to FB;
 - permitting the addition of vitamins and minerals to FB where an inadequacy or deficiency exists; and
 - setting a prescribed limit on the total sugar content of FB;
- regulation of FB ensures certainty for industry balanced against the need to provide consumer choice and prevent consumers being misled regarding the nutritional quality of the product;

- the variations to the Code meet FSANZ's statutory obligations and are consistent with Ministerial policy guidance on voluntary fortification;
- the permitted range of vitamins and minerals is consistent with the principles of minimum effective regulation and the promotion of fair trading;
- the variations to the Code provide an effective regulatory framework within which industry can work efficiently and competitively;
- the inclusion of permissions for FB in the Code promotes equity by providing a regulation which enables the manufacture of FB in Australia;
- the explicit recognition of FB in the Code provides greater certainty for industry and reduces both the costs of compliance and enforcement; and
- the regulation impact assessment concludes that the preferred regulatory option of permitting net benefits from permitting FB outweigh any potential costs to affected parties.

1. Introduction

FSANZ received an Application from the Australian Beverages Council Limited³ on 26 June 2002 requesting the development of a new standard in the Code for formulated beverages (FB).

FB are described as non-alcoholic, water-based, flavoured beverages containing claimable amounts of a range of vitamins and minerals. They are examples of recent innovative drinks that represent a growing sector of the global food market. Currently only three vitamins (vitamin C, folate and beta-carotene) are permitted to be added to general-purpose beverages including juices and fruit drinks containing at least 25% fruit juice as compared with the Application A470 request for 23 vitamins⁴ and minerals. Permissions for a range of food additives, excluding caffeine and carbon dioxide, the use of some fruit-based ingredients and sugar are also being sought.

This Draft Assessment Report discusses issues regarding the regulation of FB and proposes a preferred regulatory option and draft variations to the Code (Attachment 1). FSANZ seeks comments on this Draft Assessment Report, particularly in relation to the expected impact(s) of the proposed regulatory options from all interested parties. Comments received will assist in the preparation of the Final Assessment.

A glossary of commonly used acronyms in this Report is at Attachment 2.

1.1 Nature of Application

Specifically, the Applicant is seeking permissions for FB as follows:

- 1. the addition of vitamins and minerals, in amounts to allow 'source' (10% recommended dietary intake (RDI)) and/or 'good source' (25% RDI) claims with the exception of vitamin C at 100% RDI per 600 ml reference quantity as outlined in the table below;
- 2. sugar at unspecified amounts;
- 3. fruit juice, puree concentrates, orange peel extract and/or comminuted fruit; and
- 4. a range of food additives (57 in total) currently permitted in the Code excluding caffeine and carbon dioxide .

Vitamin / Mineral	Maximum Claimable Amount Per 600 ml Reference Quantity
Vitamins	
Vitamin A	187.5 µg
Thiamin	0.275 mg
Riboflavin	0.425 mg
Niacin	2.5 mg
Folate	50 µg folic acid
Vitamin B ₆	0.4 mg pyridoxine
Vitamin B ₁₂	0.5 µg

³ Formerly known as the Australasian Soft Drink Association Limited.

⁴ Note both retinol and carotene forms of vitamin A are considered separately increasing the total number of vitamins and minerals assessed to 24.

Vitamin / Mineral	Maximum Claimable Amount Per 600 ml Reference Quantity
Vitamin C	40 mg in total of L-ascorbic acid and dehydroascorbic acid
Vitamin D	2.5 µg
Vitamin E	2.5 mg alpha-tocopherol equivalents
Biotin	7.5 µg
Pantothenic Acid	1.25 mg
Minerals	
Calcium	200 mg
Chromium	50 μg (inorganic forms)
Copper	0.75 mg (inorganic and organic forms)
Iodine	37.5 µg
Iron	3 mg
Magnesium	80 mg
Manganese	1.25 mg (inorganic and organic forms)
Molybdenum	62.5 μg (inorganic forms)
Phosphorus	250 mg
Selenium	17.5 μg (inorganic and organic forms)
Zinc	3 mg

1.1.1 Basis of the Application

The Applicant requested the creation of a standard for FB, as a general-purpose food, partly as a means of addressing the purported disadvantage that Australian beverage manufacturers are experiencing with the importation of FB from New Zealand under the *Trans-Tasman Mutual Recognition Arrangement* (TTMRA). Currently in New Zealand such beverages can be manufactured to the New Zealand *Dietary Supplements Regulations 1985* (NZDSR)⁵, and exported and sold legally in Australia under the TTMRA. There is no explicit standard permitting manufacture of FB in Australia for sale on the Australian market. Some FB are being manufactured as special-purpose food under Standard 2.9.4 – Formulated Supplementary Sports Foods (FSSF) of the Code. However, this Standard is not intended to regulate FB and industry's preference is for explicit FB regulations. The Applicant also cited consumer demand for FB as underpinning the basis of their request.

1.1.2 Amendments to the original Application

Since the lodgement of Application A470 there have been a number of subsequent amendments. These amendments have ranged from minor changes addressing typographical errors to more substantial compositional changes. In terms of the latter, the original Application sought permissions for vitamins and minerals equivalent to those permitted for formulated supplementary sports foods (FSSF) in Standard 2.9.4 of the Code. These permissions have since been revised to 25% RDI with the exception of vitamin C, at 100% RDI per 600 ml reference quantity. The Applicant also withdrew the request for carbon dioxide as a permitted ingredient together with the addition of cyclamate and quinine as food additives. A more detailed summary of the amendments to Application A470 is at Attachment 3.

⁵ <u>http://www.legislation.govt.nz/browse_vw.asp?content-set=pal_regs</u>

1.1.3 Requests for additional information

Although work on this cost-recovered Application commenced immediately, the statutory timeframe has been suspended on three separate occasions pending receipt of information requested from the Applicant.

This additional information, requested by FSANZ under section 34 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), was necessary to enable a comprehensive, robust assessment of the Application to be completed.

These information requests primarily related to obtaining information on: FB consumption and usage data; product substitution; and proposed marketing strategies. FSANZ also sought clarification as to the requested vitamin and mineral permitted forms and food additives.

The statutory timeframe for the Application was suspended for a total of 460 days as FSANZ sought this additional information from the Applicant.

1.1.4 Extension of statutory timeframe

In addition to the suspension associated with the requests for additional information, the timeframe for Application A470 was also extended as a result of the following:

- ANZFA to FSANZ transition period. All Applications being assessed by FSANZ at 30 June 2002 were given an extension of three months to the statutory timeframe as part of the changeover from the Australia New Zealand Food Authority (ANZFA) to FSANZ;
- delay in receipt of fees which resulted in an additional 73 days being added to the statutory timeframe for Application A470; and
- extension of the statutory timeframe by six months as permitted by section 35(2) of the FSANZ Act. This was due to the complexity and volume of work required to be completed, particularly in relation to the risk assessment of the 23 vitamins and minerals, and the numerous food additives being requested.

The current revised completion date for Application A470 is 22 August 2005.

2. Regulatory Problem

Currently there are no specific provisions in the Code for the addition of vitamins and minerals to FB. Consequently, any possible public health benefits and/or safety risks have not yet been assessed so that consumer confidence can be assured. There are potential hazards to consumers of FB from over-exposure to some vitamins and minerals and from excess energy (kilojoules) consumption. Most consumers would be unaware of any potential risks associated with the consumption of FB. Hence an assessment of FB is essential to protect public health and safety.

In addition, Australian beverage manufacturers are currently unable to manufacture FB, unless they utilise the existing Formulated Supplementary Sports Foods (FSSF) Standard.

This is incongruous with the intent of the FSSF Standard which is designed to regulate special-purpose food. These products, however, can be lawfully manufactured in New Zealand under the NZDSR. New Zealand manufacturers are able to produce FB and sell them in Australia in accordance with the TTMRA. This situation results in a serious inequity between the New Zealand and Australian beverage industries.

Furthermore, the Australian beverage industry is prevented from innovating and developing new products in response to emerging consumer demands. This system of regulations also is inconsistent with the intent of the Code to create a single set of food regulations in Australia and New Zealand.

3. **Objectives**

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out, in order of priority, in section 10 of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

In having regard to the above five matters, FSANZ does so initially without assigning precedence to any one particular matter. However, FSANZ will on a case-by-case basis, balance these matters and assign them appropriate weightings, given the relevant considerations for a particular application or proposal.

In the context of FSANZ's statutory objectives, which includes having regard to Ministerial policy guidance, the specific objectives of Application A470 are to:

- protect the public health and safety of consumers of FB; and
- ensure a regulatory system which promotes efficiency and competitiveness for all sections of the FB industry.

4. Background

4.1 **Regulatory Framework**

4.1.1 Australia

In Australia, foods are regulated under the Code and therapeutic goods are regulated under the Commonwealth *Therapeutic Goods Act 1989*.

4.1.2 New Zealand

In New Zealand⁶, foods are predominately regulated under the Code, however in some instances foods are being manufactured in accordance with the NZDSR. Products of a therapeutic nature are regulated as medicines under the New Zealand *Medicines Act 1981* or as 'dietary supplements⁷' under the NZDSR.

4.1.2.1 New Zealand Dietary Supplements Regulations 1985

The NZDSR were made under the New Zealand *Food Act 1981*, and commenced in August 1985. In contrast to Australia, these regulations created a separate regulatory category for dietary supplements in addition to those for foods and medicines/therapeutic goods.

In Australia, these 'dietary supplements' could be regarded as foods i.e. food-type dietary supplements (FTDS)⁸ or medicines/therapeutic products depending on the nature of the product.

Details of the permissions for vitamins and minerals contained in the NZDSR are outlined in the table below:

Vitamins	Maximum Daily Dose (for adult) – if specified	Minerals	Maximum Daily Dose (for adult) – if specified
Vitamin A or retinol	3000 µg	Calcium	
Vitamin B1 or thiamin		Chlorine	
Vitamin B2 or riboflavin		Chromium	
Niacin or nicotinic acid	100 mg	Copper	5 mg
Pantothenic acid		Fluorine	
Vitamin B ₆ or pyridoxine		Iodine	
Vitamin B_{12} or	50 µg	Iron	24 mg
cyanocobalamin or			
hydroxycobalamin			
Vitamin C or ascorbic acid		Magnesium	
Vitamin D or calciferol	25 µg	Manganese	

⁶ Prior to 20 December 2001, foods in New Zealand were regulated by the New Zealand *Food Regulations 1984*.

⁷ The NZDSR define a dietary supplement as *any amino acids, edible substances, foodstuffs, herbs, minerals, synthetic nutrients, and vitamins sold singly or in mixtures in controlled dosage forms as cachets, capsules, liquids, lozenges, pastilles, powders, or tablets, which are intended to supplement the intake of those substances normally derived from food.*

⁸ The term food-type dietary supplement (FTDS) is used to emphasise that the products under consideration are regarded as foods. It encompasses those food type products that are manufactured or imported under the New Zealand *Dietary Supplements Regulations 1985* but are referred to as 'dietary supplements'.

Vitamins	Maximum Daily Dose (for adult) – if specified	Minerals	Maximum Daily Dose (for adult) – if specified
Vitamin D or	25 µg	Molybdenum	
cholecalciferol			
Vitamin E		Phosphorus	
Biotin		Potassium	
Vitamin K		Selenium	150 µg
Vitamin K1 or		Sodium	
phytomenadione			
Vitamin K or		Zinc	15 mg
menaphthone			_
Folic acid	300 µg		

Advice from the New Zealand Government⁹ is that the NZDSR were designed to regulate controlled dosage supplements such as tablets and capsules. Furthermore, the NZDSR were intended to cover products not regulated by the food regulations rather than provide a choice of regulatory regimes for the food industry. More recently, the New Zealand Government¹⁰ has indicated that the NZDSR *are not underpinned by a comprehensive risk-based methodology and therefore do not reflect today's best regulatory practice.*

The New Zealand Government¹⁰ has foreshadowed changes to the NZDSR including a preference for the regulation of fortified foods, currently regulated as 'dietary supplements' to be regulated under the Code. The rationale underpinning this preference includes:

- meeting risk management and safety concerns;
- enhancing consumer confidence; and
- contributing to a fair trading environment between New Zealand and Australia.

This preference is consistent with the intent of the *Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Foods Standards System* to establish a single market for food in Australia and New Zealand, underpinned by a single set of food regulations in both countries.

4.1.3 Trans Tasman Mutual Recognition

The *Trans Tasman Mutual Recognition Act 1997* gives effect to the TTMRA in Australia. The TTMRA commenced on 1 May 1998 in Australia and New Zealand to promote closer economic relations and trade between Australia and New Zealand. Under the TTMRA, a range of products, including food, which can be produced in or imported and be legally sold in one country, may be lawfully imported into and sold in the other country, without the necessity of compliance with further requirements imposed by or under the law of the jurisdiction.

The exemptions set out in the *Trans Tasman Mutual Recognition Act 1997*, prescribe legislation that must be complied with irrespective of compliance with the laws of the originating jurisdiction.

⁹ New Zealand Food Safety Authority submission to Proposal P235 – Review of Food-Type Dietary Supplements Initial Assessment Report dated 30 August 2002.

¹⁰ New Zealand Food Safety Authority Discussion Paper No. 01/04 (July 2004) *Proposed Changes to the Dietary Supplements Regulations 1985.*

Specifically, a special exemption applies to the *Therapeutic Goods Act 1989*. This means that New Zealand products captured under the *Therapeutic Goods Act 1989* must comply with that Act irrespective of whether that product complies with the laws of New Zealand. Consequently, products that complied with the NZDSR, *Food Regulations 1984*, or *Medicines Act 1981* that are not considered to be 'therapeutic goods' within the meaning of the *Therapeutic Goods Act 1989* may be lawfully imported from New Zealand and sold in Australia.

4.1.4 Joint Australia and New Zealand Therapeutic Goods Agency

Australia and New Zealand are in the process of establishing a bi-national agency that will regulate therapeutic goods in both Australia and New Zealand. The joint scheme is expected to commence by July 2006. When legislation for therapeutic goods is developed, it is expected that FTDS will be regulated by the Code.

4.1.5 International regulations

4.1.5.1 Codex Alimentarius

Codex has no specific texts that address FB other than its *General Principles for the Addition* of Essential Nutrients to Foods (CAC/GL 09-1987, Amended 1991), which provides guidance to countries in establishing their own regulatory approach to fortification of conventional foods.

4.1.5.2 Overseas regulations

There is a lack of international consistency in the regulation of FB. Although FB can be defined as '*dietary supplements*' under the NZDSR, the regulation of these products, where permitted in overseas jurisdictions, occurs under general provisions for the addition of vitamins and minerals to foods. No overseas regulation pertaining specifically to FB has been identified, although the Applicant advises that many countries, including a number of countries in Asia, allow for the production of vitamin and mineral enhanced beverages. Where they exist internationally, dietary supplements regulations refer to complementary medicines/therapeutic-type dietary supplements (e.g. tablets, capsules etc.), rather than beverages.

While there is no regulatory approach internationally for the addition of vitamins and minerals specific to FB, both Canada and the United States have respectively proposed or extant policies in relation to fortification. A review of the Health Canada policy¹¹ on fortification was released in early 2005. The proposed approach allows for an expanded range of fortified products through discretionary fortification and does not preclude beverages except for those containing alcohol. The United States Food and Drug Administration¹² does not consider it 'appropriate to fortify fresh produce; meat, poultry, or fish products; sugar; or snack foods such as candies and carbonated beverages'.

¹¹ Health Canada (2005) Addition of Vitamins and Minerals to Foods 2005 – Health Canada's Proposed Policy and Implementation Plans

¹² USFDA: Title 21, *Food and Drugs: Fortification Policy*. 45 Federal Register 6323 (1980), as amended at 58 Federal Register 2228 (1993)(codified at 21 CFR §104.20).

Similarly, the European Commission (EC)¹³ proposes to restrict the addition of vitamins and minerals to certain foods such as alcohol and fresh produce such as fruits, vegetables, meat, poultry, fish etc. The EC purport that products with an 'undesirable' nutrient profile (i.e. high in sugar, fat and/or salt) will be dissuaded from adding vitamins and minerals due to their inability to meet the proposed nutrition and health claims criteria.

4.2 Ministerial Policy Guidance

In accordance with the section 10 objectives of the FSANZ Act (see Section 3 above), in developing or varying a standard, FSANZ must have regard to a number of specific matters including any written policy guidelines formulated by the Ministerial Council.

Since completion of the Initial Assessment of Application A470, the Ministerial Council has adopted policy guidance on fortification of food with vitamins and minerals, and nutrition, health and related claims, both being of direct relevance to consideration of Application A470. The Ministerial Council has also commenced policy development work in relation to the addition of substances other than vitamins and minerals to food.

4.2.1 Fortification with vitamins and minerals

In May 2004, the Ministerial Council adopted a Policy Guideline on the *Fortification of Food with Vitamins and Minerals*¹⁴ (Policy Guideline). The Policy Guideline includes 'High Order' Policy Principles, which are FSANZ's statutory objectives, and are supplemented by separate 'Specific Order' Policy Principles and 'Additional Policy Guidance' for both mandatory and voluntary fortification. The 'High Order' Policy Principles restate the objectives of the FSANZ Act and take precedence over the policy guidance specifically provided on voluntary fortification.

The Policy Guideline contains seven 'Specific Order' Policy Principles that FSANZ must have regard to when considering voluntary fortification. The first 'Specific Order' Policy Principle lists five conditions that can be used as a basis for permitting voluntary fortification. Of relevance to Application A470 is where there is:

- a need for increasing the intake of a vitamin or mineral demonstrated by evidence of deficiency or inadequate intake; or
- generally accepted scientific evidence that an increase in a vitamin and/or mineral can deliver a health benefit.

In response to the Policy Guideline, FSANZ is in the process of developing the *Fortification Implementation Framework*¹⁵. This Framework is an internal document, which details FSANZ's decision making, in light of the Policy Guideline, on the addition of vitamins and minerals to food.

 ¹³ Commission of the European Communities Proposal for a Regulation of the European Parliament And Council on The Addition of Vitamins and Minerals and of Certain other Substances to Foods COM(2003)
671 final. Brussels

¹⁴ Policy Guideline on the Fortification of Food with Vitamins and Minerals. Available from <u>Food Regulation</u> <u>Secretariat</u>, <<u>http://www.health.gov.au/internet/wcms/publishing.nsf/Content/Food+Regulation+Secretariat-</u> 1>

¹⁵ The draft Fortification Implementation Framework is available at <u>www.foodstandards.gov.au</u>

Given FSANZ is required to have regard to the Policy Guideline in its broader consideration of Application A470, Australian Beverages were invited to respond to the Policy Guideline, particularly in terms of the 'Specific Order' Policy Principles for voluntary fortification to ensure procedural fairness had been afforded to the Applicant.

4.2.2 Nutrition, health and related claims

In December 2003, the Ministerial Council referred a *Policy Guideline on Nutrition, Health and Related Claims*¹⁶ to FSANZ for the development of a new standard to permit a broader range of claims.

FSANZ has commenced work on Proposal P293 - Nutrition, Health and Related Claims, which is the means by which FSANZ will, having regard to ministerial policy guidance, develop a Standard for the regulation of nutrition, health and related claims and an appropriate management system to support enforcement of the Standard.

Claims relating to the vitamin and/or mineral content of a food are currently regulated in Standard 1.3.2 – Vitamins and Minerals of the Code. At this stage, the review of the criteria for vitamin and mineral content claims has been excluded from consideration in Proposal P293. However, other claims (e.g. nutrition function and health claims) in relation to fortified foods including FB, do fall within the regulatory framework for nutrition, health and related claims. Therefore FB will be subject to the existing requirements for nutrition and health claims (i.e. Standard 1.2.8 – Nutrition Information Requirements, the Code of Practice on Nutrient Claims on Food Labels and in Advertisements (CoPoNC) and Transitional Standard 1.1A.2 – Health Claims), and will in time be required to meet the provisions of the new Standard.

4.2.3 Addition of substances other than vitamins and minerals

Recently the Ministerial Council initiated work on developing policy guidance on 'the addition of substances other than vitamins and minerals'. Further information on this is available from the Food Regulation Secretariat¹⁷. Although Application A470 is not seeking permissions for the addition of 'substances other than vitamin and minerals' to FB, ultimately policy guidance on this matter will have implications in the broader consideration of FTDS (see Section 4.4.1), the scope of which previously included FB.

4.3 Relevant Standards in the Code

The generic regulations contained in Chapter 1 of the Code, that apply to all foods, and regulations in Chapter 2 that are specific to various commodities, are of particular relevance to the assessment of FB.

The most relevant regulations in Chapter 1 are:

• Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions which contains the Schedule of permitted forms of vitamins and minerals;

¹⁶ Policy Guideline on Nutrition, Health and Related Claims. Available from Food Regulation Secretariat , ">http://www.health.gov.au/internet/wcms/publishing.nsf/Content/Food+Regulation+Secretariat-1>

¹⁷ Australian Department of Health and Aging, Food Regulation Secretariat http://www.health.gov.au/internet/wcms/publishing.nsf/Content/Food+Regulation+Secretariat-1

- Standard 1.2.8 Nutrition Information Requirements which sets out the labelling requirements for the provision of nutrition information including nutrition claims;
- Standard 1.3.1 Food Additives which regulates the use of food additives in production and processing and currently includes specific additive permissions for fruit juices, drinks and water based flavoured drinks; and
- Standard 1.3.2 Vitamins and Minerals, which regulates the addition of vitamins and minerals to food, and the claims which can be made about the vitamin and mineral content of food.

Standard 1.3.2 establishes minimum and maximum claim limits for permitted vitamins and minerals whereby the minimum is 10% of the RDI per serve and the maximum is up to 1250% of the RDI per serve. In effect this deters the addition of vitamins and minerals in amounts that exceed the maximum claim limit. Where necessary however, absolute maximum amounts are established for those few vitamins and minerals where there is a potential public health and safety risk.

Currently, Standard 1.3.2 permits the addition of the carotenoid forms of vitamin A (i.e. betacarotene), vitamin C and folic acid in moderate amounts to beverages that contain at least 25% fruit- or vegetable juice; and the addition of vitamin C in moderate amounts to fruitbased cordials. In addition, Standard 1.3.2 sets out the conditions and criteria for claims in relation to the vitamin and mineral content of food, including 'source' (10% RDI) and 'good source' (25% RDI) claims.

The relevant regulation in Chapter 2 is:

• Standard 2.6.2 – Non-alcoholic Beverages and Brewed Soft Drink, which regulates the majority of non-alcoholic, water-based beverages and includes product definitions, compositional and labelling requirements.

Other pertinent Standards in Chapter 2 that merit consideration include:

- Standard 2.6.4 Formulated Caffeinated Beverages (FCB) which allows for the addition of certain vitamins and minerals to FCB and details specific labelling requirements; and
- Standard 2.9.4 Formulated Supplementary Sports Foods (FSSF) defines and regulates the composition, including permissions for broad range of vitamins and minerals, and labelling of foods specially formulated to assist sports people in achieving specific nutritional or performance goals. FSSF must be labelled as 'Unsuitable for children under 15 years of age and pregnant women: Should only be used under medical or dietetic supervision'.

4.4 Other Relevant FSANZ Activities

4.4.1 Proposal P235 – Review of Food-Type Dietary Supplements

Prior to receipt of this Application, FB were considered within the scope of Proposal P235 – Food-Type Dietary Supplements.

The aim of this Proposal is to develop regulations in Australia and New Zealand in recognition of the growing market for foods containing added substances with health-related properties. FTDS often contain substances such as vitamins, minerals, non-culinary herbs and other extracts where the presence or amounts are beyond the current permissions in the Code, but are permitted under the NZDSR.

The Proposal P235 Initial Assessment Report was previously released for public comment on 26 June 2002. However, its progress has been deferred pending development of policy guidance from the Ministerial Council in relation to the addition of substances other than vitamins and minerals.

The development of policy guidance on the addition of vitamins and minerals to food provides a framework to progress Application A470 independently of Proposal P235.

4.4.2 Application A424 – Fortification of Calcium to Foods

In March 2005, FSANZ completed a First Review of Application A424 – Fortification of Foods with Calcium that is seeking to amend Standard 1.3.2 – Vitamins and Minerals of the Code, to permit the voluntary addition of calcium to fruit- and vegetable juices and drinks, soups and savoury biscuits. The First Review reaffirmed FSANZ's previous approval to permit the addition of calcium to the requested foods. FSANZ has notified the Ministerial Council of its decision at First Review.

4.5 Current Formulated Beverage Market and Product Range

In June 2003, FSANZ commissioned surveys in both Australia and New Zealand to assist in the assessment of Application A470 and Proposal P235. The objectives were two-fold. Firstly, to identify those products available which are consumed as food but are marketed or formulated as FTDS; and secondly, to examine the FTDS industry focusing on structure and market share. For both countries, beverages comprised the largest category. More recently (March/April 2005), FSANZ staff conducted surveys to determine the current FB product range in both Australia and New Zealand. Using the results from the 2003 FTDS Surveys as a base line, products were assessed in terms of availability, composition and claims.

A summary of the key findings in relation to the FB market and product range is discussed below. For specific details on the current product range refer to Attachment 4.

4.5.1 Formulated beverages market

4.5.1.1 International

FB are the latest in a series of innovative, non-alcoholic, water-based drinks that represent a growing sector of the global food market.

Current market trends indicate a shift away from beverages that are 'nutritionally inferior' towards healthier alternatives. This shift is reflected by consumers limiting soft drink intake, looking for functional beverages, being conscious of fat and sugar levels, and meeting health recommendations such as 6-8 glasses of water a day¹⁸.

¹⁸ Commercial-in-confidence industry data.

Sales of FB, FCB and other 'fortified' beverages in the United States (US), one of the most established overseas markets, have experienced a growth from a niche market in 1997 to an estimated \$US8 billion today and an expected \$US12 billion per year by 2007¹⁹. The majority of this growth has been attributed to 'energy drinks' and vitamin-enhanced beverages.

FB sales worldwide have grown at rates in excess of 10% per year. Market intelligence suggests some recent slowing in these growth rates. In 2005 growth should be a little less than 10% per year, slowing to around 5% over the next five years²⁰. Notwithstanding this decline in growth, the FB category is seen as 'relatively underdeveloped' with capacity for continuing expansion²⁰. FB follow other innovative, non-alcoholic water-based beverages, especially the energy drinks and sports drinks, and while growth in these products was strong in the past, these markets have now matured²⁰. Based on current market trend data²¹ showing consumers want products that are healthy, convenient and good value for money, there appears to be enormous potential for market growth of FB.

Internationally, the FB market is concentrated and much of the market is dominated by a few multinational companies, principally the traditional soft drink bottlers. Innovative, non-alcoholic, water-based drinks have increasingly attracted the attention of the multinational soft drink bottlers, looking for new growth areas to maintain their competitiveness as their traditional carbonates sector has matured. They have invested heavily in the FB sector by acquisition, new product development and extension of existing brands. Notwithstanding this activity, there remains a significant, though minor, share of the market that is supplied by small and medium sized companies.

4.5.1.2 New Zealand

The current regulatory arrangements have allowed the New Zealand non-alcoholic beverage industry to respond to international market trends and develop innovative products. New Zealand manufacturers are noted as early adopters of overseas trends and the local market has responded well to the offering. Enhanced fruit drinks first appeared in New Zealand stores in 1996, while the 'sports water' category was developed in 2001. In 2002 the New Zealand domestic market was valued at around \$NZ15 million²². Today, one company continues to be the market leader, with competition from other major beverage manufacturers plus a number of smaller manufacturers. Until recently, a distinctive feature of the New Zealand market had been the locally owned status of the market leader; which is now a division of a multinational subsidiary. Imports of FB onto the New Zealand market are negligible.

This solid manufacturing activity provided a base to expand into exports, valued at around \$NZ35 million in 2004, of which \$NZ32 million is exported to Australia²³.

¹⁹ An Australasian Standard for Formulated Water-Based Non-Alcoholic (Functional) Beverages – The Economic Benefits. The Allen Consulting Group, July 2002.

²⁰ Functional Soft Drinks – An International Perspective. Leatherhead Food International, November 2003.

²¹ What's Hot Around the Globe, ACNeilsen Global Services, December 2004 – used in the Retail World article.

²² The New Zealand Market for Food-Type Dietary Supplements. Food Concepts & Design Limited (NZ), June-August 2003.

²³ Statistics New Zealand – Overseas trade exports for calendar years 1995-2004. Reference number JOA7632.

The 2005 FB Survey identified ten products, compared with nine in the 2003 FTDS survey. There are five new products while four have been withdrawn from the market. Thus, there appears to have been a plateau in the number of products on the New Zealand market. Only one imported product was found on the New Zealand market in 2005.

4.5.1.3 Australia

The FB market in Australia is relatively small but is experiencing growth.

Structurally, the market is comprised of several large to medium companies with an increasing number of smaller players entering the field. It is continuing to evolve with repositioning and take-overs of existing FB. This evolution also involves a lot of opportunistic activity, with importers, distributors and manufacturers experimenting with new products to gauge consumer acceptance. Consequently, there is a considerable 'churning' of these types of products.

Unlike the New Zealand market, the Australian FB market has changed somewhat since 2003. In the 2003 Australian FTDS survey, only three products were identified that would be classified as FB. All three products were imported from New Zealand via the TTMRA. In the 2005 FB Survey the FB product range had significantly increased to 20. Of these, only four are being imported from New Zealand. The remaining products are either being manufactured under Standard 2.9.4 – Formulated Supplementary Sports Foods or appear to be non-compliant with the Code. Whilst the composition of the FB manufactured and labelled as FSSF include some of the vitamin and mineral permissions permitted under Standard 2.9.4, manufacturers do not utilise the amino acid and other ingredients permissions in these formulations.

The market for FB produced under Standard 2.9.4 is valued at approximately \$A10 million for 2004 (*personal communication* Tony Gentile 2005). Whilst some local companies have produced niche FB under this Standard, the larger multinational beverage manufacturers in Australia believe the mandatory advisory labelling requirements are particularly onerous and adversely affect consumer perceptions and marketing of FB. They also quote resistance from retailers to stock any item that is 'not suitable for children' because the retailers believe they could be legally liable if such a product was sold to a child.

In addition to the local production estimate of \$A10 million, a further \$A40 million worth of FB is estimated to be imported from New Zealand.

4.5.2 Formulated beverage products

4.5.2.1 New Zealand

As previously reported, the 2005 New Zealand Survey identified a total of 10 products in the marketplace that would be classified as FB. The ingredients ranged from FB consisting of water, flavouring and no added sugar to FB with greater than 5% fruit juice and added sugar. These formulations have remained relatively constant compared with the ingredient listings of the 2003 Survey products.

The energy and macronutrient composition per 100 ml varies between FB, however it has not changed significantly since the 2003 Survey. The protein and fat contents of all FB surveyed were less than 1 g per 100 ml. FSANZ has classified FB into four categories and provided a summary of the energy and total sugar content in the Table below:

FB Product Range	Total Sugar (%)	Energy (k.I. ner 100 ml)
Water Generative Luce added mean		2
water, flavouring + no added sugar	0	2
Water, flavouring + added sugar	2.3	41
2-5% fruit juice +/- added sugar	2.5-3.2	43-59
> 5% fruit juice + added sugar	9.7-11.3	171-196

In 2005, ten vitamins (vitamin A, thiamin, niacin, pantothenic acid, vitamin B_6 , folic acid, vitamin B_{12} , biotin, vitamin C and vitamin E) are present in FB. The same vitamins were being used in 2003, except for biotin. There has been an increase in the use of thiamin, niacin, pantothenic acid, vitamin B_6 , folic acid, vitamin B12 and vitamin E. The average number of vitamins added in 2005 is 5.7 per product, with niacin, pantothenic acid and vitamin B_6 being the most commonly used vitamins. In 2003, the most commonly added vitamins were vitamin C, together with niacin and vitamin B_6 . The percentage of the RDI per serve of a FB ranged from 10-350% in the 2005 products. Most products contained between 10-40% of the RDI for a specific vitamin.

The addition of minerals to FB has increased slightly since 2003. In 2005 six different minerals (calcium, iron, magnesium, potassium, sodium, and zinc) are used, compared with three in 2003. All ten products contain added sodium in quantities ranging from 3-20 mg per 100 ml.

In 2003, three products contained herbal extracts (guarana, ginkgo leaf and echinacea), however all these products have since been withdrawn from the market. One new product contains a green tea extract.

Serving sizes have increased from 200-400 ml in 2003 to 200-710 ml in 2005. Six of the products identified in 2005 stated a serving size of 200 ml, with five of these products sold in packages containing 800 ml or more. In addition five of the products provided maximum recommended daily intakes or serves on their product labels. The maximum intake range equated to 1600-4800 ml per day for adults and 800-1600 ml per day for children.

Many of the FB carry claims, the majority of these are vitamin content claims, while other claims pertain to the benefits with respect to antioxidant intake, hydration and energy.

4.5.2.2 Australia

The 2005 Australian Survey identified a total of 20 products in the marketplace that would be classified as FB, compared with only three products from the 2003 survey, two of which are still available. Like the New Zealand products, FB sold in Australia range from beverages consisting of water, flavouring and no added sugar to beverages with greater than 5% fruit juice and added sugar. The majority (14) contain 2-5% fruit juice with or without added sugar.

The energy and macronutrient composition per 100 ml varied between the beverages, however it has not changed significantly since the 2003 FTDS survey. The protein and fat contents of all FB surveyed were less than 1 g per 100 ml.

FB Product Range	Total Sugar (%)	Energy (kJ per 100 ml)
Water, flavouring + no added sugar	0	2
Water, flavouring + added sugar	2.3	41
2-5% fruit juice +/- added sugar	2.2-5.4	38-94
> 5% fruit juice + added sugar	10.8-11.0	182-194

Ten different vitamins make up the vitamin profile of the FB sold in Australia in 2005 (vitamin A, thiamin, niacin, pantothenic acid, vitamin B₆, folic acid, vitamin B₁₂, biotin, vitamin C and vitamin E) with the addition of vitamin A and biotin since 2003. Niacin, pantothenic acid, vitamin B₆ and vitamin B12 are the most commonly added vitamins, with an average of 4.8 vitamins added per product. Biotin is added by three manufacturers to ten products. The percentage of the RDI provided per serve of a FB ranged from 10-350% in the 2005 products, with vitamin C, niacin and vitamin B₆ provided in some products in amounts greater than 100% per serve.

Seven minerals are added to FB currently sold in Australia. These are calcium, potassium, sodium, magnesium, zinc, iron and iodine. All twenty FB contain added sodium in quantities ranging from 2-25 mg per 100 ml.

Herbal extracts have not been commonly added to FB sold in Australia. In 2003, no product contained herbal extracts, and in 2005, only one FB has added Aloe extract.

The serving size range has remained constant between 2003 and 2005 at 200-710 ml, however the average serving size has increased from 370 ml in 2003 to 480 ml in 2005. Five products provided maximum recommended daily intakes or serves on their product label, ranging from 600-3600 ml per day for adults. Only one product provided a recommendation for children, which equated to 800 ml per day.

Like the New Zealand products, many of the FB sold in Australia make claims, the majority being vitamin content claims. While other claims pertain to benefits of the beverages with respect to antioxidant intake, glycaemic index rating, healthy body, hydration and energy.

4.6 Consumer Research on Food-Type Dietary Supplements

In June 2003, FSANZ commissioned consumer research in both Australia and New Zealand to assist future decision-making on issues related to FTDS including Application A470. Specifically, the purpose of the research was to examine consumers' awareness, familiarity, understanding and use of FTDS and related labelling elements such as the term 'dietary supplement', nutrition content claims and other nutritional and non-nutritional information including 'percentage daily intake' and trigger/advisory statements.

A summary of the research findings is provided below. A copy of the full report '*A* qualitative consumer study related to food-type dietary supplement labelling' is available on the FSANZ website²⁴.

²⁴<u>http://www.foodstandards.gov.au/mediareleasespublications/publications/consumerstudyrelatedtofoodtypediet</u> arysupplementlabellingjuly2003/

A total of 10 focus groups were conducted. The sample was skewed to include more people who are health conscious or who have special health needs compared to less health conscious people. The research demonstrated that participants were unable to distinguish between general-purpose foods carrying nutrition content claims and FTDS labelled 'dietary supplement', because they are almost exclusively influenced by content claims and because manufacturers display the term 'dietary supplement' in a way which renders it difficult to discern.

Awareness and use of FTDS was low. There were very few concerns about over-consumption of supplements (in terms of vitamins, minerals, non-culinary herbs and botanicals) and therefore participants were very open to the concept of supplementation of foods in almost all processed food categories. They did, however, want labels that distinguish between foods that intrinsically contain particular nutrients and foods that contain extrinsic or 'added' nutrients. They also wanted claims to be more quantified through the use of comparative percentages or exact amounts. Content claims such as 'source' and 'good source' were viewed as advertorial in nature and imprecise, which therefore meant they were treated with scepticism, even though they were considered to be truthful. There was no awareness that such terms are regulated.

The term 'dietary supplement' was described in both positive and negative terms because consumers were confused as to whether the intent was to caution consumers or to market the product. The addition of a trigger statement directing consumers to the Nutrition Information Panel (NIP) was not well supported, nor was a cautionary statement about FTDS or a percentage daily intake column in the NIP, because none of them were seen as being necessary.

The report highlighted the need to inform and educate consumers about labels relating to FTDS as consumers' current understanding of supplementation and nutritional information is such that informed choices cannot be made. The addition of more information on labels to reflect supplementation will not be meaningful to consumers unless accompanied by education.

5. Relevant Issues

5.1 Risk Assessment

A risk assessment has been conducted in relation to the addition of vitamins and minerals to FB. The Applicant has requested the addition of the following vitamins and minerals up to a level of 25 % of the RDI per 600 ml (reference quantity): vitamin A, beta-carotene, thiamin, riboflavin, niacin, folate, vitamin B₆, vitamin B₁₂, vitamin D, vitamin E, biotin, pantothenic acid, calcium, chromium, copper, iodine, iron, magnesium, manganese, molybdenum, phosphorus, selenium and zinc. The Applicant has also requested the addition of vitamin C at 100% of the RDI per 600 ml.

In the case of the requested vitamin and mineral additions, there is a potential for both benefits and risks depending on the nutritional status of the population and the level of dietary intake of the vitamins and minerals. Both potential benefits and risks have been considered in determining the suitability of the addition of vitamins and minerals to FB.

A nutrition assessment has been undertaken to assess the potential nutrition and health need in support of vitamin and mineral additions to FB. 'Nutrition and health need' encompasses two concepts: i) nutritional need, referring to inadequate intakes or deficiency states; or ii) 'health benefits'. In addition, the nutrition assessment has also assessed the potential health risk from an increase sugar and energy intakes of the population that may occur with FB consumption. A detailed report is provided in Attachment 5 – Nutrition Assessment and is summarised below.

The potential for FB to result in a health risk associated from the over-consumption of the requested vitamins and minerals has also been examined. A detailed report is provided in Attachment 6 - Risk Assessment – Micronutrients²⁵, and is summarised below.

The methodology used for dietary modelling of the vitamins and minerals is described in Attachment 7 – Dietary Modelling Methodologies for Nutrient Intake Assessment.

In the case of food additives, the technological justification for the use of these food additives is considered in Attachment 9 – Food Technology Report. Once the technical justification has been established, the potential for health risks associated with the use of the food additives in FB has been examined. A detailed report that examines the nature of any potential hazard, an estimate of the dietary exposure from the substitution of FB for other available beverages, and a characterisation of the risk is provided in Attachment 8 – Risk Assessment – Food Additives, and is summarised below.

5.1.1 Nutrition Assessment

The purpose of the nutrition assessment is to determine the nutrition and health need for adding the requested vitamins and minerals to FB, and to examine the health risks to the broader Australian and New Zealand populations from the sugars and energy content of FB. The overarching approach to the nutrition assessment has been the consideration of the requested vitamins and minerals in the context of FSANZ's statutory objectives, including having regard to the Policy Guideline.

The Policy Guideline permits the voluntary addition of vitamins and minerals to food *where there is a need for increasing the intake of a vitamin or mineral in one or more population groups demonstrated by actual clinical or sub-clinical evidence of deficiency or by data indicating low levels of intake*. For an assessment of the 'nutrition and health need', the first step was to determine if there is a <u>nutritional need</u>, by assessing the extent of existing inadequate vitamin and mineral intakes, or alternatively the extent of vitamin and mineral deficiencies within Australia and New Zealand. If the vitamin or mineral intake was identified as being inadequate, or the vitamin or mineral status assessed as being deficient, then that vitamin or mineral was regarded as having demonstrated nutritional need and was not further considered in relation to health benefit.

The Policy Guideline also states that voluntary fortification can be permitted where there is *generally accepted scientific evidence that the fortification can deliver a health benefit*. This potential for a 'health benefit' was investigated for those vitamins and minerals that do not have an existing level of inadequacy or deficiency, as a second step in the assessment of 'nutrition and health need'.

The process used to assess the nutrition and health need for a vitamin or mineral is illustrated in Figure 1 below. It also shows the results of this process for each of the requested vitamins and minerals. The results were based on the following criteria at each step:

²⁵ For the purpose of this report the term 'micronutrient' is used for vitamins and minerals

• <u>Step 1:</u> - Inadequate intakes were defined as the situation where 3% or more of the whole population or two sub-population groups have an intake of a vitamin or mineral at a level below the Estimated Average Requirement (EAR)²⁶. Six vitamins and minerals could not be assessed on the basis of inadequacy as they had no EAR (beta-carotene, biotin, pantothenic acid, chromium, manganese) or because dietary intake data was not available for this assessment (molybdenum).

A level of deficiency was established for a vitamin or mineral if there was scientific evidence to show that clinical or sub-clinical deficiency states were prevalent in Australian and New Zealand populations.

• <u>Step 2:</u> - The potential for a 'health benefit' was determined by criteria established by FSANZ in relation to the levels of generally accepted scientific evidence; the full details of these criteria can be found in Attachment 5.

Vitamin / Mineral		Step 1	Step 2		Existence of a
		Nutrition Need	Health Benefit		Nutrition and
					Health Need
	Riboflavin				
	Folate	> 3% of population			
	Vitamin B ₆	intakes were below the			
	Vitamin D	EAR,			
	Vitamin E				Identified as
Group	Calcium	OR			having a
1	Iodine				nutrition and
					health need
	Iron	Evidence of deficiency			
		existed			
	Magnesium				
	Selenium				
	Zinc				
	Vitamin A (retinol)	< 3% of population			
	Thiamin	had intakes below the			
	Niacin	EAR,	Assessed for the		
	Vitamin B ₁₂		potential to		
	Vitamin C	AND	deliver a health		
Group	Copper		benefit		No nutrition and
2	Phosphorus	No evidence of deficiency			health need
	Beta-carotene		(none met		identified
	Chromium	Unable to assess for	FSANZ criteria		
	Biotin	inadequacy,	for a 'health		
	Pantothenic acid	AND	benefit')		
	Manganese	No evidence of deficiency			
	Molybdenum				

Figure 1: Assessment of Nutrition and Health Need

Figure 1 shows that Group 1 met all criteria for demonstration of a nutrition and health need. Therefore, the vitamins and minerals with a nutrition and health need in support of their addition to FB are as follows:

 $^{^{26}}$ The EAR is a value representing the median requirement for a vitamin or mineral. The details on the specific EARs that were allocated to each vitamin and mineral can be found in Attachment 5.

Vitamins	Minerals
Riboflavin	Calcium
Folate	Iodine
Vitamin B ₆	Iron
Vitamin D	Magnesium
Vitamin E	Selenium
	Zinc

As a final component of the nutrition assessment, FSANZ reviewed the energy and sugar content of FB and their potential impact on the overall diet. A potential risk was identified, that intakes of sugar-containing beverages (including those with a natural sugar content) would increase as a result of FB expanding the beverage sector of the market. There is evidence to show that consumption of standard sugar-containing beverages (e.g. soft drinks) can significantly increase the overall intake of energy within the diet and thus contribute to weight gain. Therefore, a potentially higher beverage intake resulting from the approval of Application A470 will likely increase the intake of sugar and energy in the Australian and New Zealand populations, and is a potential health risk.

5.1.2 Risk Assessment – Micronutrients

5.1.2.1 Micronutrients without risk for the general population

For the following vitamins and minerals, it is concluded that addition to FB at a level of 25% of the RDI / 600 ml (100% of RDI per 600 ml for vitamin C) would raise no public health and safety concerns for any sector of the population: beta-carotene, thiamin, riboflavin, niacin, folate, vitamin B_6 , vitamin B_{12} , vitamin C, vitamin D, vitamin E, pantothenic acid, calcium, magnesium, phosphorus and selenium.

5.1.2.2 Micronutrients with some risk for sensitive subpopulations

For the following minerals, it is concluded that while the general population is without risk, there may be a risk for certain sectors of the population:

<u>Copper</u>: Individuals with Wilson's disease, Indian childhood cirrhosis or idiopathic copper toxicosis may respond adversely to copper in FB at a level of 0.75 mg per 600 ml.

<u>Iodine</u>: Individuals with thyroid disorders or a long history of iodine deficiency may respond adversely to iodine in FB at a level of 37.5 µg per 600 ml.

<u>Iron</u>: Individuals who are homozygous for hereditary haemochromatosis are susceptible to iron overload, even at normal dietary iron intakes, and are generally advised to avoid iron-supplements and highly iron fortified foods. As the majority of individuals with this condition are not diagnosed until sufficient iron has accumulated to produce adverse effects, the addition of iron to FB at a level of 3 mg per 600 ml serve may be a concern to these individuals.

5.1.2.3 Micronutrients with some risk for specific age groups

For the following vitamins and minerals, there are potential risks for specific age groups if they were permitted to be added to FB:

<u>Vitamin A</u>: The dietary modelling results suggest that young children consuming FB may have excess intakes of retinol for several years and therefore be at risk of hepatoxicity. For all other age groups and life-stages, there is no appreciable risk posed by excess intake of retinol. There are potential safety concerns for children up to the age of 3 years, and maybe up to 6 years, with the addition of retinol to FB at a level of 187.5 µg in a 600 ml serve.

<u>Manganese</u>: An upper level of intake (UL) could not be established because of limitations with the human data and considerable uncertainty with the animal toxicity studies. The available data suggests that the margin between the intake level producing adverse effects in humans and animals and the estimated intake from food is very small. Based on the severity of the potential adverse effect (neurotoxicity), additional oral exposure to manganese beyond the levels normally present in food and beverages could pose a public health and safety risk. Therefore, there are potential safety concerns with the addition of manganese to FB at a level of 1.25 mg in a 600 ml serve.

<u>Zinc</u>: Dietary modelling indicated that children up to 8 years of age, who are consumers of a diet high in zinc, are predicted to exceed the UL for zinc. For adolescents up to the age of 18 years, who are consumers of a diet high in zinc, the intake is predicted to be 80% of the UL of zinc. Chronic zinc toxicity is associated with symptoms of copper deficiency. These adverse effects include anaemia, neutropaenia and impaired immune response. Furthermore, the potential contribution from other sources (e.g. dietary supplements) have not been taken into consideration in the dietary intake assessment. The intake of zinc may therefore be underestimated for children and adolescents up to the age of 18 years and, for this group, FB at a level of 3 mg per 600 ml serve pose a public health and safety risk.

5.1.2.4 Micronutrients with insufficient data to assess risk

For the following vitamins and minerals there was insufficient data to characterise the potential risk:

<u>Biotin and Chromium</u>: Due to insufficient data on potential adverse effects and only limited food composition data it was not possible to establish an UL for biotin and chromium or to undertake a complete dietary intake assessment. In the absence of sufficient information, it is currently not possible to evaluate the safety of the addition of biotin and chromium to FB.

<u>Molybdenum</u>: An UL has been established based on reproductive effects in rats. While some food composition data are available for molybdenum, it is insufficient to undertake a complete dietary intake assessment at this present time. In the absence of sufficient information, it is not currently possible to evaluate the safety of the addition of molybdenum to FB.

5.1.2.5 Assessment of permitted forms

For pantothenic acid, biotin, chromium, manganese, molybdenum and selenium, currently there are no forms permitted in Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions. The requested permitted forms for pantothenic acid, copper and selenium have been included in evaluations of their toxicity, and are considered to be acceptable as permitted forms.

5.1.3 Risk Assessment – Food Additives

A risk assessment has been conducted on 57 food additives/additive groups requested by the Applicant to be added to FB. All of these food additives are currently permitted in Standard 1.3.1 – Food Additives.

5.1.3.1 Hazard identification and characterisation

FSANZ has not performed an independent hazard identification and characterisation of the 57 food additives, but has relied upon the assessment reports from the Joint FAO/WHO Expert Committee on Food Additives (JECFA). JECFA has established numerical Acceptable Daily Intakes (ADI)²⁷ for some, and established an ADI 'not specified'²⁸ for many in this group. For several, there was not enough data available to perform an assessment.

5.1.3.2 Dietary exposure assessment

Dietary exposure assessments were conducted only on those food additives with a numerical ADI, i.e., those where there was a potential for safety concerns if the exposure significantly increased. For the majority of the food additives, the dietary exposure either did not change or changed very little when FB were included in the modelling.

5.1.3.3 Risk Characterisation

Food additives which have an ADI 'not specified' or an ADI which is sufficiently high to allow GMP use for the additive in food

For the additives with an ADI 'not specified', dietary exposure assessments were not conducted, since these food additives are considered to have low toxicity and would not be expected to pose a public health and safety risk as a result of their use in FB.

Food additives that have a numerical ADI

For the additives for which a numerical ADI existed, dietary exposure assessments were conducted. The risk characterisation concluded that the addition of the following food additives to FB at the requested concentration would pose no public health and safety risk: tartrazine, quinoline yellow, sunset yellow, azorubine, amaranth, ponceau 4R, allura red, indigotine, brilliant blue, fast green, brilliant black, brown HT, sorbates, sulphites, calcium disodium EDTA, sucrose acetate isobutyrate, glycerol ester of wood rosin, and dioctyl sodium succinate.

In the case of annatto, benzoates, acesulphame potassium (ace K), saccharin and alitame, the dietary exposure assessment predicted that there could be an increase in exposure as a result of their use in FB.

²⁷ JECFA defined the ADI *as an estimate of the amount of a food additive, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk*

²⁸ JECFA defined the term '*ADI* not specified' to mean that, on the basis of available data (chemical, biochemical, toxicological, and other), the total daily intake of the substance, arising from its use at the levels necessary to achieve the desired effect and from its acceptable background in food, does not represent a hazard to health.

This apparent increase is the result of the assumptions made about which beverages were substituted with FB in the dietary model used, and the current permissions in these particular beverages. Even taking into account these apparent increases in exposure, no public health and safety concerns were raised.

5.1.4 Risk assessment summary

5.1.4.1 Vitamins and minerals

The table below summarises the findings of the nutrition assessment and the risk assessment in relation to the addition of vitamins and minerals to FB.

Risk Assessment findings on the requested vitamin and mineral additions

Vitamin and Mineral	Outcomes of the Nutrition Assessment	Outcomes of the Risk Assessment - Micronutrients	Eligibility for Addition to FB (Combined outcomes of the Nutrition Assessment and Risk Assessment – Micronutrients)
Vitamins			
Vitamin A (retinol)			
Beta-carotene		\checkmark	
Thiamin		\checkmark	
Riboflavin	\checkmark	\checkmark	\checkmark
Niacin		\checkmark	
Folate	\checkmark	\checkmark	\checkmark
Vitamin B ₆	\checkmark	\checkmark	\checkmark
Vitamin B ₁₂		\checkmark	
Vitamin C		\checkmark	
Vitamin D	\checkmark	\checkmark	\checkmark
Vitamin E	\checkmark	\checkmark	\checkmark
Biotin		Not assessed	
Pantothenic acid		\checkmark	
Minerals			
Calcium	\checkmark	\checkmark	
Chromium		Not assessed	
Copper		\checkmark	
Iodine	\checkmark	\checkmark	\checkmark
Iron	\checkmark	\checkmark	\checkmark
Magnesium	\checkmark	\checkmark	\checkmark
Manganese			
Molybdenum		Not assessed	
Phosphorus		\checkmark	
Selenium	✓	\checkmark	✓
Zinc	\checkmark		

Whilst iodine and iron meet the nutrition assessment criteria and do not raise public health and safety concerns for the general population, there were concerns identified for sensitive subpopulations in relation to these nutrients. Risk management strategies may be considered necessary to protect these vulnerable individuals.

5.1.4.2 Macronutrients

In the context of the overall diet, there is the possibility that beverage intakes will increase as a result of FB expanding this sector of the market. This increased beverage intake is likely to increase the intake of sugar-containing beverages in the diet, and therefore increase the intake of energy via increased sugar consumption. This impact on the diet is a risk that may require management if FB are permitted to contain added vitamins and minerals.

5.1.4.3 Food additives

On the basis of currently available information, it can be concluded that the addition of the requested 57 food additives/additive groups to FB would not raise any public health and safety concerns.

5.2 Risk Management

On the basis of FSANZ's risk assessment the following sections discuss approaches to managing any identified public health and safety risks, and other broader issues requiring consideration in the development of regulations for FB.

5.2.1 Target group of formulated beverages

The Applicant identified the target group for these products as 'those consumers who are looking for these types of beverages', citing that their Application is in response to Australian consumers who are purchasing FB imported from or through New Zealand. The indicative age range of the target group appears to be adults aged 20-39 years old, with industry data provided by the Applicant showing this group accounts for approximately 70% of the total volume consumed of one leading FB product.

The Applicant has indicated that the marketing of FB would be aimed at adults, showing FB to be more interesting tasting beverages which contain low levels of vitamins and minerals. Industry research reports that quenching thirst is a key reason for selecting FB for both men and women, but more so for women. Women consumers of FB are also seeking more energy and health, where men tend to be more likely to seek rehydration from these products.

Market intelligence suggests the drivers for FB would be their appeal to young people (16-34 years) who are aware of the fashionable image and compatibility with their lifestyle, rising consumer interest in the role of diet in health and a growing desire to take a more active role in promoting and optimising personal health and wellbeing.

In response to the Initial Assessment Report, submitters identified various target groups including those who currently consume soft drinks, current supplement users who may substitute FB for supplements, the 'worried well' with disposable cash, and children and youth who are influenced by advertising and popularity.

The incidental target group for FB appear to be children and teenagers. Whilst the Applicant has advised FB will not be targeted towards children, industry data on a leading brand of FB reports 20% volume consumption by 12-19 year olds. In addition, FSANZ is aware that some manufacturers are actively promoting water-based beverages with added vitamins and minerals to children, with products being developed and labelled specifically for children.

One product currently available in Australia is labelled as a 'sportswater for kids'. Another Australian FB manufacturer has announced that they will be launching a 'junior' product aimed at children aged 5-12 years old in July 2005. A marketing campaign by one New Zealand manufacturer uses colourful cartoon images of youths and language such as 'cool', 'wickedest' and 'funky' including promotions and giveaways to promote their product.

5.2.2 Characterising the product category of formulated beverages

5.2.2.1 Purpose

At Initial Assessment, the nature of Application A470 made it necessary to consider the purpose of FB, particularly as the Applicant had not ascribed any particular purpose to FB other than to respond to consumer demand. They had however requested vitamin and mineral permissions generally exceeding those permitted in general-purpose food.

Determining the appropriate 'purpose' category for FB is fundamental to the assessment of the Application as it directs the appropriate regulatory approach particularly as policy guidance on the addition of vitamins and minerals to food excludes special purpose food.

Currently the Code distinguishes two broad categories of purpose:

- <u>General-purpose</u> food i.e. food that is widely available for consumption by the general community (the vast majority of foods); and
- <u>Special-purpose</u> food i.e. food that is produced to satisfy particular dietary requirements which exist because of a particular physical or physiological need, and/or specific diseases and disorders. Part 2.9 of the Code contains the standards for special-purpose food e.g. infant formula and foods, formulated meal replacements and FSSF.

At Initial Assessment a third category of 'supplemental' purpose was also discussed. This purpose was identified during the development of a standard for FCB (Application A394) in 2001 and sits outside the conventional nutritional paradigm. The development of the Policy Guideline, which places fortification with vitamins and minerals predominantly in a nutritional paradigm, means consideration of 'supplemental' purpose is no longer appropriate.

The Initial Assessment Report suggested that FB were not special-purpose food, as they did not address situations of particular physiological need. Submitters at Initial Assessment agreed with this, with the majority supporting regulation as a general-purpose food.

The Applicant has subsequently amended Application A470 and is now seeking lower levels of vitamin and mineral additions to FB (i.e. 25% RDI with the exception of vitamin C, at 100% RDI, per a 600 ml reference quantity). As such, it is appropriate that FB are regulated as general-purpose food. Consequently, any permission to add vitamins and minerals to FB will be incorporated in Standard 1.3.2 of the Code.

5.2.2.2 Definition

At Initial Assessment, the need to clearly define FB was raised as a key issue to ensure that the product category of FB is unambiguously described and does not inadvertently act as a means to circumvent other, more appropriate food standards. It was suggested that the definition could include reference to elements of composition and/or purpose. As FB are to be considered as general-purpose food, composition therefore represents the most suitable defining feature for FB.

In their submission to the Initial Assessment Report, the Applicant provided a suggested definition for FB of 'a water-based product, that may be sweetened and/or flavoured; may or may not contain juice; and that contains a mix of added vitamins and/or minerals'.

Other industry submitters supported a definition that would encompass a wide range of nonalcoholic water-based beverage products, including FCB and both carbonated and noncarbonated water-based drinks including those with flavours and fruit ingredients. The original Application however specifically excluded caffeinated beverages, and since Initial Assessment the Applicant has withdrawn carbonated drinks from the scope of the Application.

In August 2004, the Applicant provided further information in relation to the likely range of products that may be produced as FB. These included:

- sugar sweetened waters (may contain a blend of sugar/non-nutritive sweeteners);
- unsweetened waters (with no added sweeteners);
- non-nutritive sweetened waters;
- sugar sweetened or non-nutritive sweetened, still fruit drinks and fruit juice drinks with juice added as an ingredient;
- unsweetened, flavoured, still fruit drinks and fruit juice drinks with juice added as an ingredient; and
- fruit juice/drink cordials which may contain nutritive and non-nutritive sweeteners.

'Water-based beverage' is currently not defined in the Code but rather is recognised within the definition of a non-alcoholic beverage in Standard 2.6.2 – Non-alcoholic Beverages and Brewed Soft Drink as *a water-based beverage which may or may not contain other foods, except for alcoholic beverages*. From this context its broad composition can be inferred to include products whose <u>ingredient</u> composition ranges from mostly water to, those fruit drinks²⁹ containing mostly juice with a small amount of added water.

Given the proposed composition of FB as described by the Applicant above, FB can be considered to be a sub-category of water-based beverages, which may or may not include fruit ingredients. Therefore, FSANZ is proposing the following definition for inclusion in Standard 2.6.2.

²⁹ The Code requires fruit drink to contain at least 5% (except in the case of passionfruit which requires 3.5%) specified fruit ingredients.
Formulated Beverage is:

non-carbonated, water-based flavoured beverage that contains added vitamins and/or minerals, prepared from one or more of the following:

- water; and
- fruit juice; and
- fruit purée; and
- concentrated fruit juice; and
- concentrated fruit purée; and
- comminuted fruit; and
- orange peel extract; and
- mineral water; and
- sugar.

This definition allows for ingredient composition as requested by the Applicant noting that the Code considers non-nutritive sweeteners and flavourings as food additives. Permissions for food additives are discussed in Section 5.2.6.

5.2.2.3 Per cent fruit juice composition

The above definition although considered explicit in terms of compositional description does not necessarily distinguish FB from other water-based beverages currently regulated in the Code. For instance, there is a potential overlap of FB with other beverages such as fruit drinks, particularly those containing at least 25% fruit ingredients that are permitted to contain a small number of added vitamins in Standard 1.3.2 according to the modified restoration³⁰ principle.

As discussed previously, it is important that FB are unambiguously described and do not inadvertently act as a means to circumvent other, more appropriate food standards. As FSANZ is not proposing to require additional labelling specific to FB, a compositional requirement to distinguish FB from other fruit drinks is appropriate.

For this reason FSANZ is proposing a maximum limit for fruit ingredients of 24% so that FB are clearly distinguished from other fruit juice based products. This should also assist consumers to discern FB from other fruit drinks.

5.2.3 Appropriateness of food vehicle

It is important that consideration be given to the suitability of the requested food vehicle i.e. water-based beverages in terms of its nutritional appropriateness as a vehicle for voluntary fortification.

Submitters to the Initial Assessment Report varied in their comments about whether the composition of the food vehicle should be taken into account. The complementary medicine sector believed that the composition of the food vehicle was important particularly given the potential for FB to be consumed in large amounts.

³⁰ The principle of modified restoration is described in the Fortification Policy Guideline.

In contrast, some industry submitters believed that the food vehicle composition was of no regulatory concern as the NIP would declare the nutritional quality of the product, however another manufacturer believed it would be important to keep the energy content of these beverages low and to encourage water intake. The public health and government sectors believed that the composition of the food vehicle was important to consider particularly given the rising prevalence of obesity and dental erosion from chronic intake of acidified beverages.

Based on the FB definition above, the following beverage types could be used as potential vehicles for voluntary fortification:

- water \pm sugar \pm non-nutritive sweeteners;
- fruit juice drinks \pm sugar \pm non-nutritive sweeteners; and
- cordials \pm sugar \pm non-nutritive sweeteners.

The Policy Guideline states that permission to voluntarily fortify should not promote consumption patterns inconsistent with the nutrition policies and guidelines of Australia and New Zealand and should not promote increased consumption of foods high in salt, sugar or fat.

In accordance with the Policy Guideline, FSANZ's Fortification Implementation Framework recognises that the nature of the food vehicle can have nutritional consequences which warrant consideration when assessing any new proposed voluntary fortification measure.

On this basis, FSANZ will focus primarily on the total sugar and energy content of the above beverage types when assessing the appropriateness of the potential food vehicle.

5.2.3.1 Total sugar and energy content of formulated beverages

The table below shows the total sugar and energy content for commonly consumed waterbased beverages and FB currently on the market in both Australia and New Zealand.

Beverage Category	Sugar (g/100 ml)	Energy (kJ/100 ml)
Carbonated, sugar based soft drinks*	9.1 - 14.8	155 - 282
Fruit Juices*	5.3 - 14.1	103 - 256
Fruit Juice Drinks*	9.4 - 15.2	164 - 259
Cordials (ready to drink) [*]	9.7 - 14.8	166 - 196
FB water, flavoured +/- added sugar [‡]	0.0 - 2.3	2-41
FB 2-5% Fruit Juice [‡]	2.0 - 5.4	38 - 34
FB > 5% Fruit Juice [‡]	9.7 - 11.3	171 - 196

* = Data derived from AUSNUT Special Edition (2) – Australian Food and Nutrient Database for Nutrient Labelling: Release 2 Australia New Zealand Food Authority (2002)

[‡] = Data derived from FSANZ's market research (Section 4.6)

Although not all FB contain high levels of sugar, products of this type are contained within the present scope of the Applicant's request. The table above shows that some FB currently contain sugar levels similar to amounts found in carbonated soft drinks, cordials and fruit juices and drinks.

If the addition of vitamins and minerals to FB increases these products nutritional attractiveness and thus marketability, there is potential to increase the sugar and energy intake of the population and is therefore inconsistent with policy guidance.

5.2.3.1.1 Serving size of formulated beverages

As indicated in Section 4.5.2, the serving sizes of FB are generally larger than the standard serving size for soft drinks, juices and cordials. Market intelligence indicates that the intended purpose of FB is to provide a thirst quenching beverage and to aid hydration, hence the larger serving size. This is reflected in the Applicant's request that the reference quantity for FB be 600 ml.

One currently available FB, targeted at children, and available as a 500 ml serve, claims to have one third of the sugar content when compared with carbonated soft drinks. This comparison, however, is on a 100 ml basis but given the increased serving serve (i.e. 500 ml) as opposed to 375 ml (i.e. one standard can of soft drink), the difference is less apparent.

If consumers substitute FB for carbonated soft drinks, juices and cordials, the potential exists to increase intakes of sugar and energy due to the larger serving size of FB.

5.2.3.1.2 Risk of overweight and obesity

The increased consumption of sweetened drinks, such as soft drinks, is now recognised as an important, independent risk factor for the development of obesity in school aged children (Krebs-Smith, 2001; Ludwig *et al.*, 2001; Somerset, 2003; Berkey *et al.*, 2004; James *et al.*, 2004). It is widely acknowledged that childhood obesity is reaching epidemic proportions³¹. Since 1985, it is estimated that there has been nearly a 1% annual increase in the rates of overweight and obesity in children aged seven to 11 years in Australia (*personal communication*, Boyd Swinburn 2005).

As part of its risk assessment, FSANZ examined the potential nutritional impact of FB, including macronutrient intakes, on the population. In the Nutrition Assessment (at Attachment 5), it is concluded that there is a *risk of increased energy intakes within Australian and New Zealand diets from proposed FB permissions (via increased sugar-containing beverage consumption)*. In assessing the appropriateness of the food vehicle, it is apparent that there is potential for FB to increase both the sugar and energy intake of the population.

In order to effectively manage this risk, especially in children, FSANZ is proposing to restrict the amount of sugar in FB (refer to Section 5.2.4.2.). This will help ensure that FB do not promote the increased consumption of food high in sugar and thus is in accordance with FSANZ's statutory objective of protecting public health and safety and subsequently the 'Specific Order' Policy Principles for voluntary fortification.

5.2.3.1.3 Potential to mislead consumers as to the nutritional quality of the fortified food

As part of its assessment in determining the appropriateness of the food vehicle, FSANZ has examined the potential for consumers to be misled as to the nutritional quality of the fortified food.

³¹World Health Organization (2005) *Obesity and Overweight*

http://www.who.int/dietphysicalactivity/publications/facts/obesity/en/print.html Accessed 20 April 2005.

This is in accordance with FSANZ's second and third priority statutory objectives and the Specific Order' Policy Principle for voluntary fortification which states that *the fortification of a food, and the amount of fortificant in the food, should not mislead the consumer as to the nutritional quality of the fortified food.*

As part of FSANZ's 2003 FTDS consumer research, consumers' perceptions on the importance of the composition of the food vehicle were investigated. Most participants did not object to the addition of vitamins and minerals to various food categories, with the exception of those food categories specifically marketed to teenagers and children because of their reduced likelihood to read labels or to be 'unfairly' persuaded to buy the products. A minority view was that added vitamins and minerals should not be permitted in 'unhealthy' foods given the potential for consumers to be misled by an emphasis on the positive attributes of the vitamins and minerals without being able to balance the potentially negative attributes such as energy and total sugar content.

In the Nutrition Assessment (at Attachment 5), it was concluded that there is a risk that consumers could be misled as to the nutritional quality of FB. Some FB have similar or higher amounts of sugar when compared to many soft drinks. The addition of vitamins and minerals can enhance their nutritional attractiveness of FB, resulting in many consumers being unaware that they are consuming significant amounts of sugar and energy due to the larger serving sizes and high sugar content of some FB. This assessment supports the concerns raised by many submitters in response to the Initial Assessment for Application A470, and the views expressed by participants in FSANZ's consumer research.

A compositional restriction on the amount of sugar permitted in FB should minimise the risk of consumers being misled as to the nutritional quality of FB.

5.2.3.2 Cordial Consumption in Australia and New Zealand

The Applicant has requested cordials be included in the scope of the Application. In determining the suitability of cordial as a potential food vehicle, FSANZ has considered:

- the potential target group;
- possible public health and safety risks;
- consumers' perceptions; and
- submitters' comments as to the nutritional quality of fortified food.

National Nutrition Survey data has been used to determine which population groups consume cordial. The percentage of each population group and the mean and 95th percentile intakes of cordials for consumers of cordials, are presented in Figures 2 and 3, respectively. In general, a larger proportion of children drink cordials, however teenagers consume the largest volume of cordials for the population groups assessed.





Figure 3: Mean and 95th percentile consumption of cordials for Australian and New Zealand consumers of cordials, as recorded in the 1995/1997 National Nutrition Surveys



Using the FSANZ 1995/1997 National Nutrition Survey data, FSANZ has assessed the energy contribution from cordials as a percentage of the total energy intake for the Australian and New Zealand population groups as shown in Figure 4. This shows that the contribution of cordial to total energy intake is greatest in younger age groups.





FSANZ also sought to determine consumption trends with respect to cordial intakes. FSANZ compared the estimated mean and 95th percentile consumption of cordials from the 1983 National Dietary Survey of adults and the 1985 National Dietary Survey of school children (83 NDS and 85 NDS respectively) with the 1995 National Nutrition Survey. The population sub-groups examined were 25-64 years for the 83 NDS and 10-12 years and 13-15 years for the 85 NDS. The mean and 95th percentile for cordial consumption 1983/1985 National Dietary Surveys is shown in Figure 5 below.

Figure 5: Mean and 95th percentile consumption of cordials for Australian consumers of cordials as recorded in the 1983/1985 National Dietary Surveys



Comparison of the estimated cordial consumption between 1983/1985 to 1995 suggests that cordial consumption has increased in the period between the surveys. However, it is important to note that the data are not directly comparable due to the different methodologies used and the different age groups assessed. Therefore this information is only indicative. However, in support of this apparent trend, the 2003 FSANZ survey³² on the consumption of intense sweeteners also showed an increase in cordial consumption (both sugar sweetened and intense sweetened) from 1994 until 2003 for consumers aged 12-39 years.

Children and teenagers have been identified as a potential incidental target group for FB (Section 5.2.1). FSANZ's Product Surveys shows that some products that could potentially fall under the FB category are specifically targeted towards children. As cordials are one of the beverage types requested by the Applicant as a potential vehicle for voluntary fortification, it is likely that children and teenagers would be the main target group for this type of FB.

As previously discussed in Section 5.2.3.1.2, the increased consumption of sweetened drinks is recognised as a risk factor for the development of obesity in school aged children. Given that the addition of vitamins and minerals to cordials could potentially increase the nutritional attractiveness and thus marketability of these products, there is potential to increase cordial consumption in children and teenagers. FSANZ recognises that cordial consumption may also inadvertently result in potentially larger quantities of vitamins and minerals being unintentionally consumed through varied preparation of cordials.

At Initial Assessment submitters expressed concern regarding the appropriateness of cordial as a suitable food vehicle. Their concerns were based on cordials being particularly targeted towards children and the research linking the consumption of high sugar beverages to increased rates of childhood obesity. These concerns are similar to the views expressed by participants in the FSANZ 2003 FTDS consumer research survey who believe that vitamins and minerals should not be added to food categories specifically marketed to teenagers and children. The level of community concern regarding the appropriateness of cordial as a potential food vehicle, has previously led an Applicant to withdraw cordial from their Application (Application A424 - Fortification of Foods with Calcium).

On the basis of the potential target group i.e. children, the identified public health and safety risks and stakeholder concerns, FSANZ has determined that cordials are not appropriate food vehicles for voluntary fortification.

5.2.3.2.1 Conclusion

In assessing the appropriateness of the food vehicle, FSANZ has examined the potential for FB to adversely impact on public health and safety. Specifically, FSANZ has assessed the issues identified in the Nutrition Assessment including total sugar and energy content, and serving size of FB. In addition, FSANZ has considered the potential for the requested FB product range to mislead consumers as to the nutritional quality of the fortified food. On this basis, FSANZ is proposing to restrict the sugar content of FB and exclude cordial from the scope of the Application.

³² FSANZ (2004) *Consumption of Intense Sweeteners in Australia and New Zealand. Benchmark Survey 2003.* Evaluation Report Series No.8.

5.2.4 Composition of formulated beverages

5.2.4.1 Vitamin and Mineral Additions

The regulatory controls applied to the addition of vitamins and minerals are firstly guided by the determination of the 'purpose' category as discussed in Section 5.2.2.1 above. As FB are considered general-purpose foods, the Policy Guideline is directly relevant to decisions on the regulatory control of the vitamin and mineral additions to FB.

As previously discussed (section 4.2.1) the Policy Guideline consists of 'High Order' Policy Principles that are FSANZ's section 10 objectives, which take precedence over the 'Specific Order' Policy Principles for voluntary fortification. FSANZ's *Fortification Implementation Framework* provides the context for standards development in relation to voluntary fortification particularly as it relates to FSANZ's statutory obligations.

5.2.4.1.1 Public Health and Safety

The protection of public health and safety is paramount to the consideration of permitting the voluntary addition of vitamins and minerals to FB. The protection of public health and safety is the primary objective of the FSANZ Act. Additionally, public health and safety underpins the Policy Guideline which provides direction in relation to the need for fortification as well as assuring safety of any potential fortification.

The first 'Specific Order' Policy Principle states that the voluntary addition of vitamins and minerals should be permitted only:

	Where there is a need for increasing the intake of a vitamin or mineral in one or more population groups demonstrated by actual clinical or sub- clinical evidence of deficiency or by data indicating low levels of intake.
or	
	Where data indicates that deficiencies in the intake of a vitamin or mineral in one or more population groups are likely to develop because of changes taking place in food habits.
or	
	Where there is generally accepted scientific evidence that an increase in the intake of a vitamin and/or mineral can deliver a health benefit.
or	
	To enable the nutritional profile of foods to be maintained at pre- processing levels as far as possible after processing (through modified restoration).
or	
	To enable the nutritional profile of specific substitute foods to be aligned with the primary food (through nutritional equivalence).

The first and third conditions of this 'Specific Order' Policy Principle are the most relevant to consideration of Application A470.

In addition, the Policy Guideline also states that *permissions to fortify should ensure that the added vitamins and minerals are present in the food at levels which will not have the potential to result in detrimental excesses or imbalances of vitamins and minerals in the context of total intake across the general population.*

FSANZ's risk assessment has on the basis of 'need' and safety determined that the following vitamins and minerals can be permitted for addition to FB in the amounts requested by the Applicant. These are:

Vitamins	Minerals
Riboflavin	Calcium
Folate	Iodine
Vitamin B ₆	Iron
Vitamin D	Magnesium
Vitamin E	Selenium

FSANZ's risk assessment did identify certain sensitive subpopulation groups who may be at increased risk from the addition of copper, iodine and iron to FB.

The risk assessment found that for certain sensitive individuals, the addition of copper to FB would pose a risk. As FSANZ is not proposing to allow the addition of copper to FB, this issue does not require further consideration.

In the case of iodine, the risk assessment indicates that the addition of iodine to FB is predicted to have only a relatively small impact on dietary iodine intake for the general population. However individuals with thyroid disorders or a long history of iodine deficiency may respond adversely to levels of intake that are safe for the general healthy population. For these individuals, the addition of iodine is not considered to pose any additional risks, as the iodine content of FB will be labelled. Furthermore FSANZ is currently progressing a proposal considering the mandatory fortification of food with iodine (Proposal P230). This issue will be further investigated as part of this Proposal currently at Draft Assessment.

Similarly, FSANZ risk assessment identified that the addition of iron to FB poses no appreciable risk to public health and safety for the general population. However, individuals who are homozygous for hereditary haemochromatosis are susceptible to iron overload even at normal dietary iron intakes and are generally advised to avoid iron-supplements and highly iron fortified foods. As the majority of individuals with this condition are not diagnosed until sufficient iron has accumulated to produce adverse effects, the addition of iron to FB may pose an increased risk of iron toxicity for those undiagnosed individuals.

FSANZ's Nutrition Assessment demonstrated that there is an inadequate intake of iron in the Australian and New Zealand populations. Both Australian and New Zealand nutrition guidelines recommended consumption of iron containing foods to reduce the incidence of iron deficiency anaemia particularly in adolescent girls and women^{33,34,35}.

³³ National Health and Medical Research Council (2003) *Dietary Guidelines for Australian Adults*.

³⁴ New Zealand Ministry of Health (1998) *Food and Nutrition Guidelines for Healthy Adolescents: A background paper.*

³⁵ New Zealand Ministry of Health (2003) Food and Nutrition Guidelines for Healthy Adults.

On this basis, FSANZ considers the potential health gain from permitting the addition of iron to FB outweighs the risk to those vulnerable individuals who, prior to being diagnosed, will not know to modify their diet. For those diagnosed individuals, the addition of iron will be labelled and therefore they can make an informed choice.

Therefore, FSANZ is not proposing any additional risk management strategies in relation to the addition of iodine or iron to FB.

5.2.4.1.2 Fair Trade and Industry Competitiveness

In accordance with FSANZ's statutory objectives, i.e. the 'High Order' Policy Principles, consideration has also been given to other matters including the promotion of fair-trading and the desirability of an efficient and competitive food industry. This includes applying the principle of minimum effective regulation as required by the Council of Australian Governments (COAG)³⁶ and the New Zealand Code of Good Regulatory Practice.

Currently permissions exist in the Code for the addition of certain vitamins to other waterbased beverages e.g. Standard 1.3.2 permits the addition of vitamin C, folate and carotene forms of vitamin A (e.g. beta-carotene) to fruit drinks. These products could be viewed as fulfilling a similar primary function to FB i.e. hydration.

Standard 2.6.4 permits the addition of thiamin, riboflavin, niacin, vitamin B_6 , vitamin B_{12} and pantothenic acid to FCB. The quantities of these permitted vitamins are significantly higher than those being requested for Application A470. Whilst FCB are compositionally different when compared to fruit juice drinks, by virtue of the addition of caffeine and carbon dioxide, FB can be considered to be an alternative substitute for all categories of water-based beverages including fruit drinks and FCB.

Although the Code distinguishes these products for regulatory and enforcement purposes, from the perspective of both the beverage industry and consumers, these products could all be considered quite similar.

Also from FSANZ's 2005 Product Surveys, the majority of FB in Australia and New Zealand currently contain the following B vitamins: thiamin; riboflavin; niacin; folate; pantothenic acid; vitamin B₆; and vitamin B₁₂.

Therefore, in the interest of minimum effective regulation, industry competitiveness and fairtrading, and in the absence of public health and safety concerns, FSANZ is proposing to also permit the addition of the following vitamins to FB in the amounts requested by the Applicant:

<u>Vitamins</u> Beta-carotene Vitamin C Thiamin Niacin Pantothenic acid Vitamin B₁₂

³⁶ COAG, Principles and Guidelines for National Standard Setting and Regulatory Action by Australia and New Zealand Food Regulatory Ministerial Council and Standard Setting Bodies. (1995, amended 2004).

5.2.4.1.3 Permitted forms

The Schedule to Standard 1.1.1 of the Code lists the permitted forms of vitamins and minerals. There are currently no permitted forms for pantothenic acid and selenium. FSANZ's risk assessment found the requested permitted forms for pantothenic acid (calcium pantothenate and dexpanthenol) and selenium (seleno methionine, sodium selenate, sodium selenite) to be acceptable. As FSANZ is proposing the addition of these nutrients to FB, the above permitted forms will be included in the Schedule to Standard 1.1.1.

5.2.4.1.4 Conclusion

On the basis of public health and safety, and having regard to Ministerial policy guidance, the promotion of fair trading and the desirability for an efficient and competitive food industry, FSANZ is proposing to permit the addition of the following vitamins and minerals to FB in the amounts requested by the Applicant:

Vitamins Riboflavin Folate Vitamin B₆ Vitamin D Vitamin E Beta-carotene Vitamin C Thiamin Niacin Pantothenic acid Vitamin B₁₂ <u>Minerals</u> Calcium Iodine Iron Magnesium Selenium

5.2.4.2 Sugar content

As discussed in Section 5.2.3.1 there is potential for the consumption of FB to increase the sugar and energy intakes of the population. In order to effectively manage this risk, especially as it relates to children, FSANZ is proposing to restrict the amount of sugar permitted in FB.

Subclause 7(3) of Standard 1.2.8 – Nutrition Information Requirements stipulates a daily intake reference value for sugar of 90 g. On the basis of the requested reference quantity of 600 ml and in the light of current public health recommendations encouraging moderate sugar intake, 50% of the daily intake reference value for total sugar has been applied to the requested reference quantity of 600 ml. This equates to 45 g of sugar per 600 ml, or 7.5 g of sugar per 100 ml of FB.

From the 2005 Product Surveys, the proposed restriction on sugar will most likely impact on those FB that contain greater than 5% fruit juice and added sugar. Presently there are three FB available in Australia and four in New Zealand that contain greater than 7.5 g sugar per 100 ml.

The proposed restriction on the sugar content of FB minimises the potential risk of increased energy and sugar intakes in the population. It also provides consistency with the Policy Guideline by reducing the likelihood that FB will promote the increased consumption of foods high in sugar.

FSANZ therefore is proposing a maximum limit of 7.5 g per 100 ml of sugar in FB.

5.2.4.3 The use of formulated beverages as ingredients in other foods

In the Code, individual foods can be used as ingredients in mixed foods except in the case of Standard 2.6.4 – Formulated Caffeinated Beverages which prohibits the mixing of FCB with other non-alcoholic beverages. The reason for this prohibition was that, without the accompanying labelling statements that advised appropriate conditions of use, there could be a risk to groups such as children from the unregulated use of FCB as ingredients in other non-alcoholic beverages.

At Initial Assessment, the issue of FB being used as ingredients in mixed foods was raised with the vast majority of submitters supporting a prohibition of their use in other foods.

The Policy Guideline explicitly states that *regard should be had to the policy in the development of regulatory measures applying to the mixing of foods where one, or both of the foods may be fortified.* As previously discussed, FB present a case in point where unless unambiguously described, they could provide an avenue for inappropriate products being fortified to make use of the broader vitamin and minerals permissions available. This could also be the case for using FB as ingredients in other foods.

Consequently, FSANZ is proposing a prohibition on the mixing of FB with other beverages as a means of effectively quarantining the permissions for addition of a broad range of vitamins and minerals to those products that are intended to be FB.

5.2.5 Labelling of formulated beverages

Labelling provisions are included within the Code as a means of achieving three main objectives: to protect public health through the management of risk, to provide adequate information to the consumer to facilitate informed choice, and to prevent misleading conduct.

The Policy Guideline states that *there should be no specific labelling requirements for fortified food, with the same principles applying to non-fortified food.* Therefore, the generic labelling requirements contained in Chapter 1 of the Code will apply to FB.

This Section discusses the application of the generic labelling requirements to FB as well as specific labelling issues raised at Initial Assessment.

5.2.5.1 Vitamin and mineral content claims

The Applicant has requested that FB be permitted to carry claims of 'source' or 'good source' for vitamins and minerals. These claims are permitted under clause 6 of Standard 1.3.2 - Vitamins and Minerals providing that the added vitamin or mineral is a permitted form; and is present in a 'claimable food³⁷' in amounts of no less than 10 % RDI per reference quantity for a 'source' claim. Clause 7 of Standard 1.3.2 permits a 'good source' claim where no less than 25 % RDI is present in a reference quantity of a food.

³⁷ 'Claimable food' is defined in Standard 1.3.2.

FB will be considered a 'claimable food' under Standard 1.3.2. Therefore, vitamin and mineral claims will be permitted for FB in accordance with clause 6 and 7 of the Standard. The permission for claims is consistent with other general-purpose food. In accordance with clause 9 of Standard 1.3.2, FB will be required to also include the proportion of the RDI per serve.

5.2.5.2 Nutrition, health and related claims

Nutrition claims, other than vitamin and mineral content claims, are currently regulated either by Standard 1.2.8 or the *Code of Practice on Nutrient Claims on Food Labels and in Advertisements* (CoPoNC).

Currently, there is a general prohibition on health claims on food labels or in advertising under Transitional Standard 1.1A.2 of the Code (except for the permitted pilot health claim regarding maternal folate consumption and a reduced risk of foetal neural tube defects, such as spina bifida).

The regulation of nutrition, health and related claims are being reviewed under Proposal P293, which is currently at Draft Assessment. Until such time as Proposal P293 is finalised, the existing provisions of Standard 1.2.8, CoPoNC and the general prohibition on health claims will apply to all food, including FB.

5.2.5.3 Percentage daily intake

At Initial Assessment, it was suggested that if an average quantity of a nutrient in a serve is declared in a nutrition information statement such as a NIP, Standard 1.2.8 – Nutrition Information Requirements would permit that quantity to be expressed as a percentage of a reference daily value, which in the case of vitamins and minerals is the RDI. It was noted that if this approach were considered appropriate for FB, expressions of content up to multiples of the RDI would be possible and that such information may lead consumers to believe that these products should play a more significant role in the diet than may be warranted.

Since Initial Assessment, the requested vitamin and mineral permissions have been revised downwards to 25% of the RDI with the exception of vitamin C, at 100% of the RDI per 600 ml reference quantity. Multiples of the RDI are therefore no longer an issue and restricting vitamin and mineral claims to quantitative declarations only is not considered necessary.

5.2.5.4 Prescribed name

Prescribed names are provided in the Code primarily for use by enforcement agencies in the identification and regulatory classification of foods.

At Initial Assessment, submitters were asked whether the generic provisions in Standard 1.2.2 – Food Identification Requirements that require a label to contain ...*a name or description of the food sufficient to indicate the true nature of the food* would adequately allow for the identification of FB. Eleven submitters commented on the use of a prescribed name. The five food industry submitters who responded all considered that there is no need for FB to have a prescribed name. Their rationale being that a prescribed name would have no meaning to consumers and that claims, ingredients and nutrition information panels would be sufficient to identify FB.

The remaining six submitters (two complementary medicine industry, two public health, one consumer and one government) were in favour of a prescribed name for identification and enforcement purposes so FB can be distinguished from other beverages such as soft drinks.

The Applicant requested that the term 'formulated beverage' not be prescribed. FB currently manufactured under the NZDSR are required to label products as 'dietary supplement'. The FB manufactured in Australia to the current sports food standard are also required to label products as 'Formulated Supplementary Sports Food'. The additional labelling requirement reflects the nature of these sports foods as special-purpose food.

Given the classification of FB as general-purpose foods, for consumption by the general population, FSANZ does not consider a prescribed name for FB to be necessary for the purpose of identification for consumers and/or enforcement agencies.

5.2.5.5 Mandatory labelling statements for FB

Where appropriate, mandatory labelling statements are used to manage risk. Such statements can alert consumers to the compositional nature of a product and/or identify population groups for which particular products are not recommended.

At Initial Assessment, submitters were invited to comment on whether FB should be labelled with statements that advise against the use of FB as substitutes for a healthy diet or as providing health benefits. Of the ten submitters who provided comments, those received from the industry sector (5) did not support the use of these statements, viewing them as unnecessary, unreasonable and applicable to all food products. The remaining five submitters (one complementary medicine industry, two public health, one consumer and one government), all supported the use of such statements. One public health submitter who considered the information as essential to ensure informed consumer choice, suggesting additional statements such as: 'a healthy diet provides other essential components as well as vitamins and minerals'. The complementary medicine industry submitter considered the advisory statement appropriate and consistent with complementary medicines and other food categories.

As part of the 2003 FTDS consumer research, participants were exposed to a number of labelling elements including a statement which cautioned against regarding FTDS as 'magic bullets' – *this product should be consumed in the context of a healthy, balanced diet.* The statement was generally viewed as either obvious, condescending, or meaningless. For some, the statement was seen as a good way of cautioning vulnerable shoppers, such as those less experienced, and children, who may inadvertently consume excessive amounts of a supplemented product. Overall, however the statement was regarded as an idealistic health education message rather than a motivator to further investigate the products claim(s).

The risk assessment has not identified any population groups considered at risk from FB consumption. The proposed permitted vitamins and minerals to be added to FB are considered to be at moderate levels and are consistent with permissions for other general-purpose food. These fortified foods are not required to carry any additional advisory statements in relation to dietary advice and/or food selection. FSANZ considers that the information contained in the NIP and the ingredient listing, together with the permitted vitamin and mineral claims should ensure sufficient information is available to enable consumers to assess the appropriateness of FB when making food/beverage choices.

In light of the above comments, FSANZ is of the opinion that mandatory advisory statements are not necessary for FB.

5.2.5.5 Conclusion

In accordance with the policy guidance, FSANZ is not proposing any specific labelling requirements for FB. Therefore, the generic labelling requirements contained in Chapter 1 of the Code will apply.

5.2.6 Food additives

A detailed Food Technology Report is provided at Attachment 9.

The use of food additives is regulated by Standard 1.3.1 – Food Additives, with permissions provided by Schedules 1 to 4. Schedule 1 of this Standard permits the use of food additives at specified levels in specific foods. Maximum permitted levels are prescribed for additives where risk assessment indicates a need to restrict usage levels to protect public health and safety. Schedule 2 lists food additives that may be used to levels determined by Good Manufacturing Practice (GMP) where permitted by Schedule 1. Schedule 3 lists colours that are permitted to GMP levels where permitted in Schedule 1. Schedule 4 lists colours that are restricted to 70 mg/kg for liquids and to 290 mg/kg for solid foods and which may be further restricted by Schedule 1. Schedule 5 lists the permitted technological functions to be performed by food additives as distinct from processing aids (Standard 1.3.3) and vitamins and minerals (Standard 1.3.2).

The Applicant has requested permission for use of a wide range of food additives in FB. Some of these requests are covered by the general permissions in Schedule 2 of Standard 1.3.1 and colours have been requested for use in accordance with Schedules 3 and 4. The levels requested for other additives are compliant with the permissions currently available for non-alcoholic beverages in Schedule 1 under the categories of 14.1.2.2 – Fruit and vegetable juice products and of 14.1.3 – Water-based flavoured drinks. A comparison of the requested food additive permissions for A470 and the current permissions for food additives in comparable products is included in the appendix to Attachment 9.

It is important to note that there are some differences in food additive permissions sought for FB and those currently permitted for comparable products, and the restrictions that need to be maintained. These are listed below:

- no permissions sought for quinine;
- no permissions sought for cyclamate;
- no permissions sought for carbon dioxide;
- permissions for acesulphame potassium at 3,000 mg/kg comparable to water-based flavoured drinks;
- permissions for sodium and calcium propionate for fruit and vegetable juices and fruit and vegetable juice products only at GMP;
- permission for calcium disodium EDTA for products containing fruit flavouring, juice or pulp or orange peel extract only; and
- permission for annatto extracts for fruit and vegetable products only.

The majority of submitters to the Initial Assessment agreed with the requested list of additives, believing they were appropriate for their technological purposes and were the same as approvals for other beverages.

However, one public health submitter raised concerns about sensitive individuals with asthma, hyperactivity and chronic allergy reactions to benzoic acid, sulphites and annatto. The approvals for benzoates and sulphites are requested to be the same as for the commonly produced and consumed water-based flavoured drinks. These preservatives have an accepted technological function of preserving the drinks and they have been assessed as safe. Concerned consumers can avoid such drinks by checking the ingredient list on the labels. Annatto currently has specific approval for fruit and vegetable juice products and therefore could only be considered for comparable FB that contain such fruit ingredients.

Concerns were also raised that the maximum permitted level of calcium disodium EDTA of 33 mg/kg is more than the Acceptable Daily Intake (ADI, 2.5 mg/kg bw/day for a young child of less than 13 kg, if they consumed 1 litre of FB per day over a life time). However, the situation for calcium disodium EDTA is again consistent with current approvals for water-based flavoured drinks and fruit drinks. The permission is only for products containing fruit flavouring, juice or pulp or orange peel extract. This use is technologically justified to chelate metal ions from solution to ensure flavour retention in FB.

5.2.6.2 Conclusion

The requested food additives are technologically justified for their proposed use in FB in the same way as they are technologically justified for their current use in comparable fruit and vegetable juice products and water-based flavoured drinks.

On the basis of the dietary exposure assessment for food additives (at Attachment 8) which concludes that the requested 57 food additives/additive groups to FB would not raise any public health and safety concerns, FSANZ is permitting their addition to FB.

5.2.7 Other issues raised in submissions

At Initial Assessment, submitters were asked to comment on number of issues which, at the time, were considered to have direct relevance to the regulation of FB. These were the use of a maximum one-day quantity and the addition of non-culinary herbs. In light of the subsequent amendments to the Application and the fact that the Applicant is not seeking the inclusion of non-culinary herbs to FB, these issues are no longer considered relevant to the consideration of this Application.

No other relevant issues were raised by submitters in response to the Initial Assessment Report.

5.2.8 Risk management summary

In summary, FSANZ is proposing the following regulatory approach for FB:

- classification of FB as a general-purpose food;
- inclusion of a definition for FB in the Code, in association with a maximum limit of 24% of fruit ingredients;

- exclusion of cordials as FB;
- restriction of total sugar content to 7.5 g/100 ml;
- application of generic labelling requirements to FB;
- permissions for the range of food additives requested by the Applicant (as detailed in Attachment 9); and
- permissions for the addition of vitamins and minerals in amounts to allow 'source' (10% RDI) and/or 'good source' (25% RDI) claims with the exception of vitamin C (100% RDI) per 600 ml reference quantity as outlined in the table below:

Vitamin / Mineral	Maximum Claimable Amount Per 600 ml Reference Quantity	No Public Health and Safety Concerns	Consistent with FSANZ's s.10 (2)(c), s.10(2)(d) and s.10(2)(e)
			Objectives*
Vitamins			
Beta-carotene	200 µg	\checkmark	\checkmark
Thiamin	0.28 mg	\checkmark	\checkmark
Riboflavin	0.43 mg	\checkmark	\checkmark
Niacin	2.5 mg	\checkmark	\checkmark
Folate	50 µg folic acid	\checkmark	\checkmark
Vitamin B ₆	0.4 mg pyridoxine	✓	\checkmark
Vitamin B ₁₂	0.5 μg	✓	\checkmark
Vitamin C	40 mg in total of L-ascorbic acid and dehydroascorbic acid	✓	\checkmark
Vitamin D	2.5 μg	✓	\checkmark
Vitamin E	2.5 mg alpha-tocopherol equivalents	✓	\checkmark
Pantothenic Acid	1.3 mg	✓	\checkmark
Minerals			
Calcium	200 mg	\checkmark	\checkmark
Iodine	38 µg	\checkmark	\checkmark
Iron	3 mg	✓	\checkmark
Magnesium	80 mg	✓	\checkmark
Selenium	17.5 μg (inorganic and organic forms)	\checkmark	\checkmark

* FSANZ Act section 10(2)(c) the desirability of an efficient and internationally competitive food industry. FSANZ Act section 10(2)(d) the promotion of fair trading in food.

FSANZ Act section 10(2)(e) any written policy guidelines formulated by the Council for the purposes of this paragraph and notified to the Authority.

6. **Regulatory Options**

At Initial Assessment, two regulatory options were proposed either to maintain status quo or include regulations specific to FB in the Code. However, since this time FSANZ has determined, on the basis of its assessment, the need for an additional option. Therefore FSANZ is proposing the following three regulatory options at Draft Assessment:

6.1 Option 1 – Maintain *Status Quo*

Under this Option, there would be no change to the current regulatory arrangements for FB. FB would continue to be manufactured under the NZDSR and sold in New Zealand and/or exported to Australia. In Australia, without specific FB provisions in the Code, beverage manufacturers would have to continue manufacturing FB using the existing FSSF Standard (with specific mandatory labelling requirements), which is not intended to regulate FB.

6.2 Option 2 – Amend the Code to permit the addition of a defined set of vitamins and minerals to FB (excluding cordials) with additional specific compositional requirements.

Under this Option, FB would be permitted with a defined set of vitamin and minerals (that do not present any public health and safety concerns), in addition to a restriction on the sugar content of FB. This Option would allow Australian manufacturers to access the FB market without having to utilise the existing FSSF Standard. In addition, Australian and New Zealand manufacturers would be able to compete equitably.

6.3 Option 3 – Amend the Code to permit the addition of vitamins and minerals to FB and cordials as requested by Applicant without any other specific compositional requirements.

Similar to Option 2, this Option permits Australian and New Zealand Manufacturers to manufacture FB and compete equitably. However, Option 3 includes permission for the addition of a broader range of vitamins and minerals without additional compositional restrictions being imposed.

7. Impact Analysis

7.1 Affected Parties

The parties affected by this Application are:

- the non-alcoholic beverage industry in Australia with the capability to manufacture FB, importers of FB into Australia, and the non-alcoholic beverage industry in New Zealand that currently manufactures FB;
- consumers of FB in Australia and New Zealand; and
- agencies of the State and Territory governments in Australia and of the New Zealand government that are responsible for enforcing food regulation.

7.2 Data Collection

The impact analysis has been informed by market intelligence on FB provided by the Applicant, interviews with the Applicant on current conditions in the Australian market, research commissioned and undertaken by FSANZ into the FB product range available in Australia and New Zealand, and by official statistics supplied by the Australian Bureau of Statistics and Statistics New Zealand.

7.3 Impact Analysis

7.3.1 Option 1 - Maintain Status Quo

7.3.1.1 Impacts on Australian Industry

Currently there are no specific provisions in the Code for FB. However, some manufacturers are using the FSSF Standard to produce FB, which, as noted previously, is intended for products specially formulated to assist sports people in achieving specific nutritional or performance goals. It imposes strict labelling requirements including the mandatory advice that such products are 'Not suitable for children under 15 years of age or pregnant women: Should only be used under medical or dietetic supervision'. These labelling requirements have been acceptable to only a few Australian companies that produce distinctive products for niche markets and account for one-fifth of the Australian FB market. For most of the non-alcoholic beverage market, however, these labelling requirements are unacceptable.

The Applicant, representing the major beverage manufacturers in Australia, believes that the mandatory labelling advice is unsuitable for FB as a generally available consumer product: it would diminish consumer perceptions, marketing and distribution of the products. Hence the lack of a specific FB permission in the Code, unencumbered by mandatory labelling requirements, is a serious impediment to Australian industry. Some indication of the lost manufacturing opportunity to Australian industry is indicated by the size of FB imports from New Zealand (under the TTMRA) that are not required to carry any specific labelling advice, of around \$A40 million in 2004.

Another indication of the lost manufacturing opportunity would be the future growth in the Australian FB market that Australian industry cannot participate in. Market intelligence indicates growth of 10% p.a. would be possible and may be conservative in the next few years, fading to around 5% p.a. in five years time. These growth rates are significantly stronger than for the general soft drinks market, of a little over 1% p.a., reflecting the difference between a small developing market and a large mature market. On the basis of such future growth, the Australian FB market could be expected to double over the next ten years. Under current regulatory arrangements this burgeoning market in Australia will not be accessible to most local non-alcoholic beverage producers.

The lost manufacturing opportunity also includes forgone exports. A local manufacturing base would support additional production for export, valued by the Applicant at between \$A9 million and \$A30 million per year.

Around 80% of the Australian market is supplied by imports from New Zealand (under the TTMRA), which benefits the importers and distributors of these products.

The Australian non-alcoholic beverage industry is concerned by the lost manufacturing opportunities associated with forgone production because of the inequity in the current regulatory arrangements. While Australian industry is disadvantaged, New Zealand industry is advantaged through its ability to manufacture and its access to the Australian market that for the most part is unhindered by competition from Australia.

Importers benefit under the current regulatory arrangements because most of Australia's FB market is supplied by imports from New Zealand. The extent the benefit would be small compared with the lost manufacturing opportunities of the non-alcoholic beverage industry.

7.3.1.2 Impacts on New Zealand Industry

In contrast to Australia, the New Zealand regulatory arrangements have not constrained their industry's ability to respond to international market trends, but rather has facilitated this expansion. New Zealand manufacturers are noted as early adopters of overseas trends. The non-alcoholic beverage manufacturers developed a number of FB and one company in particular was highly innovative and now dominates this product category. The local market has responded well to the offering. FB have grown from a small market in 2000 to around \$NZ17 million in 2004. This solid manufacturing activity provided a base to expand into exports, valued at \$NZ35 million free-on-board (f.o.b.) in 2004, of which \$NZ32 million f.o.b. is exported to Australia. The regulatory arrangements in New Zealand have been beneficial to the local New Zealand non-alcoholic beverage industry.

Under this option, the New Zealand industry will continue to be at a greater advantage when compared to the Australian industry in their ability to market FB in both countries and internationally without significant competition from Australia.

7.3.1.3 Impacts on Consumers

The current regulatory arrangements permit consumers in Australia and New Zealand access to a market in FB, of around \$A50 million and \$NZ17 million respectively in 2004. Most FB are manufactured by multinational food and beverage companies and would be available in many other countries. Australian and New Zealand consumers are therefore participating in a recent innovation in non-alcoholic beverages that is a global phenomenon. The FB market, though small compared with the general market for beverages, is of sufficient size to offer a range of products, and consumers will be aware that they are able to exercise real choice in selecting their preferred product. Hence the current regulatory arrangements are supportive of consumers who have an interest in or desire to consume FB.

Australian consumers are unlikely to be aware that most FB are imported from New Zealand. They also are unlikely to perceive any restrictions on their FB purchases that may be associated with current regulations that inhibit local manufacture of these products.

Some Australian consumers have an assurance of the safety of the FB they purchase, because one-fifth of the Australian market is manufactured by local companies under the FSSF standard in the Code. The remainder of consumers in Australia and New Zealand are not provided with an equivalent level of assurance. The NZDSR, that permits the sale of the majority of FB, does set maximum daily doses for some vitamins and minerals, but it does not take into account their total daily intake by consumers, leaving open the possibility that consumption of FTDS could involve over-exposure and potential harm. Most consumers would be unaware of any potential risks associated with their consumption of FTDS and FB in particular.

7.3.1.4 Impacts on Government Enforcement Agencies

For the government sector, maintenance of the *status quo* means a continued discrepancy between Australian and New Zealand food law, not a broad united approach, which has the potential to undermine the joint food standards system. It also creates greater ambiguity for Australian enforcement agencies if two different regulatory measures are to be retained.

For example, an enforcement officer has to decide whether a product: complies with the FSSF standard; is a known import from New Zealand (under the TTMRA); or is simply non-compliant with the Code. This confusion takes time and resources to resolve, and over many products and various sites could result in significant costs to the enforcement agencies of the States and Territories. The priority that the enforcement agencies attach to monitoring and enforcing to correct product labelling of FB will depend on the resources assigned to this activity. Thus while potential the cost could be significant, in reality the cost is likely to be small.

The ambiguity surrounding the food drug interface will continue as will the inappropriate application of the existing FSSF standard to FB.

By maintaining the status quo, it is likely that the Australian Government in particular will continue to experience political pressure and lobbying from the Australian beverages industry regarding the inequity of manufacturing opportunities.

In New Zealand the regulatory arrangements might be as confusing as those in Australia, with an enforcement officer having to decide whether a product complies with: the FSSF Standard; the NZDSR; or is simply non-compliant with the Code. If most FB comply with the NZDSR, as is likely to be the case, then the potential for confusion is much reduced.

7.3.2 Option 2 – Amend the Code to permit the addition of a defined set of vitamins and minerals to FB with additional specific compositional requirements.

Option 2 would affect the current range of FB on the market in Australia and New Zealand. Some products currently produced under the NZDSR would have to be reformulated to comply with the compositional requirements for FB in the Code. For example, the removal of non-permitted vitamins and/or minerals. All products would have to be reformulated to reduce to amounts of added vitamins and minerals, although for most added vitamins and minerals the reduction would be small. Some products would have to be reformulated to reduce the sugar content.

7.3.2.1 Impacts on Australian Industry

The compositional restrictions generally would not affect consumer perceptions of FB and hence in general Australian industry could compete effectively with the current range of New Zealand imports. The exception would be the few New Zealand imports with a higher sugar content which, in some circumstances, might have a market advantage.

The impact of the new permissions would be immediate. Many Australian companies already have developed FB which could be quickly introduced onto the Australian market. This includes the major beverage manufacturers, some of whom had imported small volumes of FB from their New Zealand associated companies to establish a presence on the Australian market.

They would be expected to switch to local manufacture (to avoid high transport costs) and vigorously promote their products. Australian industry would immediately seek to compete in earnest with the New Zealand market leader of FB that currently dominates the market. The result of this competition would not simply be a redistribution of market share between Australian and New Zealand producers. The competition could trigger growth of FB. The Australian market has lagged behind international consumer trends in FB and hence it offers opportunities for development as Australia catches up to international consumer levels. Market intelligence described the Australian FB market as "extremely small, underdeveloped and fragmented" and "still in its infancy", indicating substantial upside to further development. When global FB markets developed beyond the infancy stage, they grew at rates in excess of 20% p.a. in five years, is both possible and likely to be conservative. Overall the impact would be beneficial to the Australian non-alcoholic beverage industry.

Those businesses that currently manufacture FB under the FSSF Standard would have the choice to continue under that Standard or to comply with the new Standard.

The Applicant suggests that a solid manufacturing base in Australia would provide a platform to export FB to Asia, estimated at between \$A9 million and \$A30 million per year.

Importers could lose some business with the likely loss of some market share from New Zealand suppliers. However this could be a short-term phenomenon. Over the longer-term a smaller share of a growing market could still provide net-benefits to importers. **Distributors** of imported products could similarly lose business in the short term, although this loss would be offset by gains in business by distributors of locally produced FB.

7.3.2.2 Impacts on New Zealand Industry

Under this Option New Zealand beverage companies could elect to continue to produce FB under the NZDSR, or to produce under the new permissions in the Code. If they elect to continue to produce under the NZDSR, there will be no impact on New Zealand industry. If they elect to produce under the new permissions in the Code, then the majority of FB would need to be reformulated. A few products would have to remove zinc and vitamin A. The majority of FB would have to reduce the amounts of added vitamins and minerals, although in most cases the reduction would be small and the added nutrients could still be claimed on the label. These changes would be modest and involve a once-off adjustment cost. However the permission restricting sugar content could be significant to those FB with higher sugar levels and might adversely affect their continuing acceptance by consumers.

It is difficult to predict what industry's response would be to the new permissions in the Code. Previously, in similar circumstances, industry elected to produce under a new food standard rather than the NZDSR. The New Zealand government also has given in-principle support to repeal the food aspects of the NZDSR and for FTDS (which include FB) to be regulated under the Code. However, the prospect of incurring costs to reformulate existing products, and of the higher sugar content FB losing some of their appeal, in all probability would sway New Zealand industry in the short term at least to continue to produce under the NZDSR. In the longer term the NZDSR would continue to facilitate innovation, compared with the restrictions in the new permissions in the Code that would place limits on the nature of new products, providing an incentive to New Zealand industry to continue to produce FB under the NZDSR.

If New Zealand were to retain the NZDSR there could be come ramifications for trans-Tasman trade. New Zealand FB that do not comply with the proposed standard would still be able to be sold on the Australian market under the TTMRA. This is because under the TTMRA goods that can be legally sold in New Zealand can be legally sold in Australia, irrespective of any different standards or requirements relating to sale or manufacture of goods in Australia.

The major beverage manufacturers that had supplied small volumes of FB to their associated companies in Australia would discontinue these small additional volumes of production, and avoid their company incurring unnecessary and high transport costs. This action would have only a marginal effect on the New Zealand non-alcoholic beverage industry because the volumes have been small.

The major impact of Option 2 would be on the products of the market leader that dominates the FB markets in Australia and New Zealand. It would immediately face strong competition in Australia from local producers and inevitably face some loss of market share to the local producers, entailing a reduction in export earnings to New Zealand. However the competition could trigger a surge in growth of the Australian FB market, consistent with information from market intelligence. A smaller share of a strongly growing market, over a five or ten year period, could still deliver net-benefits to New Zealand.

The activities of New Zealand's small producers in exporting to Australia, if they have, are too small to be separately identified in the importer register or official statistics. Nonetheless a dynamic Australian FB market may prove attractive to small producers with niche products.

7.3.2.3 Impacts on Consumers

The most likely scenario for Option 2 would be that the Australian industry would produce FB under the new permissions in the Code while New Zealand industry would continue to produce under the NZDSR. In New Zealand the consumer impacts will be unchanged from the status quo. In Australia it is probable that consumers will not perceive any immediate change in the range and nature of FB on the market.

The new permissions would facilitate greater competition in the Australian market. Over time, as the FB market is expanded, Australian consumers would benefit from greater product choices, not only from ongoing innovation between existing players but also from the activities of potential entrants. A possible high level of advertising associated with this competition would inform a broader group of consumers, and it is likely that new consumers of FB would appreciate their properties.

Consumers of products covered by the Code will be protected from a range of risks and potential harm. Sugar content will be restricted and hence FB will not contribute to the potential problem of obesity nor the chronic diseases associated with obesity. Consumers will be protected from any nutrients, where potential safety concerns exist. The new permissions will place limits on the amount of vitamins and minerals that can be added, protecting consumers from the potential harm that can occur with over-exposure to these nutrients. The Australian industry has no option but to abide by the Code, and hence where there is an inadequate intake in the population of certain nutrients, its products will benefit consumers, compared to the status quo.

7.3.2.4 Impacts on Government Enforcement Agencies

In Australia the requirements of the two pertinent provisions in the Code – the new FB permission and the FSSF Standard – would be clear and easy to enforce. However imports from New Zealand, which are manufactured under the NZDSR, could still be an issue. It is unclear as to whether or not New Zealand imports would comply with the new permissions rather than relying on the NZDSR and TTMRA, however it is hoped that in keeping with the spirit of the joint Code this would occur. The New Zealand Government has also given in-principle agreement to repeal the food aspects of the NZDSR and for FTDS (including FB) to be regulated under the Code. As noted previously, the NZDSR were in fact designed to regulate controlled dosage supplements such as tablets and capsules. Further, the original intention of the NZDSR was to encompass those products not regulated by the (then) New Zealand *Food Regulations 1984*, rather than provide a choice of regulatory options for the food industry. From the assessment in the preceding industry section, there are circumstances which favour New Zealand businesses switching from the NZDSR to the FB permission in the Code. However the situation is ambiguous and overall enforcement costs in Australia are likely to be much the same as under the *status quo*.

It is acknowledged that the enforcement burden may be greater in New Zealand as the new permissions are more restrictive than the NZDSR in relation to compositional requirements. They would require some effort to become familiar with new regulations and, in enforcement, determine which of two very different regulatory regimes apply to any given FB product.

7.3.3 Option 3 – Amend the Code to permit the addition of vitamins and minerals to FB as requested by the Applicant without any other specific compositional requirements.

7.3.3.1 Impacts on Industry

The set of vitamin and mineral permissions would be sufficiently broad that:

- no FB currently on the market in Australia and New Zealand would require reformulation; and
- future innovations in FB would be unrestricted in practically all cases in the choice and amount of nutrients to add to beverages.

New Zealand industry could easily move from the NZDSR to the Option 3 permissions, with little cost, and over the short term would probably do so. Competition in the Australian market would be intense, as outlined in the previous option, with the exceptions that there would be no regulatory-driven difference between products produced in Australia and New Zealand. Australian industry would benefit from access to the local market. While New Zealand industry would lose some market share, a smaller share of a growing market could still deliver net-benefits.

Importers could lose some business with the likely loss of some market share from New Zealand suppliers. However this could be a short-term phenomenon. Over the longer-term a smaller share of a growing market could still provide net-benefits to importers. **Distributors** of imported products could similarly lose business in the short term, although this loss would be offset by gains in business by distributors of locally produced FB.

7.3.3.2 Impacts on Consumers

The range and character of FB under Option 3 would be similar to what is already on the market, so consumers would perceive no immediate impact at all in moving from Option 1 to Option 3. Option 3 would facilitate greater competition and growth in the Australian market and over time Australian consumers would benefit from expanded product choices.

However, the broad set of permissions under Option 3 includes nutrients that:

- could adversely affect consumers' health at exposure levels that are possible within a normal diet; or
- are not known to be safe as ingredients in food on currently available information; or
- do not fulfil a health need.

The set of permissions is too broad to provide an assurance of safety to the public. These permissions would not be subject to compositional restrictions, increasing the possibility of overexposure of the added nutrients. These health risks could occur where future FB innovations include a broader set of vitamins and minerals, or increased amounts of vitamins and minerals. In addition the absence of a restriction on sugar content of FB would contribute to the problem of obesity and the chronic diseases associated with obesity. In these circumstances consumers potentially could incur significant costs to their health and well-being.

7.3.3.3 Impacts on Government Enforcement Agencies

The set of vitamin and mineral permissions would be sufficiently broad that industry in New Zealand and Australia would be expected to adopt it as the single standard for FB, in preference to the NZDSR or the FSSF Standard. In these circumstances, enforcement would be a simpler activity than under Option 1 and fewer resources would be required.

8. Consultation

8.1 Public Consultation

8.1.1 Initial Assessment

FSANZ received a total of 19 written submissions in response to the A470 Initial Assessment Report during the public consultation period of 15 January 2003 to 26 February 2003. Of these, 14 were from Australia, two from New Zealand and three represented Australasian interests.

Thirteen submissions were received from the industry sector, including three submissions from the complementary medicine industry. There were also three submissions from government, two from public health organisations and/or professionals and one from a consumer group.

Submitters' views were evenly divided between the two proposed regulatory options maintaining the status quo and supporting an amendment. One submitter did not state any preferred regulatory approach.

A summary of submissions received is at Attachment 10. Where appropriate, issues raised in submissions have been addressed in Section 5 of this Report. Whilst submitters' comments form an integral part of the assessment process, FSANZ notes that in some instances comments may not be as relevant as when raised in 2003.

Draft Assessment

FSANZ is now seeking comment in relation to this Draft Assessment Report. Comments received in response to this Report will be used to assist in the development of a Final Assessment Report.

Submitters are invited to provide comments in relation to the:

- issues discussed in Section 5 of this Report; and
- proposed regulatory options, and potential impacts in relation to these regulatory options.

8.2 World Trade Organization (WTO)

Australia and New Zealand are members of the WTO and are bound as parties to WTO agreements. In Australia, an agreement developed by the Council of Australian Governments (COAG) requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory. Under the Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System, FSANZ is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO.

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

There are no international regulations governing FB rather these products appear to be included in countries fortification policies more broadly. This approach is reflected in the FB permissions proposed to be contained within Standard 1.3.2 – Vitamins and Minerals of the Code.

Amending the Code to permit FB is unlikely to have a significant effect on trade. However, unless the repeal of the NZDSR occurs, FSANZ recognises that there are potential trade implications. Therefore, notification of the proposed FB regulations will be made to the WTO in accordance with the WTO Technical Barrier to Trade Agreement.

9. Conclusion and Recommendation

Option 2 permits the addition of a defined set of vitamins and minerals, which do not pose any public health and safety concerns, to FB (excluding cordials) in addition to a restriction on total sugar content. Option 2 delivers net-benefits in comparison with Option 1 (*Status Quo*).

The main benefit offered under Option 2 is the elimination of the lost manufacturing opportunity incurred by a large part of Australian industry which cannot supply the domestic market under the current regulatory arrangements. This situation is resolved in Option 2 by allowing the manufacture and sale of FB.

Option 2 would facilitate a period of strong competition and growth in the Australian market, to the benefit of Australian and New Zealand industries over the longer term. In the short term, New Zealand industry would lose some part of its share of the Australian market, but over time, the growth in the FB market would more than compensate for the loss. A smaller share of a strongly growing market could still provide net-benefits to New Zealand industry over the longer term.

Consumers are unlikely to perceive any immediate difference if Option 2 is introduced, because the New Zealand product range probably will not change and the Australian products will claim a similar range of nutrients. Over time, with competition between suppliers and expansion of the Australian market, Australian consumers will benefit in comparison with Option 1 in terms of greater choice of FB. Consumers of those products produced under the Code would also benefit from the protection of their health and safety that Option 2 would provide, through the limits placed on the amount and range of acceptable vitamins and minerals. Some consumers may perceive this protection and consume FB with greater confidence.

Option 2 fulfils the specific objectives of this Application. The health and safety of consumers is protected through limits on the level of fortification to ensure safe levels of consumption, and by excluding specific nutrients that could be potentially hazardous, or where their safety cannot be verified.

Option 2 provides a framework for the non-alcoholic beverage industry in Australia and New Zealand to produce FB under a common standard. If the New Zealand industry continued to produce FB under the NZDSR, there would be little difference in the short term because the product range would be similar to those products allowable under Option 2. Over time and with the introduction of new FB, differences could emerge between Australian and New Zealand. However there are good reasons why New Zealand industry may elect to switch from the NZDSR to the permissions under Option 2, including the previous choices of New Zealand industry in similar circumstances and the New Zealand Government's in-principle agreement to repeal the NZDSR.

Option 3, which permits the addition of vitamins and minerals to FB as requested by the Applicant without any other specific compositional requirements, provides greater netbenefits to industry compared with Option 1. These benefits to industry also exceed the benefits from Option 2, because under Option 3 manufacturers may draw from a broader range of vitamins and minerals for future development of FB, eliminating the time and cost of obtaining regulatory approval and facilitating faster innovation. However, Option 3 could potentially impose large costs on consumers, in comparison with Option 1, by allowing specific nutrients that may have adverse health impacts. In addition, by not limiting the levels of vitamins and minerals in FB, this could possibly cause overexposure to these nutrients, and potential harm to consumers. Option 3 does not achieve the objective of protecting public health and safety, and is thus rejected.

Overall, Option 2 is the preferred regulatory option.

FSANZ recommends that the proposed draft variations to the Code (Attachment 1), incorporating defined vitamin and mineral permissions, specific compositional requirements, and a definition for FB, be approved for the following reasons:

- the regulation of FB provides assurance for consumers regarding the protection of public health and safety by:
 - permitting the safe addition of vitamin and minerals to FB;
 - permitting the addition of vitamins and minerals to FB where an inadequacy or deficiency exists; and
 - setting a prescribed limit on the total sugar content of FB;
- regulation of FB ensures certainty for industry balanced against the need to provide consumer choice and prevent consumers being misled regarding the nutritional quality of the product;
- the variations to the Code meet FSANZ's statutory obligations and are consistent with Ministerial policy guidance on voluntary fortification;
- the variations to the Code are consistent with Ministerial policy guidance on voluntary fortification and are therefore consistent with FSANZ's statutory obligations;
- the permitted range of vitamins and minerals is consistent with the principles of minimum effective regulation and the promotion of fair trading;
- the variations to the Code provide an effective regulatory framework within which industry can work efficiently and competitively;
- the inclusion of permissions for FB in the Code promotes equity by providing a regulation which enables the manufacture of FB in Australia;
- the explicit recognition of FB in the Code provides greater certainty for industry and reduces both the costs of compliance and enforcement; and
- the regulation impact assessment concludes that the preferred regulatory option of permitting net benefits from permitting FB outweigh any potential costs to affected parties.

10. Implementation and review

Following the consultation period for this document, a Final Assessment of this Application will be completed. Following the preparation of the Final Assessment Report and approval by the FSANZ Board, notification will be made to the Ministerial Council.

Following this, the proposed draft variations to the Code are expected to come into effect upon gazettal, subject to any request from the Ministerial Council for a review.

ATTACHMENTS

- 1. Draft variations to the Australia New Zealand Food Standards Code
- 2. List of Commonly Used Acronyms
- 3. Amendments to Application A470 Formulated Beverages
- 4. Summary of 2005 Formulated Beverages Surveys
- 5. Nutrition Assessment
- 6. Risk Assessment Micronutrients
- 7. Dietary Intake Nutrient Methodologies
- 8. Risk Assessment Food Additives
- 9. Food Technology Report
- 10. Summary of Submissions

Attachment 1

Draft Variations to the Australia New Zealand Food Standards Code

To commence: On gazettal

[1] Standard 1.1.1 of the Australia New Zealand Food Standards Code is varied by –

[1.1] omitting from the Schedule, from Column 2, in relation to Pantothenic acid –

No permitted form specified

substituting

Calcium pantothenate Dexpanthenol

[1.2] omitting from the Schedule, from Column 2, in relation to Selenium –

No permitted forms specified

substituting -

Seleno methionine Sodium selenate Sodium selenite

[2] Standard 1.3.1 of the Australia New Zealand Food Standards Code is varied by –

[2.1] inserting in Schedule 1 item 14.1.4 the heading –

Formulated Beverages*

[2.2] *inserting in* Schedule 1 item 14.1.4 *after the heading* Formulated Beverages* –

123	Amaranth	30	mg/kg	
160b	Annatto extracts	10	mg/kg	products containing fruit or vegetable juice only
200 201 202 203	Sorbic acid and sodium, potassium and calcium sorbates	400	mg/kg	
210 211 212 213	Benzoic acid and sodium, potassium and calcium benzoates	400	mg/kg	
220 221 222 223 224 225 228	Sulphur dioxide and sodium and potassium sulphites	115	mg/kg	
242	Dimethyl dicarbonate	250	mg/kg	
281	Sodium propionate	GMP		products containing fruit or vegetable juice only
282	Calcium propionate	GMP		
385	Calcium disodium EDTA	33	mg/kg	products containing fruit flavouring, juice or pulp or orange peel extract only
444	Sucrose acetate isobutyrate	200	mg/kg	-

445 480 950	Glycerol esters of wood rosins Dioctyl sodium sulphosuccinate Acesulphame potassium	100 10 3000	mg/kg mg/kg mg/kg	
951	Aspartame	GMP		technological use consistent with Clause 4 only
954	Saccharin	80	mg/kg	
955	Sucralose	GMP		technological use consistent with Clause 4 only
956	Alitame	40	mg/kg	-
957	Thaumatin	GMP		technological use consistent with Clause 4 only
961	Neotame	GMP		-

[3] Standard 1.3.2 of the Australia New Zealand Food Standards Code is varied by –

[3.1] inserting in alphabetical order in Column 1 in the Table to clause 3 the heading –

Formulated Beverages

[3.2] *inserting in* Columns 2, 3 and 4 *in the* Table to clause 3 *under the heading*, Formulated Beverages –

600	mL	folate	50 μg (25%)
		vitamin C	40 mg (100%)
		carotene forms of	200 µg (25%)
		vitamin A	
		niacin	2.5 mg (25%)
		thiamin	0.28 mg (25%)
		riboflavin	0.43 mg (25%)
		calcium	200 mg (25%)
		iron	3.0 mg (25%)
		magnesium	80 mg (25%)
		vitamin B ₆	0.4 mg (25%)
		vitamin B12	0.5 μg (25%)
		vitamin D	2.5 μg (25%)
		vitamin E	2.5 mg (25%)
		iodine	38 µg (25%)
		pantothenic acid	1.3 mg (25%)
		selenium	17.5 μg (25%)

[4] Standard 2.6.2 of the Australia New Zealand Food Standards Code is varied by –

[4.1] *omitting from the* Purpose –

The Standard defines a number of products and sets certain compositional requirements for packaged water, electrolyte drinks and brewed soft drinks.

substituting –

The Standard defines a number of products and sets certain compositional requirements for packaged water, electrolyte drinks, brewed soft drinks and formulated beverages.

- [4.2] *inserting in the* Table of Provisions
- 9 Composition of formulated beverages
- [4.3] *inserting in clause 1*
 - **Formulated beverage** means a non-carbonated, water-based flavoured beverage that contains added vitamins and/or minerals, prepared from one or more of the following:
 - (a) water; and
 - (b) fruit juice; and
 - (c) fruit purée; and
 - (d) concentrated fruit juice; and
 - (e) concentrated fruit purée; and
 - (f) comminuted fruit; and
 - (h) orange peel extract; and
 - (i) mineral water; and
 - (j) sugars.
- [4.4] *inserting after the* Editorial note *in clause 8* –

9 Composition of formulated beverages

- (1) A formulated beverage must contain no more than:
 - (a) 240 mL/L of fruit prepared from any of the sources specified in the definition for formulated beverage in paragraphs 1(b) to (g); and
 - (b) 75 g/L of sugars.
- (2) A formulated beverage must not contain carbon dioxide.
- (3) A formulated beverage must not be mixed with other beverages.

Attachment 2

Glossary Of Acronyms

ADI	Acceptable Daily Intake
ANZFA	Australia New Zealand Food Authority
ATDS	Australian Total Diet Survey
AUSNUT	Australian Food and Nutrient Database for Nutrition Labelling
CAC/GL	Codex Alimentarius Commission/General Letter
CFR	Code of Federal Regulations
COAG	Council of Australian Governments
Code	Australia New Zealand Food Standards Code
Codex	Codex Alimentarius Commission
CoPoNC	<i>Code of Practice on Nutrient Claims in Food Labels and in</i> Advertisements
EDTA	Ethylene-diamine-tetraacetic acid
EU	European Union
FAO	Food and Agriculture Organization
FB	Formulated Beverages
FCB	Formulated Caffeinated Beverages
FRSC	Food Regulation Standing Committee
f.o.b.	free-on-board
FSANZ	Food Standards Australia New Zealand
FSANZ Act	Food Standards Australia and New Zealand Act 1991
FSSF	Formulated Supplementary Sports Food
FTDS	Food-Type Dietary Supplements
GMP	Good Manufacturing Practices
JECFA	Joint Expert Committee on Food Additives
NIP	Nutrition Information Panel
NNS	National Nutrition Survey
NUTTAB	Nutrient Composition Database
NZDSR	New Zealand Dietary Supplement Regulations
Policy Guideline	Australia and New Zealand Food Regulation Ministerial Council's Policy Guideline on <i>Fortification of Food with Vitamins and Minerals</i>
RDI	Recommended Dietary Intake
RIS	Regulation Impact Statement
SPS	Sanitary and Phyto Sanitary

TBT	Technical Barriers to Trade
TGA	Therapeutic Goods Administration
TTMRA	Trans-Tasman Mutual Recognition Arrangement
UL	Upper Level of Intake
US	United States
USFDA	United States Food and Drug Administration
WHO	World Health Organization
WTO	World Trade Organization

Subsequent Amendments to Application A470– Formulated Beverages

27.06.02 Original Application lodged.

11.11.02 Withdrawal of request for quinine as an additive and revised requested vitamin and mineral levels.

- 22.11.02 Clarification of typographical errors re: additives sulphur dioxide and sulphates and glycerol esters of wood rosin.
- 30.12.02 Clarification of typographical errors re: sorbic acid and sorbates; benzoic acid and benzoates and propionates.
- 10.04.03 Agreement to replace term 'daily dose' 'one-day quantity'.
- 25.04.04 Withdrawal of request for carbon dioxide as a permitted ingredient.
- 27.08.04 Amendment of several aspects of the Application including:
 - definition of FB:
 - sugar sweetened waters
 - unsweetened water with no added sweeteners
 - non-nutritive sweetened waters sweetened only with non-nutritive sweeteners
 - sugar sweetened, still fruit drinks and fruit juice drinks (with juice added as an ingredient) but does not include fruit juice. These may also contain non-nutritive sweeteners.
 - non-nutritive sweetened water, still fruit drinks and fruit juice drinks (with juice added as an ingredient) but does not include fruit juice.
 - unsweetened, flavoured, still fruit drinks and fruit juice drinks (with juice added as an ingredient) but does not include fruit juice. These will have no additional sweetener.
 - cordials including fruit drink cordials and fruit juice cordials (with juice added as an ingredient) containing nutritive and non-nutritive sweeteners.
 - vitamins and minerals permissions:
 - approvals per reference quantity (600 mL)
 - revised vitamin and mineral levels
 - maximum claimable amounts reduced to 25% RDI (excluding vitamin C 100% RDI)
 - Withdrawal of request for addition of cyclamate.

28.10.04 Clarification of requested food additives.

Attachment 4

Survey Results

Formulated Beverage Survey - Australia 2005

Summary

Product Name	Content Claims	Other Claims	Directions for Use	Warnings and Advisory Statements	Package Size	Serving Size
AQUAVETA Flavours: with Lemon, Lime or Orange Juice	Nutrient Enhanced Water. Iron , Zinc, Calcium.	Aquaveta is a refreshing source of iron, zinc & calcium. These are essential nutrients necessary for a healthy body. Enjoy! No preservatives. No artificial colours or flavours.	It is recommended to drink 700ml to replace fluid lost. Consume 1-2 bottles per day. Remove quality seal under cap. Best before: see neck of bottle.	This is a Formulated Supplementary Sports Drink, not suitable for children under 15 years of age or pregnant women. Should only be used under medical or dietetic supervision. This is not a sole source of nutrition and should be consumed in conjunction with a nutritious diet and with an appropriate exercise program.	700ml	700ml
FRUIT 2 0 Flavours: Peach Passionfruit, Lemon Lime, Apple Cranberry	Flavoured Spring Water with Calcium and Vitamin C	Flavoured spring water (90%) with formulated supplementary sports food (10%)			600ml	200ml
G FORCE	Fruit Drink with		Push & Go cap. To open:	Warning: Choking risk.	400ml & 800ml	400ml
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	vitamins to go!		Remove clear overcap. Push	This cap contains small		
Flavours: Apple			down centre of green sipper	parts. Not suitable for		
& Blackcurrant			firmly to pierce the seal	children under 36 months.		
and Orange &			inside. Pull sipper up, drink			
Mandarin			and enjoy!			
			C			
			Serve chilled, once opened			
			keep refrigerated.		600 I	
JODIS IQ	Iodine Enriched	Don't drink just water, drink			600ml	Not Specified
	Water	Jodis.				(assume
Flavours:						600ml)
Natural, Lemon		No added sugar.				
Lime, Cranberry,						
Mandarin,		Iodine is a crucial element				
Passionfruit		for cell metabolism				
Infusion		stimulation. Iodine is a				
		building block fro thyroid				
		hormones. Iodine is an				
		essential nutrient required for	-			
		balanced thyroid function,				
		promoting vitality and well				
		being.				

MIZONE	Contains 5	To achieve your physical	Remove safety seal under	800ml	200ml
SPORTS	essential	best your body needs lots of	sinner can	000111	200111
WATED	vitaming C B3	water and MIZONE Sports	sipper cap.		
WAILN	$P_5 D_6 D_{12}$	Water is the assist way to	Some shilled ones anonad		
	DJ, D0, D12.	water is the easiest way to	Serve chined, once opened		
Flavours:		drink it. MIZONE is a	keep refrigerated.		
Mandarın, Lime,		pleasant, light tasting blend			
Lemon,		of purified water and fruit			
Passionfruit,		flavours with vitamins so it's			
Crisp Apple		easy to drink and it works.			
		Vitamin B's aid in energy			
		metabolism and antioxidant			
		vitamin C assists with			
		recovery and protection.			
		With vitamins and a splash			
		of flavour. MIZONE Sports			
		Water will rehydrate you so			
		you can achieve your goals			
DIAV	Fluorido	Low CI Sustained Energy		500mla	500mla
	Coloium and	Low Of Sustained Energy.		Soonins	Sooms
Diackcurrani					
Low GI	vitamins.	No artificial colours,			
Sportswater		flavours, sweeteners.			
		Ultra low glycaemic index -			
		16			
PLAY - <i>Fruit</i>	Fluoride, Calcium	No added sugar. No artificial		500mls	500mls
Fest No Added	and Vitamins.	colours, flavours, sweeteners.			
Sugar Sports					
Water	No added sugar				
	sports water.				

PLAY - Orange	With fluoride	Kids need to play every day.		500mls	500mls
Sportswater for	calcium &	PLAY is a nutrient enhanced			
Kids	vitamins.	sportswater specifically			
		formulated for kids. PLAY has			
	No artificial	an ultra low GI of only 16 - low			
	colours, flavours,	GI foods provide sustained			
	sweeteners.	energy for active, healthy kids			
		and avoid sugar highs and lows.			
	Fluoride, Calcium	,			
	B Vitamins.	PLAY has only 1/3 the sugar			
		content of most soft drinks, fruit			
	Ultra low GI, low	drinks, or cordials and only 1/2			
	sugar.	the sugar content of most sports			
		drinks. PLAY is enhanced with			
	Folate.	Fluoride & Calcium important			
		nutrients for the growth and			
	5% juice.	developments of strong bones			
		and teeth. PLAY also contains			
		Folate for healthy cell renewal,			
		and 5 essential B Vitamins for			
		energy.			
		With 5% juice and no artificial			
		colours, flavours or sweeteners			
		PLAY delivers great tasting			
		hydration and refreshment for			
		kids.			

POWERADE	With 5 essential	We all know how essential	Please remove foil seal from		750ml	400ml
WATER	vitamins B3, B5,	drinking water is to our	under cap.			
	B6, B9, B12	everyday health, but for some of	f			
Flavours:		us, plain water is just hard to	Best before date-see top of bottle.			
Mandarin, Lime &		drink. Powerade Water	1			
Grapefruit		contains purified water, with a	Store in cool place.			
		refreshing splash of fruity				
		flavour, 5 essential vitamins &				
		electrolytes. Now it's easy to				
		drink water every day. So				
		whether your'e at work, at home	,			
		or on the go, drink Powerade				
		Water.				
SOLIS Bliss	A wellbeing drink	Pink grapefruit, cranberry and			350ml	350mL
		strawberry infused with calcium	1			
		and B Vitamins.				
		Contains no artificial anything.				
SOLIS Cherish	A wellbeing drink	. White peach and pear infused			350ml	350ml
		with folate and vitamin C.				
approx	TT7'.1 11 1	Contains no artificial anything.			(00.1	(00.1
SPRING	With added	Getting some of your essential	It is recommended to drink 3-4	This is a formulated	600ml	600ml
VALLEY	calcium and	vitamins, minerals and water is	bottles per day, to replace fluid	supplementary sports drink -		
· Twist ·	vitmain C.	easier than ever. Just one bottle	lost. Consume no more than 6	Not suitable for children under		
Elmon with a	Cantaina 100/ af	of this water contains 10% of	bottles per day.	15 years of age or pregnant		
Flavour - with a	Contains 10% of	the RDI of calcium and 30% of	Dogt Defense See week of hettle	women.		
iwisi oj manaarin	Calaium and 20%	the RDI of vitamin C.	Best Before. See neck of bottle.	Should only be used under		
	of the PDI of	Calcium for strong teeth and		medical or distatio		
	Vitmain C	bones and vitamin C a		supervision		
	v iunani C.	powerful antioxidant which also		supervision.		
		aids in the absorption of iron		This drink is not a sole source		
		and in the absorption of non.		of nutrition and should be		
		No preservatives No artificial		consumed in conjunction with		
		flavours or colours.		a nutritious diet and with an		
				appropriate exercise program.		

TEMPLE HYDRO anything.Indulge your mind, body and soul with Tempbe Hydrotherapy trainain water. Infused with essential nutrients to nurture your body and exotic flavours to tantalise your taste buds. No antificial colour, no artificial soul with Tempbe Hydrotherapy to tantalise your taste buds. No antificial colour, no artificial aloeRecommended consumption sports food. Not suitable for children under 15 years of age or pregnant women: should only be used under medical or dietetic supervision.500ml500ml500mlTEMPLE THERAPY - Prove frain water inficial soul with Tempbe Hydrotherapy frain mater. Infused with essential nutrients to nurture your body and exotic flavours tantalise your taste buds. No artificial colour, no artificial soul with Tempbe Hydrotherapy index (GI) 16Soul with Tempbe Hydrotherapy soul with Tempbe Hydrotherapy with intrastes vont taste buds. No artificial colour, no artificial to avaitable your taste buds. No artificial colour, no artificial sweetners, no pres							
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vitamin water with antioxidantsrefreshment with your body and exotic flavours to tantalise your taste buds. No artificial colour, no artificial Low glycemic index (GI) 16your body and exotic flavours to tantalise your taste buds. No artificial colour, no artificial Sweeteners, no preservatives. Treat yourself.only be used under medical or dietetic supervision.TEMPLE HYDRO THERAPY - Blood orange water with flavour.No artifical undex (GI) 16Indulge your mind, body and soul with Temple Hydrotherapy vitmain water. Infused with essential nutrients to nurture your body and exotic flavours to tantalise your taste buds. No artificial claciumRecommended consumption 500ml per day.Formulated supplementary sports food. Not suitable for children under 15 years of age or pregnant women: should only be used under medical or dietetic supervision.500ml	grapefruit flavour	At lasthealthy	essential nutrients to nurture	For best before - see bottle.	or pregnant women: should		
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Low grycemic index (GI) 16sweeteners, no preservatives. Treat yourself.Sweeteners, no preservatives. Treat yourself.Seteners, no preservatives. Treat yourself.TEMPLE HYDRO THERAPY - Blood orange flavour vitamin water with calciumIndulge your mind, body and soul with Temple Hydrotherapy vitmain water. Infused with essential nutrients to nurture your body and exotic flavours to tantalise your taste buds. No artificial colour no artificialRecommended consumption 500ml per day.Formulated supplementary sports food. Not suitable for children under 15 years of age or pregnant women: should only be used under medical or dietetic supervision.500ml		т 1 '	artificial colour, no artificial				
TEMPLENo artifical anything.Indulge your mind, body and soul with Temple Hydrotherapy vitmain water. Infused with flavour vitamin water with flavour.Recommended consumption soul with Temple Hydrotherapy soul with Temple Hydrotherapy soul with Temple Hydrotherapy vitmain water. Infused with for best before - see bottle.Formulated supplementary sports food. Not suitable for children under 15 years of age or pregnant women: should only be used under medical or dietetic supervision.500ml500ml		Low glycemic	sweeteners, no preservatives.				
HYDRO anything. soul with Temple Hydrotherapy 500ml south 500ml	TEMDI E	Maertifical	I leat yoursen.			5001	5001
HYDRO anything. sour with Temple Hydrotherapy Soonh per day. sports food. Not suitable for children under 15 years of age or pregnant women: should only be used under medical or dietetic supervision. THERAPY - At lasthealthy essential nutrients to nurture your body and exotic flavours to tantalise your taste buds. No artificial colour no artificial For best before - see bottle. or pregnant women: should only be used under medical or dietetic supervision.	IEMPLE	No artifical	Indulge your mind, body and	Solution for the second	Formulated supplementary	Suomi	500mi
Blood orange At lasthealthy essential nutrients to nurture For best before - see bottle. or pregnant women: should flavour vitamin refreshment with flavour. flavour state buds. No or pregnant women: should calcium artificial colour no artificial or pregnant women: should only be used under medical or	H Y DKU THED A DV	anytning.	witmain water Infused with	Soomi per day.	sports food. Not suitable for shildren under 15 years of age		
Bioda orange At fastlearing essential numeries to	I HEKAF I -	At last boolthy	vitilialli water. Illused with	For bost before see bottle	or program woman: should		
water with flavour. to tantalise your taste buds. No dietetic supervision.	flavour vitamin	refreshment with	your body and exotic flavours		only be used under medical or		
calcium artificial colour no artificial	water with	flavour	to tantalise your taste buds. No		dietetic supervision		
	calcium	114 V UII.	artificial colour no artificial		aretette supervision.		
Low glycemic sweeteners no preservatives	cuctum	Low glycemic	sweeteners no preservatives				
index (GI) 16 Treat yourself.		index (GI) 16	Treat vourself.				

TEMPLE	No artifical	Indulge your mind, body and	Recommended consumption	Formulated supplementary	500ml	500ml
HYDRO	anything.	soul with Temple Hydrotherapy	500ml per day.	sports food. Not suitable for		
THERAPY -		vitmain water. Infused with		children under 15 years of age		
White peach	At lasthealthy	essential nutrients to nurture	For best before - see bottle.	or pregnant women: should		
flavour vitamin	refreshment with	your body and exotic flavours		only be used under medical or		
water with fibre	flavour.	to tantalise your taste buds. No		dietetic supervision.		
		artificial colour, no artificial				
	A good source of	sweeteners, no preservatives.				
	added fibre.	Treat yourself.				
TEMPLE	No artifical	Indulge your mind, body and	Recommended consumption	Formulated supplementary	500ml	500ml
HYDROTHERA	anything.	soul with Temple Hydrotherapy	500ml per day.	sports food. Not suitable for		
PY - Dragonfruit		vitmain water. Infused with		children under 15 years of age		
flavour vitamin	At lasthealthy	essential nutrients to nurture	For best before - see bottle.	or pregnant women: should		
water with iron	refreshment with	your body and exotic flavours		only be used under medical or		
	flavour.	to tantalise your taste buds. No		dietetic supervision.		
		artificial colour, no artificial				
	Ultra low	sweeteners, no preservatives.				
	glycemic index	Treat yourself.				
	(GI) 16					
THORPEDO -	Ultra low GI	Thorpedo Advanced Hydration	Best before: see neck of bottle.	This is a formulated	600ml	600ml
Advanced	energy water.	provides a unique energy		supplementary sports drink,		
Hydration	Beat the fade.	management system with a	Shake well. Refrigerate after	not suitable for children under		
		blend of key performance	opening.	15 years of age or pregnant		
Flavours: Orange,		electrolytes, 6 B complex		women.		
Lemon Lime,		vitamins and 2 antioxidants that				
Berry, Tropical		work in synergy with the Ultra		Should only be used under		
		Low GI carbohydrates to		medical or dietetic		
		hydrate and sustain energy. So		supervision.		
		whether you're working,				
		playing, training or competing,		I his is not a sole source of		
		enjoy I horpedo, stay hydrated		nutrition and should be		
		and energised and reel great all		consumed in conjunction with		
		uay.		a numinous diet and with an		
				appropriate exercise program.		

WATERPLUS	Antioxidants plus	Antioxidants are vitamins that	Remove quality seal under cap.	710ml	710ml
(Bickford)	electrolytes plus B	help protect body cells from			
	vitamins.	breakdown due to the stresses	Keep refrigerated once open.		
Flavours: Peach,		of everyday life.			
Lemon & Lime,	Sugar free.				
Lemon, Melon and		Electrolytes are essential			
Mandarin		minerals that assist in hydration.			
		B vitamins boost energy levels			
		and a feeling of well being.			
WATERPLUS	5 Minerals 7	Waterplus takes the hard work	Remove quality seal under cap.	710 ml	710ml
(Sanitarium)	vitamins.	out of hydration. A refreshing			
		blend of pure mineral water,	Keep refrigerated once opened.		
Flavours: Peach,	Electrolytes are	light flavours, with vitamins			
Lemon & Lime,	essential minerals	and minerals. Waterplus is easy			
Lemon, Melon and	that assist in	to drink. And most importantly			
Mandarin.	hydration.	with no sugar and only 2			
	Antioxidants are	calories per bottle you'll burn it			
Note: Bickford has	vitamins that help	off in around 30 seconds of			
since purchased	to protect your	walking. Drink Waterplus and			
product and	body against	feel the difference.			
reformulated	harmful free				
slightly.	radicals.				
	Low joule.				

PROPEL -	Good source of 6	Fitness Water Orange with	Refrigerate after opening	500mls	240ml
Fitness Water	vitamins as part of	other natural flavours.	8		
	daily diet.				
Flavour: Orange	, , , , , , , , , , , , , , , , , , ,	Quenches and nurtures your			
	The four B	body.			
Deleted Line ~	vitamins in Propel				
June 2004	aid in energy	No fruit juice.			
	metabolism,	-			
	antioxidants C &				
	E work together to				
	neutralize free				
	radicals to				
	effectively protect				
	your body. With				
	these 6 vitamins				
	and a splash of				
	flavour Propel				
	supports your				
	daily pursuit of				
	fitness and well				
	being.				
RIDE	Low GI.	Liquid for life. Low GI Food.	Drink often, feel great.	500ml	
		Delivers sustained energy.			
Flavours:	Enhanced with B	Rapid Hydration sustained			
Mandarin etc.	vitamins plus bio-	energy.			
	available trace				
Line Deleted ~	minerals &	Ride fitness water uses all			
Sep 2004 replaced	antioxidants -	natural fructose - the low			
by Play	specially	glycaemic index carbohydrate			
	formulated to help	that avoids the energy highs and			
	convert fructose	lows you get with ordinary			
	into sustained	sugars.			
	energy.				
		With 5% juice and a splash of			
		fruit flavour, Ride delivers great			
		taste, hydration and energy			
		supplement so you can ride hard			
		all day.			

SLINKY	Slinky is enhanced	The world's perfect diet drink.	Drink often, feel great.	500ml	500ml
	with Carnitine,	Low GI foods can help you feel			
Flavour: Mandarin	Chromate ® and	full for longer and as a result			
	Biotin - co-factors	you can end up eating less over			
Deleted Lined	that may assist in	the day.			
since ~ Sep2004	fat metabolism. Is				
	infused with	Low GI Slinky is a great tasting			
	Calcium & Folate	addition to your daily hydration,			
	for healthy cell	exercise & lifestyle plan.			
	renewal and B				
	vitamins to help				
	metabolise energy.				

Formulated Beverage Survey - Australia 2005

Composition

Product Name	Serving Size	No. of serves per day	Energy (kJ)	Total Fat (g)	Protein (g)	Carbohydrate (g)	Sugars (g)	Vitamins (percentage RDI per serve)	Minerals (percentage RDI per serve)	Herbal Extracts
							Per 100 ml Product			
AQUAVETA	700 ml	1-2 Bottles per day	38	0	0	2.2	2.2		Sodium=2 mg Calcium=11.4mg (10%) Iron=0.2mg (10%) Zinc=0.2mg (10%)	
FRUIT 2 0	200 ml	NS	56	0	0	3.3	3.3	C=2 mg (10%)	Sodium=3mg Calcium=40mg (10%)	
G FORCE	400 ml	NS	184	<1	<1	10.8	10.8	C=35mg (350%) E=1mg (40%) B3=1mg (40%) B5=0.5mg B6=0.16mg (40%) B12=0.2ug (40%)	Sodium< 5.1mg	
JODIS IQ	600ml	NS	NS	NS	NS	NS	NS		Iodine=0.015mg Calcium=12mg Magnesium=1.5mg Potassium=0.4mg HCO3=45mg Chloride=1.5 mg Sodium=Not Specified	

MIZONE SPORTS WATER	200 ml	NS	43	0	0	2.5	2.5	C=20mg (100%) B3=1mg (20%) B5=0.5mg B6=0.16mg (20%) B12=0.1ug (10%)	Sodium=<5mg	
PLAY Blackcurrant Low GI	500 ml	NS	72	0	0	4.2	4	B3=2.7mg (71%) B5=0.7mg B6=0.3 mg (94%) Folate=30ug (75%) Biotin=10ug B12=0.15ug (38%)	Calcium=16mg (10%) Fluoride=0.1mg Sodium=8mg	
PLAY Fruit Fest No Added Sugar	500 ml	NS	94	0	0	5.6	5.4	B3=2.7mg (71%) B5=0.7mg B6=0.3 mg (94%) Folate=30ug (75%) Biotin=10ug B12=0.15ug (38%)	Calcium=16mg (10%) Fluoride=0.1mg Sodium=8mg	
PLAY Orange Sportswater for Kids	500 ml	NS	72	0	<1	4	4	B3=2.7mg B5=0.7mg B6=0.3 mg Folate=30ug Biotin=10ug B12=0.15ug	Calcium=28mg Fluoride=0.1mg Sodium=8mg Potassium=9mg	

POWERADE WATER	400ml	Recommend ed daily consumption , Adults up to 6 bottles, children between 3 and 13 up to 2 bottles.	41	0	0	2.3	2.3	B3=0.5mg (20%) B5=0.25mg B6=0.08mg (20%) B9=20ug (40%) B12=0.2ug (40%)	Sodium=12mg Potassium=14mg	
SOLIS Bliss	350 ml	NS	182	<1	<1	11	11	B1=0.6mg B3=3.5mg B5=1mg B6=0.9mg B12=1.1ug	Calcium=30mg Sodium=8mg	
SOLIS Cherish	350 ml	NS	194	<1	<1	11	11	Folate=12.5ug C=15mg	Sodium=9mg	
SPRING VALLEY 'Twist'	600 ml	Recommend ed 3-4 bottles per day, consuming no more than 6 bottles.	44	0	0	2.6	2.6	C=2mg (30%)	Calcium=13.3mg (10%) Sodium=3mg	
TEMPLE HYDRO THERAPY - Honeydew flavour vitamin water with calcium	500ml	NS	80	<1	<1	4.7	4.7	B3=2.7mg (135%) B5=0.7mg B6=0.3mg (94%) Folate=30ug (75%) Biotin=10ug B12=0.15ug (38%)	Calcium=16mg (10%) Sodium=2mg	

TEMPLE HYDRO THERAPY - Star fruit flavour vitamin water with aloe	500ml	NS	80	<1	<1	4.7	4.7	B3=2.7mg (135%) B5=0.7mg B6=0.3mg (94%) Folate=30ug (75%) Biotin=10ug B12=0.15ug (38%)	Sodium=2mg	Aloe extract
TEMPLE HYDROTHER APY - Pink grapefruit flavour vitamin water with antioxidants	500ml	NS	80	<1	<1	4.7	4.7	B3=2.7mg (135%) B5=0.7mg B6=0.3mg (94%) Folate=30ug (75%) Biotin=10ug B12=0.15ug (38%) E=0.2mg (10%) A=15ug (10%)	Sodium=2mg	
TEMPLE HYDRO THERAPY - Blood orange flavour vitamin water with calcium	500ml	NS	80	<1	<1	4.7	4.7	B3=2.7mg (135%) B5=0.7mg B6=0.3mg (94%) Folate=30ug (75%) Biotin=10ug B12=0.15ug (38%)	Calcium=16mg (10%) Sodium=2mg	

TEMPLE HYDRO THERAPY - White peach flavour vitamin water with fibre	500ml	NS	90	<1	<1	5.4	4.7	B3=2.7mg (135%) B5=0.7mg B6=0.3mg (94%) Folate=30ug (75%) Biotin=10ug B12=0.15ug (38%)	Sodium=2mg	
TEMPLE HYDRO THERAPY - Dragonfruit flavour vitamin water with iron	500ml	NS	80	<1	<1	4.7	4.7	B3=2.7mg (135%) B5=0.7mg B6=0.3mg (94%) Folate=30ug (75%) Biotin=10ug B12=0.15ug (38%)	Iron=0.23 (10%) Sodium=2mg	
THORPEDO Advanced Hydration	600 ml	Recommend consumption 1 bottle per day	72	0	0	4.5	4.2	B3=2.7mg (162%) B5=0.6mg B6=0.3mg (110%) E=0.2mg (10%) Folate=30ug (90%) A=12.5ug (10%) Biotin=8.3ug B12=0.15ug (45%)	Sodium=25 mg Potassium=12 mg Chloride=31mg	

WATERPLUS (Bickford)	710ml	Recommend ed consumption : up to 4 serves per day	2	0	0	<0.1	0	B1=0.04mg (10%) B3=0.35mg (10%) B5=0.18mg (25%) B6=0.06mg (25%) B12=0.07mg (25%) C=1.4mg (25%) E=0.14mg (10%)	Magnesium=4.5mg (10%) Zinc=0.17mg (10%) Sodium=6mg Potassium=6mg	
WATERPLUS (Sanitarium) Note: Bickford has since purchased product and reformulated slightly.	710 ml	NS	2	0	0	<1	0	B1=0.04mg (25%) B3=0.4mg (25%) B5=0.2mg B6=0.06mg (25%) B12=0.1mg (25%) C=1mg (25%) E=0.1mg (10%)	Calcium=11mg (10%) Magnesium=5mg (10%) Zinc=0.2mg (10%) Sodium=6mg Potassium=6mg	
PROPEL - Fitness Water Deleted Line ~ June 2004	240 mL	NS	17.5	0	0	125%	0.83	% Daily Value C=10% E=10% B3=25% B6=25% B12=25% B5=25%	Sodium=35 mg Potassium=40mg	

RIDE	500 mL	NS	72	0	<1	4	4	B3=2.7mg B5=0.7mg	Potassium=9mg Sodium=8mg	
Line Deleted ~ Sep 2004 replaced by Play								B6=0.3mg Folate=30ug Biotin=10ug B12=0.15ug	Magnesium=17 mg Optizinc=10mg Zinc=2 mg Chromemate=100u g (niacin bound- chromium)	
SLINKY Deleted Lined since ~ Sep2004	500 mL	NS	72	0	<1	4	4	B3=2.7 mg B5=0.7 mg B6 =0.3 mg Folate=30ug Biotin=10ug B12=0.15ug	Calcium=28 mg Chromemate=100u g (niacin bound- chromium)	

Formulated Beverage Survey - Australia 2005

Manufacturer & Ingredients

Product Name	Manufacturer Details	Country of Origin	Distributor Details (if necessary)	Ingredients
AQUAVETA	Spring Valley Beverages	Australia		LEMON JUICE CONTAINS: PURIFIED WATER (96%),
	2 Beverage Drive			SUCROSE, RECONSTITUTED LEMON JUICE (1%), FLAVOUR,
	Tullamarine			ACID (330), MINERALS (CALCIUM GLUCONATE, CALCIUM
	Victoria 3043, Australia			LACTATE, FERROUS GLUCONATE, ZINC GLUCONATE),
	(Cadbury Schweppes Group)			MALTODEXTRIN.
FRUIT 20	P&N Beverages Australia Pty Ltd	Australia		PEACH PASSIONFRUIT CONTAINS: FLAVOURED SPRING
	43 Mons Street			WATER (90%) [SPRING WATER, SUGAR, RECONSTITUTED
	Condell Park			PEACH AND PASSIONFRUIT JUICES (2%), FOOD ACID (330),
	NSW 2200, Australia.			FLAVOUR, PRESERVATIVES (211,223)], SUPPLEMENTARY
	PH 1800 658459			SPORTS FOOD (10%) [SPRING WATER, MINERAL SALT
				(CALCIUM LACTATE), VITAMIN C (300)].
G FORCE	Frucor Beverages Ltd	New Zealand	Frucor Beverages Australia	APPLE BLACKCURRANT CONTAINS: WATER, SUGAR,
	97 Plunket Ave		Pty Ltd	RECONSTITUTED FRUIT JUICE (APPLE (5%),
	Wiri		13 South St	BLACKCURRANT (3%)), ACIDITY REGULATORS (330, 331),
	Auckland, NZ		Rydalmere	FLAVOURS, VITAMINS (ASCORBIC ACID (C), E, B3, B5, B6,
	PH 0800 502 929		NSW 2116, Australia.	B12), STABILISER (PECTIN)), PRESERVATIVE (202),
	www.frucor.com		PH 1800 237727	COLOURS (123,133).
JODIS IQ		Not Specified	Jodis Australasia Pty	NATURAL FLAVOUR, POTASSIUM SORBATE(202), SODIUM
			11 Narloo Street	BENZOATE (211).
			Perth	Note: Full ingredient list not provided on label.
			WA 6090, Australia.	
			www.jodiswater.com.au	
MIZONE	Frucor Beverages Ltd	New Zealand	Frucor Beverages Australia	MANDARIN FLAVOUR - PURIFIED WATER,
SPORTS	97 Plunket Ave		Pty Ltd	RECONSTITUTED APPLE JUICE, FRUCTOSE, APPLE CIDER
WATER.	Wiri		13 South St	VINEGAR, MANDARIN FLAVOURING, VITAMINS
	Auckland, NZ		Rydalmere	(ASCORBIC ACID (C), B3, B5, B6, B12), ACIDITY
	PH 0800 502 929		NSW 2116, Australia	REGULATOR (CITRIC ACID).
	www.frucor.com		PH 1800 237727	

PLAY	Zenergy Beverages	Australia	PURIFIED WATER, CONCENTRATED JUICES (PEACH, APPLE
Blackcurrant Low	12A/440 Collins St		& GRAPE), FRUCTOSE, CALCIUM LACTATE (327), FLAVOUR
GI Sportswater	Melbourne		(0.1%), FOOD ACID (330), PRESERVATIVES (211,223), NIACIN
	Victoria 3000, Australia		(B3), PANTOTHENIC ACID (B5), VITAMIN B6, SODIUM
	www.zenergybeverages.com		FLUORIDE, FOLIC ACID, BIOTIN, VITAMIN B12.
PLAY Fruit Fest-	Zenergy Beverages	Australia	PURIFIED WATER, CONCENTRATED JUICES (APPLE,
No Added Sugar	12A/440 Collins St		LEMON & GRAPE), CALCIUM LACTATE (327), FLAVOURS
Sportswater	Melbourne		(0.1%), FOOD ACID (330), PRESERVATIVES (211,223),
	Victoria 3000, Australia		NIACIN(B3), PANTOTHENIC ACID (B5), VITAMIN B6,
	www.zenergybeverages.com		SODIUM FLUORIDE, FOLIC ACID, BIOTIN, VITAMIN B12.
PLAY Orange	Zenergy Functional Beverages	Australia	PURIFIED WATER, CONCENTRATED JUICES (LEMON,
Sportswater for	15 Endeavour Drive		APPLE & GRAPE), FRUCTOSE (4%), CALCIUM LACTATE
Kids	Ocean Grove		(327), NATURAL ORANGE FLAVOUR (0.06%), FOOD ACID
	Victoria 3226, Australia		(330), POTASSIUM SORBATE (202), SODIUM BENZOATE
			(211), NIACIN (B3), PANTOTHENIC ACID (B5), VITAMIN B6,
			SODIUM FLUORIDE, FOLIC ACID, BIOTIN, VITAMIN B12.
POWERADE	Coca-Cola Amatil (N.Z.) Limited	New Zealand	MANDARIN CONTAINS: WATER (97.3%), SUCROSE, FOOD
WATER	The Oasis		ACID (330), TRI-POTASSIUM CITRATE, SODIUM CHLORIDE,
	Mt Wellington		FLAVOUR, ANTIOXIDANT (300), TRI-POTASSIUM
	Auckland, NZ		PHOSPHATE, VITAMINS B3 (NIACIN), B5, B6, B9 (FOLIC
			ACID), B12.
SOLIS Bliss	Solis Beverages	Australia	PURIFIED WATER, SUCROSE, CONCENTRATED PINK
	40 Yeo St		GRAPEFRUIT (3%), CRANBERRY (2%) & STRAWBERRY (2%)
	Neutral Bay		JUICES, FOOD ACID (330), NATURAL FLAVOURS, CALCIUM
	NSW 2089, Australia		LACTATE (327) (0.2%), NATURAL COLOUR (120), NIACIN
	PH 02 89696781		(B3), PANTOTHENIC ACID (B5), Vit B6, THIAMIN (B1),
			VITAMIN B12.
SOLIS Cherish	Solis Beverages	Australia	PURIFIED WATER, SUCROSE, CONCENTRATED PEAR
	40 Yeo St		(24.5%) & PEACH (0.5%) JUICES, FOOD ACID (330), NATURAL
	Neutral Bay		FLAVOURS, VITAMIN C, FOLATE (<0.01%).
	NSW 2089, Australia		
	PH 02 89696781		
SPRING	Sring Valley Beverages	Australia	SPRING WATER (98%), SUGAR, RECONSTITUTED
VALLEY 'Twist'	2 Beverage Drive		MANDARIN JUICE (1%), FOOD ACID (330), MINERAL SALT
	Tullamarine		(CALCIUM LACTATE), NATURAL MANDARIN FLAVOUR,
	VIC 3043, Australia		VITAMIN C.
	PH 1800 244054		

TEMDLE	Carlton & Haited Damana an	A	DUDIFIED WATER FRUCTORE CONCENTRATED HUCES
TEMPLE	Cariton & United Beverages	Austrana	PURIFIED WATER, FRUCTUSE, CUNCENTRATED JUICES
HYDROTHERA	77 Southbank Boulevard		(LEMON, APPLE & GRAPE), CITRIC ACID (330), FLAVOURS,
PY - Honeydew	Southbank		CALCIUM LACTATE (327), NIACIN (B3), PANTOTHENIC
flavour vitamin	Victoria 3006, Australia		ACID (B5), VITAMIN B6, FOLIC ACID, BIOTIN, VITAMIN B12.
water with	PH 1800 007282		
calcium			
TEMPLE	Carlton & United Beverages	Australia	PURIFIED WATER FRUCTOSE CONCENTRATED JUICES
HYDROTHERA	77 Southbank Boulevard		(LEMON APPLE & GRAPE) FLAVOURS ALOE EXTRACT
PV - Star fruit	Southbank		$(\text{LEMON}, \text{III} + \text{LE} + \mathbf{C} \text{ ORALE}), \text{LEAVOORS}, \text{REOLELATIONET,}$ (LEMON, ORALE), NEACIN (B3), PANTOTHENIC ACID (B5)
	Vistoria 2006 Australia		VITAMIN DE EOLIC ACID DIOTINI VITAMIN D12
jiavour vitamin	VICIONA 5000, AUSTRAIRA		VITAMIN DO, FOLIC ACID, DIOTIN, VITAMIN D12.
water with aloe	PH 1800 007282		
TEMPLE	Carlton & United Beverages	Australia	PURIFIED WATER, FRUCTOSE, CONCENTRATED JUICES
HYDROTHERA	77 Southbank Boulevard		(LEMON, APPLE & GRAPE), FLAVOUR, CITRIC ACID (330),
PY - Pink	Southbank		COLOUR (120), NIACIN (B3), PANTOTHENIC ACID (B5),
grapefruit flavour	Victoria 3006, Australia		VITAMIN B6, ALPHA TOCOPHERYL ACETATE (VIT E),
vitamin water with	PH 1800 007282		FOLIC ACID, RETINYL PALMITATE (VIT A), BIOTIN,
antioxidants			VITAMIN B12.
TEMPLE	Carlton & United Beverages	Australia	PURIFIED WATER FRUCTOSE CONCENTRATED HUCES
HVDROTHERA	77 Southbank Boulevard	1 Iustiuliu	(I EMON APPLE & GRAPE) CALCIUM I ACTATE (327)
DV Blood	Southbank		ELMON, ATTEL & ORATL), CALCION EACTATE (327), ELAVOURS CITRIC ACID (330) COLOUR (120) NIACIN (B3)
1 1 - Dioou	Viatorio 2006 Australia		DANTOTHENIC ACID (D5) VITAMIN D6 EOLO ACID
orange jiavour	VICIONA 5000, Australia		FANTOTHENIC ACID (D3), VITAMIN D0, FOLIC ACID,
vitamin water with	PH 1800 007282		BIOTIN, VITAMIN B12.
calcium			
TEMPLE	Carlton & United Beverages	Australia	PURIFIED WATER, FRUCTOSE, CONCENTRATED JUICES
HYDROTHERA	77 Southbank Boulevard		(LEMON, APPLE & GRAPE), POLYDEXTROSE, CITRIC ACID
PY - White peach	Southbank		(330), FLAVOUR, COLOUR (120), NIACIN (B3), PANTOTHENIC
flavour vitamin	Victoria 3006, Australia		ACID (B5), VITAMIN B6, FOLIC ACID, BIOTIN, VITAMIN B12.
water with fibre	PH 1800 007282		
TEMPLE	Carlton & United Beverages	Australia	PURIFIED WATER, FRUCTOSE, CONCENTRATED JUICES
HYDROTHERA	77 Southbank Boulevard		(LEMON, APPLE & GRAPE), CITRIC ACID (330), FLAVOURS,
PY - Dragonfruit	Southbank		COLOUR (120), NIACIN (B3), PANTOTHENIC ACID (B5).
flavour vitamin	Victoria 3006 Australia		VITAMIN B6 FERROUS GLUCONATE (579) FOLIC ACID
water with iron	PH 1800 007282		BIOTIN, VITAMIN B12.

THORPEDO Advanced Hydration	Manufactured under licence for Thorpedo Foods Pty Ltd www.thorpedofoods.com.au	Australia	So Natural Foods Australia Ltd 80 Box Rd Taren Point NSW 2229, Australia	ORANGE FLAVOUR: PURIFIED WATER, CONCENTRATED JUICES (LEMON, APPLE, & GRAPE), FRUCTOSE (4%), ELECTROLYTES (CALCIUM LACTATE (327), SODIUM CHLORIDE, POTASSIUM CITRATE, MAGNESIUM LACTATE (329)), ORANGE FLAVOUR (0.1%), FOOD ACID (330), PRESERVATIVES (211, 223), NIACIN (B3), PANTOTHENIC ACID (B5), VITAMIN B6, VITAMIN E (ALPHA TOCOPHEROL ACETATE), FOLIC ACID, VITAMIN A (RETINOL PALMITATE), BIOTIN, VITAMIN B12.
WATERPLUS (Bickford)	Manufactured in New Zealand for: Bickfords Australia Pty Ltd 34 Starr Ave Plympton South Australia 5037, Australia	New Zealand	Bickfords Australia Pty Ltd 34 Starr Ave Plympton South Australia 5037, Australia	PEACH FLAVOUR: WATER (99%), MINERALS (POTASSIUM CITRATE, SODIUM CHLORIDE, MAGNESIUM GLUCONATE,CALCIUM LACTATE, ZINC GLUCONATE), VITAMINS (C, B3, E ACETATE, B5, B6, B1, B12), FOOD ACIDS(MALIC ACID, CITRIC ACID), PEACH FLAVOUR, ARTIFICIAL SWEETENER.
WATERPLUS (Sanitarium) Note: Bickford has since purchased product and reformulated slightly.	Sanitarium Health Food Company 124 Pah Road Royal Oak Auckland, NZ	New Zealand		LEMON LIME FLAVOUR: WATER (99%), MINERALS (MAGNESIUM GLUCONATE, CALCIUM LACTATE, POTASSIUM BICARBONATE, SODIUM CHLORIDE, ZINC GLUCONATE), VITAMINS (C, B3, E ACETATE, B5, B6, B1, B12), FOOD ACIDS (MALIC ACID, CITRIC ACID), LEMON LIME FLAVOUR, ARTIFICIAL SWEETENER.
PROPEL - Fitness Water Deleted Line ~ June 2004	Cadbury Schweppes 2 Beverage Drive Tullamarine Victoria, Australia	NS	Distributed by Gatorade Company PO Box 049003 Chicago USA	PURIFIED WATER, SUCROSE SYRUP, CITRIC ACID, NATURAL ORANGE FLAVOUR WITH OTHER NATURAL FLAVOURS, SODIUM CITRATE, POTASSIUM CITRATE, ASPARTAME, VITAMIN C (ASCORBIC ACID), VITAMIN E ACETATE, ACESULFAME POTASSIUM, NIACINAMIDE (VIT B3), CALCIUM PANTOTHENATE (VITAMIN B5), VITAMIN B12, PYRIDOXINE HYDROCHLORIDE (VITAMIN B6). PHENYLKETONURICS: CONTAINS PHENYLALANINE

RIDE	Zenergy Beverages 12A/440 Collins St	Australia	FLAVOURED MANDARIN DRINK CONTAINS PURIFIED WATER, CONCENTRATED JUICES, (LEMON, APPLE &
Deleted Line ~	Melbourne		GRAPE), FRUCTOSE (4%), NATURAL MANDARIN FLAVOU
Sep 2004 replaced	Victoria 3000, Australia		(0.06%), FOOD ACID(330), POTASSIUM SORBATE(202),
by Play	www.zenergybeverages.com		SODIUM BENZOATE (211), MAGNESIUM LACTATE (329), I
			OPTIZINC ® (ZINC L-METHIONINE), NIACIN (B3),
			PANTOTHENIC ACID(B5), VIT B6, CHROMEMATE (R)
			(NIACIN-BOUND CHROMIUM), FOLIC ACID, BIOTIN,
			VITAMIN B12.
SLINKY	Zenergy Beverages	Australia	LOW-JOULE FLAVOURED MANDARIN DRINK CONTAINS
	12A/440 Collins St		PURIFIED WATER, CONCENTRATED JUICES, (LEMON,
Deleted Lined	Melbourne		APPLE & GRAPE), FRUCTOSE (4%), CALCIUM
since ~ Sep 2004	Victoria 3000, Australia		LACTATE(327), NATURAL MANDARIN FLAVOUR (0.06%),
	www.zenergybeverages.com		COLOUR (120), FOOD ACID(330), POTASSIUM
			SORBATE(202), SODIUM BENZOATE (211), CARNITINE,
			NIACIN (B3), PANTOTHENIC ACID(B5), VIT B6,
			CHROMEMATE ® (NIACIN-BOUND CHROMIUM), FOLIC
			ACID, BIOTIN, VITAMIN B12.

Formulated Beverage Survey - New Zealand 2005

Summary

Product Name	Content Claims	Other Claims	Directions for Use	Warnings and Advisory Statements	Availability	Package Size	Serving Size
AQUA SHOT	Active water.	If you want to grab life's opportunities, you need to	Please remove foil seal from under cap.	Recommended daily consumption:	Supermarkets and dairies	800ml	200ml
Flavours: Lime,	Picture of the	be on your game. Aqua	_	adults up to 6 bottles;			
Raspberry,	flavouring fruit with	Shot is active water with a	Store in a cool place.	children between 3 and 13			
Mandarin and	5 B-vitamin	refreshing burst of fruit	_	up to 2 bottles.			
Apple	symbols attached.	flavour and the boost of 5	For best before date	-			
		essential vitamins, making	see bottle.				
		it the tastiest way to keep					
		hydrated, so you'll never					
		miss a shot.					
WATERPLUS	Low joule.	Waterplus takes the hard	Remove quality seal		Supermarkets and	710ml	710ml
	5	work out of hydration. A	under cap.		dairies		
Flavours: Peach,	5 minerals. 7	refreshing blend of pure	1				
Lemon & Lime,	vitamins.	mineral water, light	Keep refrigerated once				
Lemon, Melon		flavours, with vitamins and	opened.				
and Mandarin	Electrolytes are	minerals. Waterplus is	1				
	essential minerals	easy to drink. And most					
	that assist in	importantly with no sugar					
	hydration.	and only 2 calories per					
		bottle you'll burn it off in					
	Antioxidants are	around 30 seconds of					
	vitamins that help to	walking. Drink Waterplus					
	protect your body	and feel the difference.					
	against harmful free						
	radicals.						

CHARLIE'S	No added sugar.		Serve chilled,		800ml & 3L	200ml
SPORTS	No artificial		refrigerate after			
WATER	sweeteners. No		opening.			
	preservatives.					
Flavours:			Consume within four			
Cranberry &	Vitamins charged		days of opening.			
Raspberry,	C, B3, B5, B6, B12,					
Mandarin,	E		Remove safety seal			
Lemon & Lime			under sipper cap.			
and Blackcurrant						
e2	Liquid Energy.	e2. The powerful fruit hit	Best before date see	The cap contains small	400ml &	200ml
		that's packed with full-on	top of bottle.	parts and is therefore not	800ml	
Flavours: Apple	With fruit juice and	fruit flavours and vitamins.		suitable for unsupervised		
Crush, Orange,	vitamins.	With a wicked combination	Serve chilled. Store in	children under 36 months.		
Lemon & Lime,		of fruit juice, vitamins,	cool place.			
Mango and	Lists 'A, B1, B5,	minerals and electrolytes,				
Blackcurrant &	B6, E' under the	you're drinking liquid	Refrigerate after			
Apple	product title.	energy, bursting with	opening.			
		awesome flavour. Re-				
		fuelling your body, keeping				
		you charged. Doing the				
		things you want to.				
		Whenever, wherever. e2,				
		don't run out of 'juice'.				
G FORCE	Fruit drink with		Push & go cap	Warning: Choking risk.	800ml	400ml
	vitamins to go!		instructions.	This cap contains small		
Flavours: Apple				parts. Not suitable for		
& Blackcurrant			Serve chilled, once	children under 36 months.		
and Orange &			opened keep			
Mandarin			refrigerated.			

MIZONE	5 essential vitamins	Active hydration.	Remove safety seal	Warning: Choking risk.	800ml	200ml
SPORTS	C, B3, B5, B6, B12.	MIZONE Sportswater is a	under sipper cap.	This cap contains small		
WATER		great tasting blend of		parts. Not suitable for		
	Vitamin C - assists	purified water and fruit	Serve chilled, once	children under 36 months.		
Flavours:	with recovery and	flavours with the benefits	opened keep			
Mandarin, Lime,	protection.	of 5 essential vitmains	refrigerated.			
Lemon,	-	that's easy to drink and				
Passionfruit,	B vitamin's - aid in	helps you feel at your best.				
Crisp Apple	energy metabolism.	MIZONE Sportswater				
		helps you rehydrate your				
		body so you can get in your				
		zone and achieve your				
		goals.				
MIZONE	5 essential vitamins	It's the combination of Iron	Remove safety seal	Warning: Choking risk.	650ml	650ml
PEAK	plus Teavigo.	and Teavigo in MIZONE	under sipper cap.	This cap contains small		
Performance		Peak Sportswater which		parts. Not suitable for		
Sportswater	Teavigo EGCG -	helps you to perform at	Serve chilled, once	children under 36 months.		
-	green tea extract	your best by keeping you	opened keep			
Flavours:	which helps utilise	hydrated and assisting you	refrigerated.			
Mandarin and	energy, increases	to maximise energy output.				
Lime	blood flow and acts					
	as a potent					
	antioxidant.					
	Iron - to help get					
	oxygen around the					
	body.					
	B vitamins - aid in					
	energy metabolism.					
	Vitamin C - assists					
	with recovery and					
	protection.					

					100 1
POWERADE	With 5 essential	We all know how essential	Please remove foil seal	750ml	400ml
WATER	vitamins B3, B5,	drinking water is to our	from under cap.		
	B6, B9, B12	everyday health, but for			
Flavours:		some of us, plain water is	Best before date see		
Mandarin, Lime		just hard to drink.	top of bottle.		
& Grapefruit		Powerade Water contains			
		purified water, with a	Store in cool place.		
		refreshing splash of fruity			
		flavour, 5 essential			
		vitamins & electrolytes.			
		Now it's easy to drink			
		water every day. So			
		whether you're at work, at			
		home or on the go, drink			
		Powerade Water.			
THEXTON'S	With vitamins A, C		Store in a cool place.	3L	200ml
FRUIT DRINK	& E.		1		
			Refrigerate after		
Flavours: Pink			opening.		
Grapefruit.					
Cranberry and			For best before date		
Red Grape			see top of bottle.		
CAPRI-SONNE	With 12% fruit		Best before: see	10x 200ml	200ml
MULTI	iuice		narrow side flap	1011 2001111	200111
VITAMIN	J				
,	Enriched with 9				
Fruit Juice Drink	vitamins.				

Formulated Beverage Survey - New Zealand 2005

Composition

Product Name	Serving Size	No. of serves per day	Energy (kJ)	Total Fat (g)	Protein (g)	Carbo-hydrate (g)	Sugars (g)	Vitamins (percentage RDI per serve)	Minerals (percentage RDI per serve)	Herbal Extracts
							Per 100 ml product	,		
AQUA SHOT	200ml	Adults - 24 maximum Children - 8 maximum	44	0	0	2.5	2.5	B3=0.5mg (10%) B5=0.25mg B6=0.08mg (10%) B9=20ug (20%) B12=0.2ug (20%)	Soduim=3mg	
WATERPLUS	710ml	Not Specified	2	0	0	<0.1	0	B1=0.04mg (25%) B3=0.4mg (25%) B5=0.2mg B6=0.06mg (25%) B12=0.1mg (25%) C=1mg (25%) E=0.1mg (10%)	Sodium=6mg Potassium=6mg Calcium=11mg (10%) Magnesium=5mg (10%) Zinc=0.2mg (10%)	
CHARLIE'S SPORTS WATER	200ml	8 serves	59.3	0.01	0.06	3.34	3.2	B3=1.0mg (20%) B5=0.5mg (20%) B6=0.16mg (20%) B12=0.1ug (10%) E=0.5mg (10%) C=20.0mg (100%)	Sodium=9mg (0.8%)	
e2	200ml	Recommended daily consumption, adults up to 2 litres, children above 3 years up to 800ml.	171	<1	<1	9.8	9.7	B1=0.06mg (10%) B3=0.5mg (10%) B5=0.3mg B6=0.08mg (10%) A=37.5ug (10%) E=0.5mg (10%)	Sodium=20mg Potassium=8.3mg Calcium=3.8mg	

G FORCE	400ml	Not Specified	177	<1	<1	10.4	10.4	C=35mg (350%) E=1mg (40%) B3=1mg (40%) B5=0.5mg B6=0.16mg (40%) B12=0.2ug (40%)	Sodium=4.7mg	
MIZONE SPORTS WATER.	200ml	Not Specified	43	0	0	2.5	2.5	C=20mg (100%) B3=1mg B5=0.5mg B6=0.16mg (20%) B12=0.1ug (10%)	Sodium=<5mg	
MIZONE PEAK Performance Sportswater	650ml	Not Specified	53	0	<1	3	2.9	C=6mg (100%) B3=0.3mg (20%) B5=0.15mg B6=0.05mg (20%) B12=0.03ug (10%)	Sodium=<5mg Iron=0.18mg (10%)	Epigallocatechi n Gallate (EGCG) - Green Tea extract
POWERADE WATER	400ml	Recommended daily consumption, Adults up to 6 bottles, children between 3 and 13 up to 2 bottles.	41	0	0	2.3	2.3	B3=0.5mg (20%) B5=0.25mg B6=0.08mg (20%) B9=20ug (40%) B12=0.2ug (40%)	Sodium=12mg Potassium=14mg	
THEXTON'S Fruit Drink	200ml	Recommended daily consumption, adults up to 2 litres, children above 3 years up to 1.2 litres.	196	<1	<1	11.3	11.3	A=50ug (13%) C=8mg (40%) E=0.6mg (12%)	Sodium=12mg	

CAPRI-SONNE	200ml	Not Specified	179	<0.1	<0.1	10.2	10.2	B1=0.21mg (15%)	Sodium=<20mg (as	
MULTIVITAM								B3=2.7mg (15%)	per distributors	
IN Fruit Juice								B5=0.9mg (15%)	label)	
Drink								B6=0.3mg (15%)		
								B9=30ug (15%)		
								Biotin=22.5ug(15%		
)		
								B12=0.15ug (15%)		
								C=9mg (15%)		
								E=1.5mg (15%)		

Formulated Beverage Survey - New Zealand 2005

Manufacturer & Ingredients

Product Name	Manufacturer Details	Country of Origin	Distributor Details (if necessary)	Ingredients
AQUA SHOT	Coca-Cola Amatil (N.Z.) Limited The Oasis Mt Wellington Auckland, NZ	New Zealand		WATER, APPLE JUICE FROM CONCENTRATE (4.5%), FRUCTOSE, APPLE CIDER VINEGAR, FLAVOUR, FOOD ACID (330), LACTOSE, VITAMINS (B3 (NIACIN), B5, B6, B9 (FOLIC ACID), B12).
WATERPLUS	Sanitarium Health Food Company 124 Pah Road Royal Oak Auckland, NZ	New Zealand		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), FLAVOUR, ARTIFICIAL SWEETENER.
CHARLIE'S SPORTS WATER		New Zealand	Charlie's Trading Company Ltd 125 The Strand Parnell Auckland, NZ PH 0800 126 435 office@charlies.co.nz/www.ch arlies.co.nz	WATER (95%), RECONSTITUTED APPLE JUICE, VITAMINS C, B3, B5, B6, B12, E, APPLE CIDER VINEGAR, FLAVOUR, FOOD ACID (330).
e2	Coca-Cola Amatil (N.Z.) Limited The Oasis Mt Wellington Auckland, NZ	New Zealand		BLACKCURRANT & APPLE CONTAINS: WATER, SUGAR, BLACKCURRANT JUICE FROM CONCENTRATE (2.7%), APPLE JUICE FROM CONCENTRATE (2.3%), FOOD ACID (330), FLAVOUR, MINERALS (POTASSIUM, SODIUM, CALCIUM), VITAMINS (A, NIACIN, E, B5, B6, B1), PRESERVATIVES (211, 202), COLOURS (150d, 102).
G FORCE	Frucor Beverages Ltd 97 Plunket Ave Wiri Auckland, NZ PH 0800 502 929 www.frucor.com	New Zealand		ORANGE & MANDARIN CONTAINS: WATER, RECONSTITUTED FRUIT JUICE (ORANGE (7%), MANDARIN (3%)), SUGAR, ACIDITY REGULATORS (330, 331), FLAVOURS, VITAMINS (ASCORBIC ACID (C), E, B3, B5, B6, B12), STABILISER (PECTIN), COLOURS (160A, 123), PRESERVATIVE (202).

MIZONE	Frucor Beverages Ltd	New Zealand	Frucor Beverages Australia	PURIFIED WATER, RECONSTITUTED APPLE JUICE, FRUCTOSE,
WATER	Wiri Auckland, NZ PH 0800 502 929 www.frucor.com		99 Derby St Wilversater NSW 2128, Australia PH 1800 237 727	B5, B6, B12), FLAVOURING, ACIDITY REGULATOR (CITRIC ACID).
MIZONE PEAK Performance Sportswater	Frucor Beverages Ltd 97 Plunket Ave Wiri Auckland, NZ PH 0800 502 929 www.frucor.com	New Zealand	Frucor Beverages Australia Pty Ltd 99 Derby St Wilversater NSW 2128, Australia PH 1800 237 727	PURIFIED WATER, RECONSTITUTED APPLE JUICE, APPLE CIDER VINEGAR, ACIDITY REGULATOR (CITRIC ACID), FLAVOURING, VITAMINS (ASCORBIC ACID (C), B3, B5, B6, B12), GREEN TEA EXTRACT (EGCG), IRON (FERROUS GLUCONATE).
POWERADE WATER	Coca-Cola Amatil (N.Z.) Limited The Oasis Mt Wellington Auckland, NZ	New Zealand		MANDARIN CONTAINS: WATER (97.3%), SUCROSE, FOOD ACID (330), TRI-POTASSIUM CITRATE, SODIUM CHLORIDE, FLAVOUR, ANTIOXIDANT (300), TRI-POTASSIUM PHOSPHATE, VITAMINS B3 (NIACIN), B5, B6, B9 (FOLIC ACID), B12.
THEXTON'S Fruit Drink	Coca-Cola Amatil (N.Z.) Limited The Oasis Mt Wellington Auckland, NZ			RED GRAPE CONTAINS: WATER, SUGAR, RED GRAPE JUICE FROM CONCENTRATE (5%), FOOD ACID (330), FLAVOUR, COLOUR (150D, 122), VITAMINS (C,E,A), MINERAL SALT (452).
CAPRI-SONNE MULTIVITAMI N	Deutsche Sisi-Werke GmbH & Co. Betriebs KG, D-69009 Heidelberg, Germany	Germany	Impex International Trading Ltd P.O. Box 528 Kerikeri, NZ. PH 09 407 4277	WATER, SUGAR, LEMON JUICE (4%), ORANGE JUICE (4%), APPLE JUICE, GRAPEFRUIT JUICE, GLUCOSE-FRUCTOSE SYRUP, PINEAPPLE JUICE, PASSIONFRUIT JUICE, BANANA JUICE, KIWI JUICE, VITAMINS (C, NICOTINAMIDE, E, PANTOTHANTE, B6, THIAMIN, FOLACIN, BIOTIN, B12), NATURAL FLAVOURING (FROM CONCENTRATE).

Food-Type Dietary Supplement Survey - Formulated Beverages - Australia 2003

Summary

Product Name	Content Claims	Other Claims	Directions for Use	Warnings and Advisory Statements	Package Size	Serving Size
MIZONE	Contains 5 essential	Colour free and low in sugar.			800ml	200ml
SPORTSWATER	vitamins - C, B3, B5,					
	B6, B12	Vitamin B's aid in energy metabolism				
		and antioxidant Vitamin C assists				
		with recovery and protection.				
SANITARIUM	5 minerals and 7	Electrolytes are essential minerals that			710ml	710ml
WATERPLUS	vitamins	assist in hydration. Antioxidants are				
		vitamins that help tp protect your				
	Low joule	body against harmful free radicals.				
PROPEL	Vitamin enhanced	In a daily diet, B vitamins aid in			700ml	200ml
FITNESS	water beverage	energy metabolism. Antioxidant				
WATER		Vitamin E helps neutralize free				
		radicals. Folate is a B vitamin that is				
		needed for healthy growth and				
		development.				

Food-Type Dietary Supplement Survey - Formulated Beverages - Australia 2003 Composition

Product Name	Serving Size	No. of serves per day	Energy (kJ)	Total Fat (g)	Protein (g)	Carbohydrate (g)	Sugars (g)	Vitamins (percentage RDI per serve)	Minerals (percentage RDI per serve)	Herbal Extracts
							Per 100ml			
MIZONE SPORTSWATER	200ml	Not Specified	43	0	0	2.5	2.5	C=20mg B3=1mg B5 0.5mg B6 0.16mg B12 0.1ug	Sodium <5mg	
SANITARIUM WATERPLUS	710ml	Not Specified	2	0	0	<0.1	0	B1=0.04mg B3=0.4mg B5=0.2mg B6=0.06mg B12=0.1ug C=1mg E=0.1mg	Calcium=11mg Magnesium=5mg Zinc=0.2mg Sodium=6mg Potassium=6mg	
PROPEL FITNESS WATER	200ml	Not Specified	17.5	0	0	0.83	0.83	E=0.5mg B3=1mg B5=0.5mg B6=0.16mg B9=15ug B12=0.1ug	Sodium=2mg Potassium=0mg	

Food-Type Dietary Supplement Survey - Formulated Beverages - Australia 2003

Manufacturer & Ingredients

Product name	Manufacturer -	Country of origin	Distributor details	Ingredients
	Tun contact uctans		(If necessary)	
MIZONE	Frucor Beverages Ltd	New Zealand	Frucor Beverages Australia	PURIFIED WATER, RECONSTITUTED APPLE JUICE,
SPORTSWATER	97 Plunket Ave		Pty Ltd, 99 Derby St.	FRUCTOSE, APPLE CIDER VINEGAR, MANDARIN
	Wiri		Silverwater Nsw2128,	FLAVOURING, VITAMINS (ASCORBIC ACID (C), B3, B5,
	Auckland, NZ		Australia	B6, B12), ACIDITY REGULATOR (CITRIC ACID).
	PH 0800 502 929			
	www.frucor.com			
SANITARIUM	Sanitarium Health Food	New Zealand	Australian Health & Nutrition	WATER (99%), MINERALS (MAGNESIUM GLUCONATE,
WATERPLUS	Company		Association Limited, 1	CALCIUM LACTATE, POTASSIUM BICARBONATE,
	124 Pah Road		Sanitarium Drive, Berkeley	SODIUM CHLORIDE, ZINC GLUCONATE), VITAMINS (C,
	Royal Oak		Vale NSW 2261.	B3, E ACETATE, B5, B6, B1, B12), FOOD ACIDS (CITRIC
	Auckland, New Zealand			ACID, MALIC ACID), LEMON LIME FLAVOUR,
				ARTIFICIAL SWEETENER.
PROPEL FITNESS	Imported into New Zealand	USA	Imported and distributed in	WATER, SUCROSE SYRUP, FRUCTOSE, CITRIC ACID,
WATER	by Pepsico Australia		Australia by Cadbury	NATURAL FLAVOURS, VITAMIN E ACETATE,
	Holdings Pty ltd, Sydney,		Schweppes Pty Ltd, 636 St	NIACINAMIDE (B3), CALCIUM PANTOTHENATE,
	Australia.		Kilda Road, Melbourne,	PYRIDOXINE HYDROCHLORIDE (B6), FOLIC ACID,
			Victoria 3004, Australia.	VITAMIN B12.

Food-Type Dietary Supplement Survey - Formulated Beverages - New Zealand 2003

Summary

Product Name	Content Claims	Other Claims	Directions for Use	Warnings and Advisory Statements	Package Size	Serving Size
AQUANA - Alive Zest & Vigour	Water for wellbeing. Guarana, B Vitamins & natural citrus flavour.	Aquana alive brings you all the benefits of purified water and may help give zest and vigour to your life. A vital mix of purified water, B vitamins, guarana herb and a hit of natural citrus flavours. <1 Calorie/100ml Natural flavours. No colours.	Store in a cool place.		750ml	200ml
AQUANA - Strong Defend & Support	Water for wellbeing. Antioxidants & natural berry flavours.	Aquana strong brings you all the benefits of purified water and may help support your body's defences. Purified water blended with the natural protection of antioxidants, ginkgo biloba extracts and a hint of natural berry flavours. <1 Calorie/100ml Natural Flavours. No colours	Store in a cool place.		750ml	200ml
CHARLIE'S SPORTS WATER Flavours: Lemon & Lime	No added sugar or artificial sweetener. Contains 6 essential vitamins - C, B3, B5, E, B6, B12		Serve chilled, refrigerate after opening. Consume within four days of opening. Remove safety seal under sipper cap.	This product is not a sole source of nutrition and should be consumed in conjunction with a nutritious diet and an appropriate physical exercise program.	800ml	200ml

e2	Liquid Energy naturally	e2 is for people like you that exercise, work	Drink chilled.		400ml &	250ml
	blended with apple & mango	hard or just need a lift to get through the			1.25L	
Flavours: Apple	Juices	day.				
Mango,						
Watermelon,	With vitamins A, C & E and	Vitamins A, B5, B6, C, E and Niacin are				
Strawberry Citrus,	minerals	blended with fruit juices and sucrose to give				
Mango, Apple		a real energy boost and to put back what life				
Blackcurrant		takes out.				
		Some vitamins are known to prevent the				
		effects of free radicals. Calcium may assist				
		in maintaining strong healthy bones.				
		Electrolytes help in assisting hydration and				
		giving a quicker recovery after exercise.				
GFORCE	Information not obtained	Information not obtained			800ml	400ml
GIOREE					0001111	roomi
Flavours: Annle &						
<i>Blackcurrant</i>						
Blueberrry &						
Raspherry, Mango						
& Pineannle						
Orange Mandarin						
Pineannle & Lime						
Raspherry &						
Lemon						
MIZONE	Contains 5 essential vitamins C	To achieve your physical best, your body	Remove safety seal		800ml	200ml
SPORTS	B3 B5 B6 B12	needs lots of water and MIZONE Sports	under sinner can		0001111	200111
WATER	<i>D³</i> , <i>D</i> ³ , <i>D</i> ³ , <i>D</i> ¹ <i>²</i> .	Water is the easiest way to drink it Vit	Serve chilled once			
WITLEN	Purified water and fruit flavours	B's aid in energy metabolism and	opened keep			
Flavours	with vitamins	antioxidant Vit C assists with recovery and	refrigerated			
Mandarin Lime	with vituiling.	protection With vitamins and a splash of	Terrigeratea.			
I emon	Colour free and low in sugar	flavour MIZONE Sports Water will				
Passionfruit Crisn	colour nee and low in sugar.	rehydrate you so you can achieve your				
Annle		goals				
<i>ippi</i> c		Sours.		1	1	

POWERADE WATER Flavours: Mandarin, Lime & Grapefruit	With 5 essential vitamins B3, B5, B6, B9, B12	Powerade water contains purified water, with a refreshing splash of fruity flavour, 5 essential vitamins & electrolytes.	Please remove foil seal from under cap.	Store in a cool place.	750ml	400ml
THEXTON'S Blackcurrant Drink	Quality Beverage of New Zealand. Naturally flavoured with Blackcurrant juice. Rich in Vitamin C.	OK for kids as part of a balanced diet. Blackcurrant juice has been shown to have high levels of Vitamin C and is very beneficial for your health. No Apple base.	Serve chilled. Refrigerate after opening.		1L	250ml
THEXTON'S Flavours:Pink Grapefruit, Cranberry & Red Grape	Quality Beverage of New Zealand. Naturally flavoured with juice. With Vitamins A, C & E plus Echinacea.	OK for kids as part of a balanced diet.	Store in a cool place. Serve chilled. Refrigerate after opening.		1L & 3L	250ml
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Composition

Product Name	Serving Size	No. of serves per day	Energy (kJ)	Total Fat (g)	Protein (g)	Carbohydrate (g)	Sugars (g)	Vitamins (percentage RDI per serve)	Minerals (percentage RDI per serve)	Herbal Extracts
							Per 100ml	•	·	
	• • • • •		0.4	0	0	<u>_</u>	product			~
AQUANA -	200ml	Not Specified	0.1	0	0	0	0	C=3.8mg (20%)	Sodium=1mg	Guarana
Alive Zest &								B6=0.1mg(10%)		extract
Vigour	200 1		0.1	0		0		B3=0.5mg (10%)		<u> </u>
AQUANA -	200ml	Not Specified	0.1	0	0	0	0	C=5.0mg(25%)	Sodium=1mg	Ginkgo leaf
Strong Defend								E=0.5mg(10%)		extract
& Support	2001	Quandar.	50.2	0.01	0.06	2.24	2.2	$C = 20.0 \text{m} \approx (1000/)$	Codium-0.0mo	
CHARLIE'S	200mi	8 per day	59.5	0.01	0.06	5.54	3.2	C=20.0 mg (100%) $D_2=1.0 \text{mg} (200/)$	Sodium-9.0mg	
SPUKIS WATED								$B_{5}=1.0111g(20\%)$		
WAIEK								$B_{5}=0.5 \text{ mg}(20\%)$		
								B12=0.1mg(10%)		
								E=0.5mg(10%)		
e2	250ml	Recommended	157	0	0	10.3	9.52	A=1389IU(14%)	Calcium=3 83mg	
		daily	10,	Ũ	Ũ	10.0	2.02	B1=0.04mg(14%)	Sodium=11mg	
		consumption,						B3=1.06mg (14%)	Potassium=20mg	
		adults up to 2						B5=0.3mg (14%)	C	
		litres, children						B6=0.089mg (14%)		
		under 13 up to						C=3.3mg (33%)		
		800ml						E=0.55mg (14%)		
G FORCE	400ml	NS	184	<1	<1	10.8	10.8	C=35mg (350%)		
								E=1mg (40%)		
								B3=1mg (40%)		
								B5=0.5mg		
								B6=0.16mg (40%)		
								B12=0.2ug(40%)		

MIZONE SPORTS WATER	200ml	Not Specified	43	0	0	2.5	2.5	C=20mg (100%) B3=1mg (20%) B5=0.5mg B6=0.16mg (20%) B12=0.1ug (10%)	Sodium=<5mg	
POWERADE WATER	400ml	Recommended daily consumption, Adults up to 6 bottles, children between 3 and 13 up to 2 bottles	41	0	0	2.3	2.3	B3=0.5mg (20%) B5=0.25mg B6=0.08mg (20%) B9=20ug (40%) B12=0.2ug (40%)	Sodium=12mg Potassium=14mg	
THEXTON'S Blackcurrant Drink	250ml	Recommended daily consumption, adults up to 2 litres, children under 12 up to 1.2 litres.	225	<1g	<1g	14.2	14.2	C=45mg (280%)		
THEXTON'S	250ml	Recommended daily consumption, adults up to 2 litres, children under 12 up to 1.2 litres	188	0	0	12	11.5	A=50ug (15%) C=5mg (30%) E=0.6mg (15%)	Sodium = 20mg	Echinacea

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Manufacturer & Ingredients

Product Name	Manufacturer Details	Country of Origin	Distributor Details (if necessary)	Ingredients
AQUANA - Alive Zest & Vigour	Coca-Cola Amatil (N.Z.) Limited The Oasis Mt Wellington Auckland, NZ	New Zealand		WATER, APPLE JUICE FROM CONCENTRATE (0.5%), NATURAL FLAVOUR, GUARANA EXTRACT, VITAMIN C, VITAMIN B3, VITAMIN B6.
AQUANA - Strong Defend & Support	Coca-Cola Amatil (N.Z.) Limited The Oasis Mt Wellington Auckland, NZ	New Zealand		WATER, NATURAL FLAVOURS, VITAMIN C, GINKGO LEAF EXTRACT, VITAMIN E
CHARLIE'S SPORTS WATER		New Zealand	Charlie's Trading Company Ltd 125 The Strand Parnell Auckland, NZ PH 0800 126 435 office@charlies.co.nz/w ww.charlies.co.nz	WATER (95%), RECONSTITUTED APPLE JUICE, VITAMINS (C, B3, B5, E, B6, B12), APPLE CIDER, VINEGAR, LEMON & LIME FLAVOUR, FOOD ACID (330).
e2	Coca-Cola Amatil (N.Z.) Limited The Oasis Mt Wellington Auckland, NZ	New Zealand		APPLE MANGO CONTAINS: WATER, SUCROSE, APPLE AND MANGO JUICE CONCENTRATE, FOOD ACID (330), FLAVOURS, COLOURS (133, 102), MINERALS (POTASSIUM, SODIUM, CALCIUM), VITAMINS (C, A, NIACIN, E, B5, B6, B1), POTASSIUM SORBATE (202).
G FORCE	Frucor Beverages Ltd 97 Plunket Ave Wiri Auckland, NZ PH 0800 502 929 www.frucor.com	New Zealand		APPLE & BLACKCURRANT CONTAINS: WATER, SUGAR, RECONSTITUTED FRUIT JUICE (APPLE (5%), BLACKCURRANT (3%)), ACIDITY REGULATORS (330, 331), FLAVOUR, VITAMINS (ASCORBIC ACID (C), E, B3, B5, B6, B12), STABILISER (PECTIN), PRESERVATIVE (202), COLOURS (123, 133).

MIZONE SPORTS WATER	Frucor Beverages Ltd 97 Plunket Ave Wiri Auckland, NZ PH 0800 502 929 www.frucor.com	New Zealand	Frucor Beverages Australia Pty Ltd, 99 Derby St, Wilversater, NSW 2128, Australia PH 1800 237 727	PURIFIED WATER, RECONSTITUTED APPLE JUICE, FRUCTOSE, APPLE CIDER, VINEGAR, MANDARIN FLAVOURING, VITAMINS (ASCORBIC ACID C), B3, B5, B6, B12, CITRIC ACID.
POWERADE WATER	Coca-Cola Amatil (N.Z.) Limited The Oasis Mt Wellington Auckland, NZ	New Zealand		MANDARIN CONTAINS: WATER (97.3%), SUCROSE, FOOD ACID (330), TRI-POTASSIUM CITRATE, SODIUM CHLORIDE, FLAVOUR, ANTIOXIDANT (300), TRI-POTASSIUM PHOSPHATE, VITAMINS B3 (NIACIN), B5, B6, B9 (FOLIC ACID), B12.
THEXTON'S Blackcurrant Drink	Rio Beverages Ltd 40 Springs Rd East Tamaki Auckland, NZ PH (09) 274 5299	New Zealand		WATER, SUGAR, RECONSTITUTED BLACKCURRANT JUICE, NATURAL FLAVOURS, FOOD ACID (330), ASCORBIC ACID, COLOURS (123, 122, 129, 133).
THEXTON'S	Coca-Cola Amatil (N.Z.) Limited The Oasis Mt Wellington Auckland, NZ	New Zealand		PINK GRAPEFRUIT CONTAINS: WATER, SUGAR RECONSTITUTED PINK GRAPEFRUIT JUICE, ACIDITY REGULATOR (330, 331), FLAVOUR, VITAMINS (C,E,A), COLOUR (163), ECHINACEA EXTRACT (0.033%).

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